Government of Western Australia
Department of Health

Guideline on continuation of opioid substitution treatment in hospitals

1. Background

Opioid substitution treatment (OST) is made available to drug dependent individuals in Western Australia (WA) through the Community Program for Opioid Pharmacotherapy (CPOP). Initiation of OST must be by an authorised CPOP prescriber, who has completed specific CPOP training and been authorised by the Department of Health (DOH) to treat each individual patient.

When a patient receiving opioid pharmacotherapy is admitted to hospital, methadone or buprenorphine treatment should continue provided it is safe and clinically appropriate to do so. The Medicines and Poisons Regulations 2016 include clauses to allow continuation of previously authorised OST for inpatients without the hospital-based prescriber requiring any additional approval from the DOH, provided inpatient treatment does not continue beyond one month.

Current OST products used in WA include oral/sublingual therapy using methadone syrup/solution, buprenorphine sublingual tablets as Subutex® and buprenorphine with naloxone sublingual films as Suboxone® as well as depot buprenorphine injections (Buvidal® or Sublocade®).

This guidance document provides information to assist hospital staff in determining whether it is safe to continue OST while a patient is in hospital and details of how to manage supervised OST dosing. The primary aim of these recommendations is to avoid overdose with OST.

This Guideline is intended to be read in conjunction with the *WA Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence* and the *Clinical guidelines for use of depot buprenorphine (Buvidal and Sublocade) in the treatment of opioid dependence for WA CPOP prescribers*. The Guideline is not intended to be used as a substitute for compliance with legislation, Policy Frameworks or the policies and procedures of Health Service Providers.

Methadone is associated with a high-risk of overdose. Deaths due to overdose have occurred when methadone is used for OST, including the death of patients in hospital. The complex properties of methadone mean its use is considered ‘high-risk’ in all settings and for all indications. Methadone is to be prescribed with specialist oversight.

Advice on clinical management of CPOP patients can be obtained via CPOP Advice and Support (previously known as the Clinical Advisory Service, CAS), at any time. CPOP Advice and Support is a 24 hours-a-day 7 days-a-week telephone service available to support health practitioners involved in methadone and buprenorphine treatment across metropolitan and regional WA on telephone 9442 5042 or free call 1800 688 847 outside the Perth metropolitan area.

For more general clinical advice on management of patients experiencing alcohol and other drug use, the Drug and Alcohol Clinical Advisory Service (DACAS) is a specialist consultancy service available 0800 to 2000 Monday to Friday on telephone 6553 0520. Messages can be left after hours with a return call provided the next business day. DACAS is a collaboration between the Mental Health Commission and Next Step Drug and Alcohol Services.

Note about induction, including re-induction: This Guideline is about the **continuation** of OST. The suitability of induction (including re-induction after a break in treatment) of OST during hospital admission requires careful consideration, on a 'case-by-case' basis. The first few weeks of OST treatment (the induction period) is the time when the patient is most at-risk. Induction (including re-induction) of OST cannot occur unless an authorised CPOP prescriber is available to manage the patient within the public health service facility and contact has been made with the Community Pharmacotherapy Program (CPP) and/or CPOP Advice and Support service prior to induction (or re-induction) commencing.

2. Dose confirmation and documentation

It is critical that OST is not prescribed for any patient until their participation in the CPOP is confirmed.

Dosing information must be established prior to administering the first dose of OST in hospital to avoid 'double dosing' and the risk of overdose.

Opioid withdrawal is safer to the patient than overdose, particularly if alcohol or illicit drugs (including other opioids) have been used prior to presentation.

Regardless of when the patient presents to the hospital, continuation of oral/sublingual OST dosing within the hospital cannot commence until:

- it has been conclusively determined that the patient is currently receiving Suboxone®, Subutex® or methadone; and
- the details of the most recent OST dose, including whether any 'takeaway' doses have been provided and whether any 'takeaway' doses remain, has been independently verified.

If the patient's usual CPOP prescriber and/or dosing pharmacy are not available, the CPOP Advice and Support service is available 24 hours-a-day 7 days-a-week; however, the CPOP Advice and Support service will not have details of the patient's current dosing information.

2.1 Determining whether the patient is "in treatment"

Even where a patient has a current OST prescription, it must be determined whether they have been taking their doses before they can be determined to be 'in treatment'.

A patient who interrupts dosing (misses doses) will lose tolerance to opioids. The reduction in tolerance may result in an overdose if the patient re-commences OST at the same dose as was previously administered.

This is of high concern if the patient commenced treatment within the past 2 weeks (the induction phase of OST). In addition, tolerance may be reduced if the patient is in the maintenance phase of treatment and they have not received an oral OST dose for four or more days, or if they have not received their depot buprenorphine injection within the recommended treatment interval.

If the patient has missed doses, OST is not to be prescribed until the hospital-based prescriber has consulted with the patient's CPOP prescriber or has contacted the CPOP Advice and Support service, if the usual CPOP prescriber is unavailable, such as after hours, or on weekends. Where doses have been missed, dose adjustment may be necessary or, depending on the individual patient circumstances, advice may be to suspend treatment temporarily.

The risk of overdose is greatest when there has been a significant break in CPOP treatment and, for these patients, re-induction into treatment rather than continuation of treatment is likely to be required. Re-induction of OST cannot occur unless an authorised CPOP prescriber is available to manage the patient within the public health service facility and contact has been made with the CPP and/or the CPOP Advice and Support service prior to re-induction commencing.

A significant break in CPOP treatment with depot buprenorphine injections includes:

- More than 14 days between Buvidal® weekly doses
- More than 8 weeks between monthly depot buprenorphine injection doses

2.2 Special considerations for depot buprenorphine injection

Where OST is being administered by depot injection, once the patient is stable, there is some flexibility in when the next dose needs to be administered. For example, Buvidal® Monthly depot injection can be administered up to a week after the dose was due. This means dosing may be able to be delayed until the patient is discharged from hospital. The patient's CPOP prescriber or the CPOP Advice and Support service should be contacted for advice.

Conversely, for some patients being treated with Buvidal®, a supplemental or 'top up' dose may be clinically indicated, such as, if the patient is experiencing opioid withdrawal, cravings or persistent unsanctioned opioid use. This is more likely during the early period of treatment. 'Top up' doses are not to be used when the patient is treated with Sublocade®. Again, the advice of the patient's CPOP prescriber or the CPOP Advice and Support service should be sought.

2.3 Verifying the most recent dose

Regardless of whether a patient claims they are currently dosing, the details of their last dose must be independently verified with their dispensing/dosing pharmacy and, in the case of depot buprenorphine injection, with the clinic at which their CPOP prescriber is located.

Any details of the dosing pharmacy provided by the patient should be independently checked, such as by using an online search or a telephone book. This is to confirm the telephone number belongs to the pharmacy, not a friend or associate of the patient. When contacting the pharmacy, ask to speak to the pharmacist.

Some patients are authorised to have opioid pharmacotherapy dispensed at more than one pharmacy, for example, if the usual pharmacy is closed on Sundays and public holidays or, are allowed a 'takeaway' dose(s) under certain conditions. Verification of the most recent dose (including takeaway doses) may need to be obtained from more than one pharmacy.

Depot buprenorphine injections are dispensed for each patient at their pharmacy and then supplied to the clinic at which their CPOP prescriber is located, for administration to the patient by a health professional. Depot buprenorphine injections are never supplied directly to patients.

For depot buprenorphine injections, verification of the last administration will require contact with the CPOP prescriber or the CPOP Advice and Support service if the CPOP prescriber is not available. The date of administration, the dose administered and the specific site of administration, should be verified.

Note: An additional dose may have been dispensed by the patient's pharmacy but this injection may not yet have been administered at the time of admission to hospital.

If the patient's usual dosing pharmacy indicates the patient's prescription has recently expired, OST should not be prescribed until the patient's usual CPOP prescriber (or the CPOP Advice and Support service where the usual CPOP prescriber is unavailable) has been contacted to enquire whether they wish to continue treatment.

If takeaway doses have been supplied, they must be accounted for before further doses are prescribed or administered.

2.3.1 Takeaway doses

There are strict rules regarding takeaway doses due to the risk of double dosing and diversion. Continuation of OST for hospital patients does not allow for provision of any takeaway doses, even at discharge.

Staff should be aware of the following:

- takeaway doses brought in to hospital by the patient are not to be administered or otherwise used within hospitals
- patient's own takeaway doses are not to be returned to the patient, including at discharge
- doses are *never* to be supplied on discharge (including if the patient is on day/weekend leave)

There are strict requirements around eligibility for takeaway doses in the *WA Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence* and, depending on the reason for presentation or admission, the patient may no longer be eligible for takeaway doses once they return to the community.

2.4 Documentation in the patient's medical record

A copy of the patient's current prescription and their dosing record should be requested from their dosing pharmacy and filed in the patient's medical record.

The following information about the confirmed dose should be documented in the patient's medical record:

- OST product being used and dose (see table below)
- date, time and location of last supervised dose (for oral/sublingual dosing) or
- date, site of injection and practice location of last depot dose injected (for long-acting buprenorphine injections)
- number of takeaway doses, if any, have been dispensed, and details of any remaining/unaccounted doses
- details of other dosing locations, where applicable
- name of pharmacy, name of pharmacist and telephone number

2.5 Opioid substitution treatment products

Drug	Brands	Strengths available	Notes
Methadone liquid	Aspen Methadone® Syrup	25 mg per 5 mL	
	Biodone Forte®	25 mg per 5 mL	May not be available within public health service facilities.
Buprenorphine sublingual tablets	Subutex®	0.4 mg, 2 mg, 8 mg	Not routinely used, may be in use where documented allergy to other products or where low dose treatment is prescribed. May also be used in pregnant and breastfeeding women; however, Suboxone® is now considered as safe in this patient group.
Buprenorphine with naloxone sublingual film	Suboxone®	2 mg/0.5 mg, 8 mg/2 mg	Buprenorphine: naloxone in 4:1 ratio. Naloxone added to reduce abuse potential.
Depot buprenorphine subcutaneous injection	Buvidal®	Multiple ranging from 8 mg to 128 mg	Weekly or monthly injection. Administration via upper arm, thigh, abdomen or buttocks.
	Sublocade®	100 mg, 300 mg	Monthly injection. Administration via abdomen.

Note: Buprenorphine 200 microgram tablets (Temgesic®) are indicated for pain management and must not be used for OST.

3. Administration of Opioid Pharmacotherapy

With the exception of depot buprenorphine injections, OST is usually administered at community pharmacies during the morning and as a single dose. Buprenorphine sublingual preparations may sometimes be administered every second or third day, rather than every day.

Methadone liquid should be charted using both the mg dose and the amount in millilitres, to minimise the potential for errors (and possible five-fold overdose). For example, methadone syrup 5mg/mL: 22.5 mg = 4.5 mL each morning.

Buprenorphine sublingual formulations are intended for sublingual dosing and will be inactive if swallowed.

3.1 Supervision of oral/sublingual dosing

To minimise the risk of diversion, all opioid pharmacotherapy dosing must be supervised appropriately to ensure the patient has actually taken their dose. Doses of OST must never be left with a patient for self-administration.

Supervision requirements in community pharmacies are detailed in *WA Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence*. These requirements are generally applicable to inpatient OST dosing. CPOP patients should already be familiar with the requirements for 'in pharmacy' dosing.

The dose must be consumed in direct view of the administering staff with no turning of the patient's head. The patient's hands and mouth must be visible to administering staff at all times. Any dosing equipment, such as disposable cups, must be handed back to the administering staff immediately after the dose has been consumed.

For methadone, the administering staff must watch the patient swallow the dose. Administering staff should engage the patient in a short conversation after dosing to reduce the risk of the dose being retained in the mouth for later injection or diversion.

Buprenorphine tablets and buprenorphine/naloxone films are administered sublingually.

For buprenorphine tablets (Subutex®), these must be crushed using a commercial tablet crusher to the consistency of course coffee ground prior to administration. The public health service facility should determine whether crushing is undertaken within the Pharmacy Department or in the patient care area.

Crushing buprenorphine tablets reduces the supervision time and risk of diversion. It is also the way in which the doses are presented to the patient in community pharmacies. The patient should pour the prescribed dose of crushed Subutex® under their tongue and be supervised for at least three minutes.

For buprenorphine film (Suboxone®), the patient should be watched placing the prescribed dose under their tongue and supervised for at least one minute. If multiple films are required, they must be placed so they do not overlap. Usually two films at a time can be placed on opposite sides under the tongue.

3.2 Administration of depot buprenorphine products

Administration of depot buprenorphine products should only be necessary where a patient has a prolonged admission and discharge is unlikely to occur until after the window for their next dose, as detailed in the *Clinical guidelines for use of depot buprenorphine (Buvidal and Sublocade) in the treatment of opioid dependence for WA CPOP prescribers*.

If, and only after discussion with the patient's usual CPOP prescriber or the CPOP Advice and Support service, a decision is made to administer a dose of depot buprenorphine injection to an admitted patient, it is important that the same depot product brand is used as previously. There are no clinical studies and very limited anecdotal reports about transferring between brands of depot buprenorphine products.

The relevant Product Information should be reviewed before administering Buvidal® Weekly, Buvidal® Monthly or Sublocade® injections. Buvidal® and Sublocade® injections are each packaged differently and each brand has specialised and unique administration instructions.

Australian Product Information is available from the Therapeutic Goods Administration website at: tga.gov.au/product-information.

Buvidal® Weekly, Buvidal® Monthly and Sublocade® injections are intended for subcutaneous use only. There should be sufficient subcutaneous tissue to allow for the injection. The area should be free of scarring, nodules or other lesions and not be inflamed, infected or bruised. A slow steady push should be used as slower injections are generally better tolerated.

The dose must not be administered intravascularly or intradermally.

Buvidal® should be administered in the upper arm, thigh, abdomen or buttocks. Sublocade® should be administered in the abdomen.

Injection sites should be rotated between injections.

Warning: Risk of serious harm or death with intravenous administration

Serious harm or death could result if depot buprenorphine injections are administered intravenously. Sublocade® and Buvidal® form a gel or solid depot upon contact with body fluids and may cause occlusion, local tissue damage and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.

3.3 Patient monitoring

All opioid medicines, including those used for OST, are considered to be 'high-risk' medicines and clinical monitoring must therefore be consistent with the potential harmful effects of these medicines.

Even though methadone and buprenorphine are being administered for opioid pharmacotherapy rather than pain management, the patient is still at-risk of developing adverse effects, including respiratory depression and reduced level of consciousness. Overdose and deaths have occurred when patients are treated with OST, including while the patient is in hospital.

4. Acute pain management

Patients on methadone or buprenorphine who need acute pain management in the hospital setting can be managed as for patients who are not opioid dependent, although doses of opioid analgesic drugs may need to be higher.

Buprenorphine exerts a degree of blockade to the effects of full agonist opioids, which may complicate the prescribing of additional opioids for pain management. Liaison with an Acute Pain Service or CPOP Advice and Support service, is recommended.

If pain management requirements mean alterations to a patient's OST is considered necessary, advice should be sought from the CPOP Advice and Support service.

Because all patients treated under the CPOP will have been recorded as a 'drug dependent person', if Schedule 8 medicines for pain management are being contemplated after discharge, prescribing authorisation from the DOH, will be necessary. This will require the support of a pain management consultant.

5. Discharge

CPOP patients must not be given a discharge prescription for OST or supplied with takeaway doses at discharge.

When a patient is to be discharged and OST treatment is to be continued, the patient's usual CPOP prescriber and dosing pharmacy must be advised. It is particularly important that the dosing pharmacy knows the current dose and the date and time the last dose in hospital was administered.

The CPP should also be advised, so they can follow up on any transition of care arrangements.

If the patient's prescription at their dosing pharmacy has expired or the current dose is inconsistent with the prescription, the patient will require a new prescription to be able to continue dosing. The patient's usual CPOP prescriber must be contacted so the CPOP prescriber can issue a new prescription. Alternatively, the CPOP Advice and Support service can be contacted to provide an interim prescription of up to one month.

The new/interim prescription will be sent directly to the dosing pharmacy by the usual CPOP prescriber or the CPOP Advice and Support service prescriber.

6. CPOP patients attending Emergency Department out-of-hours seeking Opioid Pharmacotherapy medication

Patients may present to healthcare facilities, particularly at a time when the pharmacy at which they usually dose is not open, with complaints they have missed their methadone or buprenorphine dose, lost or had their takeaway doses stolen, or have vomited soon after taking their takeaway dose. Such patients may state they are in withdrawal and request a replacement or additional dose.

Missed doses are not a medical emergency, and it is not appropriate for patients to seek or be prescribed methadone or buprenorphine from the Emergency Department of a hospital.

The long half-lives of methadone and buprenorphine mean missing one dose is unlikely to cause significant physical discomfort, especially in a patient who is in maintenance phase opioid pharmacotherapy.

Treating staff can seek advice about the patient's status from the CPP or clinical advice about further treatment from the CPOP Advice and Support service.

Definitions

Term	Definition
CPOP Advice and Support	A 24 hours-a-day 7 days-a-week telephone service available to support health practitioners involved in methadone and buprenorphine treatment across metropolitan and regional Western Australia. Telephone 9442 5042 or free call 1800 688 847 outside the Perth metropolitan area.
Community Pharmacotherapy Program	Provides support, information and advice to clients, pharmacists and medical practitioners involved in methadone and buprenorphine treatment across metropolitan and regional Western Australia. Telephone 9219 1913 or 9219 1907.
Community Program for Opioid Pharmacotherapy	Framework developed to regulate the prescribing of opioid pharmacotherapy medicines for the treatment of opioid dependence in Western Australia. Regulatory controls are via the Medicines and Poisons Regulations 2016.
Induction phase	The first few weeks of commencement on opioid pharmacotherapy treatment.
Opioid substitution treatment	Treatment with specific long acting opioids (methadone and buprenorphine) as a replacement for heroin and other opioids, also known as OST. The goal of OST is to stabilise the lives of people experiencing drug dependence, reduce their drug use and reduce the harm associated with drug use.
Takeaway doses	Community treatment of opioid dependence with methadone or buprenorphine is based on daily, supervised dosing at a pharmacy; however, in the community, some well stabilised patients with particular needs may be prescribed some of their doses as ‘takeaway’ doses. Takeaway doses are dispensed to the patient by their dosing pharmacy, using a standardised procedure. Public hospitals are not authorised to supply ‘takeaway’ doses to patients or to return previously supplied patient’s own ‘takeaway’ doses at discharge.

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This document can be made available in alternative formats on request for a person with a disability.