

SESLHD PROCEDURE COVER SHEET



Health
South Eastern Sydney
Local Health District

NAME OF DOCUMENT	Drug and Alcohol – Management of missed consecutive doses: methadone and buprenorphine/ buprenorphine – naloxone
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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Dr Marianne Gale Director, Population and Community Health
AUTHOR	SESLHD D&A Services OTP Working Group
POSITION RESPONSIBLE FOR THE DOCUMENT	Nicholas Lintzeris, SESLHD Director Nicholas.Lintzeris@health.nsw.gov.au
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SUMMARY	The procedure provides guidance to all SESLHD clinical staff, with particular note for registered nurses, medical officers and pharmacists working in inpatient hospital settings and SESLHD Opioid Treatment Programs (OTPs) to ensure that clients who miss doses of methadone (Methadone Hydrochloride 5 mg/1mL) buprenorphine and buprenorphine – naloxone are reviewed and dosed in a manner that minimises the risk of overdose and optimises retention in treatment.

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

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Drug and Alcohol – Management of missed consecutive doses: methadone and buprenorphine/ buprenorphine – naloxone**SESLHDPR/411****1. POLICY STATEMENT**

This document is based on the NSW Clinical Guidelines: Treatment of Opioid Dependence (2018) and National Policy and Guidelines for Medication-Assisted Treatment of Opioid Dependence (2014). It provides further specific detail for use in South Eastern Sydney Local Health District (SESLHD).

2. BACKGROUND**Missed doses**

Repeated missed doses (patients not taking their regular dose of methadone or buprenorphine, buprenorphine - naloxone) can be associated with reduced opioid tolerance, opioid withdrawal and/or use of other substances, which in turn impact on treatment safety and effectiveness.

There are particular safety concerns for:

- Patients recommencing methadone after missing doses on three or more days because of reduced opioid tolerance and risk of overdose on recommencement of methadone, particularly if other sedative drugs have been used.
- Patients recommencing buprenorphine, buprenorphine - naloxone after missing doses on four or more days because of precipitated withdrawal if the patient has been using opioid agonists (e.g. heroin, morphine, methadone).

An assessment and calculation of a safe and appropriate recommencement dose is required in order to ensure that the risk of harm is reduced, while the goal of retaining the patient in treatment is achieved by expediting the return to a stable dose.

This document provides guidance to SESLHD clinical staff in the management of missed doses.

3. DEFINITIONS

Methadone: The term 'methadone hydrochloride' as referred to in this document includes all liquid brands of the drug methadone hydrochloride 5 mg per 1mL. Methadone is a synthetic opioid agonist which is rapidly absorbed from the gastrointestinal tract with measureable concentrations in plasma within 30 minutes of oral administration and peak plasma levels generally between two to four hours. It has a highly variable elimination half-life (14-58 hours). The effects of methadone are qualitatively similar to morphine and other pure agonist opioids.

Buprenorphine is a partial opioid agonist with high receptor affinity. A partial agonist is a drug that binds to a receptor but does not produce maximum stimulation. It is used for the treatment of opioid dependence and also as an opioid analgesic.

Naloxone is an opioid antagonist. It is used in combination with buprenorphine sublingually to limit the abuse potential of buprenorphine by reducing the potential for injection. Naloxone has poor bioavailability when taken sublingually. It does not reduce the bioavailability of buprenorphine when taken in combination sublingually.

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Precipitated Withdrawal is a state of opioid withdrawal which may be induced by poorly timed initiation of buprenorphine in the presence of full opioid agonists such as heroin, methadone or morphine. It is characterised by opioid withdrawal symptoms such as abdominal pain, diarrhoea, muscle aches, anxiety and sweating. It may be a risk if buprenorphine is administered when the patient has missed several days of scheduled buprenorphine doses, and has taken a short acting opiate (e.g. heroin) within the last six to 12 hours, or a longer acting opioid (e.g. methadone) in the past 24 to 36 hours.

DARF (Drug and Alcohol Review Form) is an electronic form in the eMR which includes:

- Clinical observations including pulse, respiratory rate, pupil size, oxygen saturation (if available), blood pressure, breath alcohol reading, the Clinical Opiate Withdrawal Scale (COWS) and the Glasgow Coma Scale (GCS).
- History of drug use since last dose, patient's reasons for missing their dose, and any other relevant clinical issues (e.g. medical, psychiatric or social).
- As directed in the DARF, clinicians should complete a paper version of the COWS or other clinical instruments as clinically indicated.

4. RESPONSIBILITIES

Employees will:

- All clinical staff involved in patient care of people in opioid pharmacotherapy treatment will act in accordance with this procedure.

Line Managers will:

- Implement and monitor the management of patients who miss consecutive doses of Opioid Agonist Treatment (OAT).

District Managers/ Service Managers will:

- Facilitate discussion about the implementation of this procedure.
- Work with authors to implement relevant policies, procedures and guidelines in their teams and ensure their staff's compliance with them.
- Develop strategies to manage non-compliance.

5. PROCEDURE

A. Inpatient Hospital Settings: Assessment of clients who have missed consecutive doses of methadone or buprenorphine, buprenorphine – naloxone

All inpatients on methadone or buprenorphine, buprenorphine – naloxone treatment programs must be assessed for suitability of dosing in the event that they have missed four or more consecutive days. Doses may have been omitted prior to hospital admission, early in admission or interruptions occurred during admission (e.g. nil by mouth, surgery etc.).

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Missed doses will be identified using the **Details of Inpatient on Opioid Treatment Program Form** (Form No. SEI060.136 Stock order code s0339).

Inpatient and Emergency Department staff must consult with SESLHD Drug and Alcohol medical officer on-call for advice regarding further assessment and management.

**SESLHD DRUG AND ALCOHOL MEDICAL OFFICER ON CALL via
Sydney Hospital Switchboard: 9382 7111**

Outpatient settings: Assessment of patients who have missed consecutive doses of methadone or buprenorphine, buprenorphine – naloxone

Repeated missed doses (patients not taking their regular dose of methadone or buprenorphine) can be associated with reduced opioid tolerance, opioid withdrawal and/or use of other substances, which in turn impact on treatment safety and effectiveness. There are particular safety concerns for:

- Patients new to, or early in opioid treatment
- Patients recommencing methadone after missing doses on four or more days because of reduced opioid tolerance and risk of overdose on recommencement of methadone, particularly if other sedative drugs have been used
- Patients recommencing buprenorphine after missing doses on four or more days because of the risk of precipitated withdrawal if the patient has been using opioid agonists (e.g., heroin, morphine, methadone).

Patients who miss 1, 2 or 3 consecutive missed doses should be reviewed by a clinician prior to dosing, and may require escalation to a senior clinician or medical officer if there are concerns.

When a patient misses more than three consecutive doses, a review or consultation with the prescriber or the on-call SESLHD Drug and Alcohol Medical Officer if the prescriber is not available, must occur before the next dose of medication is administered.

The following procedures are recommended for missed doses, and summarised in Appendix.

B.1 – Patients who have missed 1, 2 or 3 doses

A clinician experienced in the treatment of drug and alcohol problems needs to review the patient prior to dosing.

Normal dosing can be resumed if there are no concerns regarding intoxication, significant withdrawal or other clinical issues.

If the patient presents intoxicated, in severe withdrawal or if there are other significant medical or psychiatric concerns, the clinician should complete the eMR *Drug and Alcohol Review Form* (DARF) and consult with a senior clinician or medical officer. An altered dose of methadone or

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buprenorphine may be indicated according to the clinical circumstances (e.g. split or reduced dose), following communication between dosing staff and prescribing doctor.

B.2 – Patients who have missed 4 or 5 consecutive doses

All patients who present for a methadone or buprenorphine, buprenorphine - naloxone dose after missing four or more consecutive days must be assessed for suitability for dosing by a clinician using the eMR *Drug and Alcohol Review Form (DARF)* and then the clinician should consult with the prescriber or on-call SESLHD Drug and Alcohol Medical Officer.

If there is to be a change in the administered dose, a prescription or telephone order from the Medical Officer must be obtained prior to dosing.

As a guide for prescription:

- Patients on methadone less than 40mg: may recommence on regular dose.
- Patients on methadone 40 mg or more: may recommence on 40mg or half regular dose, whichever is higher. Patients should be assessed by a clinician on subsequent days prior to dosing (using the DARF), aiming to return to the regular dose within five to seven days, usually in increments of up to 20mg per day. Regular assessment should occur until the patient's dose has stabilised.
- Patients on buprenorphine 8mg or less: may recommence up to regular daily dose.
- Patients on buprenorphine 8mg or more: may recommence on 8mg or half regular daily dose whichever is higher. Patients should be assessed by a clinician on subsequent days prior to dosing (using the DARF), aiming to return to the regular daily dose within two to three days, usually in increments of up to 8mg per day. Regular assessment should occur until the patient's dose has stabilised.

In the event that the prescriber cannot be contacted or is unable to provide a valid prescription, the patient cannot be dosed.

B.3 – Patients who have missed more than 5 consecutive doses

The patient **must** be reviewed by the prescriber or on call doctor prior to recommencing treatment. Methadone dose induction should generally commence low (less than or equal to 40mg/day) with careful subsequent titration. Buprenorphine dose induction should generally commence on 8mg/day with subsequent titration.

B.4 – Reviewing patients who repeatedly miss doses

A minority of patients have poor attendance for dosing. This may be due to ambivalence about treatment, access issues (e.g. transport, work, limited dosing hours) or medical issues (mobility problems, cognitive impairment).

Clients who regularly miss doses should be reviewed by their treating team, examining reasons for missed doses and consider options with the patient for enhancing treatment adherence, such as changes in dosing sites, take-away conditions or organise altered dosing hours.

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Some patients who repeatedly miss doses may report that their methadone or buprenorphine doses are inadequate. Regular attendance should be encouraged prior to any dose increases.

6. DOCUMENTATION

- The registered nurses administering the dose will refer to the current prescription.
- The actual dose administered will be recorded on the medication chart or the computerised dosing system with details of client history and presentation documented in the client clinical notes. Missed doses will be recorded in the OTP Dosing Card and computerised dosing system in SESLHD OTP settings.
- Methadone and buprenorphine/ buprenorphine – naloxone are Schedule 8 (S8) drugs and the usual requirements for recording S8 drugs must be complied with.
- The eMR *Drug and Alcohol Review Form* (DARF), once completed, is to be printed and filed in the client’s medical record. As directed in the DARF, clinicians should complete a paper version of the COWS or other clinical instruments as clinically indicated which is to be filed in the client’s medical record.
- Details of Inpatient on Opioid Treatment Program Form (Form No. SEI060.135, Stock Order Code s0156), once completed, is to be filed in the client’s medical record.

7. AUDIT

- Medication audits of OTP and inpatient medication charts by pharmacists.
- IIMS/IMS recording of medication errors within SESLHD DAS e.g. non-compliance with this procedure.

8. REFERENCES

NSW Clinical Guidelines: Treatment of Opioid Dependence (2018)

[National Guidelines for Medication-Assisted Treatment of Opioid Dependence \(2014\)](#)

9. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
October 2014	0	Authors SESLHD OTP NUM's Approval: A/Prof Nicholas Lintzeris, Director SESLHD D&A Service
April 2015	1	Approval: A/Prof Nicholas Lintzeris, Director SESLHD D&A Service
April 2016	2	Reviewed by Opioid Treatment Program Clinical Specialty Group Approval: Prof Nicholas Lintzeris, Director SESLHD D&A Service
April 2018	3	Changes: <ul style="list-style-type: none"> • Wording changed to be consistent with draft NSW OTP guidelines – no substantive change to process. Reviewed by Opioid Treatment Program Clinical Specialty Group

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		Approval: Prof Nicholas Lintzeris, Director SESLHD D&A Service
May 2018	3	Endorsed by Executive Sponsor
June 2018	3	Endorsed by SESLHD Quality Use of Medicines Committee
April 2019	4	Review by Opioid Treatment Program Clinical Specialty Group Reference included: <ul style="list-style-type: none"> NSW Clinical Guidelines: Treatment of Opioid Dependence (2018) Approval: Prof Nicholas Lintzeris, Director SESLHD D&A Service.
May 2019	4	Formatted by Executive Services and published.
March 2020	5	Executive Sponsor updated. Published by Executive Services.
July 2020	6	Risk rating amended from Extreme to High Risk. Review date amended to align with a High Risk rating. Approved by Executive Sponsor.

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**Appendix
SUMMARY BUSINESS RULE FOR MISSED DOSES IN SESLHD OTP SETTINGS**

<p>1, 2 or 3 days consecutive missed days</p>	<ul style="list-style-type: none"> • Assessment by experienced clinician. • Administer normal dose as per script if there are no concerns regarding intoxication, significant withdrawal or other clinical issues. • If there are concerns regarding intoxication, significant withdrawal or other clinical issues, complete the DARF and consult with senior clinician or medical officer. A split or reduced dose may be considered.
<p>4 or 5 days consecutive missed days</p>	<ul style="list-style-type: none"> • Assessment by experienced clinician, including DARF • Consult with prescriber, or on call D&A MO • Provision of new prescription or telephone order if the dose is to be altered. • Document on Dosing Card, patient clinical record and computerised dosing system <p>Prescribing guide for recommencing methadone:</p> <ul style="list-style-type: none"> – Patients on less than or equal to 40 mg: may recommence up to regular dose. – Patients on more than 40 mg: may recommence at 40 mg or half dose, whichever is higher. – Aim to return to regular dose within five to seven days at increments of up to 20 mg per day. <p>Prescribing guide for recommencing buprenorphine:</p> <ul style="list-style-type: none"> – Patients on less than or equal to 8 mg: may recommence up to regular daily dose. – Patients on more than 8 mg: may recommence at 8 mg or half regular daily dose, whichever is higher. – Aim to return to regular daily dose within two to three days at increments of up to 8 mg per day.
<p>6 or more consecutive days</p>	<ul style="list-style-type: none"> • Assessment by experienced clinician, including DARF • Patient to be assessed by medical officer for re-induction. • Prescribing guide for methadone: recommence on less than or equal to 40 mg. • Prescribing Guide for buprenorphine: recommence on less than or equal to 8 mg.

Complete relevant documentation on OTP Dosing Card, patient clinical record and computerised medication system.