

Te Whatu Ora Health New Zealand Hauora a Toi Bay of Plenty CLINICAL PRACTICE MANUAL	OPIOID SUBSTITUTION TREATMENT (OST) MANAGING CO-EXISTING CONDITIONS	Protocol CPM.M9.5
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PURPOSE

This document describes the processes for managing medical and other conditions commonly impacting tāngata whai ora / service users on opioid substitution treatment (OST), and conditions that may affect or be affected by OST, and how the OST service assists tāngata whai ora / service users with chronic and terminal medical conditions, including liaison with other services and individuals involved with the tāngata whai ora / service user's care.

STANDARDS TO BE MET

1. Blood Borne Viruses (BBVs)

The infective complications of drug use are a common cause of liver damage. In combination with pharmacological therapies, tāngata whai ora / service user education about BBVs and prevention of infectious diseases, plus enrolment in primary medical care are important in the medical management of acute and chronic stages of viral infections in the liver. Individuals not receiving care and treatment for hepatitis infection, as well as those not responsive to hepatitis treatment, are at risk of progressing to end-stage liver disease or decompensated cirrhosis, leaving orthotopic liver transplantation (OLT) as the only life-saving alternative.

1.1. Testing

- a) All tāngata whai ora / service users are encouraged to be tested for BBVs including Hepatitis B, and C and HIV. OST clinicians inform the tāngata whai ora / service user of the possible outcomes of testing and the implications for their health and possible treatment options should the tests be positive. Tāngata whai ora / service users are offered written information.
- b) Tests are:
 - i. Hepatitis A antibody
 - ii. Hepatitis B Surface antibody
 - iii. Hepatitis B Core antibody
 - iv. Hepatitis B Surface antigen
 - v. Hepatitis C Antibody
 - vi. HIV
- c) The OST service provides the tāngata whai ora / service user with a laboratory request form and the results are shared with the tāngata whai ora / service user's GP. The tāngata whai ora / service user is told that any follow-up required after initial testing will be by their GP as OST medical practitioners do not take on the primary care role of the GP. However, the OST medical practitioners will assist in referral to specialist services for the above conditions as required. OST clinicians should consider what support would need if the received a positive test result for BBVs.

1.2. Process

- a) An OST medical practitioner or nurse requests the relevant test, copied to GP.
- b) The tāngata whai ora / service user's OST medical practitioner reviews the results.
- c) The tāngata whai ora / service user is informed of hepatitis results and HIV negative results by the medical practitioner or the key worker (after discussion with the medical practitioner). This can be face to face or by telephone depending on the tāngata whai ora / service user and the result.

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- d) If Hepatitis A and / or B vaccination is advisable due to lack of immunity, tāngata whai ora / service users are advised to attend their GP for vaccination. Alternatively, the tāngata whai ora / service user can be advised to attend a Sexual Health Clinic or a private clinic that specialises in vaccinations.
 - e) Where necessary the medical practitioner writes a referral letter for the tāngata whai ora / service user. Most sexual health clinics have a walk-in service.
 - f) For HIV positive results, the medical practitioner informs the tāngata whai ora / service user face-to-face.
 - g) The medical practitioner liaises with the specialist HIV service and makes a referral to that service.
 - h) The medical practitioner informs the GP of all significant results both positive and negative.
 - i) This can be by telephone if urgent (e.g. new HIV positive) or by letter.
- 1.3. Management
- Medical management of HIV / HCV and HBV by the OST service is dependent on resources and includes:
- a) Education and information about these diseases, particularly modes of transmission and preventing re- infection, and provide advice on vaccination where appropriate.
 - b) Referral for Hepatitis C treatment, either to the tāngata whai ora / service user's GP, or the local hospital services as required.

2. Liver Disease

- 2.1. Methadone and buprenorphine are metabolised in the liver. If the liver function is significantly impaired, care must be taken with the early doses, particularly of methadone, to avoid overdosing. In general, initial doses should be reduced if significant liver impairment is established or suspected.
- 2.2. Therapeutic doses of buprenorphine have been linked to the development of acute hepatitis and renal failure. Liver function monitoring must be considered in the first few weeks of buprenorphine treatment in susceptible patients such as those with hepatitis, alcohol abuse or concomitant use of drugs inducing mitochondrial toxicity.
- 2.3. OST tāngata whai ora / service users with chronic liver disease do not generally require alterations in their dose. However, if there is severe liver disease or an abrupt change in liver function the tāngata whai ora / service user may require dose adjustment. The development of a raised bilirubin level or of jaundice always prompts an early review of the tāngata whai ora / service user and possibly an OST dose reduction.
- 2.4. As a precaution, when there may be significantly impaired liver function following Hepatitis B or C infection or prolonged alcohol use, the dose of OST should be regularly reviewed, and if necessary reduced. Serum methadone levels may assist in making decisions about methadone dosing.
- 2.5. Discuss with a Specialist Gastroenterologist if there are concerns. Refer also to section Management of Hepatitis C, see page 5.

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3. Acute and Chronic Respiratory Disorders

- 3.1. Methadone is a respiratory depressant and care is taken in prescribing methadone to tāngata whai ora / service users with respiratory disorders to ensure that respiratory function is not compromised.
- 3.2. Buprenorphine has a ceiling effect on respiratory depression when used alone and may be safer in tāngata whai ora / service users with respiratory disorders. However, when combined with other respiratory depressants, especially benzodiazepines, it can cause death due to respiratory depression, so vigilance is required.
- 3.3. Tāngata whai ora / service users with acute and chronic respiratory disorders are often prescribed antibiotics. Care must be taken when prescribing antibiotics to tāngata whai ora / service users on methadone because of interactions. In particular, rifampicin (used to treat TB) and fusidic acid reduce methadone levels via liver enzyme induction; macrolides (such as erythromycin) and ciprofloxacin raise methadone levels via liver enzyme inhibition. Erythromycin also prolongs the Q-T interval and should be avoided if possible.
- 3.4. See also section Drug interactions with opioids, page 6.

4. Epilepsy

- 4.1. It is important to check which anticonvulsant therapy any epileptic tāngata whai ora / service user is receiving as the drugs may interact with methadone.
- 4.2. Carbamazepine, phenytoin and barbiturates reduce methadone levels via liver enzyme induction. Changes in doses of carbamazepine made by a tāngata whai ora / service user's GP or specialist, or due to adherence issues, are a common cause for changes in a tāngata whai ora / service user's response to their usual methadone dose.
- 4.3. See also section Drug interactions with opioids, page 6.

5. Clients Presenting with Sedation

- 5.1. BOPAS OST tāngata whai ora / service users presenting with sedation must be assessed by a medical practitioner or nurse to ensure the tāngata whai ora / service user's on-going safety. A community pharmacist may decline to dose a sedated tāngata whai ora / service user, and inform the service of this decision.
- 5.2. Where there is a marked or serious level of sedation, transfer is arranged to a hospital Emergency Department for further assessment and monitoring.
- 5.3. Basic life support is administered if required whilst awaiting the arrival of an ambulance.
- 5.4. At Tauranga Hospital assistance is available by calling 777.

6. Pain Management

- 6.1. Tāngata whai ora / service users with pain management issues who present to the OST service need to be thoroughly assessed to establish whether they are opioid dependent and whether they have a maladaptive pattern of use. Liaison with other agencies is likely to be required, including:
 - a) the GP
 - b) the Clinical Pain Service
- 6.2. Other practitioners managing the tāngata whai ora / service user's pain or involved in the tāngata whai ora / service user's health care. See section Management of iatrogenic opioid dependence (IOD), page 7.

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6.3. Acute Pain Management

- a) The OST service does not prescribe analgesia for acute pain but will advocate for tāngata whai ora / service users to ensure they receive adequate acute pain management within other health services. This may include advocating for engagement with the specialist Pain Service where appropriate. Effective management of mild to moderate acute pain is usually provided by simple analgesics (including mild opioid medications) and / or other medications.
- b) OST tāngata whai ora / service user may receive inadequate analgesia for acute severe pain especially as they often require higher doses of opioid agonists than non-tolerant tāngata whai ora / service users in order to achieve adequate pain relief. In addition, the partial agonism at μ (mu) opioid receptors and antagonism at κ (kappa) opioid receptors, makes the concurrent use of buprenorphine and opioid analgesia difficult.
- c) The OST service will always recommend that where opioids are required for acute pain management, it is dispensed as per the tāngata whai ora / service user's OST schedule, for example if tāngata whai ora / service user consumes methadone daily, collect additional opioids daily. There also needs to be a clear plan agreed to by the prescriber and the tāngata whai ora / service user as to when the prescription will end.

6.4. Chronic Pain Management

- a) The OST service does not prescribe medication solely for the management of chronic pain. GPs are advised to consult a specialist pain management service before considering the regular prescribing of opioid medication for pain.

6.5. Hospitalisation

- a) Under Section 24(2)(d) Misuse of Drugs Act 1975, hospital prescribers need to be authorised by the specialist service medical practitioners to continue to treat a tāngata whai ora / service user with controlled drugs whilst in hospital.
- b) When informed that a tāngata whai ora / service user has been hospitalised, the key worker:
 - i. confirms the tāngata whai ora / service user's last dispensed dose and date
 - ii. liaises with the hospital to enquire after the identity of the responsible Physician
 - iii. prepares an authority with the above information to be signed by the OST medical practitioner
 - iv. faxes this authority to the hospital (ward and inpatient Pharmacy) after it has been signed by the medical practitioner to ensure continuation of OST
 - v. provides information on discharge planning (e.g. who to contact, advising that the OST service will manage all community OST prescriptions)
 - vi. temporarily stops the tāngata whai ora / service user's OST prescription at their usual pharmacy
 - vii. arranges a prescription for continued OST following discharge if appropriate
 - viii. notes the information in the tāngata whai ora / service user's file (HCC).

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- ix. If the tāngata whai ora / service user has been hospitalised on a weekend, the ward must fax chart and send CD requisition book to the inpatient Pharmacy.
 - c) The Hospital Pharmacist:
 - i. confirms the tāngata whai ora / service user's last dispensed dose and date
 - ii. temporarily stops the tāngata whai ora / service user's prescription if possible (if Pharmacy contactable)
 - iii. notifies tāngata whai ora / service user's keyworker as documented under Regional Clinical Portal (RCP) alerts and requests the authority to be prepared by key worker as soon as possible after the weekend.
 - d) On discharge, the OST medical practitioner must:
 - i. be satisfied that the tāngata whai ora / service user's OST dose and takeaway regimen are appropriate
 - ii. sign the authorisation to recommence dispensing on discharge after receiving the following information (or contact the hospital if necessary):
 - the diagnosis / reason for admission,
 - the dose of OST dispensed in hospital and when the last administration of this dose occurred,
 - any changes in the tāngata whai ora / service user's circumstances that may make their dose or take away regime inappropriate.
 - iii. Note: only the medical practitioner may **verbally** inform a prescriber for purposes of continued prescribing
- 6.6. Tāngata whai ora / service users on buprenorphine
- a) Mild to moderate pain
 - i. The tāngata whai ora / service user should be transferred to daily dosing if they are on less-than-daily dosing, then prescribed adequate pain relief. Mild to moderate pain may be successfully managed by temporarily increasing, and possibly splitting the usual buprenorphine dose (into 2 or 3 doses) as the ceiling effect on respiratory depression does not extend to its analgesic effect. This is the simplest option and can be achieved with doses of up to 32 mg daily.
 - ii. Analgesia should be prescribed in a step-wise manner starting with non-opioid analgesics such as paracetamol, aspirin and non-steroidal anti-inflammatory drugs. Standard opioid analgesia should be trialled for its effectiveness.
 - iii. If analgesia is needed in specific sites, local anaesthesia could be considered.
 - b) Moderate to severe pain
 - i. For any admission involving the possibility of moderate to severe pain likely to require opioid analgesia, the best strategy may be continuation of buprenorphine, with supplemental short-acting opioids. Other strategies such as dividing the buprenorphine dose in 4 to be given throughout the day, the use of PCA and fentanyl can also be implemented.

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- ii. Switching to methadone and managing pain with additional opioids is rarely required, but may be requested by the Surgical / Anaesthetic team. This would require careful monitoring and advance planning. The tāngata whai ora / service user can be transferred back to buprenorphine later using the micro-dosing regimen, if required.

7. Mental Health

7.1. Process

- a) For tāngata whai ora / service users who present with co-existing mental health issues the key worker and / or medical practitioner liaises with the current provider of mental health services if any and supports the tāngata whai ora / service user and the mental health services provider where appropriate.
- b) For tāngata whai ora / service users not engaged with a mental health service, depending on acuity and appropriateness, the tāngata whai ora / service user may:
 - i. be referred for treatment through their GP
 - ii. be provided with OST medical practitioner assessment and treatment
 - iii. have key worker and / or medical practitioner consultation with the BOPAS Psychiatrist / Psychologist
 - iv. have BOPAS Psychiatrist / Psychologist assessment and follow-up (e.g. complex conditions)
 - v. be referred to their local community mental health acute care team (crisis team)
 - vi. have Police follow-up (e.g. where violence is a risk).

8. Management of Hepatitis C

- 8.1. The OST service aims to ascertain the hepatitis C status of all tāngata whai ora / service users to ensure that appropriate advice is given, and further investigation / management is addressed. (See table 8.5 below).
- 8.2. Note that there is a sero-conversion window for Hepatitis C. If the Hepatitis C antibody test is found to be negative and a tāngata whai ora / service user has undertaken activity which may have put them at risk of exposure to Hepatitis C within the previous 6 months, a repeat Hepatitis C antibody test should be undertaken after a 3-month interval.
- 8.3. Informing the tāngata whai ora / service user of the results of a positive hepatitis viral load (PCR) test can be done by the medical practitioner or by the key worker after discussion with the medical practitioner if necessary. Depending on the tāngata whai ora / service user's expectations the result may be given face to face or by telephone, whichever is appropriate in the circumstances.
- 8.4. If waiting for the usual medical practitioner's appointment would cause undue delay and the test results suggest that immediate action is advisable, an appointment is made at the earliest opportunity for discussion of results and post-test counselling with the medical practitioner.

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8.5. OST service recommended guidelines for Hepatitis C management

For all OST tāngata whai ora / service users the service will encourage a hep C antibody test is completed at the start of treatment, and three months after potential exposure

If positive

Offer PCR test (if they have not had this done), follow- up LFTs and Hepatitis A & B screening if required.

If PCR positive, recommend the tāngata whai ora / service user visit their GP for a referral or treatment, or refer directly to the local Gastroenterology Service / Liver Transplant Unit

If negative

Advise tāngata whai ora / service user of outcome and offer counselling on safe injecting if appropriate.

Note: For those with poor venous access, Liver Function Tests (LFTs) require half a microtainer sample and the hepatitis antibody and Hepatitis B antigen tests require 1.5 to 2 microtainer samples (i.e. 2 microtainer samples in total for all these tests). The Hepatitis C PCR requires a single full microtainer. Each microtainer tube takes 1 mL.

9. Drug Interactions with Opioids

- 9.1. It may be hazardous to take opioids with other drugs.
- 9.2. Synergism of actions with consequent toxicity and death has occurred as a result of mixing opioids with some drugs. Where more than one drug is used with opioids the effects can be unpredictable. Substances that alter liver metabolism may increase or decrease the metabolism of opioids.
- 9.3. The pharmacology and pharmacokinetics of, and a list of important drug interactions with, methadone and buprenorphine can be found in the [New Zealand Practice Guidelines for Opioid Substitution Treatment 2014](#), Appendices 3 and 5
- 9.4. Managing co-existing benzo / hypnotic dependence:
 - a) Benzodiazepines and benzodiazepine-like hypnotics and anxiolytics are medicines which bring about a state of sedation, increased sleepiness, relaxation and impaired memory formation, depending on the drug and formulation used. Benzodiazepine-like hypnotics are often referred to as z-drugs due to the alliteration in their naming (zopiclone, zolpidem, zaleplon) and indication as hypnotics. Zopiclone is the only z-drug available in New Zealand. Benzodiazepines are Class C controlled drugs; zopiclone is not a controlled drug at present.
 - b) When a tāngata whai ora / service user presents with evidence of dependence / misuse of benzodiazepines or hypnotics, the service will take the following immediate actions:
 - i. Provide appropriate advice on the risk associated with mixing sedatives such as benzodiazepines and hypnotics with OST
 - ii. Review safety measures around OST dosage, takeaway doses, additional medications prescribed etc.
 - c) If GP prescribed, ask the GP to dispense daily in the first instance, and advise the GP on a suitable reduction regimen to follow. Should this advice not be adhered to, or there is ongoing evidence of misuse, then the service should take over the prescribing of the benzodiazepines or hypnotics. When the service takes over prescribing of benzodiazepines or hypnotics, it will always be dispensed alongside OST. In the case of benzodiazepines, the tāngata whai ora / service user will be expected to consume a partial

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dose observed in the pharmacy daily. For hypnotics dispensing the service will dispense this daily as per OST schedule for nocte consumption.

- d) As evidence does generally not support the prescribing of hypnotics on a longterm basis, and for most people a reduction plan will be discussed as soon as possible, and initiated. A transfer to an equivalent dosage of a benzodiazepine such as diazepam can be considered to support the tāngata whai ora / service user in reducing off.
- e) Those on benzodiazepines such as clonazepam or lorazepam can also be offered a transfer to diazepam to facilitate a smoother reduction.
- f) Where a tāngata whai ora / service user is not GP prescribed, but there is evidence of misuse / dependence, it might be appropriate to support the tāngata whai ora / service user with a benzodiazepine stabilisation prescription to support them in addressing their dependence. There needs to be evidence of consistent use, such as urine drug screens and serum levels for benzodiazepines before commencing a prescription. The medical practitioner will discuss the stabilisation regimen with the tāngata whai ora / service user, and agree on a suitable dose to start.
- g) Diazepam is the benzodiazepine that will usually be used in stabilisation regimen, as it is long-acting, adherence and compliance can easily be monitored with serum levels and urine drug screens, and reductions can be completed in smaller increments.
- h) The purpose of offering a stabilisation regimen is to allow the tāngata whai ora / service user to seek appropriate help and support to address their benzodiazepine / hypnotic dependence, and this will only be offered as a temporary measure. It is anticipated that within 3 months from commencing a stabilisation prescription, a reduction plan will be discussed and initiated.
- i) Consistent on top use of benzodiazepines or hypnotics whilst on a stabilisation regimen, will require review of the suitability of ongoing prescribing of diazepam, and can be discussed in MDT.

10. Management of iatrogenic opioid dependence (IOD)

- 10.1. IOD is dependence on opioids subsequent to consuming legally prescribed and / or over-the-counter (OTC) opioids for pain management. IOD frequently features behaviours which are usually attributable to unstable dependence such as early collection of repeat prescriptions, obtaining additional supplies from original prescriber, another prescriber or another source, and irritability when denied extra doses.
- 10.2. Typically people who are at risk of developing IOD are those who have experienced chronic pain issues.
- 10.3. Principles for working with tāngata whai ora / service users with IOD
 - a) A GP or other medical practitioner cannot legally prescribe opioid medications to any person who is receiving those medications to treat an opioid addiction, unless that prescriber has been authorised to prescribe to that person under a GP shared-care agreement with the secondary addictions service.
 - b) Good communication and liaison between all agencies and the tāngata whai ora / service user are essential.

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10.4. Referrals

On receipt of a referral or self-referral for a tāngata whai ora / service user with possible IOD:

- a) The MDT:
 - i. reviews all relevant supporting tāngata whai ora / service user information (e.g. GP, Pain Service, Psychiatric Service, discharge letters on RCP)
 - ii. discusses the referral in the MDT meeting
 - iii. if indicated, make an appointment for assessment with the key work or medical practitioner as appropriate.

10.5. Not attending for assessment

If a tāngata whai ora / service user does not attend for assessment at BOPAS OST, the team discusses and decides on appropriate recommendations which may include:

- a) Informing the referrer that the tāngata whai ora / service user did not attend, and any recommendations.
- b) In conjunction with the usual prescriber, withholding or managing the usual prescription of opioids (e.g. until the tāngata whai ora / service user attends the assessment).
- c) Informing the Medical Officer of Health.

10.6. Outcome of initial assessment

The key worker discusses the tāngata whai ora / service user's situation and presentation with the medical practitioner and MDT and, if appropriate, obtains any additional information and schedules a medical assessment. Options following the medical assessment include:

- a) OST.
- b) Continued GP prescribing without BOPAS OST involvement in the event that
- c) addiction criteria are absent. The GP may be advised to refer to the Pain Service.

11. **Pregnancy**

11.1. "The treatment of pregnant tāngata whai ora / service user's is a priority for BOPAS OST. Wherever possible, if a OST tāngata whai ora / service user becomes pregnant good communication should occur across primary and secondary care. Opioid agonist maintenance is thought to have minimal long-term developmental impacts on children when compared to the risk of maternal heroin use and resulting harms. – WHO 2009" [New Zealand Practice Guidelines for Opioid Substitution Treatment 2014](#)

11.2. Pregnant tāngata whai ora / service users in GP Shared Care

- a) In recognition of the potentially complex issues associated with methadone or Buprenorphine / Naloxone treatment in pregnancy, BOPAS prefer to provide specialist care to the tāngata whai ora / service user and additional support to the GP once a tāngata whai ora / service user's pregnancy is confirmed.
- b) The Addiction Liaison Clinician will contact the GP to discuss appropriate management and support during the pregnancy.

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11.3. Pregnancy and OST

- a) Illicit opioid use in pregnancy is associated with maternal and foetal acquisition of blood-borne viruses, preterm labour and delivery, intrauterine growth retardation, pre-eclampsia, placental abruption and intrauterine foetal death. Opioid substitution treatment in pregnancy has been found to reduce illicit drug use, improve maternal engagement in antenatal care and improve neonatal birth weight.
- b) For pregnant women entering OST, methadone is currently the preferred treatment, as there is a greater body of data about long-term efficacy and safety with respect to its use in both pregnancy and breastfeeding.
- c) Methadone metabolism and circulating blood volume may change significantly during pregnancy, leading to lower plasma methadone concentrations and symptoms of withdrawal. A tāngata whai ora / service user may require increased doses of methadone, usually in the late second or third trimester. It may also be worth splitting the daily methadone dose into two 12-hour doses in addition to, or as an alternative to, a dose increase, in order to minimise the impact of pre-dose trough levels. It is important to monitor the methadone dose after delivery, as a reduction might be required to avoid sedation/toxicity. If a tāngata whai ora / service user has been on a split dose, this can be returned to a single daily dose after delivery.
- d) Buprenorphine / Naloxone should be used in pregnancy only when the potential benefit justifies the potential risk to the fetus. Buprenorphine crosses the placental barrier and the neonate should be monitored for a withdrawal syndrome. Due to the long half-life of buprenorphine, this monitoring should continue for several days. Buprenorphine is excreted into human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for buprenorphine/naloxone and any potential adverse effects on the breastfed child from the drug or from the underlying maternal condition.
- e) Contact between the key worker and tāngata whai ora / service user is made on a regular basis according to tāngata whai ora / service user choice, with a minimum of monthly contact for the first 7 months and increasing contact thereafter as the due date approaches.

11.4. Withdrawal of OST during pregnancy

- a) Methadone and buprenorphine/naloxone increase engagement in antenatal care and improve outcomes for mother and baby during pregnancy, including reduced risk of low birth weight, prematurity and neonatal death.
- b) The National Guidelines (2014, page 54) state: "Pregnant women in OST should be encouraged not to cease it while they are pregnant. Severe opioid withdrawal symptoms may induce a spontaneous abortion in the first trimester of pregnancy, or premature labour in the third trimester."
- c) If a tāngata whai ora / service user expresses a wish to reduce or withdraw from their OST medication during pregnancy a full discussion of the advantages and disadvantages is to be undertaken. If after full discussion a tāngata whai ora / service user still wishes to withdraw from OST during pregnancy, BOPAS OST supports her to ensure the process is as comfortable and as safe as possible for mother and baby.

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11.5. Methadone metabolism in pregnancy

- a) As a result of alterations in methadone metabolism and volumes of distribution in pregnancy a tāngata whai ora / service user's methadone dose may need increasing as the pregnancy progresses. Conversely, after delivery methadone requirements may reduce and the tāngata whai ora / service user is monitored accordingly by their key worker (see Postnatal management of methadone dose, 11.9, page 11)

11.6. Vomiting in pregnancy

- a) The key worker, Pharmacist or medical practitioner receiving the report of vomiting in pregnancy must be satisfied that the dose has been vomited.
- b) Procedure
 - i. *Methadone*: A vomited dose is replaced only when the tāngata whai ora / service user vomits within approximately 20 minutes of consuming the dose and the replacement is clinically justified. The entire dose will have been absorbed within 30 minutes of ingestion.
 - ii. *Buprenorphine*: doses are absorbed sublingually within 2 – 7 minutes. Vomiting after this time makes no difference to the absorbed dose.
 - iii. The range of replacement for vomited doses is between 50% and 100%.
 - iv. The full clinical picture is taken into consideration when determining the replacement dose. The medical practitioner signing the prescription must be satisfied that the replacement dose is necessary and safe.
 - v. All replacements are fully documented in the clinical notes.
- c) In situations when a second replacement dose has been given, no further replacement doses will be authorised until the tāngata whai ora / service user has been assessed by a BOPAS OST medical practitioner, their GP or the specialist antenatal service provider(s) so that strategies for the management of vomiting in pregnancy can be discussed and established.
- d) Strategies to reduce or prevent vomiting of methadone in pregnancy include:
 - i. eating prior to dosing
 - ii. remaining seated for a few minutes before consuming
 - iii. changing the timing of dosing to later in the day
 - iv. sipping the methadone dose more slowly
 - v. temporary prescription of anti-emetic such as metoclopramide
- e) If a tāngata whai ora / service user continues to vomit on metoclopramide, they should be referred for specialist obstetric review. Second line anti-emetics used by Obstetricians include cyclizine and ondansetron.
 - i. Cyclizine is commonly misused – including via injection - this should be considered before it is prescribed.
 - ii. Ondansetron can be associated with QT interval prolongation.
- f) All replacement doses must be prescribed and must be consumed in the Pharmacy.

11.7. Split dosing

- a) Splitting the dose may be considered for stable pregnant tāngata whai ora / service users to avoid the necessity for increasing the methadone dose, as pregnancy-related changes in volume of distribution and metabolism of methadone may lead to decreased serum levels.

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11.8. Treatment plan

The BOPAS OST key worker co-ordinates care for a pregnant tāngata whai ora / service users whether the tāngata whai ora / service user is prescribed by the specialist service or by the GP, as follows:

- a) Obtain confirmation of pregnancy and expected delivery date.
- b) Provide tāngata whai ora / service user with a copy of the OST pregnancy information sheet.
- c) Ensure the pregnant wahine / woman has a LMC
- d) Complete treatment review together with prescriber.
- e) Establish appointment frequency:
 - i. More frequent face to face sessions with the tāngata whai ora / service user are recommended to proactively manage potential withdrawal due to increased blood volume.
 - ii. Arrange with tāngata whai ora / service user monthly key worker appointments.
 - iii. See prescriber at onset of pregnancy and as necessary according to medical practitioner / key worker / tāngata whai ora / service user assessment thereafter.
- f) Organise diagnostic tests for the tāngata whai ora / service user, if indicated. Discuss the need and result with the medical practitioner.
- g) Manage other issues proactively, e.g. encourage / assist tāngata whai ora / service user to follow-up general health needs and / or LMC appointments.
- h) Co-ordinate prescribing and dispensing
- i) Ensure tāngata whai ora / service user has information, e.g. recommended OST in pregnancy, detoxification in pregnancy, breastfeeding.

11.9. Postnatal management of methadone dose

- a) In order to ascertain the changing requirements, if any, for OST in the immediate postnatal period whilst the tāngata whai ora / service user is in hospital, the BOPAS OST key worker liaises closely with the tāngata whai ora / service user and the lead maternity care provider to check for evidence of intoxication (such as post dose drowsiness) or of under-dosing post-delivery. Plasma levels of methadone may rise rapidly due to post-delivery reduction in volume of distribution.
- b) On discharge from hospital the key worker frequently follows up with the tāngata whai ora / service user, in conjunction with the medical practitioner or GP, to ensure appropriateness of OST dose and dosing regimen.
- c) If a tāngata whai ora / service user has had her methadone dose split during pregnancy, it is usual to return to once daily dosing following delivery.
- d) The tāngata whai ora / service user is seen at BOPAS OST within 6 weeks following delivery for medical review and treatment, and recovery planning.
- e) Liaise with maternity provider as soon after delivery as possible.
- f) *On day 4:* Obtain subjective dose stability feedback from tāngata whai ora / service user.
- g) If the tāngata whai ora / service user is a current or recent in-patient obtain in-patient nurse feedback re pre and post-dose presentation. Perform a 4-hour post-dose check (in the tāngata whai ora / service user's ward if still an in-patient and unable to travel).

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- h) Discuss treatment options with BOPAS OST medical practitioner and GP if prescriber, and follow up (e.g. dose reduction / serum methadone levels). Ensure tāngata whai ora / service user is informed of reduction plan if indicated. If tāngata whai ora / service user does not concur, review further with prescriber.
- i) If serum methadone levels are required obtain pre-dose serum, at least 3 days post-partum and preferable 5 – 6 days post-partum. Obtain copies of results within 24 hours of completion and discuss with the specialist medical practitioner.
- j) Ensure tāngata whai ora / service user, pharmacy and hospital nurse communication for discharge planning and continued consumption.
- k) Schedule follow-up medical and key worker treatment and recovery planning appointment with tāngata whai ora / service user to take place within 4-6 weeks of hospital discharge.
- l) Arrange GP prescriber re-authorisation, where indicated, following specialist medical appointment.

11.10. Breastfeeding

- a) Mothers on OST are encouraged to breastfeed unless there is a contraindication (e.g. tāngata whai ora / service user is HIV positive). Hepatitis C is not in general a contraindication to breastfeeding. However, Hepatitis C positive mothers who develop bleeding, cracked nipples should express their milk and discard it until the nipples have healed.
- b) Negligible amounts of methadone are excreted into breast milk and are insufficient to prevent neonatal abstinence syndrome. However where possible, weaning from breastfeeding should be undertaken gradually to avoid the potential for withdrawal symptoms in the baby.
- c) Buprenorphine is also transferred into breast milk at low levels. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for buprenorphine / naloxone and any potential adverse effects on the breastfed child from the drug or from the underlying maternal condition.

12. **Methadone and risk of QTc prolongation**

The risk of QTc prolongation in tāngata whai ora / service users who are using or being prescribed methadone is unpredictable and does not appear to be dose dependent. (National Guidelines 2014).

12.1. Contraindications

- a) Tāngata whai ora / service users are asked about any history of liver or heart disease, including structural heart defects, arrhythmia, syncope and unexplained seizures, and about family history of unexplained collapse or death during assessment.
- b) Clinical assessment should cover other risk factors for prolongation of the QTc interval including:
 - i. concomitant treatment with drugs which may affect the metabolism of methadone
 - ii. treatment with other drugs with the potential to cause QTc prolongation
 - iii. the presence of hypokalaemia (assessed by U&E testing at admission and as clinically indicated).

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12.2. Information for tāngata whai ora / service users

- a) Clinicians ensure that the tāngata whai ora / service user is fully informed of the reasons for the clinical assessment and is involved in the decision-making process for their treatment. Specifically, tāngata whai ora / service users are informed of the risk of arrhythmia when they take methadone.

12.3. Risk Analysis

- a) The decision to perform an ECG prior to commencement of methadone treatment is based on a risk-benefit analysis. A baseline ECG should be considered in tāngata whai ora / service users with the presence of the above-mentioned risk factors or symptoms, and repeated after 3 months of treatment with methadone. Tāngata whai ora / service users tāngata whai ora / service users are able to access a free ECG at Tauranga Hospital, however they may also choose to access this via their GP, but this will incur a cost to them. BOPAS OST is not able to fund this ECG.
- b) Reassessment should occur if the tāngata whai ora / service user's health or prescribed medications change during the course of treatment, and an ECG performed if appropriate. The performance of an ECG should also be considered if a tāngata whai ora / service user's dose of methadone exceeds 100 mg and they are on any other prescribed medication that could prolong QT interval, and should be performed annually if a tāngata whai ora / service user's dose of methadone exceeds 150 mg. The need and interval for repeat ECGs should be assessed clinically based on the circumstances and the results of previous ECGs.
- c) If a tāngata whai ora / service user declines or otherwise fails to have an ECG performed the reasons for the ECG should be discussed with them again. If the tāngata whai ora / service user still does not have an ECG performed the medical practitioner, clinician and tāngata whai ora / service user will decide together upon the best course of action for that tāngata whai ora / service user, which may involve reducing the methadone dose or otherwise modifying the risk for QTc prolongation, such as changing other medication the tāngata whai ora / service user is taking. All such discussions should be fully documented.
- d) The most usual management of QTc prolongation will be a reduction in methadone dose and / or a modification of any other modifiable risk factors specific to the tāngata whai ora / service user concerned. Treatment with alternatives to methadone will be considered if a tāngata whai ora / service user has ECG evidence of excessive or symptomatic QTc prolongation and the advice from a Cardiologist is that an alternative opiate substitute to methadone would be recommended.
- e) BOPAS OST does not prescribe quetiapine or amitriptyline for the management of insomnia, due to the increased risk of QTc prolongation, and the lack of evidence supporting longterm prescribing of medication for insomnia. Often GPs will prescribe these medications off-label, and in this case the medical practitioner will advise the GP of the risk, and remind the GP of the need to do an annual ECG if they choose to continue the prescription.

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13. Chronic Medical Conditions and End of Life Care

13.1. Chronic Medical Conditions

- a) Identification and recording
 - i. The following may suggest that a tāngata whai ora / service user's chronic condition is not being well managed and may require more pro-active intervention(s) by BOPAS OST:
 - The tāngata whai ora / service user does not engage with medical care external to BOPAS OST
 - The tāngata whai ora / service user chooses not to respond to treatment recommendations
 - The tāngata whai ora / service user does not attend requested clinical investigations
 - The tāngata whai ora / service user's physical presentation deteriorates
 - There are health concerns indicated via routine metabolic monitoring undertaken by the key worker or the tāngata whai ora / service user refuses to undertake metabolic monitoring.
 - The tāngata whai ora / service user chooses not to accept the implications of having the chronic condition
 - ii. Such concerns are discussed with the OST medical practitioner and, if required a plan to support the tāngata whai ora / service user is developed collaboratively with the tāngata whai ora / service user wherever possible.
- b) Support:

Support may include:

 - i. Assisting the tāngata whai ora / service user to enrol with a GP
 - ii. Liaison with the tāngata whai ora / service user's GP
 - iii. Liaison with other involved health care providers including hospital / hospice specialists
 - iv. Referral to hospital specialists
 - v. More intensive key worker engagement with the tāngata whai ora / service user including home visits
 - vi. Motivational work and education including health literacy support, around medical issues, lifestyle issues, self-care and self-management
 - vii. Assisting the tāngata whai ora / service user with obtaining benefits and entitlements to assist their engagement with medical care
 - viii. Opportunistic monitoring of medical conditions at medical practitioners' appointments and communication with the tāngata whai ora / service user's GP
 - ix. Liaising with family / carers including assistance on managing, administering and safety of OST doses where applicable (e.g. private hospitals and residential facilities)
 - x. Seeking additional support from peer networks, and from peer or community support workers.

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13.2. End of Life Care

- a) BOPAS OST tāngata whai ora / service users who require end of life or palliative care usually require input from other services including their general practitioner, palliative care / hospice services and hospital. BOPAS OST works closely with these services to ensure:
 - i. OST tāngata whai ora / service users receive the same level of care as would patients not receiving / engaged in OST; and
 - ii. any circumstances needing special attention due to the tāngata whai ora / service user's OST are taken into consideration.
- b) For tāngata whai ora / service users with complex physical conditions the key worker consults closely with the medical practitioner.
- c) Medication adjustments
 - i. Tāngata whai ora / service users may need the dose or frequency of administration of opioid medication adjusted under certain circumstances such as:
 - to provide better pain relief
 - to prevent over-sedation in liver failure
 - to prevent respiratory depression in respiratory failure
 - to take account of drug interactions
 - because of difficulties attending the pharmacy
 - to allow closer monitoring by the pharmacist.
 - ii. The key worker and medical practitioner liaise closely with other carers and with the tāngata whai ora / service user to ensure that any issues that may arise are anticipated in advance or dealt with quickly and effectively.
- d) Responsibility for OST prescribing and pain relief
 - i. Tāngata whai ora / service users undergoing palliative care often have pain issues. Opioid substitution medications prescribed for addiction will not normally address pain issues adequately.
 - ii. BOPAS OST does not offer treatment for pain issues in the absence of addiction but may adjust OST as part of a wider pain relief regimen if appropriate. The BOPAS OST medical practitioner advises clinicians prescribing pain medications to ensure that tāngata whai ora / service user has adequate pain relief supplied in a safe manner, which may include short interval prescribing of pain medications (e.g. weekly or daily collection).
 - iii. As for any patient with pain the WHO analgesic ladder is applicable:

Mild Pain	Moderate Pain	Severe Pain
Paracetamol 1g Q4-6H Max 4g / 24 hours	Paracetamol 1g Q4-6H Max 4g / 24 hours +/- Ibuprofen 400mg Q6-8H (or other NSAID where no contra- indications present) +/-codeine 30 – 60 mg Q4-6H (max 240 mg / 24 hours); or tramadol 50 – 100mg Q4-6H Max 400mg / 24 hours	Paracetamol 1g Q4-6H Max 4g / 24 hours +/- Ibuprofen (or other NSAID); or Tramadol 50 – 100mg Q4-6H Max 400mg / 24 hours + an appropriate opioid e.g. morphine, fentanyl, oxycodone. Consider long-acting with short-acting for breakthrough pain.

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- e) Shared Care
- It may be appropriate for a tāngata whai ora / service user's GP or palliative care medical practitioner to take over prescribing of OST. The usual criteria for suitability for shared care apply and the medical practitioner is authorised by BOPAS OST.
 - When it becomes apparent that OST is being prescribed principally as part of a terminally ill tāngata whai ora / service user's pain relief regimen at the very end of life, the prescribing of all opioid medication may, on discussion and agreement with the palliative care medical practitioner involved, be handed over to the Palliative Care team who may continue to prescribe the medication for pain without need for authorisation from BOPAS OST.
 - This constitutes a discharge from treatment for addiction and therefore authority to prescribe for addiction should be withdrawn by BOPAS OST to prevent any subsequent confusion arising.

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- [Ministry of Health. 2014. New Zealand Practice Guidelines for Opioid Substitution Treatment. Wellington: Ministry of Health](#)
- [NZ Formulary. methadone hydrochloride](#)
- [NZ Formulary. buprenorphine + naloxone](#)
- [NZ Formulary. codeine phosphate](#)
- [New Zealand Datasheet. Biodone Oral solution. Biomed Limited. 14 December 2022](#)
- [New Zealand Datasheet. Buprenorphine Naloxone BNM. BNM Group. 19 August 2022](#)

ASSOCIATED DOCUMENTS

- [Te Whatu Ora Hauora a Toi Bay of Plenty policy 1.1.1 Informed Consent](#)
- [Te Whatu Ora Hauora a Toi Bay of Plenty policy 2.5.2 Health Records Management](#)
- [Te Whatu Ora Hauora a Toi Bay of Plenty policy 4.1.0 Infection Prevention and Control Management](#)
- [Te Whatu Ora Hauora a Toi Bay of Plenty Clinical Practice Manual protocol CPM.M9.2 Pharmacist Dispensing Opioid Substitution Treatment \(OST\)](#)
- [Te Whatu Ora Hauora a Toi Bay of Plenty Clinical Practice Manual protocol CPM.M9.3 Admission to Opioid Substitution Treatment \(OST\)](#)

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- [Te Whatu Ora Hauora a Toi Bay of Plenty Clinical Practice Manual protocol CPM.M9.4 Opioid Substitution Treatment \(OST\) Client Pathway](#)
- [Te Whatu Ora Hauora a Toi Bay of Plenty Clinical Practice Manual protocol CPM.M9.5 Opioid Substitution Treatment \(OST\) Managing Co-existing Conditions](#)
- [Te Whatu Ora Hauora a Toi Bay of Plenty Clinical Practice Manual protocol CPM.M9.6 Opioid Substitution Treatment \(OST\) Prescribing and Dispensing](#)
- [Te Whatu Ora Hauora a Toi Bay of Plenty Mental Health & Addiction Services OST Overseas Travel Letter template](#)

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