

Involuntary reduction of opioid substitution therapy and methadone dispensing error

1. Ms A had been receiving methadone¹ as part of opioid substitution treatment² (OST) since 2009 and had been registered with the Health New Zealand | Te Whatu Ora (Health NZ) Hauora a Toi Bay of Plenty (BOP) Addiction Service since late 2019.
2. Ms A complained that in 2023 the BOP Addiction Service reduced her methadone dose involuntarily on two occasions, and on another occasion required her to undergo unnecessary methadone serum level testing.³ The complaint also raised concerns about a methadone dispensing error at Unichem Greerton Pharmacy (Unichem Greerton).
3. Having considered these concerns, for the reasons below I find Health NZ BOP in breach of Rights 4(1)⁴ and 4(4)⁵ of the Code of Health and Disability Services Consumers' Rights (the Code). Further, I find Unichem Greerton in breach of Right 4(2)⁶ of the Code and have made adverse comment about pharmacist Mr B.

Care provided by Health NZ BOP

First reduction

4. On 21 June 2023, Ms A was told by case manager Mr C that because of her recent intravenous (IV) use of illicit opioids, missed appointments, and missed medical reviews she should switch to buprenorphine – an opioid used for maintenance therapy in opioid dependence.⁷ When Ms A declined, she was told that the service would begin reducing her methadone dose (at that stage 48mg/day) by 2mg per day. This occurred two days later (23 June). Health NZ BOP said that the decision to reduce Ms A's methadone dose was made by the OST Multidisciplinary Team (MDT) in response to their concerns about her safety related to potential overdose. The dose reduction was implemented without a medical review of Ms A and without an option for Ms A to appeal or seek a second opinion. Mr C told Ms A

¹ An opioid used for maintenance therapy in opioid dependence and for chronic pain management.

² Treatment that offers people with dependence on opioids (such as heroin) an alternative, prescribed medicine — most typically methadone or buprenorphine — which is swallowed rather than injected.

³ Measurement of the concentration of methadone in the blood.

⁴ Right 4(1) states: 'Every consumer has the right to have services provided with reasonable care and skill.'

⁵ Right 4(4) states: 'Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.'

⁶ Right 4(2) states: 'Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.'

⁷The risk of overdose is lower with buprenorphine than with methadone.

that a doctor's appointment had been scheduled for 4 July to 'discuss the plan moving forward'.

5. I obtained advice from an independent addiction psychiatrist, Dr Emma Schwarcz, regarding this reduction. Dr Schwarcz advised that several elements of Health NZ BOP's care of Ms A departed severely from accepted standards, including the New Zealand Practice Guidelines for Opioid Substitution Treatment 2014 (OST Guidelines).⁸ In Dr Schwarcz's view, Ms A's original dose was sub-therapeutic⁹ and, combined with ongoing opioid use, should have signalled an increase in dose (rather than reduction).
6. Dr Schwarcz also advised that the risks associated with involuntary reduction of medication (that is, a reduction of methadone without the agreement of the consumer), including rapid decompensation¹⁰ and overdose, 'far outweighed' the risks of ongoing occasional opioid use and patchy engagement. These circumstances did not present an acute risk to warrant involuntary withdrawal, which should be considered only as a last resort and should be informed by medical review. Dr Schwarcz considered that the Addiction Service failed to take a harm-reduction approach.
7. Having considered Dr Schwarcz's report, Health NZ BOP acknowledged that the decision to reduce Ms A's methadone dose and encourage transfer to buprenorphine 'was identified prematurely, somewhat unilaterally, and to the exclusion of other alternatives such as a dose increase'.
8. Dr Schwarcz also considers that the Addiction Service's communication with Ms A prior to the methadone reduction was inadequate, as was the short time between advising of and enforcing the decision, noting that it left little opportunity for appeals processes or making plans to cope. These were identified as moderate to severe departures. Dr Schwarcz further considered that the rate of reduction (2mg/day) was too rapid, and that this was also a severe departure.
9. Once the dose reduction began, Ms A and her partner repeatedly told the Service that she was not coping well physically or psychologically and that she was at risk of self-harming and of 'purchasing drugs and overdosing'. Ms A was not offered any physical or psychological support. Limited contact was initiated by the Addiction Service.
10. Dr Schwarcz considers that the management of Ms A's discomfort once the reduction began was a severe departure from accepted standards, noting there was little contact from the Service and no tangible physical or psychological support to her. In addition, the letter advising of the decision was inadequate and contained no discussion about risks, benefits, side-effects, withdrawal management, recourse, or how Ms A might re-engage in OST other than attending a medical review 12 days away.
11. On 4 July, Mr C asked Ms A via text message whether she wished to start buprenorphine. Ms A told HDC that Mr C told her that her scheduled medical review would not proceed

⁸ [New Zealand Practice Guidelines for Opioid Substitution Treatment 2014](#) (superseded in October 2025 by the New Zealand Practice Guidelines for Opioid Substitution Treatment 2025).

⁹ A therapeutic dose is within 60–120mg per day.

¹⁰ An acute worsening of physical and/or psychological stability.

unless she agreed to begin buprenorphine.¹¹ Mr C further advised Ms A that her request to cease the methadone reduction and/or resume her usual dose would be considered by the OST MDT on 11 July.

12. On 6 July, Ms A agreed to start on buprenorphine ‘under duress’, but she did not tolerate this well and she reverted to the reduced methadone dose.
13. On 11 July, an OST MDT meeting and urgent medical review with the BOP Addiction Service’s psychiatrist resulted in a plan to stop buprenorphine immediately and gradually increase Ms A’s methadone dose.
14. Health NZ BOP acknowledged that the care provided to Ms A prior to this point was insufficient, and the tone and directness of communication between the case manager and Ms A was ‘not sufficiently client-centered, nor in line with the gravity of the issues at hand’. However, Health NZ BOP also said that it considers that the ‘suboptimal procedures in Ms A’s treatment and care’ identified by Dr Schwarcz were ‘mitigated at [this] first face-to-face appointment [on 11 July] with [the BOP Addiction Service’s psychiatrist].’
15. Health NZ BOP identified systemic factors for the deterioration in the therapeutic relationship with Ms A. These, in its view, included the level of autonomy that Mr C had in decision-making and the reduced frequency and amount of information flowing to the OST MDT. However, Health NZ BOP accepted that the decision to reduce Ms A’s dose rested with the whole MDT but stated that the MDT may not have had access to all the necessary information when making critical decisions. This included that the MDT was unaware of the extent of Ms A’s distress, had assumed that a dose increase had been discussed, and believed that Ms A was a ‘willing partner’ in the transfer to buprenorphine. Health NZ BOP stated that if the methadone reduction had been conceived as an involuntary withdrawal, the MDT would have required more information, feedback, and consideration of the likely physical and psychological impacts of this. Health NZ BOP noted that none of this minimises the responsibilities of the MDT.

Serum-level testing

16. On 22 August 2023, Ms A told Mr C that she was experiencing withdrawal symptoms and requested an increase to her dose (40mg/day at the time). When this was not supported, she asked that her serum levels be tested to show that the current dose was not ‘holding’ her. On 30 August the serum results had not yet been returned and the OST MDT agreed that there would be ‘no increase of dose without definitive evidence that this is required’. On 6 September the OST MDT noted that the serum results were ‘low’, and it was agreed to repeat serum testing ‘for due diligence’. Ms A’s usual dose was withheld.
17. Ms A complained that further serum tests were not medically necessary. She noted that her damaged veins make it ‘extremely difficult’ to give blood. Each serum test required her to give blood once before her methadone dose, and again afterwards (pre- and post-dose).

¹¹ Health NZ BOP subsequently informed Ms A and HDC that the doctor’s appointment planned for 4 July 2023 had never been booked. In response to the provisional decision, Mr C said that he had booked an appointment with the Addiction Service’s psychiatrist; however, he said that when Ms A arrived, the psychiatrist refused to see her unless she agreed to switch to buprenorphine.

18. Dr Schwarcz advised that there was no clinical indication for either set of serum tests. She stated that the Addiction Service's approach was not consistent with the OST Guidelines, did not appear to be client-centred, and was a severe departure from accepted practice. She stated that a sub-therapeutic dose of 40mg/day in conjunction with withdrawal symptoms was an indication to increase the dose. There was also no apparent reason for the tests to be of the 'pre and post' kind rather than the usual pre-dose levels. Requiring serum tests delayed a stabilisation of Ms A's dose and added to her overall instability and risks.
19. In response, Health NZ BOP stated that 'the exact circumstances of the first [serum] test were unclear'. Health NZ BOP said that Ms A's dose was increased after the first serum tests, and the second set of tests were requested to determine the efficacy of the dose increase. Health NZ BOP stated that pre- and post-dose tests were requested to determine whether the difference between peak and trough levels were sufficient to suppress any withdrawal symptoms.
20. There is no evidence in the clinical records of a dose increase between the first set of serum testing on 23 August and the second set being requested on 6 September. Dispensing records from Unichem Greerton for September 2023 show that from 1 to 6 September Ms A was dispensed 8ml (40mg) of methadone per day.

Second reduction

21. On 1 September 2023, the Addiction Service was notified that Ms A's dispensing pharmacy had accidentally given her another patient's methadone dose — 90mg instead of her usual 40mg. After first checking on her wellbeing, the Addiction Service told Ms A that her usual dose would be halved for the next two days. Ms A was distressed about this decision.¹² The OST doctor subsequently reviewed the decision and prescribed 20mg of methadone for one day, with the usual dose reinstated by the next day, on the basis that preservation of the therapeutic relationship was paramount.
22. Dr Schwarcz advised that this outcome was consistent with usual practice.

Decision: Health NZ BOP — breach

23. Under Right 4(1) of the Code, Health NZ BOP had a responsibility to provide Ms A with services with reasonable care and skill.
24. Health NZ BOP indicated that systemic deficiencies resulted in the OST MDT making decisions about Ms A's treatment based on incomplete and erroneous information (as outlined in paragraph 15). Dr Schwarcz advised that these decisions severely departed from accepted standards, and I accept that advice. I acknowledge Health NZ BOP's submission that its 'suboptimal procedures' were mitigated on 11 July 2021 when urgent medical review resulted in a decision to stop buprenorphine and begin gradually increasing Ms A's methadone dose. However, I do not accept that this eventual change to the treatment plan mitigates the poor procedures and decision-making that came before this.
25. I find that by failing to have adequate oversight and communication systems in place to ensure that decisions regarding Ms A's treatment were based on complete and correct

¹² Ms A contacted HDC about this matter, and HDC communicated Ms A's distress to the BOP Addiction Service. HDC did not ask the Addiction Service to make changes to Ms A's prescription.

information and in line with the OST Guidelines, Health NZ BOP failed to ensure that treatment was provided with adequate care and, accordingly, breached Right 4(1). This includes that there was a degree of coercion to have her agree to transfer to buprenorphine in the situation where she did not want this and had no reasonable opportunity to challenge that decision.

26. Under Right 4(4) of the Code, Health NZ BOP also had a responsibility to provide Ms A with services in a manner that minimised the potential harm to her and optimised her quality of life.
27. As a result of the deficiencies identified in Health NZ BOP's care of Ms A, she experienced acute and unnecessary discomfort and distress. I am highly critical that the first dose reduction was implemented without the opportunity for medical review, at a dangerously rapid rate, and without appropriate discussion of risks, withdrawal management strategies, and physical and psychological support options. I agree with Dr Schwarcz that Health NZ BOP failed to take a harm reduction approach.
28. Further, I am critical that in August and September 2023 the Addiction Service again delayed optimisation of Ms A's treatment by requiring her to undergo unnecessary and onerous serum-level testing. In this respect, the evidence does not support that Ms A's dose was increased following the first set of serum tests. As such, I do not accept Health NZ BOP's explanation that the second set of tests was to determine the efficacy of a dose increase. Therefore, with reference to Dr Schwarcz's advice, I conclude that both sets of serum testing were unnecessary.
29. I consider that each of these failings (as outlined in paragraphs 27 and 28) resulted in real harm and increased the risk of harm to Ms A.
30. In response to the provisional decision, Health NZ BOP said:

'The harm claimed to have occurred by Ms A is unverified by independent psychiatric assessment and appears to be the realm of discomfort/distress. [Health NZ BOP] is unaware of any ACC treatment injury claim having been made as a result and would thus be unable to comment on the level or veracity of her claim, or to assume that serious harm had in fact occurred.'
31. I do not accept this argument. I accept that Ms A experienced a high level of distress because of the sudden and rapid withdrawal of her OST medication, as evidenced by the documented reports from her and her partner that she was not coping well physically or psychologically, and that she was at risk of self-harming and of 'purchasing drugs and overdosing'. I do not consider that a consumer's experience of harm must be verified by an independent psychiatric assessment or be part of an ACC claim to be accepted as genuine harm. Further, the harm experienced by Ms A was not in the realm of discomfort, which might, from time to time, be expected in the context of living with opioid dependence and receiving OST; this harm was a direct result of a poor treatment decision. Ms A's self-reported distress is also congruent with Dr Schwarcz's advice that the dose reduction was too rapid.

32. For the reasons discussed, I find that Health NZ BOP failed to provide services in a manner that minimised the potential harm to, and optimised the quality of life of, Ms A, and, accordingly, breached Right 4(4).
33. Based on Dr Schwarcz's advice, I am satisfied that the care provided by the Addiction Service in relation to the second dose reduction was appropriate.

Other comment

34. In October 2023, HDC wrote to the Director of Mental Health and Addiction Services, expressing concerns that many OST services are being provided in a way that is inconsistent with people's rights under the Code. The letter highlighted that OST consumers were not always being respected as partners in their care and that treatment planning or decisions to amend or discontinue treatment were being made without consumers being involved in those discussions. Specific concern was also expressed about the involuntary withdrawal of methadone, at rates which are far from gradual and for reasons not clear to consumers. Poor communication was also a feature of HDC's complaint data.
35. As a consequence of this letter and following a cross-agency meeting on the issues, it was agreed that – in an upcoming review of the OST Guidelines – consideration would be given to enhancing their language to better reflect shared decision-making. Consideration was also to be given to how the three-yearly OST Service audits (as undertaken by the Ministry of Health) could be better utilised to drive and monitor improvement.
36. HDC will continue to monitor these agreed actions.

Care provided by Unichem Greerton

37. On 1 September 2023, Ms A's dispensing pharmacy, Unichem Greerton, accidentally gave her another patient's dose of 90mg of methadone rather than her prescribed dose of 40mg. The two patients' doses had been stored in the controlled drug safe. While retrieving Ms A's dose, pharmacist Mr B inadvertently selected the other patient's dose and gave it to Ms A. Unichem Greerton identified that contributing factors for the error were that Ms A and the other patient shared a similar first name; a 'momentary lapse in attention' may have led to insufficient verifications of the name on the bottle; and as most of the pharmacy's patients receiving methadone arrive early in the morning, resulting in staff feeling pressure to serve quickly to avoid patients waiting long. The pharmacy stated that prescription volume and staffing levels that day were normal.
38. In response to the provisional decision, Unichem Greerton said that while having patients receiving methadone arriving simultaneously early in the morning can lead to staff wanting to ensure that no one is waiting long, the pharmacy does not believe that this created any unusual time pressure or excessive workload that day.
39. Mr B noticed the error immediately and took steps in line with relevant guidelines,¹³ including informing and apologising to Ms A, checking on her condition, reporting the incident to the Addiction Service, and providing safety-netting advice. The pharmacy investigated and documented the incident.

¹³ As per section 9.3.6 of the OST Guidelines.

40. Section 9 of the OST Guidelines sets out the responsibilities and functions of the pharmacist in supporting the community-based management of clients in OST. The OST Guidelines note that if a client receives a higher-than-normal dose of methadone, the potential for complications, including death, are high. To avoid this, section 9 stipulates that pharmacists must use systems and procedures to minimise the chances of dispensing errors,¹⁴ including ‘positively identifying clients’,¹⁵ ensuring that appropriate identification (such as a photograph) is accessible to all staff working with OST clients,¹⁶ and placing warnings in files and dispensing software where client names are similar.¹⁷
41. Greerton Pharmacy had a Standard Operating Procedure (SOP) for ‘Methadone dispensing’. This included a requirement that the pharmacy receive a current named photograph of each new OST patient. There was no process for ‘positively identifying clients’ prior to giving a dose and no procedure for placing warnings where client names are similar.

Decision: Unichem Greerton — breach

42. Under Right 4(2) of the Code, Unichem Greerton had a duty to provide services that complied with legal, professional, ethical and other relevant standards. In this case, this included the standards in the OST Guidelines. I consider that in failing to have policies that set out a process for ‘positively identifying clients’ or a requirement to place warnings where OST clients had similar names, Unichem Greerton did not adequately safeguard against the dispensing error that occurred on 1 September 2023. Considering the controlled nature of methadone and the potentially harmful or fatal outcomes of a dispensing error, I find this extremely concerning.
43. ‘Positive identification’ of OST clients has been discussed in a previous report by this Office.¹⁸ In that report, an independent pharmacist advised: ‘By implication, a positive identification of the client helps to ensure that the patient is matched with their prescribed dose.’ The independent pharmacist also stated that it is accepted practice to have all doses pre-poured and labelled for the day (as had been done at Greerton Pharmacy in this case), and that this ‘prompts a second check for both the correct patient and dose’. That report also noted that requiring OST clients to state their full name before their dose is given would have provided an extra safety net to ensure that the correct person received the correct dose.
44. I acknowledge that the dispensing error was in part caused by Mr B’s ‘momentary lapse in attention’. However, in my view, if Unichem Greerton had had appropriate policies and procedures in place to require warnings to be placed in the pharmacy’s systems (as per the OST Guidelines), this would have reduced the risk of the dispensing error by creating a heightened awareness of the potential for the two patients’ doses to be mixed up and the need for extra care when giving out their doses. Further, I am critical that Unichem Greerton’s Methadone Dispensing SOP did not provide any guidance about ‘positively identifying’ OST clients prior to giving them their doses, as required by the OST Guidelines. If the SOP had provided for this (for example, by requiring clients to state their full name

¹⁴ Section 9.1.

¹⁵ Section 9.2.1.

¹⁶ Section 9.3.6.

¹⁷ Section 9.3.6.

¹⁸ Case 19HDC02146.

and matching this to the label on the dose prior to giving it out), this would have presented an opportunity to identify Mr B's error before Ms A was administered another client's dose. For these reasons, I consider it appropriate to hold Unichem Greerton responsible for the dispensing error. For failing to have adequate policies and processes in place to ensure that its services complied with sections 9.2.1 and 9.3.6 of the OST Guidelines, I find Unichem Greerton in breach of Right 4(2) of the Code.

45. With reference to section 9.3.6 of the OST Guidelines, I am satisfied that Unichem Greerton took appropriate actions once the error was identified, including checking on Ms A's wellbeing, providing safety-netting advice, and reporting, documenting, and investigating the incident.

Decision: Mr B — adverse comment

46. As a registered pharmacist, Mr B was responsible for providing services with reasonable care and skill (Right 4(1)) and in compliance with legal, professional, ethical, and other relevant standards (Right 4(2)). This included taking care to positively identify clients to ensure safe dispensing of OST medication.
47. In this case, it appears that Mr B correctly identified that the person he was giving the methadone dose to was Ms A. However, he failed to check adequately that the name on the dose to be given matched hers. As indicated by the advisor in case 19HDC02146, the purpose of 'positive identification' is to match the client to their prescribed dose. It is therefore essential to the process that the name on the dose is matched to that of the identified client. This should have been done (for example, by asking Ms A to state her full name and checking this against the label on the dose to be given). I am very critical that that Mr B failed to do so and that consequently he gave Ms A an overdose of methadone. Nevertheless, I consider that this failing is mitigated by the fact that Mr B was not supported adequately to provide safe care, as Greerton Pharmacy did not have adequate policies and procedures in place to minimise the risk of this error occurring.

Responses to provisional decision

48. Ms A was invited to comment on excerpts of the provisional report, and her comments have been considered.
49. Health NZ BOP was invited to comment on relevant sections of the provisional decision. It agreed with the proposed recommendations as facilitating the development and improvement of the BOP OST services. Health NZ BOP's comments have been incorporated into this report where appropriate.
50. Unichem Greerton was invited to comment on relevant sections of the provisional decision, and its comments have been incorporated into this report where appropriate. Unichem Greerton said that it is disappointing that the dispensing error in this case occurred, and it is sorry that this occurred. It assured HDC that methadone dispensing is 'treated with utmost seriousness at our pharmacy' and said that, prior to this event, it had maintained an eight-year record without any methadone dispensing errors. Unichem Greerton said that this case prompted 'extensive internal review and renewed focus on the best way to provide robust care to our patients.'

51. Mr B was invited to comment on relevant sections of the provisional decision. He had no further comment to make.

Changes made

52. Health NZ BOP advised that following reflection on this case, the process of information sharing and decision-making between the OST case manager and the rest of the OST MDT has been made 'more transparent' and is considered 'a key part of team function'.
53. Unichem Greerton advised that since the September 2023 dispensing error it has implemented the following changes to enhance patient safety:
- Different patient dosages are more clearly separated in the controlled drug safe.
 - All pharmacists have discussed the importance of accurately identifying the correct dosage and name selected at the time of giving the dosage, and of taking enough time to do this carefully even at busy times.
 - The pharmacy's Accuracy Checking SOP was reviewed by all pharmacists, who confirmed that they understood the procedures. The SOP was felt to be appropriate, and no changes were made.
 - Mr B reflected on the incident, reviewed his personal checking procedure when handing out methadone doses, and on 11 February 2025 he completed an Opioid Substitution Therapy refresher course.
 - The pharmacy's Methadone SOP has been updated to include a 'double check' process, which provides that, where practicable, immediately before a methadone dose is handed to a patient, a second dispensary staff member must double check that the correct patient and dose are selected. In situations where a 'double check' is not possible, the pharmacist must complete a 'positive identification' process, which involves asking the patient for their full name and verifying this against the label on the bottle.¹⁹ A copy of the updated Methadone SOP was provided to HDC.
 - The pharmacy's Methadone SOP now requires that warnings are placed in patient files in the electronic controlled-drug register (Toniq) when patients receiving methadone have similar names. Additionally, a printed label reading 'similar named patient' is to be affixed to all dispensed methadone bottles for these patients prior to collection, to provide an immediate alert for the pharmacist when selecting the dose from the controlled drug safe.
 - As at May 2025, all current pharmacists had completed an Opioid Substitution Therapy refresher course. Evidence of this was provided to HDC.
 - As at May 2025, Unichem Greerton's Director was undertaking the course 'Improving Accuracy in your Dispensary', with the intention to lead a team discussion on this topic, share insights, and identify any relevant changes.

¹⁹ In response to the provisional decision, Unichem Greerton said: 'we are mindful that repeatedly asking for full names from familiar patients can create unnecessary tension, especially considering the occasional volatile dynamic associated with opioid dependency. We believe that this dual safety net provides a more robust approach.'

Recommendations

Health NZ Hauora a Toi Bay of Plenty

54. I recommend that Health NZ BOP:

- a) Provide a written apology to Ms A for the breaches of the Code discussed in this report, with reference to the shortcomings identified by Dr Schwarcz. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Ms A.
- b) Use this case as a basis for developing education/training for the OST service, with reference to the World Health Organization's publication 'Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence' and with a focus on the following aspects of the New Zealand Practice Guidelines for Opioid Substitution Treatment 2014:
 - Optimal starting and ongoing methadone doses (sections 3.1.1 and 3.3.1)
 - Planned withdrawal (section 3.9.1)
 - Involuntary cessation of OST (section 3.9.2)
 - Measuring methadone serum levels (section 5.5)
 - Managing problematic substance use (section 6.1), including continued opioid use (section 6.1.1)
 - Rights of people receiving OST (section 11.3)
 - The complaints procedure (section 11.4)
 - Managed withdrawal (Appendix 8)
 - Recovery-oriented treatment (Appendix 10)

The training should also include discussion of concerns or reservations around increasing OST clients' methadone doses, including risk management, harm reduction, and risk tolerance continuums. If possible, this training is to be facilitated externally and held with OST consumer advisor or advocate participation. Evidence confirming the content of the education/training (eg, training material) and delivery (eg, attendance records) is to be provided within six months of the date of this report.

- c) Include the Te Pou online module 'Training Programme for the Opioid Substitution Treatment Workforce'²⁰ as mandatory training for current and future OST staff. Evidence of current staff completing this training, in the form of completion certificates, as well as confirmation that this has been included in mandatory training for all staff involved with the provision of OST, is to be provided to HDC within three months of the date of this report.
- d) Consider requiring the current Health NZ BOP OST team's prescribing psychiatrist to become a member of the National Association of Opioid Treatment Providers (NAOTP), or, alternatively, advise that they are already a member. HDC is to be advised of the outcome of this consideration, the reasons for the outcome, and any plans to implement the outcome or future consideration, within two months of the date of this report.
- e) Consider requiring a member of the current Health NZ BOP OST team to attend/participate in at least two NAOTP meetings per year (occurring three times per

²⁰ <https://www.tepou.co.nz/initiatives/opioid-substitution-treatment>.

year) for at least two years. HDC is to be advised of the outcome of this consideration, the reasons for the outcome, and any plans to implement the outcome or future consideration, within two months of the date of this report.

- f) Consider establishing an addiction-specific consumer advisor and liaison role in the Addiction Service, with a view that the role would assist OST clients to liaise with the Addiction Service, including appealing decisions to cease OST against the client's wishes, and be involved with policy writing, complex care reviews, and quality improvement processes. HDC is to be advised of the outcome of this consideration, the reasons for the outcome, and any plans to implement the outcome or future consideration, within six months of the date of this report.

Unichem Greerton

55. Considering the changes made, I recommend that Unichem Greerton:

- a) Audit its compliance with the requirement in the amended Methadone SOP to place warnings on patient files in Toniq where patients have similar names and affix a label to the dispensed dose noting 'similar named patient'. This audit is to be completed within two months of this report. A summary of the audit findings with corrective actions implemented or to be implemented should non-compliance be identified is to be provided to HDC within four months of this report.
- b) Provide HDC with evidence (eg, meeting minutes) of its team discussion about learnings from the 'Improving Accuracy in your Dispensary' course, outlining insights and any relevant changes made. Evidence of this is to be provided within two months of this report.

Follow-up actions

56. Health NZ BOP will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken. In making this referral, I have considered the following:

- Health NZ BOP's lack of adequate oversight or communications systems and the resultant serious failures to provide care that minimised the potential harm to Ms A.
- Health NZ BOP's failure to adequately respond to her acute and growing distress resulting in harm and potential risk for more serious harm, particularly in the context of a situation it had invoked (the inappropriate rapid reduction of methadone).
- The number and severity of the departures from the accepted standard of care.
- The inherent power imbalance in the relationship where Health NZ BOP was providing a controlled and dependence-forming drug to Ms A.
- Health NZ BOP's concerning persistence to persuade Ms A to start on buprenorphine in circumstances where she had been clear that she did not want this and, eventually, agreed to trial buprenorphine 'under duress'.

57. I acknowledge Health NZ BOP's submission requesting that referral to the Director of Proceedings not occur for reasons outlined in its response. However, I am not satisfied that such reasons outweigh the public interest in such referral, and specifically those matters listed in paragraph 56.
58. A copy of this report with details identifying the parties removed, except Health NZ Hauora a Toi Bay of Plenty, Unichem Greerton, and the independent advisor on this case, will be sent to the Australasian Chapter of Addiction Medicine (Royal Australasian College of Physicians), the Addiction Practitioners Association Aotearoa New Zealand (DAPAANZ), Medicines Control (Manatū Hauora | Ministry of Health), the Director of Addiction Services (Manatū Hauora | Ministry of Health), the Pharmacy Council of New Zealand, the Health Quality & Safety Commission, the Pharmaceutical Society of New Zealand, the New Zealand Pharmacovigilance Centre, and Te Pou o te Whakaaro Nui, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Morag McDowell
Health and Disability Commissioner

Names (except Health New Zealand | Te Whatu Ora Hauora a Toi Bay of Plenty, Unichem Greerton and the independent advisor on this case) have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from psychiatrist Dr Emma Schwarcz:

'Clinical advice

To: HDC Investigator
From: HDC Advisor Dr Emma Schwarcz
Consumer: Ms A
Provider: [Health NZ] Te Whatu Ora Hauora o Toi Bay of Plenty
File Number: 23HDC01722
Date: 26 November 2023

My name is Emma Schwarcz. I am a graduate of Auckland University Medical School and I am a vocationally registered psychiatrist with a current APC. My qualifications are BHB MBChB (1999), FRANZCP 2007, Certificate Adult Psychiatry, Certificate Addiction Psychiatry, PGDipCBT (Massey) and PGCertHlthSci (Canterbury).

Thank you for your letter dated 26 October 2023 asking me to provide clinical advice to HDC on case number 23HDC01722 regarding the care provided by the Te Whatu Ora Hauora o Toi Bay of Plenty Addiction Service ([Health NZ BOP]). I have read and agree to follow HDC's Guidelines for Independent Advisors. I am not aware of any personal or professional conflicts of interest with any of the parties involved in this complaint.

I am aware that my report should use simple and clear language and explain complex or technical medical terms.

I have reviewed the following information provided to me:

1. Letter from HDC to author dated 2 October 2023 outlining the clinical background and specifics of the request for advice
2. Letters from Te Whatu Ora (Hauora o Toi Bay of Plenty) ([Health NZ BOP]) to Ms A dated 21 and 23 June 2023
3. Letter of complaint dated 3 July 2023
4. Letter from [Health NZ BOP] to HDC dated 21 July 2023, letter from [Health NZ BOP] to Ms A dated 20 July 2023, and letter from Dr D dated 11 July 2023
5. [Health NZ BOP]'s response dated 27 July 2023
6. Clinical records from [Health NZ BOP]
7. Relevant [Health NZ BOP] policies
8. Further information from Ms A dated 1 September and 4 September 2023, in relation to change of dose on 1 September 2023

Names (except Health New Zealand | Te Whatu Ora Hauora a Toi Bay of Plenty, Unichem Greerton and the independent advisor on this case) have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

9. Further information from Ms A dated 12 September 2023, in relation to requirement for further serum level testing. As per the author's request on 3 November 2023, further information was made available to the author on the 13 November 2023:
10. [Health NZ BOP] progress notes prior to 8 June 2023 regarding the three previous medical appointments, and corresponding progress note entries
11. [Health NZ BOP] notes subsequent to 25 July 2023 relating to the September concerns
12. [Health NZ BOP] Opioid Treatment Service (OST) Multidisciplinary (MDT) team participation (who was in each of the MDT meetings).

Complaint:

Between June and mid-September 2023, several concerns were raised by Ms A relating to three clinical scenarios and the care provided by [Health NZ BOP]:

1. Methadone reduction from 22 June 2023 in the context of opioid use
2. Methadone reduction after an error on the part of the pharmacy on 1 September 2023
3. The request for further serum levels on 7 September 2023

This report has been set out by the author according to these three areas of concern.

Specifically, the author has been asked to comment on the following:

1. Whether the decision to reduce Ms A's methadone was appropriate, with reference to the OST guideline. Please also include comment on the decision to reduce Ms A's methadone dosage on 1 September 2023, following an error on the part of the pharmacy.
2. Whether the timing/speed of the reduction in methadone was appropriate, and whether Ms A's discomfort was managed appropriately. Please also include comment on the decision to reduce Ms A's methadone dosage on 1 September 2023, following an error on the part of the pharmacy.
3. Whether it was reasonable and appropriate to require Ms A to undergo further serum level tests on 7 September 2023.
4. Whether a second opinion from an independent addiction medicine specialist should have been sought prior to making the decision to reduce Ms A's methadone.
5. What risks and side-effects should have been discussed with Ms A prior to the reduction in methadone dosage and was the information provided to her adequate?
6. What risks and side-effects should have been discussed with Ms A in relation to buprenorphine and was the information provided to her adequate?

7. Whether the communication with Ms A in relation to the change in methadone dose was adequate.
8. The adequacy of [Health NZ's] policies.
9. Any other matters in this case that you consider warrant comment.

For each question, the author has been asked to advise:

- a. What is the standard of care/accepted practice?
- b. If there has been a departure from the standard of care or accepted practice, how significant a departure (mild, moderate, or severe) do you consider this to be?
- c. How would it be viewed by your peers?
- d. Recommendations for improvement that may help to prevent a similar occurrence in future.

1. Methadone reduction from 22 June 2023 in the context of opioid use

Brief summary of clinical events:

Ms A had been a client of the service since transfer from [another District Health Board (DHB)] in 2019 on a dose of 48mg of methadone. The treatment journey appeared (to the author) relatively stable between 2019 and June 2023, with an occasional urine drug screen (UDS) testing positive for opioids (indicating use of opioids on top of methadone treatment), occasionally missing an appointment (eg noted mid 2021), and on occasion having lower serum levels than expected (July 2022). Ms A had been put forward for GP Shared Care from 2020, indicating a reasonably high level of stability at the time, with this being pursued until June 2022, coinciding with a lower than expected serum level (15/7/22), observed to have purchased needles (29/6/22), and reporting a spilt dose (14/6/22).

Correspondence to the GP from the three routine medical reviews prior to June 2023 by Dr D noted reasonable stability, briefly summarised as follows:

2/11/21: Phone review (during COVID). Stable, no change. Needs to make an appointment re GP Shared Care.

10/8/22: Phone review. As always, polite and engaging. Chatty, can return to previous (dosing) status now that serum levels were at baseline and for random UDS in 2–3 weeks.

23/1/23: Unclear from the notes if an appointment was made, but notes state “*No answer to phone call*” by Dr D.

14/2/23: Phone review. Well. Stable, to continue. In the lead-up to the reduction of methadone in June 2023, progress notes were summarised as follows, with direct quotes from the notes in italics:

17/5/23: Ms A attended as a support person for her partner, and it is noted in Ms A's progress notes that during his appointment she had been *"belligerent, obstructive and controlling"*, and *"unsuitable for GP Shared Care at present"*.

23/5/23: Ms A emailed her OST case manager asking to reschedule her appointment due to feeling unwell. Case manager *"advised"* client regarding the appointment on 26/5/23, *"awaiting reply"*. (Notes don't state whether or not there was a response from Ms A regarding this).

8/6/23: MDT meeting with *"last UDS positive for opiates"* and *"full supervision required"*. The case manager called Ms A about this and of the decision by the team to change to daily dispensing. A face-to-face appointment was booked to see her on the 13 June 2023 and to see the doctor after a *"full breakdown in the urine screen"* had been obtained.

13/6/23: Ms A met with case manager and disclosed the use of intravenous (IV) morphine sulphate on three occasions. *"We discussed switching to buprenorphine which she agreed may be something that could help her break the cycle of use ... We discussed the benefits of buprenorphine and she will consider this before attending her next scheduled MO review next week. I agreed to provide her with information on Buprenorphine."*

15/6/23 MDT. Full time work is noted, along with recent IV morphine use. Noted *"CM (case manager) has discussed the option of transfer to buprenorphine as methadone is not preventing IV use of opiates. Plan: MO (medical officer) review next week, discuss transfer to buprenorphine"*.

21/6/23 Notes state Ms A phoned after request sent to pharmacy. Ms A apologised for missing yesterday's appointment. Case manager noted *"I asked her if she had made any decision about buprenorphine and she stated she had not and wondered if we had any interest in the product. I advised her we did not and that I needed to have an answer by Friday as if she did not switch to buprenorphine we will start reducing her methadone. I made it clear that remaining on methadone was not facilitating recovery per se but was allowing her to lapse to opioid use whenever she felt a craving, that perhaps she needed to break that dependence and transfer to a safer, recovery focused medication ie buprenorphine. Ms A agreed to have a think about this and call me back asap."*

22/6/23 MO apt booked for 4/7/23. Case manager advised Ms A that the team and doctor would reduce the dose, *"perhaps 5mg per week?"* and that it would be easier if she decided to switch. Ms A twice requested to see a doctor before changes were made but this was not agreed to.

MDT. *"Client undecided whether wishes to switch. To reduce risk of OD, will commence reductions from methadone 2mg/day, starting tomorrow."* *"Option to switch to buprenorphine remains"*.

Advice sought regarding:

a) Whether the decision to reduce Ms A's methadone was appropriate, with reference to the OST (2014) Guidelines¹. (See below re appropriateness of dose reduction after error on part of pharmacy)

Dose reduction of methadone started on the 23 June 2023 at the rate of 2mg per day from a starting stable (non-varying) dose of 48mg per day.

The reduction of methadone seems related to the initiation of buprenorphine. The rationale for starting buprenorphine and reducing methadone appears to be related to ongoing IV use, patchy engagement with a missed doctor's appointment on the 20 June 2023, two recent drug screens positive for opiates and Ms A's acknowledgement of IV use of morphine sulphate without specific trigger on the 13 June 2023. The MDT notes a concern about the risk of overdose.

The move to buprenorphine seemed to be a priority to the team, rather than the client. As per the case manager's progress notes:

13/6/23: *"we discussed switching to buprenorphine which she agreed may be something that could help her break the cycle of use"*

"we discussed the benefits of buprenorphine and she will consider this ..."

"I agreed to provide her with information on buprenorphine"

21/6/23: *"I asked her if she had made any decision about buprenorphine and she stated she had not and wondered if we had any interest in the product. I advised her we did not and that I needed to have an answer by Friday as if she did not switch to buprenorphine we will start reducing her methadone"*

"I made it clear that remaining on methadone was not facilitating recovery ... allowing her to lapse to opioid use whenever she felt a craving ... perhaps needed to ... transfer to ... buprenorphine"

As per the MDT notes:

15/6/23: *"Case manager has discussed option of transfer to buprenorphine as methadone is not preventing IV use of opiates", with "no trigger for cravings".*

"Plan. ... discuss transfer to buprenorphine"

22/6/23: *"UDS (again) positive for opiates". "Still undecided whether she wishes to switch to buprenorphine".*

"To reduce risk of overdose team will now commence reductions from methadone ..."

¹ Ministry of Health. 2014. New Zealand Practice Guidelines for Opioid. Substitution Treatment. Wellington: Ministry of Health.

As per letter dated 21 June 2023 to Ms A from [Health NZ BOP], which included the following excerpts:

“You were discussed today in our team meeting due to the concerns around your recent urine screens, missing appointments and your admitted use of IV opioids”.

“As indicated by yourself, your use of IV opioids occurs without any triggers and therefore the risk remains that you will continue to use IV opioids”

“Due to this risk and the fact you missed the recent scheduled doctor’s appointment the team has decided to start reducing your dose by 2mg per day.”

“You may choose to switch to buprenorphine at any time during these reductions or just continue reducing.” Appointment with the doctor noted for 4 July 2023, *“during which we will discuss the plan moving forward”.*

In the author’s opinion, the reduction of methadone was not appropriate, for the following reasons:

1) The methadone dose of 48mg was likely sub-therapeutic, however an increase in dose does not appear to have been considered.

A sub-therapeutic OST dose is often associated with ongoing opioid use. This is because the receptors have not been saturated and a person may still have either withdrawal, or receive benefits (at a neurotransmitter level) from using opioids on top. Section 3.3.1 (Page 17) of the New Zealand Practice Guidelines for Opioid Substitution Treatment 2014 (Guidelines) notes *“Optimal methadone doses will generally be in the range of 60–120mg daily”.* The author can find no evidence of discussion of a dose increase during this period.

— Ongoing opioid use is an indication to review a dose for increase, rather than decrease. Section 6.1.1 Continued opioid use (Page 43) of the Guidelines notes:

“When a client is not achieving or maintaining stability, the aim should be to optimise treatment by increasing the intensity of the OST rather than reducing it. This approach may also involve ensuring the dose is provided within the therapeutic range 60–120 mg, changing opioid substitutes, increasing case management or psychosocial interventions and increasing supervised consumption”.

In Ms A’s case, the dose could have been increased to be in the therapeutic range, and in addition, additional supports could have been provided. Neither appears to have been considered in relation to this episode.

2) Methadone reduction was involuntary (against Ms A’s wishes) and appeared to have no endpoint mentioned either in the progress notes, nor in the letter to Ms A, and so amounted to an “involuntary withdrawal” of OST. Involuntary withdrawal is considered as a last resort measure.

- Section 3.9.2 Involuntary cessation of OST (Page 28) notes that service providers *“should approach a decision to withdraw a client from OST medication against their wishes with caution”, and “This course of action may increase the risk of fatal overdose ... (and other medical and social risks)”*.

It is noted that involuntary withdrawal can have a significant impact on others, including partners. The scenarios given in the Guidelines as examples cite *“uncontrolled frequent overdose or intoxication”, “threatens or is violent to staff”, and “repeatedly displays an inability to keep to the safety requirements — eg repeated diversion, loss of doses, failure to keep doses secure or repeated lack of attendance at appointments”*.

The Guidelines note (Page 28)

“injection of methadone or regular use of other drugs is not usually an indication for involuntary withdrawal”, and that specialist services “are expected to work with clients to reduce or cease illicit opioid use ...”

It is also noted (Page 28) that involuntary withdrawal should occur *“preferably after a second opinion from an independent addiction medicine specialist (ie one from a different service of DHB) or equivalent”*.

In Ms A’s case, whilst she missed the medical appointment on 20 June 2023, she had seen the case manager the week before on 13 June 2023. Notes stated she greeted the case manager warmly, engaged well, and was open about the issues she was currently facing. Her social situation was noted to be *“no change, working fulltime and enjoying it immensely, no current legal issues”*. It was noted she knew how to access naloxone (antidote for opioid overdose) if required. She had cancelled the previous appointment with the case manager for 23 May 2023, citing unwellness, and had attended her previous medical (phone) appointments on the 10 August 2022 and 14 February 2023, although possibly missed a phone call from the doctor on 23 January 2023, which may have been a planned medical (phone) appointment although this is unclear from the notes. In short, whilst engagement was certainly not perfect, it did not, in the author’s opinion, meet the threshold described in the Guidelines, that is either egregious, uncontrollable, or demonstrating an inability to keep safe. The fact that Ms A was continuing to work fulltime and remain in an unchanged and stable social situation with no legal changes is further indication that involuntary withdrawal was not yet required as a treatment of last resort.

3) The use of opiates on top of OST, even when therapeutic, is not uncommon, and does not necessarily indicate instability. In addition, a harm reduction approach does not appear to have been discussed or taken.

- It is well recognised (by author and in consultation with author’s peers) that many clients taking OST do not cease their use of licit or illicit drugs (of choice), including injecting of drugs. This can be due to a range of reasons. Section 6.1 (Page 42) notes that OST services *“should not focus on abstinence to the exclusion of substance using harm reduction”*.

Page 42 of the Guidelines also notes *“specialist services ... are expected to assist clients with reducing or ceasing use of other drugs ... and minimising problems associated with it”*.

The author can find no evidence that there was discussion with Ms A about how to reduce risks of her use. That is, discussions about needle purchasing, use, sterilisation, sharing, blood borne viruses, using orally, using smaller amounts, less often, not in conjunction with other medications/drugs etc. Nor is there evidence of a more in-depth discussion or understanding of the value and benefits for the client regarding use of additional opiates, eg using the client’s goals to assist the direction of the treatment plan, which may have included either a dose increase, or tolerance by the treating team of IV use (whilst assessing, addressing and reducing any harms attached to this), or further psychological input regarding understanding this use further (eg it is recorded later in the notes that going to Auckland was a high risk situation). Instead it seems that the client’s admission (or documentation of this admission) regarding *“no particular stressor”* (for use) on the 13 June 2023 seems to have been used against her as evidence of a lack of control, or risk of overdose.

However, in the author’s opinion the risk of overdose was low given Ms A’s own experience with morphine sulphate, and known strength (100mg tablets). On the basis of the Guidelines, experience and consultation with peers, the author believes that the risks associated with an involuntary reduction, (overdose, decompensation, psychological instability, additional illicit opioid use etc) in the manner in which it occurred (rapidly, with little client choice/autonomy, and no recourse for discussion for some 12 days until the next medical appointment etc), far outweighed the risks of the client’s ongoing and occasional morphine sulphate use. In short, it is riskier to be off treatment. As noted above, a harm reduction approach would have included increasing the dose, rather than decreasing it.

The accepted standard of care/accepted practice might have included a number of options:

An increase in dose, rather than a decrease in dose was appropriate. The lack of a consideration given to an increase in dose is a severe departure from accepted practice given the dose was not within the therapeutic range. The author cannot find any evidence of a discussion of an increase in dose within the progress notes prior to June 2023. The author’s peers also immediately considered a dose increase as a first consideration when the (anonymised) scenario was put to them. The Guidelines are clear about the recommended therapeutic range, and that ongoing opioid use is an indication for an increase, and in itself is not sufficient evidence of instability to warrant reduction.

Recommendations include reading the Guidelines in their entirety and watching the OST e-learning modules hosted on the Te Pou website².

² <https://www.tepou.co.nz/initiatives/opioid-substitution-treatment>

Discussion with peers who practice addiction medicine, and involvement with NAOTP (National Association of Opioid Treatment Providers) meetings are also recommended. The World Health Organization's Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence may also be helpful reading³.

The accepted standard of care when a client repeatedly does not engage in treatment (eg medical reviews) in spite of repeated discussions, reminders, problem solving any barriers etc, can include "(with)holding" a dose (at the pharmacy) (i.e. not provide it) on the day of a medical appointment, to ensure engagement (with the dose being provided at, or soon after the person's attendance). The author's peers at Auckland Opioid Treatment Service viewed that this would be preferable to "counting down" (involuntary withdrawal), although different districts may well have differing approaches to encourage attendance.

Many of these approaches, if overused, or reactively used, can be viewed as punishment by the client, so OST providers need to constantly be mindful of any power dynamic and the need to discuss such decisions in a team environment and in clinical supervision. (Ministry of Health) audits can also sometimes be helpful in evaluating the culture of a service and whether client choice, autonomy and mana is upheld as much as possible given the power dynamics in providing a controlled and dependence-forming drug.

In the author's opinion, the decision to switch to buprenorphine or reduce the methadone, for reasons of ongoing opioid use and engagement issues (and without being able to discuss this treatment decision directly with the doctor) to be a severe departure from the usual standard of care. The author, and peers from the Auckland OST service consider the risks of ongoing occasional morphine sulphate use did not warrant involuntary withdrawal, and likely caused significant and unnecessary distress and decompensation. The client was told that they would have to wait 12 days before this decision would be reviewed with a doctor, amounting to a total of 2mg x 12 days = 24mg — a 50% reduction in dose. The author and peers from the Auckland OST service thought that a medical review was warranted prior to such a significant decision being made and that this was a severe departure from accepted practice.

Recommendations to guard against this happening in the future include familiarity with the Guidelines about the significance of involuntary withdrawal (Section 3.9.2), and the usual scenarios that would lead to this, along with acceptance that many clients who used drugs before OST still use drugs after starting OST, especially in the context of an insufficient treatment dose. Further recommendation includes watching the OST e-learning modules as noted above. The author would also recommend team level training to discuss anxiety and fears around not reducing the dose, and discussions about where the risk really lies (ultimately with the client, but in the author's opinion

³ World Health Organization. Department of Mental Health and Substance Abuse, International Narcotics Control Board, & United Nations Office on Drugs and Crime. (2009). *Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence*. World Health Organization.

there is frequently significant fear of repercussion around the risk of potential adverse events such as accidental overdose). This process would ideally be externally facilitated, with OST consumer advisor or advocate participation. An alternative or additional strategy might be to facilitate practice visits to (and from) other OST teams in other areas, and discussions about risk management and risk tolerance continuums.

Second opinions, and/or case discussions at NAOTP (National Association of Opioid Treatment Providers) meetings (which run three times a year) may also be helpful in assisting with team culture and decision making. All of these are particularly important where the medical doctors and/or team members are not specifically addiction trained (ie have addiction-specific qualifications).

b) Whether the timing/speed of the reduction in methadone was appropriate, and whether Ms A's discomfort was managed appropriately. (See below re appropriateness of timing/speed of reduction after error on part of pharmacy)

From 23 June 2023, the dose of methadone was reduced from 48mg at a rate of 2mg per day to 24mg methadone by the 12th day. In the author's opinion, the rate of 2mg per day was not appropriate for the following reasons:

1) As noted above, an increase in dose (rather than a decrease) is likely to have been more appropriate, and/or other attention and support given to harm reduction, engagement, overall stability and the client's goals etc.

2) A reduction of 2mg per day would be considered by the author, the Guidelines and by the author's peers (doctors working at the OST service in Auckland) to be a rapid reduction. Section 3.9.1 Planned withdrawal (Page 27) of the Guidelines notes *"Completion of methadone withdrawal is more likely to be successful if undertaken slowly over a long period of time, through a gradual stepped tapering regime involving dose reductions in only 25–50 percent of the weeks of the reduction process. As a guide, the reduction rate might be between 5 and 10 percent of the current dose every 1–4 weeks depending on the individual characteristics of the client."*

For Ms A, this would have amounted to between about 2.5mg–5mg reduction every 1–4 weeks, rather than 2mg/day (which amounts to 14mg per week).

3) In relation to involuntary reduction, section 3.9.2 (Page 29) of the Guidelines notes

"The rate of reduction in the case of involuntary withdrawal will depend on the circumstances, but rapid dose reduction is not recommended. A gradual reduction, as described in the case of a planned withdrawal, should be undertaken unless it is unavoidable (eg, in cases of violence on the part of the client)."

In Ms A's case it is hard for the author or her peers to understand why the dose had to be reduced so rapidly. There had been no frequent overdose, uncontrolled intoxication, threats/actual violence or inability to keep to the safety requirements of the OST provider (as per the examples given in section 3.9.2 on page 28). The team also noted

they suspected Ms A had been using opioids on occasion and on top of methadone for some time so there appeared to be no imminent or acute risk. There was also no change in clinical presentation or other factors which might indicate instability, with the case manager noting on the same day that Ms A admitted IV morphine sulphate use (13 June 2023) she presented as *“warm, engaged, with no change in social situation, working full time and enjoying it immensely”*.

4) The rate of reduction changed over the course of the day. On the morning of 22 June 2023, Ms A was advised by her case manager that her dose would probably reduce by *“perhaps 5mg per week?”* The team meeting later that day determined the reduction to be *“2mg per day, starting tomorrow”*. No rationale for this revised or particularly rapid rate was noted, other than what is noted above regarding reporting IV use, and that there was potentially an overdose risk. A letter was sent to Ms A regarding the rate of 2mg per day, but not the reason for the new (to Ms A) increased rate of reduction.

5) Ms A requested twice during the conversation with her case manager on the 22 June 2023 that no changes be made to her medication until she saw a doctor. She was advised instead that the team and doctor *“would probably reduce her dose in the interim”*, with the reduction starting the following day on 23 June 2023, and the next medical appointment arranged for 4 July 2023, 12 days later. Whilst the usual treating doctor was present at the MDTs where the decision for the reduction occurred, it would have been ideal that such a serious and impactful decision occur at a medical appointment where the issue could have been discussed in full, and ideally with Ms A's supports and usual case manager present. Section 3.9.2 Involuntary cessation of OST (Page 29) of the Guidelines notes *“Service providers should give clients the opportunity to appeal against the [decision] to cease OST against their wishes. Wherever possible, the service should retain the client in the programme pending resolution of the appeal. The service should provide the client with information about accessing a consumer advocate for the purposes of this process.”*

The author can find no evidence that this appeal was discussed. There is no evidence that information was provided about accessing a consumer advocate.

The author (and the author's peers) considers the accepted practice would have been a rate of reduction rate of between 2.5mg–5mg per week, noting that the circumstances did not appear to warrant a reduction in the first instance. Furthermore there was no evidence that a rapid reduction was required. The rate of reduction was a severe departure in accepted practice given the circumstances. Several of the author's peers wondered if by reducing the methadone so rapidly, the service was forcing Ms A to accept buprenorphine which for reasons unknown (to the author or the author's peers), would have been preferable to the service. The author and the author's peers remain confused as to why the service thought that buprenorphine would have been a less risky choice for Ms A, given that clients can generally continue to inject strong opioids such as morphine sulphate “on top” of low to medium doses of buprenorphine if they want to. In short, the switch to buprenorphine may not have curtailed

intravenous use, and the risks of rapid decompensation of methadone were realised for Ms A, with subsequent loss of her job and compromised emotional and physical stability.

Recommendations for improvement include reading the Guidelines, particularly section 3.9.2 relating to involuntary withdrawal and seeking a second opinion and peer consultation in all cases relating to involuntary withdrawal.

In the author's opinion, Ms A's discomfort (relating to methadone reduction) was not managed appropriately, for the following reasons:

1) Contact with Ms A was sparse over the 12 days from the reduction starting on the 23 June 2023 until the MO appointment on the 4 July 2023, despite evidence that she was not coping well, with three brief entries in the progress notes:

- MDT note on the 27 June which noted that Ms A remained opposed to recent treatment decisions and blames the service for all problems
- A phone call on 3 July from Ms A's partner saying that she was "in a bad way", and that she was "at risk of purchasing drugs and overdosing"
- A text message sent on 4 July by the case manager to Ms A: "Hi ..., have you made a decision about whether you will switch to buprenorphine? if you let me know asap we can start the switch today (case manager's name)" "Plan: await contact, discuss with doctor and team at review meeting."

Only one of these three progress notes during this time was a service-initiated contact with the client, and this was a text asking about the switch to buprenorphine.

2) There was no evidence from the progress notes that there was any psychological or physical support offered to Ms A or her supports, despite the rapid rate of reduction and the partner's concerns for her well-being. No information, advice or support was given regarding the potential risk of overdose, illicit use or additional opioid and/or other drug/alcohol use. Section 3.9.2 (Page 29) notes

"When a specialist service imposes involuntary cessation of OST, it needs to:

- give the client reasons for the withdrawal of OST in writing
- caution the client about risks of overdose (due to reduced tolerance) and driving and operating machinery during the withdrawal process
- offer the client support during the withdrawal process
- provide the client with a future-directed specific treatment plan
- inform the client of other treatment options available and assist with referral where appropriate.

Whilst the reasons for the withdrawal of OST were provided in writing to Ms A, and the suggestion of switching to buprenorphine, there was no evidence that any of the other

recommendations were followed or that care was taken to ensure risks associated with rapid reduction (overdose, withdrawal symptoms and psychological instability) were minimised.

The support provided was a severe departure from an acceptable standard of care, with little contact from the service (other than asking about buprenorphine) and no tangible psychological, physical or other support offered. Involuntary withdrawal in the author's experience has been for egregious acts of violence or threats of violence towards staff or uncontrolled and repeated intoxication and instability. Ideally, the rapid involuntary withdrawal of Ms A's methadone could have been avoided upstream with a comprehensive review of the treatment and dose etc, and by getting a second opinion and slowing the whole process down and consulting further with Ms A and her supports.

The impacts from this level of reduction (50% drop in total dose) would possibly be a challenge to support even in an inpatient environment given the physical and psychological aspects of rapid withdrawal. The psychological impacts were likely made worse given the breakdown in communication by this stage and over the course of the 12 days after the reduction was commenced. There is a range of evidence-based adjunctive and supportive medications and treatments that are often provided to assist the symptoms of opioid withdrawal — which includes symptoms such as diarrhoea, poor sleep, muscle aches, sweating, cramps, nausea and vomiting etc. There is no evidence that either pharmacological or complementary medication, or any other support was provided during this period of withdrawal, or recommendation to attend her usual GP.

The usual pharmacy had been cautioned by the team on the 22 June to *“not get caught up in the decisions made by the team regarding her dosing etc”*, so were perhaps unlikely to extend support regarding the symptoms of opioid withdrawal. Although it had been discussed in the past notes, there was no evidence that naloxone was discussed during this period of care (for treatment of overdose, which is a reasonable risk should the person use opioids to reduce their withdrawal symptoms and cravings).

Recommendations include reading Appendix 8 of the Guidelines: Managed withdrawal. This outlines supportive care and pharmacological support for opioid withdrawal. The online OST modules noted above also discuss support for opioid withdrawal. Experience in, or practice visits to inpatient settings that actively manage opioid withdrawal may also be helpful for the practitioners involved. Knowledge of the Nationwide Health & Disability Advocacy Service (<https://advocacy.org.nz>) would perhaps also be of value to the team.

c) Whether a second opinion from an independent addiction medicine specialist should have been sought prior to making the decision to reduce Ms A's methadone.

The decision regarding the reduction of methadone (and suggested switch to buprenorphine) was made in the MDT. MDT meetings consisted of the locum consultant psychiatrist (or “MO” (Medical Officer)) working with the OST team, the psychiatry registrar (a training psychiatrist), team leader, nurses and case manager. The last

meeting with the OST doctor (the locum psychiatrist) had been the 14 February 2023 and there was no discussion about the reduction of methadone at this point.

In the author's opinion, a second opinion should have been sought, based on the following reason:

1) Recommendation in the Guidelines. 3.9.2 Involuntary cessation of OST (Page 28) notes

"The final decision to cease OST should be made by the prescribing doctor with the key worker and the MDT, including the service manager or the primary health care team (whichever applies), and preferably after a second opinion from an independent addiction medicine specialist (ie, one from a different service or DHB) or equivalent".

Although the Guidelines use the word "preferable" rather than necessary, or even recommended, the author considers that a second opinion would have been prudent given:

- The lack of certified addiction training of the locum psychiatrist
- The lack of recent review by the doctor (since 14 February 2023)
- The reason for the reduction (for a scenario other than those described in section 3.9.2 Involuntary cessation, Page 28)
- The chosen rate of the reduction (rapid), contrasting with the guidance provided in the Guidelines (Section 3.9.2, Pages 27, 29)
- The requests for review of this decision by Ms A on 22 June 2023
- The request for support by Ms A's partner 3 July 2023 (albeit after the fact)
- The small sized team at Hauora o Toi Bay of Plenty (meaning less diversity, dissenting or contrasting views which is more likely to be present in a large team of many clinicians from each discipline).

The author considers this a mild departure from the standard of care. The author (and their peers) is aware of many services who don't request second opinions, and the language in the Guidelines of "preferable" leaves this as perhaps optional. To this end, NAOTP (the National Association of Opioid Treatment Providers) is currently (as of October 2023) considering a national review group specifically for the purpose of issuing second opinions, especially for when involuntary withdrawal is being considered by a service.

Recommendations include erring on the side of obtaining a second opinion in the case of involuntary withdrawal rather than not obtaining it. There is little to be lost and the process is an important peer and service-level benchmarking and quality improvement process, and ensures clients benefit from clinical decisions that have been peer-reviewed.

d) What risks and side-effects should have been discussed with Ms A prior to the reduction in methadone dosage and was the information provided to her adequate?

The first mention in the progress notes of a possibility of a reduction in methadone was on the 21 June 2023. The case manager records that in a phone conversation with Ms A, *“I asked her if she had made any decision about buprenorphine (discussed the week prior, on 13 June 2023), and she stated she had not and wondered if we had any interest in the product. I advised her we did not and that I needed to have an answer by Friday (23 June) as if she did not switch to buprenorphine we will start reducing her methadone.”*

In relation to the risks of methadone reduction (or involuntary withdrawal), it is not documented that Ms A was aware of the actions that the team would undertake should she miss/re-schedule appointments and/or have evidence of opiates in the urine drug screen, and/or admit IV morphine sulphate use.

After the rapid and unilateral decision to reduce the methadone was made by the team, it is difficult to know how the team would have made information about the risks and side effects of reduction available to Ms A. Ms A requested to see a doctor prior to this decision to reduce (on 22 June 2023), but this was not agreed to/made available.

There seemed little opportunity to discuss any risks or benefits of a reduction, or opportunity to discuss any alternative approaches (eg daily consumption at the pharmacy, or dose increase, or increased psychological input, or family discussion, or increased case manager contact etc). The reduction started the very next day on the 23 June 2023. A brief letter to Ms A from the case manager, dated 21 June 2023 outlines the reasons for the reduction, the option to switch to buprenorphine, and the doctor’s next appointment on 4 July 2023 (12 days later). Beyond *“If you have any queries, please call to discuss”*, there is no specific discussion of risks, benefits, side effects, withdrawal management, recourse or support etc.

It is difficult to know how much of a departure from accepted practice it is to not provide risks and side effects of an involuntary (non-consenting) reduction of a dependence-forming medication. By the time the decision is made to reduce medication against a client’s wishes, relationships are likely to be strained, and normal informed consent processes likely abandoned (given the lack of consent involved in involuntary withdrawal).

The author considers not providing the person with the risks and side effects a mild departure from accepted practice given the nature of involuntary withdrawal and it being done without consent, and the rarity of such events. As with all treatment, as much information as possible regarding risks and impacts of such decisions could have been discussed further, but in practice (in the author’s opinion), the relationship is significantly impaired by this stage, with often even basic communication compromised.

Recommendations include ensuring involuntary withdrawal truly is a treatment of last resort, and ensuring as much helpful information as possible is incorporated into

written correspondence, involving family in decision-making, and making repeated attempts to communicate effectively with the client.

e) What risks and side-effects should have been discussed with Ms A in relation to buprenorphine and was the information provided to her adequate?

The first mention of buprenorphine as a possibility for OST was in a doctor's letter dated 2 September 2019 (a different doctor from the doctor above), who discussed potential benefits of buprenorphine so that the client could be "fully informed". The client is noted to say at the time that she wasn't sure if it would be of any benefit. Buprenorphine is next mentioned 13 June 2023 in relation to Ms A's discussion about recent morphine sulphate use: "*We discussed the benefits of buprenorphine and she will consider this before attending her next scheduled MO review next week. I agreed to provide her with information on buprenorphine (via pharmacy).*" Buprenorphine remained the treatment of choice in the team's eyes, and this was offered several times to the client over this period.

After around 10 days of rapid withdrawal from methadone, Ms A reluctantly agreed to start buprenorphine on 7 July 2023. "*However I record that I am only requesting to do so under duress as I am feeling more and more unwell and no other options have been made available to me. Due to my recent relapse and resulting instability, I strongly believe that it is not the right time to transfer me to buprenorphine however as referred above due to increasing physical discomfort I do not have any other choice.*" After one dose of this, she elected to stop this due to headache, and she continued to have her methadone reduced at 2mg per day. She was seen by the doctor four days later on the 11 July 2023 and methadone was increased by 10mg to a total of 20mg, with further increases planned thereafter.

The author is unclear what information was provided about buprenorphine via the pharmacy as per the case manager's notes above. No details about any verbal discussion of risks, side effects, interactions (with other medication etc), or benefits were documented in the progress notes other than on the 13 June 2023 "*We discussed the benefits of buprenorphine (and she will consider this before attending her next scheduled MO review next week)*". Because the buprenorphine was offered as an alternative to the unwanted methadone reduction, any usual informed consent process was likely impacted by anxiety connected to the corresponding reduction. Ms A indicated she had to accept buprenorphine under duress as evidenced in the case manager's note of 21 June 2023 "*I advised her we did not and that I needed to have an answer by Friday (23 June) as if she did not switch to buprenorphine we will start reducing her methadone.*" Any discussions about risks and benefits (if they did occur) would have been clouded by this impaired autonomy and lack of choice. In addition, it was not the doctor who had a discussion with Ms A about buprenorphine, but the case manager. It was unclear whether any usual side effects were discussed with Ms A so that she knew what to expect. She started the first (and only) dose on a Friday (7 July 2023) which would have meant little initial support over the weekend should she have continued beyond the first dose. It did not come as a surprise to the author that Ms A

experienced symptoms after the first dose, given the anxiety, lack of choice and autonomy, and given how unwell the client was already feeling.

The author therefore finds the information provided regarding buprenorphine to be less than adequate, or perhaps inadequately documented. Accepted practice would be discussion with the doctor of the risks and benefits of such medication (and ideally with support present, as per client's wishes), with opportunities for questions and discussion along with written information and further discussion with the case manager and doctor as required. Ideally the process would have taken as long as it needed to have taken, and of course been with the client's full consent. It seems to the author that it will perhaps be difficult to revisit the idea of buprenorphine in the future given its connection to this involuntary withdrawal process and the feeling of "duress". New medication is ideally not started on a Friday, although the alternative would have been to continue the reduction — a difficult choice.

Recommendations include discussing and documenting all aspects of any proposed treatment, even if it is being offered under duress (although as outlined above, ideally isn't). The NZ Medical Council statement "Good Prescribing Practice" is a useful guide to prescribing, although the situation with Ms A was obviously significantly complicated by this stage and the author appreciates that best practice was unrealistic.

f) Whether the communication with Ms A in relation to the change in methadone dose was adequate.

In the author's opinion, the communication in relation to the reduction of methadone dose was not adequate, for the following reasons:

1. The consequence of missing appointments and/or using opioids on top (involuntary withdrawal) were not clearly communicated. It is not documented that Ms A was aware of the actions that the team would undertake should she miss/reschedule appointments, and/or show evidence of opiates in the urine drug screen, and/or admit IV morphine sulphate use. The suggestion of switching to buprenorphine occurred on the 13 June 2023, noting by MDT on the 15 June it was "an option", but after missing a doctor's appointment on the 20 June 2023, then on the 21 June 2023, a more certain "will start" (reducing, if she didn't switch to buprenorphine). On the 22 June 2023, Ms A requested to see a doctor prior to this decision to reduce but this was not agreed to/made available and the reduction started the next day on the 23 June 2023.

2. The communication of the possibility of reduction occurred on the 21 June and was started two days later on the 23 June. This gave little time for the client to discuss other options, digest the impact or make plans to cope. The first mention in the progress notes of a possibility of a reduction in methadone was on the 21 June 2023. The case manager records that in a phone conversation with Ms A, "I asked her if she had made any decision about buprenorphine (discussed the week prior, on 13 June 2023), and she stated she had not and wondered if we had any interest in the product. I advised her we did not and that I needed to have an answer by Friday (23 June) as if she did not switch

to buprenorphine we will start reducing her methadone." The methadone reduction began on the 23 June 2023.

3. The communication occurred by the case manager, but involved decisions made at the MDT. The client was not involved in the MDT process (as recommended in the Service's OST Pathway policy), and the client was not able to speak to the doctor directly about the decision, despite it being noted that she asked twice during the phone call of 22 June 2023 with the case manager. This seemed to lead to an understandable sense of helplessness and powerlessness, as it wasn't the person she was speaking to who was making the decisions.

4. Written communication was somewhat perfunctory, and did not contain enough material. A brief letter dated 21 June 2023 to Ms A from the case manager outlines the reasons for the reduction, the option to switch to buprenorphine, and the doctor's next appointment on 4 July 2023. Beyond *"If you have any queries, please call to discuss"*, there is no specific discussion of risks, benefits, side effects, withdrawal management, recourse or support etc. The tone lacks warmth or kindness and does not discuss how the client might re-engage in OST other than attending a meeting some 12 days away. As noted above, section 3.9.2 notes that when a service imposes involuntary withdrawal, it needs to

- give the client reasons for the withdrawal of OST in writing
- caution the client about risks of overdose (due to reduced tolerance) and driving and operating machinery during the withdrawal process
- offer the client support during the withdrawal process
- provide the client with a future-directed specific treatment plan
- inform the client of other treatment options available and assist with referral where appropriate

The author has noted above that whilst the reasons for withdrawal were given in writing, other aspects of this checklist did not appear to have been observed, or documented.

5. An appeals process was not provided to Ms A, in contrast to the recommendation in the Guidelines Section 3.9.2 (Page 29) *"Service providers should give clients the opportunity to appeal against the decision to cease OST against their wishes. Wherever possible, the service should retain the client in the programme pending resolution of the appeal. The service should provide the client with information about accessing a consumer advocate for the purposes of this process."*

6. Communication throughout the reduction was poor, with only one service-initiated text from the case manager asking about starting buprenorphine. This conveyed (in the author's opinion) little concern for the client's welfare during the rapid withdrawal process, and didn't provide a mechanism for the return to treatment (other than having to accept buprenorphine).

The accepted practice would have been to discuss the possibility, and reasons leading to, any involuntary reduction of dose (should the behaviour have been egregious enough to warrant this), well in advance of the actual reduction, communicated both verbally and in writing, and over some weeks (as long as the situation wasn't acute). A discussion with both the doctor and the keyworker, with the invitation of family and/or support involvement before, rather than after the fact, would likely have helped Ms A understand the reasons for a proposed reduction, along with the options and process of returning back to treatment or gaining support from other services/measures, including physical, psychological and social supports. The appeals process, second opinion process and complaint processes might have been outlined as options for Ms A.

The author considers the lack of communication to be a moderate to severe departure in accepted practice for the reasons outlined above, although considerations should be given to the constrained medical and case manager resource in smaller services, which may only have one or two doctor sessions a week for example.

Recommendations include ensuring the service is familiar with the Code of Health and Disability Services Consumers' Rights, Right 5 (Right to effective communication), along with reading Section 11.3 of the Guidelines, "Rights of people receiving OST" and 11.4 "The complaints procedure" to ensure that these processes are offered early to clients. Written communication could be reviewed by peers or other services to ensure that language is strength-based and recovery focused as much as possible. Consumer advisor and liaison roles in the service would also help assist with both the process and communication of the process. Links to advocacy services would also likely help with ensuring communication is the best it can be in such circumstances. Again it must be mentioned that avoidance of involuntary reduction would have been preferable.

g) The adequacy of Te Whatu Ora Hauora a Toi Bay of Plenty's policies.

The following policies were provided for review:

1. Mental health and addiction services (MH&AS) Assessment
2. Risk Assessment (MH&AS)
3. Treatment Plan (MH&AS)
4. Multidisciplinary Team (MDT) Meetings (MH&AS)
5. OST Pathway ("Pathway")
6. OST Managing co-existing conditions
7. OST Prescribing and Dispensing ("P&D")

The first four policies in the list above are generic to mental health and addiction services and the author considers them to be broadly adequate, when compared with other similar policies that the author has read. There is mention of the treatment plan being collaboratively designed with the person and their family, and that it is tailored

to the person's individual stage in *"the recovery/person-centered care process"*. The plan relating to Ms A could have referenced these aspects of the policy, with a fuller discussion of all the options available to Ms A, with her family involved and over a longer period of time rather than over only a few days, and largely not in-person (face to face).

The last three policies in the list are OST specific. The policies note that they will be reviewed in line with the NZ OST Guidelines to reflect best practice. The policies themselves appear broadly adequate. Some broad comments regarding adequacy and/or application of the policies to Ms A's case include:

- The language on the whole reflects the language found in the Guidelines, that is, that care is recovery-focused, individually tailored and client-centred. In Ms A's case, and in relation to the reduction of methadone, it would have been helpful to apply some of the statements in the Pathway policy, eg *"some service users will require more support and input than others, the person moves at their own pace, the service recognises that change takes time, some service users will aim for abstinence and some will not"* etc.
- It was pleasing to see a range of references had fed into the OST policies, with consideration of a broad range of authors and views, including topics relating to harm reduction, motivational interviewing and recovery management. However, it is noted that these references, along with much of the content of the Service's OST documents has been obtained directly from the Auckland OST service's controlled documents. This in and of itself is not an issue, except that perhaps that the culture of the Service may not embody, or live by the values contained in the policies, nor would the culture of the team have developed in relation to the "borrowed" content or references. The references themselves would be helpful literature for the OST service to read, if the team has not done so already.
- The Pathway 1.2(e)iv notes that *"involuntary withdrawal is undertaken as a last resort, only after input from the MDT and all attempts have been made with the tāngata whai ora/service user to solve the relevant issues."* In Ms A's case, "all attempts" did not appear to have been made, and other strategies could have been employed to facilitate improved engagement. The policies are silent on the possible reasons for involuntary withdrawal, but these are outlined further in the (NZ) Guidelines, which is (to the author) adequate.
- In relation to engagement, the Pathway notes (2.1) that where expectations (of attendance etc) are not met, an MDT review of treatment is undertaken with the person wherever possible. This seems appropriate. In Ms A's case, this did not appear to have happened, and the last appointment with the doctor had been done in February, and by phone. There may have been other ways, as described above, to facilitate any required attendance (being clear about expectations of attendance, ensuring client knew what was at stake should they not attend a specific appointment, withholding the dose on the morning of an appointment (as well described in the Bay of Plenty's policies — OST Pathway section 2.10(b), and in the P&D policy section 6.1(a)) etc).

- The Pathway notes (2.7(a)) that a formal review and/or case conference is used, *“especially relevant where treatment might fall outside of the recommendations of the National guidelines”*. This policy statement is appropriate, and in Ms A’s case, it could have been used to involve other people to discuss the issues and treatment plan.
- The OST Managing Co-Existing Conditions policy also seems broadly adequate in relation to Ms A’s issues, and covers a broad range of issues. Ms A had no co-existing conditions, so the policy has less relevance for her situation.
- The OST Prescribing and Dispensing policy outlines methadone and buprenorphine as the treatments for opioid dependence along with key points regarding routine prescribing, including rationale for increasing doses, and takeaway doses etc. The policy does note the usual therapeutic dose range (60mg–120mg), however this is found only in the “High Dose” section (5.2(a)) rather than at the beginning of the document where it might be more helpful. It does note earlier on in the policy that extra precaution is taken for over 120mg (3.3(b)ii).
- Likewise, it is confusing to the author that the (sound and sensible) routine indications for increase are best outlined in the “High Dose” section (5.2(a)) *“OST should be titrated according to the management of opioid withdrawal and dependence symptoms, with ongoing craving, misuse and compulsion being frequent indicators. Withdrawal symptoms and/or signs (including pre-dose or peak presentation) help evaluate the efficacy of the current dose.”* In the author’s opinion, some of these well-explained considerations could be added higher up in the document, as part of section 3.3(b) (Routine prescribing, ongoing OST). The High Dose section could instead be made more specific and outline specific considerations for doses above 120mg, in keeping with Section 3.3.1 of the (national) Guidelines.
- Section 3.3(b)v of the P&D policy notes that reduction plans should be discussed and planned at the service user’s review with their medical practitioner and keyworker. This does not appear to have been observed in Ms A’s case, although the section appears to be written for planned withdrawal, rather than unplanned, or involuntary withdrawal. The author wonders if there could be additional guidance written in the P&D policy for these circumstances, or that the reader of this policy is referred to the Pathway policy, where it could be further strengthened.
- The section on takeaways in the P&D policy looks adequate and in line with the NZ Guidelines. The service could consider additional policies to help guide culture and practice. The author’s service has the following policies which may be helpful to the Bay of Plenty service and could be made available:
 - Urine Drug Testing
 - Responding to Challenging Behaviour
 - Naloxone Emergency Kit
 - Client consent to and terms of OST
 - Treatment Planning and Recovery Planning
 - etc

h) Any other matters in this case that you consider warrant comment.

The author wondered whether the service had addiction-specific consumer advisory staff as part of the team, and if so, whether they are involved in policy writing and complex care reviews or decision making or other such quality processes. The author also wondered how the service gains feedback from clients regarding the experience of treatment and of the team culture, and if so, how the results are incorporated into the service's processes.

2. Withholding methadone and reduction after an error on the part of the pharmacy on 1 September 2023*Brief summary of clinical events:*

On the morning of Friday 1 September, the service received a phone call from the community pharmacy notifying them that they had accidentally provided Ms A with 90mg methadone rather than her prescribed dose of 40mg. Ms A was contacted by both the pharmacy and the OST service the same day to ensure she was okay. Ms A was advised later that day that the doctor had been consulted and she would receive half her usual dose (ie 20mg) for the next two days (Saturday and Sunday). Ms A expressed her displeasure at this and requested resumption of her usual prescribed dose (40mg) from the Sunday. Ms A phoned the HDC, who then communicated with the service, and who in turn phoned Ms A. After 5pm that same evening (of 1st September), the usual OST doctor from the service entered a progress note regarding reviewing this decision, and determined that the (medical) risks of the usual dose of 40mg on the Sunday would be less than the risks (to the relationship) of the half dose (20mg). 20mg was prescribed for the Saturday, and the usual dose of 40mg for the Sunday.

*Advice sought regarding:***a) Whether it was appropriate to reduce Ms A's methadone dosage on 1 September 2023, following an error on the part of the pharmacy.**

Section 8.7 (Pharmacy dispensing errors) of the service's (OST) Prescribing and Dispensing policy outlines the approach to such errors, and is in line with the NZ Guidelines (section 9.3.6 Dispensing errors (Page 70)). Both documents mention the need to contact the client and to be advised of the follow up plan, eg *"to see the key worker/medical practitioner over the next four hours"*. The service notes in their P&D policy 8.7(b)(xiv) *"If considering altering or withholding the following dose, the tāngata whai ora/service user is reviewed face to face"*. The service also notes the additional risk in low-dose tolerance, eg below 50mg methadone. The policy notes that the service user may need to be seen the following day before consuming (8.7(b)(xiii)). The Guidelines outline the process taken and note the need for following the procedure *"so that appropriate monitoring and actions (such as reducing or stopping the following day's dose) can occur"*.

Both the Guidelines and the service's P&D policy are not prescriptive regarding the amount of medication withheld the following day after a pharmacy error. This is likely because of the many variations possible, eg in dose accidentally given (greater amount means a greater risk of overdose), dose of methadone the client usually takes (a lower

usual prescribed dose means a greater risk of overdose) etc. It is appropriate that the service conducts their own risk analysis based on the clinical information.

However, it is the author's experience that following such an error, it is just the one dose that is halved, or even quartered, or withheld (depending on the clinical circumstances) before the usual dose is resumed. However the author acknowledges that this practice is from experience and word of mouth, rather than it being clearly documented as such. A further consideration is that the error occurred on a Friday, leaving the client "unmonitored" over the weekend with the service being closed over weekends and with only the mental health crisis team and usual emergency services being available for any follow-up. The OST doctor did review the decision on the Friday afternoon, and did reinstate the usual dose for the Sunday.

As such, the outcome (halved dose the following day, and the usual dose from the second day) was consistent with the author's experience of usual practice, and consistent with both the service's policies and the (national) Guidelines. Should it have happened, the halving of the second day's dose may have been seen as unreasonable by some clinicians, and reasonable by others, given the lack of clinical oversight over the weekend.

Recommendations include consideration of reviewing the client face to face on the same day (at peak dose) before making a decision about the following doses — in keeping with both the service's P&D policy and the Guidelines. In addition, consideration could be given to an after-hours service, other than the mental health or emergency services. This could potentially be done in conjunction with other districts in the broader region. The medical doctor could have considered consulting with a peer from another OST service to discuss the plan regarding reduced doses, as a way to benchmark practice and get support regarding clinical decision making.

b) Whether the timing/speed of the reduction was appropriate and whether Ms A's discomfort was managed appropriately in relation to the error on the part of the pharmacy.

As per above, the reduction (halving) of the next day's dose was not inappropriate. In fact to continue the same dose the next day (and not halve it) would likely have been more inappropriate given the potential risks of overdose, especially with Ms A being on a lower dose of methadone (and hence at greater risk of overdose than if she had been on a higher, more "protective" dose of methadone (something which in the author's opinion is often misunderstood)).

The physical discomfort associated with a halved usual dose (20mg) on the Saturday, after taking more than double dose (90mg) on the Friday would have been minimal if experienced at all, given the long half-life of methadone. The nurse noted sound medical advice regarding possible symptomatic relief which was made available in the notes should Ms A make contact, including with the mental health crisis team. The author is unclear whether Ms A was advised that the after-hours crisis team would have this information available to them, as the conversation ended with Ms A hanging up.

The author believes that the timing/speed of the reduction was good practice (half dose the next day, usual dose the following day), and that aspects of withdrawal were managed appropriately. The author notes that the doctor was able to review the situation the same day (albeit after some tense exchanges between Ms A and the team, and involving the HDC) and change his mind in keeping with his understanding of the value of (and potential threats to) the relationship with Ms A.

c) The adequacy of Te Whatu Ora Hauora a Toi Bay of Plenty's policies.

Noted as above to be adequate in relation to pharmacy error and service response requirements.

d) Any other matters in this case that you consider warrant comment.

Nil

3. Requesting further serum levels 7 September 2023

Brief summary of clinical events:

On the 22 August 2023, it is noted in the progress notes that Ms A reported to her case manager that she was experiencing withdrawal symptoms and requested to be able to increase her dose (from 40mg). The case manager noted that he responded "*I queried what the plan would be as she would be right back where she started with no change.*" Ms A then requested serum levels (which as she explained to the HDC in a later letter (on or after the 7 September 2023) would demonstrate that her dose was not holding her, as she recalls the low serum levels demonstrated in 2022 when she was on a dose of 48mg). A request for the (pre-dose and 4-hours post-dose) serum levels, along with a urine drug screen were sent out and completed the following day on the 23 August 2023. MDT progress notes from the 30 August 2023 note recent cancelled appointments with the case manager, and ordered a further urine drug screen as per the case manager's request. On the 31 August, Ms A phoned regarding the serum results and was advised that these had not returned.

In the meantime, pharmacy error led to 90mg being dispensed on 1 September 2023 as described above. Progress notes from the MDT on 6 September 2023 note that "*the serum tests were low and these were instigated by (Ms A)*". It is noted that her usual case manager was on extended leave, and that she was "*unstable, not truly in treatment*", although does not expand on this. The recommendation was to allocate Ms A to the stabilisation nurse while the case manager was away, and to "*repeat serums this Friday (8 September) to compare to last results*". A letter dated 7 September was sent from the stabilisation nurse to Ms A with a request for further serum levels. "*We have received the results of the recent methadone serum levels, for due diligence, we would like to repeat the serum levels and get another UDS. I have attached the forms. Please call me if you would like to discuss ...*" The dose was withheld at the pharmacy until Ms A had undertaken this.

Advice sought regarding:

a) Whether it was reasonable and appropriate to require Ms A to undergo further serum level tests on 7 September 2023.

In the author's opinion, it was not reasonable or appropriate to require Ms A to undergo further serum tests for the following reasons:

1. Ms A requested the serum levels to support the case to increase her methadone dose, as this had been the process in the past (as described in the first issue above). As described above, the Guidelines note that the therapeutic dose range for methadone is 60mg–120mg. 40mg is a sub-therapeutic dose and in conjunction with withdrawal symptoms was indication alone to increase the dose at Ms A's request. The Guidelines note in section 3.1.1 (Page 14) that *"The dose should be sufficient to ensure the client experiences the minimum of withdrawal symptoms, is retained in treatment, can function adequately in their social roles and is clinically stable"*.

There is no requirement in either the Guidelines or the Service's policies for serum levels as part of consideration for a dose increase, unless perhaps the dose is over 120mg (Section 3.3.1, Page 17 of the Guidelines).

2. It was unclear why either of the two serum tests were ordered, and why these were of the pre (dose) and (4-hour) post (dose) type (meaning four blood tests in total), and what the team was hoping to find or demonstrate. The low serum levels from the first test were likely an indication of the sub-therapeutic dose and further supported the need for the dose to go up, and the author is unclear what the clinical concern was or why a second set was ordered. The Guidelines note (Section 5.5 Measuring methadone serum levels (Page 39)) that serum levels can be useful in the following situations:

- a client's responses to methadone OST does not align with the expected response
- the service provider is considering a change in the daily dose; particularly to a dose above 120 mg
- a client is suspected of poor compliance with the programme, or of diverting their dose (comparison of serum level measurements taken on the same individual within the last 6–12 months, with careful observation of dosing and retention of doses, may assist in determining compliance)
- there is doubt about the clinical indications for a dose increase, or the accuracy of reported methadone consumption information
- there is a suspected drug interaction
- the service provider is considering split doses (refer to section 5.6: Split methadone doses)
- a client is pregnant
- a client has serious liver or other physical disease and there may be methadone accumulation.

None of these issues seem to apply in Ms A's case, noting it was Ms A who requested the first test to expedite a dose increase, as the case manager had not supported an increase at the time, suggesting that Ms A would be going backwards. The risk of diversion did not seem to be a concern for the team or relevant to Ms A who was already on daily dispensing of her medication (serum levels can be useful before, and then after a period of daily dispensing to indicate whether the client is taking their takeaway doses). Pre-dose and (4 hour) post-dose levels can be used to check whether a person is a fast metaboliser of methadone (as per the Guidelines, page 17), but there was no evidence that this was being assessed.

3. The 22 August 2023 progress notes by the case manager indicate that he seemed to consider Ms A's request for a dose increase from 40mg to be a step backwards. *"I queried what the plan would be as she would be right back where she started with no change."* This does not seem consistent with the approach taken in the Guidelines, nor consistent with the collaborative client-centred approach outlined in the Service's policies. As outlined above, the dose was low, and insufficient to manage the withdrawal symptoms, which as outlined in the Guidelines (Page 14) can leave a client at risk of using opioids on top (potentially illicitly, or harmfully, eg IV), at risk of dropping out of treatment, and at risk of poor functioning in their social roles (Page 14). The author notes that the request for serum levels and waiting for their return further delayed any increase in dose.

4. Ms A requested the serum levels in the first place, to expedite a dose increase. The reasons stated by the service in their insistence on further serum levels (on account of the dose being withheld at the pharmacy until she had completed this) were unclear in the correspondence to Ms A, citing "due diligence". It is unclear what the clinical rationale associated with "due diligence" was. Given the impact on Ms A (two blood tests, four hours apart) who has limited venous access, and the limited, if any, value of the test as part of a routine dose increase in someone with a low dose and also withdrawal symptoms, this request seems unreasonable.

The author considers that the accepted practice would be to state on the script to increase the dose at the client's request, by 5mg up to every 4 days, with medical reviews at certain points along the way, for example every 20mg or so, without any requirement for serum levels until indicated (as per Page 39 of the Guidelines). The author considers the approach taken by the Service as a severe departure from accepted practice, and can find no evidence for the use of serum levels in the way that they were used, and that it further delayed a stabilisation of the dose and added to Ms A's overall instability and risks.

The author's peers agree that 40mg is a low dose and that serum levels were not clinically indicated, and would add little if any value to the clinical picture for this sub-therapeutic dose of 40mg and in the presence of withdrawal symptoms. The author's peers did not understand why the serum tests were of the "pre and post" kind, rather than just the usual pre-dose level requested (should indications have been met). Recommendations include reviewing the aspects of the Guidelines which relate to

serum levels (Section 5.5, Measuring methadone serum levels. Page 39), and those that relate to Recovery-oriented treatment (Appendix 10, Page 112). As per the first issue, recommendations also include team-level discussions about the role of recovery and OST, and how to obtain client feedback regarding team culture.

b) The adequacy of [Health NZ BOP]’s policies.

The [Health NZ BOP] OST Pathway notes in section 2.10. Holding doses, *“Occasionally there might be a need for a random blood or urine test to be completed. This will usually be to inform safe clinical practice and/or ongoing prescribing.”* It is perhaps unclear to a reader of this statement whether a random (serum) blood test is necessary in order to continue to practice safely, or whether there are certain indications or safety issues that would suggest a test is appropriate. The Service’s policies could perhaps refer to, or note the indications for serum testing as outlined in the Guidelines on Page 39. The Service’s policies (appropriately) do not suggest the use of serum levels as part of routine dose increase, and are adequate in relation to this.

c) Any other matters in this case that you consider warrant comment.

Nil’