HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Man dies nine days after starting methadone treatment

Introduction

1. This Office received a complaint from Mrs B in August 2022, who raised concerns about the care provided to her husband, Mr B in the period around his entry onto the methadone programme in March 2022. Mr B died nine days after starting methadone treatment for opiate dependence. Mrs B is concerned that the transition to the methadone regimen was not prescribed in a manner that minimised potential harm and that the methadone programme contributed to her husband's death. My sincere condolences go to Mrs B and her family for the loss of a beloved husband, father, and grandfather.

2. Mr B was diagnosed with lung cancer in 2017. Mrs B said he was not expected to survive beyond seven months and was prescribed opiate medication to control his pain. He had a history of back pain, and a pain specialist had diagnosed complex regional pain syndrome in August 2011. Following chemotherapy and radiation treatment, Mr B's cancer went into remission, but he continued to experience pain and was reliant on opiate medication, prompting his decision to accept treatment with methadone. Mr B also suffered from anxiety.

3. It is important to note at the outset that it is not the role of this Office to determine cause of death. My investigation is focused on the care provided to Mr B before he died and whether that care was provided with reasonable care and skill.

Information gathered

4. Mr B was diagnosed with lung cancer in December 2017. On 6 January 2018, he was admitted to an oncology ward to start chemotherapy treatment. At the time, he was taking various pain relief medications as well as medications for anxiety and gastric issues. During his hospital stay, Mr B's pain medication was changed and he was prescribed M-eslon[1] 30mg twice daily and Sevredol[2] 10mg as needed. Both are opiate medications.

5. Mr B completed his cancer treatment in May 2018 and was thereafter under the care of a hospice for ongoing pain control. His opiate medications (now including fentanyl patches) were increased. Mr B reported attempting to stop supplementary recreational drug use (cannabis, methamphetamine, and morphine).

6. In June 2018, investigations showed that Mr B was in remission from his cancer; however, he was continued on his opiate pain medications and benzodiazepines for ongoing anxiety. Efforts to decrease his medications throughout 2018–2020 were somewhat unsuccessful, although he continued to receive medical support from his general practitioner (GP) and, on occasion, from community mental health services (the latter for mental distress, including

[1] Extended-release morphine medication used to manage moderate to severe chronic pain.
[2] A morphine sulphate pain relief used for severe pain.

Names have been removed (except Health New Zealand | Te Whatu Ora and the clinical advisor on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

thoughts of self-harm, agitation, and abusive behaviour). Mr B was also reported to be using illicit drugs from time to time. He was discharged from hospice in mid-2019.

7. On 17 August 2020, Mr B discussed with his GP, Dr A, his desire to reduce his dependence on fentanyl and OxyNorm.[3] However, over the next year Mr B's clinical records note increasing overuse of medications, including midazolam and lorazepam,[4] difficulty sleeping, and depression with episodes of suicidal thoughts, agitation, and aggressive behaviour. By 12 February 2021, he was prescribed twice-weekly midazolam, totalling five bottles per week, and was requesting additional prescriptions.

Events June–December 2021

8. In the first half of 2021, Mr B began to express interest in the methadone programme. Accordingly, following further engagement with Hospice, Dr A formally referred Mr B to the Alcohol and Other Drugs (AOD) service on 23 June 2021. The next day, a social worker from AOD spoke to Mr and Mrs B over the phone and discussed whether referral to the pain clinic to support Mr B with reducing his medication would be more appropriate. The AOD clinical record notes that a letter was to be sent to Mr B's GP recommending referral to the pain clinic. However, there is no record of a letter being generated, and Mr B's GP practice did not receive any acknowledgement of the referral or recommendation to contact the pain clinic. The AOD clinical record for 7 July 2021 notes 'no response from GP' and exit from the AOD service.

9. During July 2021, Mr B continued to request further benzodiazepines (midazolam), and efforts to restrict his use of this medication were unsuccessful.

10. On 2 August 2021, Mr B went to his GP practice without having an appointment because he wanted to discuss his medication. A passerby found him asleep in his car. The police were contacted and said it took a bit of shaking to wake him up. The police expressed concern about Mr B's ability to drive. Mr B told the practice nurse that he had been taking two additional lorazepam at night. On 4 August 2021, the clinical record notes a plan to not prescribe further midazolam. Mr B had also been discharged from a counselling service that had been supporting him and had referred him to AOD the day before. On 5 August 2021, Mr B requested an additional bottle of midazolam because he was running out. His GP declined the request, and another referral was made to AOD (13 August).

11. On 2 September 2021, AOD received a further referral for Mr B from the police. This referral was declined because it did not meet the criteria for mental health or AOD involvement.

12. It would therefore appear that, between 23 June 2021 and 3 September 2021, Mr B was referred to AOD four times. He was referred by GPs at the practice on 23 July and 13 August 2021, by a counselling service on 3 August, and by the police on 2 September 2021. On each occasion, AOD did not proceed with the referral.

13. On 31 August 2021, Dr A contacted Dr C, a senior medical officer at the Opiate Substitution Therapy (OST) service, to discuss options for opiate substitution and AOD involvement. Around this time, Mr B continued to struggle with managing anxiety and requested additional

[3] A strong opioid medication used for the short-term relief of severe pain.

[4] Lorazepam and midazolam are benzodiazepines, a class of medication for anxiety; they were initially prescribed on 10 May 2019.

midazolam, which was increased to a prescription for seven bottles per week on 29 September 2021. On 9 September 2021, he had reported feeling overwhelmed and suicidal for approximately three weeks.[5] He was reluctant to start opiate substitution with methadone.[6] The clinical record for 4 October 2021 notes that Mr B declined methadone treatment and that it should not be discussed with him further.

14. From October 2021 through to January 2022, Mr B continued to overuse his medications, including lorazepam. Mr B viewed anxiety as his main issue, which he managed with midazolam, lorazepam, and alcohol.

Health New Zealand | Te Whatu Ora – AOD service

15. Health New Zealand | Te Whatu Ora (Health NZ) told the Health and Disability Commissioner (HDC) that Mr B was well known to the AOD service as he had previously been under its care six times between 2010 and 2017 and that comprehensive assessments and care plans were completed each time.

16. After talking to Dr A on 31 August 2021, Dr C documented Mr B's current medications and the calculated total daily dose of morphine and diazepam equivalent on 20 September 2021. He described the situation as extraordinary, noting that not only were the doses very high – equivalent to 430mg morphine and 120mg diazepam daily – but that there was also an over-reliance on short-acting agents. Three days later, Dr C discussed Mr B's unusual situation with a psychiatrist, and on 30 September 2021 sent an email to Medicines Control at the Ministry of Health asking that it considers sending Mr B's GP a formal request for information with the aim of making it clear to all parties that review of medication by AOD was required. At the time (30 September 2021), Mr B was not officially under the care of AOD as previous referrals had been declined.

17. On 15 December 2021, AOD returned a call from Mrs B and spoke to Mr B, who described mental distress, including worsening suicidal thoughts and panic attacks. Mr and Mrs B were provided with the contact number for the appropriate acute assessment mental health service. The next day, Mr B contacted AOD in distress because his GP had reduced his lorazepam medication. He reported yelling at his GP and the chemist. However, it is noted that there is no documentation in the GP practice records of a reduction in lorazepam dose or an altercation. AOD followed up with a phone call that afternoon. Mr B reported getting anxious when he is withdrawing and that he had run out of his extra lorazepam but had his usual nighttime dose. He also admitted to sometimes snorting his OxyNorm. A plan was put in place for Mr B to self-present to AOD and for his clinical record to be forwarded to the AOD triage clinician.

18. Mr B arrived at AOD on 23 December 2021 requesting to be considered for the methadone programme. He was interviewed by a social worker, and a note was added to the file documenting an intent to re-enter Mr B into the AOD system and requesting advice from Dr C. The records note, 'can you please advise what process you would like him to undergo' with an email response from Dr C asking staff to arrange an appointment with Mr B. Health NZ stated that the re-entry of Mr B into the system appeared to have been logged incorrectly and

[5] At the time, Mr B was receiving counselling and had two funded sessions left before needing to reapply.
[6] Long-acting synthetic opioid medication that is used to treat chronic pain and opioid addiction.

that, even though Mr B self-referred on 23 December 2023, Dr A should have been entered as his GP. Instead, the GP was recorded as unknown, which may have compromised normal tracking systems and communication.

Events January–February 2022

19. An appointment with Dr C was arranged for Mr B on 13 January 2022 and later rescheduled for 20 January 2022. Mr B was upset about the rescheduling of his appointment and was contacted on 10 January 2022 by a nurse, who documented that Mr B reported falling asleep everywhere and had minor injuries from falling down a lot. He had been told by an acquaintance that zopiclone[7] has the same ingredients as lorazepam and to substitute if he ran out of lorazepam. The nurse firmly discouraged this use of medication.

20. Dr C stated that, unlike most patients, who have a triage appointment a few weeks before meeting him, Mr B had had his initial triage appointment for the methadone programme in June 2021 (seven months prior). At that time, he was returned to GP care with advice to seek input from the pain team.

21. On 20 January 2022, Mr B attended an appointment with Dr C, who documented that his letter to the Ministry of Health was not in the Clinical Portal system and that he would remedy the error. Mr B was noted to be taking OxyNorm 40mg four times a day, lorazepam 1mg three times a day, seven bottles per week of midazolam, and applying a 75mcg/hour fentanyl patch. Dr C documented that Mr B's medication was much the same as in September 2021. However, the clinical record notes the dose of OxyNorm as 140mg per day in September 2021, and on 20 January was now 160mg daily, equivalent to 320mg of morphine.

22. Dr C outlined a three-step plan: first, to initially transfer Mr B from OxyNorm to methadone 80mg daily, at a methadone-to-opiate ratio of 1:4; second, to reduce the fentanyl patches and increase methadone to a likely total of 100–110mg daily; and third, to address Mr B's intake of lorazepam and midazolam. The prescribing of the fentanyl, lorazepam, and midazolam was to be left with Mr B's GP while the transfer from opiates to methadone was carried out.

23. Dr C noted on 20 January 2022 that Mr B used cannabis most days, had not recently used methamphetamine, and had given up alcohol years ago. In contrast, Mr B's GP record for 12 January 2022 notes that Mr B used alcohol to manage his anxiety, and the referral letter to AOD dated 23 June 2021 notes 'Nondependent alcohol abuse – previous history of drug and alcohol abuse ... intermittent heavy use currently.' The New Zealand Practice Guidelines for Opioid Substitution Treatment 2014 (OST Guideline) notes a risk of overdose when methadone is taken in combination with central nervous system depressants such as alcohol or benzodiazepines.

24. There was no written communication to Dr A following this assessment, although the clinical record notes an intention to call him.

25. Dr C stated that patients would normally have had two appointments prior to seeing him (triage and assessment) and that the case manager would complete the consent documentation with the patient. That did not occur for Mr B (as discussed later in this report).

[7] Hypnotic medication used to treat sleeping problems. Zopiclone is not a benzodiazepine.

Dr C further stated that his usual practice is to engage in a conversation about consent with each patient in their first meeting. However, there is no documentation of a discussion on the risks associated with methadone treatment or consent to proceed during the 20 January 2022 consultation.

26. On 14 February 2022, Mr B arrived at the service asking to see Dr C because he wanted to know when he would start methadone. He was tearful and appeared sedated and stated that he was desperate to start methadone as he couldn't continue the way he was going. Mr B was seen by a case manager who explained that Dr C was not available and that she would call Mr B to let him know of the plan. The case manager was unable to contact Mr B the next day to let him know that the plan to start medication changes would be discussed at the next OST meeting. On 28 February, a letter was sent to Mr B, with a copy to his GP, outlining the dates and doses for transfer from OxyNorm to methadone over a period of two weeks starting on 7 March 2022.

Events March 2022

27. Mr B started methadone on 7 March 2022. The methadone and OxyNorm were prescribed by Dr C. Mr B's GP continued as the prescriber for his fentanyl patches and benzodiazepine medications, midazolam, and lorazepam. Dr C stated that Mr B's situation differed from the typical patient where Dr C would be the sole prescriber and the patient would cease taking any other opiate medication. The reason Dr C gave for deciding to allow Mr B to continue with fentanyl patches was complications in Mr B's personal life and a desire to minimise disruptions to Mr B's usual routine. Dr C was confident that allowing Mr B to remain on fentanyl was safe, as regular monitoring was in place and a multidisciplinary team (MDT) approach was being taken.

28. Mr B's first daily dose of methadone on 7 March 2022 was 20mg with OxyNorm 120mg. No face-to-face assessments occurred after initiation of methadone. Health NZ stated that usual assessment and monitoring was affected by the COVID-19 Omicron surge occurring at the time. The clinical record notes a case manager from AOD contacted the dispensing pharmacy and confirmed that a pharmacist had spoken to Mr B, who was comfortable with the methadone but concerned about his lorazepam being reduced. There was no change to the lorazepam. The next day, Mr B was dispensed the same doses of methadone and OxyNorm. The case manager again contacted the pharmacist, who reported that Mr B looked anxious but was not sedated in any way.

29. On the third day of transition (9 March 2022), the dose changed to methadone 40mg and OxyNorm 80mg. That day, the case manager spoke to the pharmacist and Mr B by phone. Mr B had told the pharmacist that he had concerns about being addicted to methadone and just needed his lorazepam increased. He told the case manager that things were going ok and that he did think his lorazepam needed to be increased. The case manager explained that the plan was to address opiates first. Mr B reported not feeling over-sedated and being comfortable with the dose of methadone. The case manager contacted Mr B by phone two days later, on 11 March 2022. Mr B wanted to talk about midazolam and was reminded to focus on one medication at a time. He was given 'takeaway' doses of the medication to cover the weekend. Mr B was advised to store medication safely away from children and to take the methadone and OxyNorm he had been provided to cover the weekend at the same time each day.

30. On Monday, 14 March 2022, the dose of methadone increased to 60mg and OxyNorm decreased to 40mg. The next day, the case manager attempted to contact Mr B, who did not answer the phone. The case manager spoke to the pharmacist, who confirmed that Mr B had picked up his medication on 14 March 2022 and had appeared calm and relaxed, 'better than they had seen him in some time'. Sadly, Mr B passed away on the evening of 15 March 2022 after going for an afternoon sleep.

31. Mr B's death was referred to the coroner, and an autopsy was carried out. The autopsy included toxicology testing, which noted that Mr B had levels of methadone consistent with normal levels where tolerance has been developed but also within levels associated with drug-related fatalities. The toxicology report noted that non-regular users of methadone are unlikely to develop a tolerance to its toxic effects and that concurrent use of other central nervous system depressant drugs may enhance the toxicity of methadone. The report referenced a study on the role of benzodiazepines and methadone toxicity that found that benzodiazepines may contribute to methadone deaths by increasing airway obstruction.

32. The postmortem also showed severe narrowing and hardening of a major artery on the surface of the heart sufficient to explain sudden death. The forensic pathologist determined that Mr B's death was due to coronary artery disease as there was no history of increased sedation while on methadone, opiate substitution prescribing appeared (on the face of what was available to the pathologist) appropriately managed by AOD, and Mr B was likely to have developed cross-tolerance to methadone from his long-term use of OxyNorm.

Applicable OST Guideline

33. At the time of these events, the OST Guideline was in place, which outlines appropriate dosing regimens and opioid conversion rates,[8] as well as other relevant guidance referred to in my discussion below.

Decision

34. The issue for me to determine is whether Mr B was provided services with reasonable care and skill, and in this respect, I have focused on the care provided to him by Dr C and Health NZ. I am not critical of the care provided while Mr B was a patient with the Oncology Department and have decided to take no further action on this aspect of care. To assist my decision, I have considered independent clinical advice from addiction medicine specialist Dr Vicki Macfarlane (**Appendix A**). Dr Macfarlane found severe departures in the care provided to Mr B in multiple areas, including the assessment of Mr B, treatment planning, risk assessment, consent, documentation, communication, monitoring and supervision, and dose calculation. Dr Macfarlane's advice was provided to Dr C for comment. Dr C included in his response a report from addiction medicine specialist Dr D, which I have also considered in my review of the care provided to Mr B.

Dr C – breach

35. Mr B had complex needs because his opiate medication had been increased in the context of palliative care, he was on very high doses with an over-reliance on short-acting medication, he had co-existing anxiety and a chronic pain disorder, and he had a history of suicidal ideation

[8] The OST Guideline was updated in 2025. This report refers to the guideline available to clinicians at the time of events.

and aggressive behaviour. Dr C had a responsibility to understand Mr B's complex needs and the associated risks before initiating treatment.

Assessment

36. My clinical advisor, Dr Macfarlane, advised that the accepted standard prior to the commencement of OST is to complete a comprehensive clinical and risk assessment. The assessment includes a comprehensive substance use history, any previous drug treatment, what treatment the patient is prepared to consider, and a general physical and mental state examination with investigations such as a urine drug screen and blood tests. Dr Macfarlane further advised that the assessment should be clearly documented.

37. Dr D agreed with this advice, stating that a comprehensive assessment should have been done given the complexity of Mr B's medical history.

38. Dr C overall accepts Dr Macfarlane's opinion and provides context to how he typically became involved in a patient's care. He noted that usually there would be a 'triage' consultation followed by a bio-medical assessment with a case manager or other member of staff, following which he would then have a consultation with the patient himself. Thereafter would follow a team meeting and, if consensus was reached, a starting date for OST would be initiated, and a further appointment would occur with him.

39. This process was not followed in Mr B's case. As noted above, Dr C considered that Mr B's triage occurred in June 2021 (nine months prior to the commencement of methadone), following which he was referred back to his GP, and that in September 2021 Dr C instigated engagement with Mr B's GP proposing methadone treatment. Although Dr C comments on consenting issues (discussed in paragraph 44), he does not specifically address the concerns raised by my clinical advisor regarding the apparent lack of a comprehensive assessment, including the concerns about failing to undertake a risk assessment.

40. I am satisfied that no comprehensive assessment of Mr B was conducted before developing a treatment plan. I accept that Mr B had a very complex history, that he was known to the service, and that his entry into the service in January 2022 did not follow a usual pathway, but this does not obviate the duty to properly assess a patient prior to methadone treatment, noting the inherent serious risks associated with the treatment. I also do not accept that the 'triage' in June 2021 was an adequate assessment for the purpose of initiating methadone nine months later (noting that the outcome of that phone consultation in June 2021 and subsequent MDT meeting was referral back to his GP). Clearly, a more up-to-date assessment was warranted. In this respect, I note that, in addition to concurrent drug use, Mr B was experiencing psychological distress (including thoughts of suicide) in the months preceding his methadone treatment. I further note that Dr C and Mr B's GP each had a very different impression of Mr B's alcohol use and that the OST Guideline identifies alcohol as having a synergistic or potentiating effect alongside opioids. These factors were clearly relevant to Mr B's risk profile. I therefore concur with my advisor's view that the failure to undertake a comprehensive assessment was a severe departure from the standard of care.

Consent

41. My advisor has stated that starting methadone is associated with an elevated level of risk of overdose because opioid levels accumulate and that special care is needed when a patient is

taking other sedatives, including benzodiazepines. Accordingly, there needs to be a careful consenting process, including the provision of written information and a signed consent form. The practice guidelines for OST make clear the requirement for written information outlining, among other things, the range of treatment options and psychosocial interventions; the benefits, side effects, and limits of OST, including the increased risk of overdose during induction; the interactive effects of OST with other drugs; the potential effect on activities such as driving; and complaint options.

42. I note that these requirements are consistent with Rights 6 and 7 of the Code of Health and Disability Services Consumers' Rights (the Code), which are the rights to be fully informed, make an informed choice, and give consent.

43. There is no explicit documented evidence in the clinical record that Mr B was appropriately consented to the methadone programme.

44. Dr C has acknowledged the lack of documentation and 'that the unique pathway through which Mr B came to receive care from the service, may have had an impact on the thoroughness of the consenting process.' Dr C further commented that it is typically the role of the case worker to complete the consenting paperwork, with ultimate responsibility for consent resting with the treating clinician, and that the record keeping and information technology systems were not as integrated in 2022 as they are now. Dr C indicated that it is usual practice for patients to receive in-depth information during their initial triage appointment. He also believed it 'probable' that he and Mr B had a general discussion about consent prior to commencement of the treatment during their consultation.

45. Notwithstanding Dr C's explanation, I am highly critical that Mr B was not appropriately consented to the methadone programme. I am left with considerable doubt as to whether Mr B was advised at all of the risks of methadone treatment, and – given that the contact in June 2021 was by phone – it is likely that he was not provided with the appropriate written information. Even if Mr B had received verbal information in the June 2021 consultation (which is by no means certain), this would not have been sufficient in the context of the evolving complexities of his drug use (and mental state) or to ensure effective communication and understanding of the risks. There should have been active conversations with him in early 2022 when he re-engaged with the service. Ultimately, as the clinician responsible for forming the treatment plan, the responsibility to ensure appropriate consent rested with Dr C.

<u>Calculation of methadone substitution</u>

46. To calculate an appropriate methadone dose, it is necessary for a clinician to convert the prescribed opioids to methadone. This is done by calculating first to morphine equivalence and then to methadone.

47. At the time of Mr B's care, the recommendations for conversion were contained within Appendix 7 of the OST Guideline with a conversion rate of 1:10. Dr Macfarlane has said that it is accepted practice in New Zealand to refer to this guideline. She also commented that all the guidelines recommend particular caution when a person is taking benzodiazepines.

48. Dr C used an outdated article (2004) to calculate Mr B's methadone (1:4), which resulted in a dose that was more than twice that recommended by the OST Guideline (80mg instead of

27mg). In addition, my clinical advisor, Dr Macfarlane, advised that methadone should not be increased any faster than every four days and by no more than 10mg at a time regardless of the prescribed doses of opioids. Mr B's methadone dose was increased by 20mg on day three of his treatment. Dr Macfarlane advised that, although the first dose was appropriate, over the period of his treatment the total dose was too high and increased too quickly, representing a severe departure from the accepted standard of care.

49. Dr D advised that opioid conversion to methadone is complex and that guidelines are approximate, allowing for individual variation. He acknowledges that more recent guidelines support a 1:10 conversion ratio with high-dose opioid users but points to difficulties finding this information within the OST Guideline. Dr D advised that Dr C's experience with Mr B and his history with the service led Dr C to the conclusion that a more rapid induction than with street drug users was reasonable in the circumstances and that considering this a 'severe departure' from the expected standard of care is too harsh. However, Dr D does comment that he accepts Dr Macfarlane's view that the induction to methadone and the incremental increases should ideally have been lower and less frequent (while acknowledging that Mr B's circumstances and prior drug dependence and tolerance may have influenced Dr C's decision-making). In his view, a slower induction would have been more appropriate.

50. Dr C accepts that the conversion rate was based on outdated guidance, for which there is no excuse; however, he maintained that the levels were suitable for Mr B's tolerance at the time. He further comments that, although a slower up-titration would have been desirable, Mr B was nevertheless coping well with the medication.

51. Although I accept it is appropriate for clinicians to bring their individual judgment to bear on the clinical circumstances of the patient, they should still have regard to appropriate guidance. I therefore consider that Dr C did depart from the standard of care in respect of the conversion and titration. It is accepted that Dr C used outdated guidance, and the weight of expert advice (including that of Dr D) is that the incremental increases of the methadone should also have been lower and less frequent. I note further that, although Dr C was familiar with Mr B, no adequate recent assessment had occurred to inform clinical decisions on what individual variation may have been appropriate. As well as being Mr B's methadone prescriber, Dr C was the lead clinician for the OST service and had a responsibility to promote best practice and maintain professional development education in the most recent guidelines and protocols.

<u>Environment in which care was provided and management of other medications</u>

52. The evidence is clear that, at the time of his methadone treatment, Mr B was concurrently taking other medications, including benzodiazepines. Dr Macfarlane commented that accepted practice would be to be extremely cautious when starting methadone in a person who is also taking other opioids and/or sedatives. Additional safety mechanisms, such as close observation in an inpatient unit if available, or a very slow conversion with close monitoring in the community, should be considered. This is because of the increased risk of mortality associated with drugs such as benzodiazepine and alcohol, which have a synergistic effect when combined with methadone.

53. It is relevant that care was being provided in a regional service, which undoubtedly posed challenges – a matter that both Dr D and Dr C commented on. I acknowledge the lack of access to inpatient services as well as the resourcing constraints and Dr C's assessment that he did

not consider Mr B the type of patient who would react well to a controlled setting. For these reasons, I am not critical of the plan to commence treatment in the community.

54. However, special care was needed because of Mr B's concurrent drug use, and I am not persuaded that appropriate care was taken.

55. In particular, I am critical that prescribing for the other opioids and benzodiazepines was left for the GP to manage in the absence of specialist advice, and I consider that the AOD service should have taken over this prescribing. Dr D concurs. This is particularly relevant noting the high dosage of methadone prescribed by Dr C and that the rapid up-titration was not in accordance with accepted standards.

Follow-up

56. The OST Guideline makes clear and prescriptive recommendations regarding the necessary observations and follow-up required for when a person is commenced on methadone. This is to ensure monitoring of potential drug accumulation and toxicity, or withdrawal. Responsibility for such monitoring in the first four to five days is given to the prescriber or caseworker. It is not accepted practice to allow takeaway doses while being stabilised on methadone.

57. Mr B was commenced on methadone on 7 March 2022 without prior recent face-to-face assessment by any AOD clinician. Monitoring was effectively left to the pharmacist on days one and two, who reported to the AOD nurse/case manager that Mr B did not appear sedated, although he was somewhat anxious. There was phone contact with Mr B by his case manager on day three (when his methadone dose was doubled and OxyNorm decreased) and on day five, at which point he expressed being okay but worried about needing an increase of lorazepam. For the weekend (days six and seven), Mr B was using 'takeaway' doses of methadone with no contact by any clinician. On Monday, 14 March 2022, there was a further dose increase with no contact by the caseworker – although the following day, Tuesday, 15 March (the day of Mr B's death), the pharmacist advised that he had appeared calm and relaxed when he had picked up his medication on the Monday.

58. Health NZ provided some context for why face-to-face assessments of Mr B did not occur at this time, specifically that COVID-19 Omicron case numbers were surging, which impacted on the ability to provide in-person monitoring. Although there was discussion about switching to audiovisual assessments, this did not occur in Mr B's case. Health NZ identified that, nevertheless, there was telephone contact with the dispensing pharmacist and both Mr B and his wife during this initial period of induction. Health NZ accepts that this practice was outside the OST Guideline. Health NZ also commented that the COVID-19 surge directly impacted on Dr C's workload, noting that he was the Medical Officer of Health for the mid-central region, responsible for public health.

59. Dr C has also commented that he was heavily reliant on the support of his wider team to assist with the monitoring of Mr B.

60. Having carefully considered the circumstances of Mr B's monitoring, I am not critical of Dr C in this respect, and I agree that he should have been able to rely on members of his team to conduct appropriate checks. I am also mindful of the COVID-19 context. That said, I consider

Mr B's monitoring to be less than satisfactory, noting the extent of the departure from the OST Guideline. These standards are about minimising the potential for patient harm, and given the complexity of Mr B's condition, closer monitoring was clearly warranted, particularly given the significant doses of methadone and the decision to allow him takeaway doses after only five days of treatment. This criticism rests against Health NZ, as discussed in paragraphs 66 and 67.

Conclusion

61. While appreciating that Dr C was endeavouring to assist Mr B with his complex addiction needs, I am nevertheless greatly concerned at the extent to which the care he provided fell short of accepted standards in multiple areas. Dr C did not follow appropriate guidelines, prescribed methadone at a dose and titration rate well outside accepted practice, did not appropriately manage Mr B's concurrent drug prescriptions, and did not complete the appropriate assessments (including a risk assessment) before Mr B started OST treatment. For these reasons, I find that Dr C did not provide services with reasonable care and skill, breaching Right 4(1)[9] of the Code. In addition, Mr B did not receive sufficient information on the risks, benefits, and choice of treatment to allow him to make an informed choice and consent to methadone treatment. Ultimately, the responsibility for consent rests with the treating clinician. Accordingly, I also find that Dr C breached Rights 6(1)(b)[10] and 7(1)[11] of the Code.

Health NZ – breach

62. It is evident from my review of Mr B's care that there were issues with the documentation systems and processes in operation at Health NZ at the time of events. On two occasions, information was not loaded and available in the clinical record, including communication of the outcome of Dr A's referral to AOD in June 2021, which was not received by Dr A's practice but assumed to have been actioned (with the result that the Pain team was not engaged). In addition, there is no record of the referral sent from Mr B's GP practice to AOD on 13 August 2021 or the outcome of that referral.

63. Health NZ conducted its own review of Mr B's care and identified that multiple services had attempted to refer Mr B to AOD and that these referrals were declined. Over a period of two months (August and September 2021), Mr B's GP practice referred him to AOD twice (with a further phone call from Dr A requesting assistance directly from Dr C). Over the same period, the police and Mr B's counsellor also independently referred Mr B to AOD.

64. In its review, Health NZ found that the multiple declined referrals showed that the complexity of Mr B's situation was missed at triage and multidisciplinary review. It took nearly four months after Mr B's GP spoke to Dr C on 31 August 2021 for Mr B to be accepted into AOD.

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[9] The right to services of an appropriate standard. Right 4(1) states 'Every consumer has the right to have services provided with reasonable care and skill.'

[10] The right to be fully informed. Rights 6(1)(b) states 'Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including … an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option'.

[11] The right to make an informed choice and give informed consent. Right 7(1) states 'Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.'

Acceptance occurred only following significant self-advocacy from Mr and Mrs B, who contacted AOD by phone on 15 December 2021 and were interviewed by a social worker on 23 December 2021 when Mr B self-presented to AOD without an appointment. I am highly critical of Health NZ's repeated failure to provide timely support to Mr B and his primary care clinicians. Mr B had complex health needs, including anxiety, thoughts of self-harm, illicit drug use, chronic pain, and opiate and benzodiazepine dependence. When AOD eventually accepted Mr B into the service, he was taking increasingly higher levels of short-acting opiates and benzodiazepines to manage his pain and anxiety, a situation that Dr C described as 'extraordinary'.

65. Dr C stated that the usual process for admission into the methadone programme is for the patient to have two appointments with an AOD clinician before having an appointment with Dr C and for consent documentation to be completed at these initial appointments. Although Dr C had discussed Mr B with Dr A on 31 August 2021 and was assessing his suitability for the methadone programme in September 2021, Mr B was not at the time accepted into the AOD service. This caused confusion when Mr B was interviewed by a social worker who was the triage clinician on 23 December 2021. This social worker requested direction on which pathway to follow, and no assessment appointment was scheduled before Mr B was booked in to see Dr C. In my view, this demonstrates insufficient clarity for staff on the process for Mr B's entry into the methadone programme, and in this instance, I consider that a critical step was missed by not providing Mr B with an assessment appointment, which meant the key assessment (including risk assessment) was not undertaken and consenting processes were highly compromised.

66. Dr Macfarlane further advised that the monitoring of Mr B during the initiation of and transition to methadone was inadequate and a severe departure from the accepted standard of care. Although Dr C was the lead clinician, monitoring was ordinarily carried out by the case manager. The OST Guideline requires a face-to-face meeting at 30 minutes and four hours after the dose on day one. Dr Macfarlane advised that initial dose increases in a person on multiple sedatives should not be made without a face-to-face assessment. In addition, monitoring should be at least daily for the first three days and then every two to four days.

67. In fact, Mr B's 'monitoring' of his initiation onto the methadone programme was undertaken by the pharmacist, who the case manager relied on to assess for any adverse effects or sedation. The case manager did not have any face-to-face contact with Mr B but rather relied on reports from the pharmacist and did not contact Mr B until day three of his transition (a phone contact). This does not, in my view, amount to adequate monitoring or compliance with the guidelines, which are designed to ensure patient safety. I acknowledge that an Omicron surge was occurring at the time, which may have limited face-to-face client interaction, and I am also aware that, at the time, conversations were under way regarding the need to implement telehealth options. However, there was no adequate contingency plan for managing methadone transition assessments in these circumstances – specifically noting the complexity of Mr B's condition and that this service was being provided in the community. This should have been planned for, if not just for Mr B's situation, but more broadly, noting that COVID-19 had been evolving since March 2021. I am highly critical of the decision to rely on Mr B's pharmacist for assessment of sedation and of the decision to increase doses of methadone without a face-to-face assessment by an AOD clinician, particularly given the increased risk of toxicity when concurrently taking benzodiazepines and fentanyl patches and

the considerable risk of overdose in the few days while methadone accumulates. It is clear to me that Mr B's case manager did not assess him for toxicity or withdrawal after his first dose of methadone, nor was he assessed three or four hours later at peak plasma level. In my view, it is Health NZ's responsibility to ensure that processes are in place to support compliance with accepted standards. There would have been the opportunity for at least more fulsome telephone contact, or – better still – telehealth consultations in the COVID-19 environment.

Conclusion

68. Systems in place at the time of these events did not support the AOD clinicians to gain a full picture of Mr B's situation or to safely manage his transition to methadone. Important information was not loaded in the clinical records, Mr B experienced a delay in receiving support, and – when he was accepted into the service – his pathway diverged from the usual assessment and consenting process, which led to serious failings in those processes. After starting methadone, Mr B was not adequately monitored.

69. Numerous errors were made by numerous people, indicating a system that did not support appropriate or safe care and for which Health NZ is ultimately accountable. For the reasons above, I find that Health NZ did not provide Mr B with service with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Response to provisional decision

70. Mrs B was provided with a copy of the 'information gathered' section of my provisional decision. She remains concerned about the high levels of methadone detected in Mr B's blood as noted in the toxicology report. She reports Mr B being scared to take the amount of methadone he was given while on his other medication and concerned that he might overdose. Mrs B does not believe that Mr B had a tolerance to methadone as he had only been taking it for a short time before his death.

71. Mrs B stated that the methadone plan was developed without Mr B being present, despite requesting to be, and that he was not monitored by the AOD service, only by the pharmacist.

72. Mrs B also outlined Mr B's struggles with breathing and pain on the right side of his chest since 2018.

73. Dr C and Health NZ were provided with a copy of the provisional decision. Both parties accept my decision, and their comments have been incorporated into this report.

Changes made since events

74. Dr C retired from all clinical practice in July 2026. His previous role at OST has been increased to a full-time position and attends regular National Association of Opioid Treatment Providers (NAOTP) collaboration and peer-review sessions, as well as receiving clinical supervision from a peer. Additional support is provided by an experienced OST nurse who has joined the team, allowing for on-site peer review, and recruitment is under way for an additional GP prescriber, to assist with prescribing and to allow more time for essential clinical governance tasks.

75. Health NZ outlined several leadership changes in the district where Mr B received care, including the appointment of an Associate Director for Mental Health and Addictions, who is supporting quality improvement initiatives. Quality assurance initiatives include auditing for

adherence to the OST Guideline. The leadership has issued a directive that all complex cases such as those with coexisting prescriptions of sedatives and opioids be discussed at the NAOTP meeting or in a specially convened meeting with an NAOTP peer.

76. The medical documentation system in use at the time was replaced in July 2022 with the Dragon Medical Workflow system, which interfaces with the electronic health record and allows for electronic transmission of letters to primary care. The system prompts the medical transcriptionist to seek clarification if no primary provider is specified or if no letter is received for transcription after a patient-contact appointment.

77. Changes to clinical practice include the following:

- The move from a single triage clinician to a single point-of-entry team.
- A comprehensive assessment that includes both mental health and addiction assessment and risk assessment.
- Standard practice of face-to-face assessment on date of initiation and transition and at dosage increment points, followed by a low threshold for using an inpatient or other closely supervised setting (such as a respite facility).
- Ensuring that close follow-up provisions are adhered to and ensuring whānau and patients have gained access to naloxone,[12] know how to use it, and know the warning signs of overdose. A lack of suitable community or whānau support is grounds for initiation in a controlled setting.

78. The AOD service is transitioning to a shared suite of procedures and documentation that complies with guidelines. These include shared consent and information provision processes and comprehensive assessment processes and documentation, including risk assessments, shared processes for initiation and monitoring, and negotiation of shared resources for inpatient care of people with complex conditions undergoing initiation of, or changes in, their opiate-substitution therapy. There is now a focus on improved documentation, routine audit activity, development of quality indicators, and stronger governance oversight of high-risk cases. Health NZ stated that a move towards regional OST governance is strongly supported to ensure that no service, clinician, or provider operates in isolation.

Recommendations and follow-up actions

79. Recommendations are designed to improve practice and systems with the aim of preventing similar situations occurring to other consumers. Although this investigation has identified areas for improvement in Dr C's clinical practice, his retirement makes any recommendations aimed at improving individual practice impractical.

80. I make the following recommendations:

Dr C

a) That Dr C provide a formal written apology to Mrs B and her whānau for the deficiencies identified within this report. The apology is to be sent to HDC within three weeks of the date of this report for forwarding to Mrs B.

[12] A lifesaving medication used to reverse opioid overdose.

Health NZ

81. Health NZ has taken significant steps in improving the service provided by the OST clinicians and the AOD service. I note that Health NZ has expressed its deepest condolences to Mr B's wife and whānau in its response to HDC and are open to meeting with Mr B's whānau should they wish. In addition, I recommend the following:

a) Health NZ provide a formal written apology to Mrs B and her whānau for the deficiencies identified within this report. The apology is to be sent to HDC within three weeks of the date of this report for forwarding to Mrs B.

b) Health NZ use this anonymised case to provide training on the OST Guideline and dose calculation in relation to converting opioids to methadone to all staff involved in opiate substitution and training regarding informed consent in the context of OST. Training records and an outline of the course content are to be provided to HDC within six months of the date of this report.

c) Health NZ provide HDC with copies of the results of the last two audits carried out for compliance against the OST Guideline and a report on any corrective actions taken. The information is to be provided within three months of the date of this report.

d) Health NZ provide HDC with a progress report on the transition to a shared suite of procedures and documentation that complies with the OST Guideline. The report is to be provided within three months of the date of this report.

82. A copy of the sections of the final report that relate to Dr C will be sent to the Medical Council of New Zealand.

83. A copy of the final report will be sent to the Office of the Coroner.

84. A copy of the final report with details identifying the parties removed, except Health NZ and the independent clinical 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 and the Director of Mental Health and Addiction (Ministry of Health | Manatū Hauora), the New Zealand Pharmacovigilance Centre, Te Pou o te Whakaaro Nui, and the Mental Health Foundation of New Zealand and placed on the HDC website, www.hdc.org.nz, for educational purposes.

Director of Proceedings referral

85. Noting the serious departures from the standard of care in this matter, I have decided to refer Health NZ 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. I have done so noting the severity of the departures from the standard of care relating to Mr B's care coordination, the failures to properly monitor Mr B's induction onto the methadone programme, the failure of the service to ensure a proper assessment and consenting process for Mr B, and its repeated failures to support Mr B's admission into the service. While acknowledging the various mitigating factors, including the COVID-19 environment and workforce challenges, it was nevertheless Health NZ's responsibility to ensure that a reasonable standard of care was provided to Mr B, noting his particular

vulnerabilities and risks. In my view, referral is in the public interest and is consistent with other cases of a similar nature.[13]

86. In reaching this decision I have taken into consideration submissions made on behalf of Health NZ that referral to the Director of Proceedings is not necessary to secure system improvements (noting the work it has already taken to address the concerns raised in this matter) and querying the utility of such referral and lack of restorative process. It has said the public interest is better served by no referral. I have also considered the wishes of the complainant, who is supportive of referral and seeking accountability.

87. I am not persuaded by Health NZ's submissions to change my decision to refer Health NZ to the Director of Proceedings for the reasons outlined in paragraph 85. I remain of the view that there is a public interest for cases of a serious nature to be referred to the Director of Proceedings for the purpose of accountability and to indicate my view of the seriousness of this matter.

88. For completeness, I note that I considered whether to refer Dr C to the Director of Proceedings, given the serious departures from the standard of care associated with his individual practice (as outlined above in this report). However, I am mindful that Dr C has retired from practice and was not well supported by the system given the competing demands on his time. Ultimately, I am satisfied that referral of Health NZ is more appropriate and in the public's interest.

Other comment

89. In October 2023, HDC wrote to the Director of Mental Health and Addiction, Dr John Crawshaw, 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.

90. 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 Guideline, consideration would be given to enhancing its 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.

91. HDC will continue to monitor these agreed actions.

Morag McDowell
Health and Disability Commissioner

[13] See C23HDC01722.

Appendix A: Independent clinical advice to the Commissioner

The following independent advice was obtained from Dr Vicki Frances Haeata Macfarlane:

'I have been asked to provide an opinion to the Health and Disability Commissioner (the Commissioner) on case number C22HDC02090, and I have read and agree to follow the Commissioner's Guidelines for Independent Advisors, and I am not aware of any conflicts of interest.

I am an addiction medicine specialist and gained my Fellowship in Addiction Medicine with the Royal Australasian College of Physicians in 2015. I am a vocationally registered general practitioner (GP) with the Royal New Zealand College of General Practitioners, and I was a GP from 1996 until 2010. I have been working for the Auckland Community Alcohol and Drug Services, Waitematā District Health Board, full time since 2011. I have experience working in both the opioid treatment service and the medical detoxification service. I am the current New Zealand Branch Chair on the Australasian Chapter of Addiction Medicine Committee (AChAM) and was also on the committee from 2016 until April 2022. I am also on the FAChAM training committee.

The Commissioner has specifically asked for an opinion on the care provided by Dr [C], Te Whatu Ora, to Mr [B] (dec) and advise whether I consider the care provided to Mr [B] by Te Whatu Ora was reasonable in the circumstances, and why.

In particular, I have been asked to comment on:

1. The adequacy of Dr [C's] overall management of methadone substitution for Mr [B].
2. The adequacy of the plan to first substitute the use of oxycodone for methadone and then address Mr [B's] use of fentanyl and benzodiazepines.
3. The appropriateness of the guidelines used by Dr [C] regarding calculation of conversion for methadone substitution.
4. The adequacy of Dr [C's] calculation of conversion for methadone substitution.
5. The adequacy of the consideration given to the concurrent use of other medications, including lorazepam, midazolam spray, fentanyl patches, and zopiclone.
6. The adequacy of the consideration given to patient factors, including Mr [B's] propensity to use above-prescribed doses of benzodiazepines.
7. The adequacy of the care provided by Dr [C] following the commencement of methadone substitution.
8. Any other matters in this case that you consider warrant comment.

For each question, please 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.

I have reviewed the following documents:

1. Copy of complaint dated 24 August 2022
2. Te Whatu Ora's response dated 25 August 2022
3. Dr [C's] first report to the Coroner dated 25 August 2022
4. Dr [C's] supplementary report to the Coroner, undated
5. Toxicology report dated 10 May 2022
6. Post mortem report dated 27 June 2022
7. Copy of Adverse Events Review Report by Te Whatu Ora dated 9 December 2022
8. Clinical records from Te Whatu Ora [district where Mr B received AOD/OST services] covering the period December 2017 to March 2022
9. Clinical records from Te Whatu Ora [district where Mr B received cancer treatment] covering the period December 2017 to March 2022
10. Clinical records from Mr [B's] GP practice covering the period December 2017 to March 2022
11. Confirmation of death minute from the Coroner

I have spoken to a number of peers who are very experienced in opioid-substitution treatment.

I have reviewed relevant opioid treatment guidelines from New Zealand, Australia, the United States of America, and the United Kingdom (see references).

Summary

In December 2017, Mr [B] was diagnosed with extensive small-cell lung cancer, which was successfully treated with chemotherapy and radiation therapy. He was commenced on opioids during his treatment to manage bilateral pleuritic chest pain, back pain, and shortness of breath. Notes indicate that the back pain was longstanding and related to an accident in 1989.

Prior to his diagnosis of lung cancer, Mr [B] had been taking prescribed DHC, Sevredol, lorazepam, clonazepam, and baclofen. In January 2018, he was started on midazolam nasal spray by oncology for shortness of breath and anxiety. I note that, during his cancer treatment, in May 2018, the hospice stopped the morphine and commenced OxyNorm

10mg, which was increased to OxyNorm 20mg, two capsules four to six hourly. Fentanyl patches were also commenced and the lorazepam dose increased to 3mg daily. Mr [B] continued to be prescribed these medications, and attempts to reduce them had been unsuccessful due to a recurrence of pain and anxiety.

Mr [B's] GP, Dr [A] became increasingly concerned about Mr [B's] opioid and short-acting benzodiazepine use, challenging behaviour, and possible misuse of his medications and, on 23 June 2021, Dr [A] referred Mr [B] to the Alcohol and Drug Service (AOD). A phone discussion with Mr [B] and his partner and an AOD case manager occurred on 24 June 2021, and a pain clinic referral was advised, but it is unclear whether this was communicated to Dr [A].

In August 2021, Mr [B] was found asleep in his car and difficult to rouse by a member of the public and was referred by the police to the AOD service. This referral was declined. Dr [A] made a second referral to the AOD service on the 13 August 2021. On 31 August 2021, Dr [A] spoke to Dr [C] [a Senior Medical Officer at the Opiate Substitution Therapy (OST) service], and discussed options, including methadone and further involvement by the AOD service. On 22 September 2021, Dr [A] had a further discussion with Dr [C] about Mr [B]. They discussed the best way to help Mr [B], including the possible substitution of his current medications with methadone and a long-acting benzodiazepine. This conversation was documented by the GP but not Dr [C].

On 23 September 2021, Dr [C] spoke to a psychiatrist, and it was agreed that there would be a formal approach to the Ministry of Health. I cannot see any document to Medicines Control in the clinical notes; however, the Adverse Events Review Report [by] Te Whatu Ora includes an email sent by Dr [C] to Medicines Control on 30 September 2021. There is no formal response in the documents I have reviewed from Medicines Control. Throughout October and November 2021, Mr [B] contacted his GP a number of times, reporting increasing anxiety and insomnia and repeatedly ran out of his medications early.

On 4 November 2021, Dr [A] completed a request for information pursuant to regulation 35 of the Misuse of Drugs Regulation 1977. This was forwarded to the Medical Officer of Health, Medicines Control, at Medicines Control. No written response from Medicines Control was included in the notes I received.

On 16 December 2021, a registered nurse from the Acute Mental Health and Addiction Services (MHAS) spoke to both Mr [B] and his wife as he had run out of one of his anxiety medications and was anxious and distressed. He was advised to self-refer to the AOD service. There was further contact with acute MHAS on 23 December 2021, with mention of running out of medications early, snorting gabapentin, and suicidal ideation. He requested a referral to the methadone programme as soon as possible. He was assessed by a co-existing AOD clinician, and an appointment was made to see Dr [C].

On 10 January 2022, Mr [B] was contacted to inform him that the appointment to see Dr [C] had been postponed from 17 January to 20 January, and he reported feeling suicidal and hung up. He was followed up by MHAS later that day and was very distressed and crying. A plan was made, and he was encouraged to seek support if needed.

On 20 January 2022, Mr [B] was seen by Dr [C] and a key worker with his wife, and it was agreed that the prescribed opioids (fentanyl and oxycodone) would be converted to methadone and the short-acting benzodiazepines (midazolam and lorazepam) to diazepam in a stepwise process. There was no record of any verbal or written communication with Mr [B's] GP following this appointment.

Mr [B] presented to the addiction service on 14 February 2022 asking when the conversion would start. He was tearful and appeared somewhat sedated. He was informed by a registered nurse and opioid substitution treatment case manager that Dr [C] was unavailable but that he would be contacted and that Mr [B] would then be informed of the plan. There was a discussion about the dispensing pharmacy and a written plan.

On 21 February 2022, Dr [A] had a consultation with Mr [B], who expressed frustration that he had not heard from the AOD service. Dr [A] spoke to Dr [C], and Dr [C] agreed to contact Mr [B] with a plan. On 24 February 2022, at a multidisciplinary meeting, it was noted that Mr [B's] GP had requested a care plan with a copy to be sent to the dispensing pharmacy. On 28 February 2022, Dr [C] wrote to Dr [A], the pharmacy, and Mr [B] outlining the plan for transferring the OxyNorm®, a short-acting form of oxycodone, to methadone starting on 7 March 2022. There was no advice included regarding the benzodiazepine and zopiclone prescribing and the risks during the stabilisation process. There was no face-to-face meeting with Mr [B] prior to starting methadone.

The OST case manager nurse spoke to the dispensing pharmacist on 7 March 2022, the day that the methadone was commenced. The pharmacist reported that Mr [B] had dosed and been given clear instructions about the OxyNorm® dose. The nurse spoke to the pharmacist on 8 March 2022 and 9 March 2022, and the pharmacist reported that Mr [B] did not present as sedated. The dose was increased from 20mg to 40mg on 9 March 2022, and the OxyNorm® was reduced from 120mg daily to 80mg daily. The OST case manager called Mr [B] on 9 March 2022, and he reported that he was not feeling over-sedated. He expressed concern about the lorazepam dose, as he was feeling anxious. He was advised that both medications can be sedating and so only one medication would be changed at a time.

The nurse made a phone call to Mr [B] on 11 March [2022], and nil concerns were reported. On Monday 14 March, the pharmacy reported that Mr [B] was calm and relaxed prior to his dose, which increased to 60mg that day. I note that the GP prescribed zopiclone on 14 March 2022. On 15 March [2022], Mr [B] consumed his methadone in the pharmacy. Later that day, Mr [B] passed away. GP notes state he went to sleep with his wife and was unresponsive when she woke up.

Dr [C]

1. The adequacy of Dr [C's] overall management of methadone substitution for Mr [B].

I would like to acknowledge that there are significant challenges associated with providing addiction care, especially provision of opioid-substitution treatment (OST) in a regional service; however, in my opinion, overall, Dr [C's] management of methadone substitution for Mr [B] was below the usual standard of care in a number of areas.

- I could not find a comprehensive assessment or risk assessment completed by either Dr [C] or a case manager.
- I could not find any evidence that consent forms were signed and that written information was given to Mr [B] or his wife at the time of the initial assessment.
- I could not see any documentation that Mr [B] or his wife were informed about the risks of overdose when starting methadone, especially in the context of Mr [B] being prescribed fentanyl, benzodiazepines, and zopiclone.
- There was no written communication to the referrer, Mr [B's] General Practitioner (GP), following the assessment of Mr [B] by Dr [C] in September 2021 or January 2022.
- Mr [B's] GP had to follow up on his behalf as there had been no communication from the AOD service for a month following the assessment in January 2022.
- There was no documentation in the notes of the resource or resources used to determine the dose conversion of OxyNorm® to methadone.
- There was no face-to-face discussion or risk assessment about the treatment plan prior to starting methadone. The written treatment plan that was given to Mr [B] and sent to the GP and pharmacist did not include any information about risk of over-sedation or who to contact in an emergency.
- On the day that Mr [B] had his first dose of methadone, there was no face-to-face assessment pre-dose nor 30 minutes or three to four hours post dose to assess for toxicity or withdrawal.
- The methadone dose was increased after two days from 20mg to 40mg and after a further five days from 40mg to 60mg. There was no clinical assessment prior to these dose increases and no documentation of what other medication Mr [B] had been taking. [He had been taking] benzodiazepines throughout that time.
- Mr [B] was given takeaway doses in the first week of starting methadone.
- There was no consideration given to starting methadone in a more closely supervised environment due to the high doses of sedative medications that Mr [B] was taking and his history of becoming emotionally distressed, anxious, and suicidal and overusing medications.

a. What is the standard of care/accepted practice?

Accepted practice prior to commencing OST includes completing an initial comprehensive assessment. The initial assessment should follow standard practice for assessment of a complex clinical condition and incorporate collateral information where appropriate.[1,4] The assessment includes a comprehensive substance use history, any previous drug treatment, and what treatment the patient is prepared to consider. A general physical and mental state examination is usually conducted, as is a urine drug screen. Investigations, including for blood-borne viruses, are usually undertaken as needed.

Assessment of risk is an important part of the comprehensive assessment and should be clearly documented in the clinical notes. Starting methadone is associated with an elevated risk of overdose as opioid levels accumulate. The risk of overdose is discussed with clients and their support people, and they are informed that the accumulating nature of methadone requires initial prescribed doses to be conservative and the doses will be increased slowly. This is particularly important when a patient is also taking other sedatives, including benzodiazepines or zopiclone. Usual standard of care would include the patient signing a consent form and being given written information about the risks.

In addition, as per NZ Practice Guidelines for Opioid Substitution Treatment (NZGOST),[1] service providers must provide the client with written information on:

- their rights (including in terms of the Code of Health and Disability Services Consumers' Rights 1996) and their obligations/responsibilities to the service
- the range of treatment options and psychosocial interventions available and the benefits, side effects, and limitations of opioid-substitution medicine – including the increased risk of overdose during induction
- the potential effect of opioid substitution medication on activities such as driving and operating machinery
- the interactive effects of opioid-substitution medication with alcohol and other substances (prescribed and illicit)
- the process for making complaints
- the availability of consumer advocacy and peer support services
- limits of confidentiality under the Health Information Privacy Code 1994 (ie, situations under which the specialist service may need to break confidentiality)
- OST medication pharmacology, side effects, and drug interactions.

These forms should be documented, and accessible, in clients' medical records. Keeping clear and accurate medical records is a requirement of the MCNZ [Medical Council of New Zealand].[2] Usual standard of care is for the specialist service to communicate with the referrer after an assessment has been completed and to ensure that they are kept fully informed.[3] This is particularly important when the patient is commencing OST for prescription opioid dependence and is on other prescribed sedatives.

I will make comments about the other aspects of care in my response to questions 3 to 7.

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?

I would consider the departure from the standard of care to be severe.

c. How would it be viewed by your peers?

Peers would consider the departure from the standard of care to be moderate to severe.

d. Recommendations for improvement that may help to prevent a similar occurrence in the future.

Ensuring that all staff working in Opioid Treatment Services are aware of the current New Zealand Practice Guidelines for Opioid Substitution Treatment.[1]

Development of a comprehensive assessment form that includes a risk assessment and is completed prior to commencement of OST.

Development of a checklist that includes consent forms, discussion about risk, and communication with family/whānau and any health professionals involved in the person's care.

Implementing a robust multidisciplinary team (MDT) process for complex clients, including another Medical Officer with experience in OST. I note that Te Whatu Ora have allocated additional Senior Medical Officer time to the service, which will include reviewing MDT decisions.

Raising awareness within services that when converting the dose of opioids to methadone there is great inter-patient variability and that the recommendations in NZGOST should be used when calculating a dose equivalent. In addition, methadone should not be increased any faster than every four days and by no more than 10mg at a time, regardless of prescribed doses of opioids.

A requirement for a face-to-face assessment prior to starting OST and at 30 minutes and four hours post dose on day one. In a person on multiple sedatives, initial dose increases should not be made without a face-to-face assessment.

Close clinical follow-up of all patients that are starting OST and taking multiple central nervous system (CNS) depressants in recognition of the increased risk of overdose, especially in the first two weeks.

In consultation with health services in the region, developing a pathway for more complex patients to commence OST in an inpatient setting.

Provision of naloxone to all clients starting on OST.

2. The adequacy of the plan to first substitute the use of oxycodone for methadone, and then address Mr [B's] use of fentanyl and benzodiazepines.

a. What is the standard of care/accepted practice?

There is not one definitive approach to commencing OST in a patient on multiple prescribed opioids, and in my opinion the plan to substitute methadone for the oxycodone first was a reasonable plan. There are particular challenges when converting fentanyl patches to methadone, and – because the conversion was occurring in the community and Mr [B] was also on benzodiazepines and zopiclone – conversion of the oxycodone to methadone in the first instance would be 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?

The plan to substitute oxycodone with methadone first would be accepted as an accepted standard of care.

c. How would it be viewed by your peers?

Peers would consider this plan as accepted practice.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

No recommendations.

3. The appropriateness of the guidelines used by Dr [C] regarding calculation of conversion for methadone substitution.

a. What is the standard of care/accepted practice?

Appendix 7 in the NZGOST[(1)] makes recommendations for converting prescribed opioids to methadone and it is accepted practice in New Zealand to refer to these guidelines.

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?

Dr [C] reports using the article from 2004 published in the medical journal *Addiction* for his initial calculation. This is not an appropriate guideline on which to base calculating a conversion to methadone, as acknowledged by Dr [C] in his follow-up letter to the Coroner. In his follow-up letter, Dr [C] made reference to the December 2008 [World Health Organization] WHO-Analgesic Ladder Step 3: Safe and Effective Use for Chronic Pain guideline. These guidelines are more appropriate when calculating an estimate of dose equivalence. The guideline initially used resulted in an estimated dose of methadone that was more than twice the dose (80mg instead of 27mg) had the accepted guidelines been used and thus was a severe departure from the standard of care.

c. How would it be viewed by your peers?

Peers would view this as a significant departure from standard care.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

Services should be directed to use the recommendations in the current NZGOST[1] when converting opioids to methadone.

4. The adequacy of Dr [C's] calculation of conversion for methadone substitution.

a. What is the standard of care/accepted practice?

As per question two, the NZGOST[1] make recommendations about dose equivalents for opioids. The guidelines also state:

> "Practitioners should consider these dose equivalents as crude approximations only, as reports of opioid equi-analgesic doses vary considerably, and many equi-analgesic tables underestimate methadone potency. The accepted practice in converting from one opioid to another is to calculate the conversion to morphine equivalence first and then to the required substance (eg, methadone). This is because equivalence studies compare medications to morphine as a reference. […] methadone analgesic equivalence to morphine (and other opioids) varies significantly with chronic dosing and total daily morphine dose. The relationship between methadone dose and morphine dose is not linear and is influenced by individual variables, such as incomplete cross-tolerance. An estimate of the oral methadone:oral morphine ratio in long-term dosing is 1:10; that is, in chronic dosing 10 mg oral methadone is approximately equivalent to 100 mg of oral morphine, or 30 mg of parenteral morphine."

The Faculty of Pain Medicine[4] recommends reducing the dose by up to 50% if a person is on high doses of opioids and notes that, "Conversion factors are an approximate guide only because comprehensive data are lacking and there is significant inter-individual variation."

The New South Wales Clinical Guidelines: Treatment of Opioid Dependence[5] state "Published equivalent opioid doses may not be reliable for guiding dose transfers onto methadone, as they usually relate to short term, not chronic opioid use, describe analgesic equivalence for single doses and not 24-hour dosing periods and have usually been determined with relatively low levels of opioid use (e.g. comparing 20 or 30 mg morphine)." These guidelines also point out that the clinician should "not assume that what is being prescribed is what is being taken – patients may be using more or less than is prescribed."

All the guidelines I reviewed recommended particular caution when a person is taking benzodiazepines or other CNS depressants.[1,5–8]

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?

In his letters to the Coroner, Dr [C] referenced two conversion rates. Dr [C] initially referred to a conversion of 1:2 oxycodone to morphine and 4:1 morphine to methadone with a

recommended dose of methadone of 80mg, but in the second letter I note Dr [C's] revised calculations recommended an equivalent methadone dose of 27mg (160mg oxycodone). Dr [C's] initial calculation was based on an old guideline and significantly overestimated the methadone dose that would be required to substitute for 160mg oxycodone. This would be considered a severe departure from standard of care.

c. How would it be viewed by your peers?

This would be considered as a severe departure from standard of care.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

All OST services should refer to Appendix 7 in the current NZGOST(1) when converting doses of opioids to methadone.

5. The adequacy of the consideration given to the concurrent use of other medications including lorazepam, midazolam spray, fentanyl patches, and zopiclone

a. What is the standard of care/accepted practice?

Accepted practice would be to be extremely cautious when starting methadone in a person who is also taking other opioids and/or sedatives. This may necessitate close observation in an inpatient unit, if available, or a very slow conversion with close monitoring in the community. In some services, usual standard of care would be that other opioid medication and benzodiazepines would be prescribed by the specialist service during the stabilisation period. This would reduce the risk of additional sedatives being prescribed by another clinician. If the client has an addiction to other controlled drugs (these include opioids and benzodiazepines; zopiclone was not a controlled drug in 2021), the specialist service must authorise the GP to continue to prescribe for dependence or prescribe these medications as per the requirements under Section 24 of the Misuse of Drugs Act. The NZ OST Guidelines(1) state:

> "although benzodiazepines have minimal effect on cardio-respiratory depression when used in isolation, mortality rates in cases of combined opioid and benzodiazepine use are markedly raised. Concurrent prescribing or use should be avoided wherever possible. If a client uses benzodiazepines at any level, or alcohol in excess, service providers may need to closely supervise OST, imposing greater dispensing restrictions, employing caution in dose determination and paying attention to treating the other substance use. Extreme caution is recommended when a person is taking benzodiazepines or other CNS depressants."

Furthermore, "methadone is associated with an increased risk of overdose, particularly in the first two weeks of treatment. The majority of deaths that occur during the induction stage involve the use of other substances; particularly other opioids. Any substance that has a synergistic or potentiating effect alongside opioids (including alcohol, benzodiazepines and antidepressants) has the capacity to cause overdose when combined with methadone."

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?

The decision to commence methadone in the community with a rapid titration and minimal oversight in a patient who is also taking another strong opioid, zopiclone, and benzodiazepines would be considered a severe departure from accepted practice. The GP continued to prescribe all other medication and, apart from the letter documenting the plan, had no information from the specialist service about being cautious about prescribing additional sedatives during the stabilisation period. In my opinion, this is a severe departure from accepted practice.

c. How would it be viewed by your peers?

Peers would view this as a severe departure from usual practice.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

MDT discussion involving another doctor experienced in OST prior to starting methadone in the community in complex clients taking multiple CNS depressants. If no second doctor is available to attend the MDT in person, consideration should be given to facilitating this through Telehealth.

If methadone is started in the community in a complex client, ensure that there is regular face-to-face review and the titration is done cautiously.

Consideration should be given to the specialist service also prescribing other CNS depressants during the OST stabilisation period.

6. The adequacy of the consideration given to patient factors, including Mr [B's] propensity to use above-prescribed doses of benzodiazepines.

a. Standard of care

Patients who have serious or unstable physical and/or mental health issues are at higher risk during the stabilisation period and, as per question 6, require a close level of supervision or consideration of starting methadone in an inpatient setting. A face-to-face review, including a risk assessment, immediately prior to starting methadone is usual standard of care. If there are concerns about a person's mental health, usual standard of care would include ensuring that the patient has the contact details for [a] crisis team or mental health follow-up is in place.

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?

Mr [B] has a history of becoming distressed and at times suicidal, and he had contacted both his GP and acute mental health services in the months preceding being started on methadone, and, in my opinion, Mr [B] would have required close clinical follow-up whilst being stabilised on methadone. There was no clinical review of Mr [B's] mental health needs or risk assessment prior to starting methadone, nor was there any face-to-face

review in the period of stabilisation prior to his death. For these reasons, in my opinion this is a severe departure from usual standard of care.

c. How would it be viewed by your peers?

Peers would agree that this is a severe departure from usual standard of care.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

Robust MDT discussion in a team that includes another doctor experienced in OST prior to commencement of methadone of clients with mental health problems. If no second doctor is available to attend the MDT in person, consideration should be given to facilitating this through Telehealth.

Completion of a face-to-face assessment, including a risk assessment prior to starting methadone in the community.

Ensuring all clients and their whānau are given contact details for a crisis service or, if needed, have support from a mental health service during the stabilisation period.

7. The adequacy of the care provided by Dr [C] following the commencement of methadone substitution.

a. What is the standard of care/accepted practice?

It is known that the pharmacokinetics of methadone vary between individuals and that it takes four to five days for tissue levels to stabilise, but accumulation continues for 10 days. During this time, there is a risk of drug accumulation, so increases should be cautious and gradual.

Section 3.1.1 of the NZGOST[(1)] makes clear recommendations about starting methadone;

> "Following a client's first dose, the prescriber or key worker should observe the client's response after 30 minutes, and again after 3–4 hours (ie, at peak plasma level concentration) to assess for toxicity or withdrawal. For this reason, providers should dispense the first dose in the morning. Dose increases within the first three to four days pose considerable risk due to the effect of methadone accumulation. It takes an average of four days to achieve a steady state plasma level. The implications of this are that signs and symptoms of intoxication may appear on the third or fourth day of treatment. Prescribers or key workers should observe clients' response three to four hours after the dose on the fourth day to assess for toxicity."

On page 14 of the NZGOST[(1)]:

> "Due to the risk of opioid overdose, particularly in people who have not previously been on methadone, prescribers or key workers should undertake frequent monitoring in the first two weeks (eg, at least daily for the first three days and then every two to four days until a stable dose is reached). After the first two weeks, the risk falls to very low levels. A standard written reminder of

> the risks should be provided to clients with their first increased dose; this could be provided by the pharmacist when they dispense the first dose increase."

The UK Guidelines[7] state that "Over a period of a few days or more, methadone can accumulate in the body such that small doses can build to an amount that causes an overdose. Overdose is more likely if the service user also uses other depressant drugs, medicines or alcohol. For this reason, it is vital that methadone induction is done slowly and cautiously."

The NSW Guidelines[5]:

> "All doses of methadone should be supervised. A clinician (doctor, nurse, pharmacist) should review the patient daily prior to dosing during the first week of treatment, which is the greatest risk period for methadone-related overdose. Commence with 20-30mg daily and increase every 3-5 days by 5-10mg after patient review if features of withdrawal. If higher or more rapid dose increases are needed an inpatient setting with closer monitoring is recommended."

All the above guidelines are clear that no takeaway doses of methadone should be given for the stabilisation period, which is usually a period of three months except in exceptional circumstances.

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?*

The initial starting dose of methadone 20mg [is] consistent with Section 3.11 of the NZ Guidelines.[1] The dose increase by 20mg on day three to 40mg and to 60mg on day eight was not within any guidelines[5–8] that I reviewed and hence a departure from accepted practice. There was also inadequate assessment prior to starting methadone and inadequate clinical follow-up after commencing methadone. The provision of takeaway doses of methadone after only three days is not usual practice. For these reasons, my opinion is that Dr [C's] care following commencement of methadone was a severe departure from accepted practice.

c. *How would it be viewed by your peers?*

My peers would consider Dr [C's] care a severe departure from accepted practice.

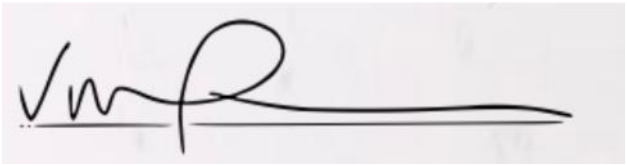
d. *Recommendations for improvement that may help to prevent a similar occurrence in future.*

The recommendations in the NZGOST[1] should be followed when starting methadone. All complex clients should be discussed in an MDT meeting that includes another doctor experienced in OST. This could be done using Telehealth if there is not another doctor working within the service.

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

I have no further comments.'

Signed:



Dr Vicki Frances Haeata Macfarlane
FRNZCGP, FAChAM

15 January 2024

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Addendum received 13 April 2026

'1. Thank you for sending me the responses to my report written in May 2024 from Dr [C] and Dr [D]. These letters are dated 26 September 2025 and 29 September 2025, respectively. I received these letters from you on 2 April 2026.

2. I appreciated the opportunity to get a better idea from Dr [C] of the context in which the care to Mr [B] was provided. I note that in 2022 there were still some restrictions on health care delivery throughout Aotearoa New Zealand following the COVID pandemic and that I did not comment on this in my original report. I also note that Dr [C] only worked two days a week in the Alcohol and Drug Service.

3. In my report I acknowledged the challenges of working in a small regional service and that they are often under resourced and many services that are available in larger centres are not accessible. Dr [D] rightly points out that these challenges are not able to be reflected clearly when writing a report of this nature.

4. Dr [C] responded to my comments about informed consent and stated that Mr [B] was known to the service and had actively sought treatment and that he was sure that both he and the case manager discussed consent, including the risks associated with commencing methadone. In my report, I have noted that accepted practice is for a consent form to be signed and a copy kept in the medical records. In addition, as mentioned in my report, any discussion of the risks should be clearly documented in the notes.

5. Dr [D] commented on the service being pressured to commence methadone and that Mr [B] had presented as "desperate to start as could not continue how he was going. Tearful and appeared somewhat sedated." In my opinion, this presentation would have indicated a need for a review of Mr [B] in person prior to starting methadone to assess his risk.

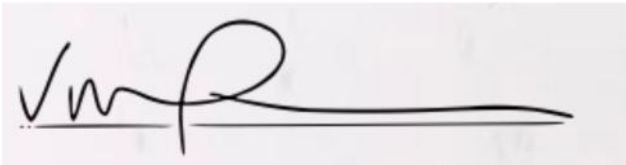
6. The appropriateness of the approach to the dose conversion was commented on by both Dr [C] and Dr [D]. Dr [D] commented that Dr [C] used a well-known and long-standing calculation of 1:4 (methadone: morphine) to arrive at the final estimate of 80mg and refers to the 2014 NZGOST as giving a 1:3 methadone: morphine conversion in the body of the guideline and that advice about a more cautious conversion is not clearly visible and that the guidelines are poorly written. He concludes that all guidelines are approximate and that there is individual patient variation. The review that he attached to his response is in accordance with this and in the discussion, it states, "a clinician motivated to use methadone should remember that opioid rotation should not be focused on the exact numerical dose of the method, but on the importance of individualized titration, diligent assessment and careful monitoring." In a complex patient on high doses of opioids and other sedatives, in my opinion regardless of guidelines, a high degree of caution must be exercised when converting a short-acting opioid to methadone, and this was reflected in my report when responding to questions 3 and 4.

7. Dr [D] comments on the rapid induction and monitoring during the induction period, and his opinion is that I was too critical regarding these aspects of care. He has suggested that Dr [C's] experienced clinical judgement should be considered. I agree with Dr [D] that

the initial starting dose was conservative, and this was appropriate due to the multiple sedatives that Mr [B] was taking, including an ongoing dose of OxyNorm®. Dr [D] also highlighted that the pharmacist reported that Mr [B] was "calm and relaxed" on the 15 March prior to his dose of methadone, which increased from 40mg to 60mg that day, and in my opinion, this would suggest that the dose did not need to be increased further. My opinions on the dose increases and lack of face-to-face assessments both before and after commencing methadone remain unchanged and are documented in my response to question 8 of the report.

8. I agree with Dr [C] and Dr [D] that this was a highly complex patient and that the care provided may have been impacted by both resource constraints and the COVID pandemic; however, my report was written after careful consideration of the information provided, review of numerous clinical guidelines, and consultation with several peers throughout Aotearoa New Zealand, and my opinion that a severe departure from the expected standard of care occurred has not changed.

Kind regards,



Dr VFH Macfarlane

FRNZCGP, FAChAM

MCNZ 15790'