



IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2015 1085

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)

Section 67 of the Coroners Act 2008

Findings of:	Paresa Antoniadis Spanos, Coroner
Deceased:	Daniel Isaac Semple
Date of birth:	29 December 1975
Date of death:	Between 5 and 6 March 2015
Cause of death:	Multiple drug toxicity (methadone, diazepam, oxazepam, carbamazepine, levetiracetam, mirtazapine) in a man with epilepsy
Place of death:	North Melbourne, Victoria 3051

INTRODUCTION

1. Mr Semple was a 39-year old single unemployed man who lived in North Melbourne. He is survived by his mother, two younger brothers and his two children.
2. According to his former long-term partner, Heba Kalek, Mr Semple had a lengthy history of polysubstance use including the regular intravenous use of methadone prescribed as opioid replacement therapy.¹ Though the pair struggled with housing insecurity for much of their relationship, there were periods of relative stability when they lived and worked selling *The Big Issue* together, and Mr Semple moderated his use of illicit drugs. However, Ms Kalek considered that their lives spiralled out of control in 2014, culminating in her hospitalisation late in the year, and the breakdown of their relationship by the time she was discharged from hospital in November 2014.²
3. Mr Semple's medical history included acquired brain injury, epilepsy, hepatitis B and C, depression, opiate and benzodiazepine dependence, and amphetamine and cannabis abuse.³ His medical management was coordinated by general practitioners (GPs) at Melbourne Central Medical and Dental (MCM) who prescribed 500mg levetiracetam⁴ twice daily and 400mg carbamazepine⁵ three times daily to manage epilepsy, 45mg mirtazapine⁶ twice daily for depression, 30mg oxazepam⁷ and 5mg diazepam⁸ three times daily to treat benzodiazepine dependence and 240mg methadone⁹ daily for opioid dependence, with three "takeaway"¹⁰ doses permitted

¹ Coronial Brief, Statements of Heba Kalek and IMJ.

² Coronial Brief, Statement of Heba Kalek. Ms Kalek stated that she did not return to the home she had shared with Mr Semple upon her discharge from hospital and that since then she has lived with family.

³ Coronial Brief, Statement of Dr Naren Morris and Mr Semple's Melbourne Central Medical and Dental medical records.

⁴ Levetiracetam is an antiepileptic used for the control of partial onset seizures.

⁵ Carbamazepine is an anticonvulsant.

⁶ Mirtazepine is an antidepressant.

⁷ Oxazepam is a sedative/hypnotic drug of the benzodiazepine class.

⁸ Diazepam is a sedative/hypnotic drug of the benzodiazepine class.

⁹ Methadone is a synthetic narcotic analgesic used for the treatment of opioid dependence (methadone maintenance program) or for the treatment of severe pain. Individuals prescribed methadone as pharmacotherapy for drug addiction must have a permit issued from the Drugs and Poisons Regulation Group, Department of Health; there was a current permit in respect of Mr Semple's treatment with methadone.

each week.¹¹ Mr Semple's prescribed medications were ordinarily dispensed at Melbourne Central Priceline Pharmacy (**Pharmacy**).

CIRCUMSTANCES IMMEDIATELY PROXIMATE TO DEATH

4. On 4 March 2015, Mr Semple attended the Pharmacy to collect his daily methadone dose. Pharmacist Carole Vu observed him to be his 'normal self'.¹² Mr Semple consumed his methadone dose in front of the pharmacist, who then dispensed takeaway doses for the next three days.¹³
5. Mr Semple spent the afternoon at home with a friend, IMJ. The two men 'had a few bongos' and retired early for the evening, Mr Semple in his own room and IMJ sleeping on one of the couches in the lounge room.¹⁴
6. IMJ rose at about 7am on 5 March 2015 but Mr Semple was not awake. When he was uncharacteristically still not up by 8.30am, IMJ went to Mr Semple's room to check on him and found him having an epileptic seizure. IMJ remained with Mr Semple until the seizure subsided and then brought him his medication.¹⁵
7. On the afternoon of 5 March 2015, Jason Holzigan arrived at Mr Semple's home. Mr Holzigan thought Mr Semple 'was stoned' and noticed a bong and some cannabis in a bowl on the coffee table.¹⁶ The men sat together in the lounge room, talking and watching television. Mr Semple complained of a headache.¹⁷

¹⁰ Although the opioid dependence treatment with methadone in Victoria is presumptively a regime of supervised methadone consumption, takeaway dosing may occur if the prescriber considered the patient suitable for this method of delivery. Takeaway dosing occurs when the patient is provided a quantity of methadone that is taken away from the dispensing pharmacy for consumption.

¹¹ Mr Semple's Melbourne Central Medical and Dental medical records and the Statement of Dr Shakeeb Bani Yaseen dated 10 February 2020.

¹² Coronial Brief, Statement of Carole Vu. Ms Vu's described Mr Semple's typical presentation as occurring 'first thing in the morning', that he was 'never drug ... or substance-affected' [or] aggressive'.

¹³ Ibid.

¹⁴ Coronial Brief, Statement of IMJ.

¹⁵ Ibid.

¹⁶ Coronial Brief, Statement of Jason Holzigan.

¹⁷ Ibid.

8. At about 10.30pm, Mr Holzgal saw Mr Semple take medication from an orange-coloured tablet bottle and then use a syringe to inject methadone into his left hand.¹⁸ A short time later, Mr Semple's speech was slurred and he seemed drowsy; at 11pm he said goodnight to Mr Holzgal.¹⁹ Both men fell asleep on couches in the lounge room.
9. At about 8.20am on 6 March 2015, Mr Holzgal awoke to find Mr Semple lying on the floor next to the couch,²⁰ cold and unresponsive.²¹ He contacted emergency services and, on arrival, Ambulance Victoria paramedics confirmed that Mr Semple had died.
10. Victoria Police members also attended and commenced the coronial investigation.

PURPOSE OF A CORONIAL INVESTIGATION

11. The purpose of a coronial investigation of a *reportable death*²² is to ascertain, if possible, the identity of the deceased person, the cause of death and the circumstances in which death occurred.²³ For coronial purposes, *death* includes suspected death.²⁴
12. The *cause* of death refers to the *medical* cause of death, incorporating where possible the *mode* or *mechanism* of death. For coronial purposes, the *circumstances* in which death occurred refers to the context or background and surrounding circumstances but is confined to those circumstances sufficiently proximate and causally relevant to the

¹⁸ Ibid.

¹⁹ Coronial Brief, Statement of Jason Holzgal.

²⁰ Form 83 prepared by First Constable Thomas Asciak on 6 March 2015.

²¹ Coronial Brief, Statement of Jason Holzgal.

²² The term is exhaustively defined in section 4 of the *Coroners Act 2008* (**the Act**). Apart from a jurisdictional nexus with the State of Victoria a reportable death includes deaths that appear to have been unexpected, unnatural or violent or to have resulted, directly or indirectly, from an accident or injury; and, deaths that occur during or following a medical procedure where the death is or may be causally related to the medical procedure and a registered medical practitioner would not, immediately before the procedure, have reasonably expected the death (section 4(2)(a) and (b) of the Act).

²³ Section 67(1).

²⁴ See the definition of "death" in section 3 of the Act.

death, and not all those circumstances which might form part of a narrative culminating in death.²⁵

13. The broader purpose of any coronial investigations is to contribute to the reduction of the number of preventable deaths through the findings of the investigation and the making of recommendations by coroners, generally referred to as the *prevention* role.²⁶
14. Coroners are empowered to report to the Attorney-General in relation to a death; to comment on any matter connected with the death they have investigated, including matters of public health or safety and the administration of justice; and to make recommendations to any Minister or public statutory authority on any matter connected with the death, including public health or safety or the administration of justice.²⁷ These are effectively the vehicles by which the coroner's prevention role can be advanced.²⁸
15. It is important to stress that coroners are not empowered to determine the civil or criminal liability arising from the investigation of a reportable death and are specifically prohibited from including in a finding or comment any statement that a person is, or may be, guilty of an offence.²⁹

CORONIAL INVESTIGATION

16. One of the Victoria Police members who attended the scene of Mr Semple's death was Detective Senior Constable Ryan Montgomery of Melbourne North Crime Investigation Unit; he investigated the death, and later compiled the brief of evidence on which this finding is largely based. During an examination of the scene, DSC

²⁵ This is the effect of the authorities – see for example *Harmsworth v The State Coroner* [1989] VR 989; *Clancy v West* (Unreported 17/08/1994, Supreme Court of Victoria, Harper J.)

²⁶ The 'prevention' role is now explicitly articulated in the Preamble and purposes of the Act, compared with the *Coroners Act 1985* where this role was generally accepted as 'implicit'.

²⁷ See sections 72(1), 67(3) and 72(2) regarding reports, comments and recommendations respectively.

²⁸ See also sections 73(1) and 72(5) which requires publication of coronial findings, comments and recommendations and responses respectively; section 72(3) and (4) which oblige the recipient of a coronial recommendation to respond within three months, specifying a statement of action which has or will be taken in relation to the recommendation.

²⁹ Section 69(1). However, a coroner may include a statement relating to a notification to the Director of Public Prosecutions if they believe an indictable offence may have been committed in connection with the death. See sections 69 (2) and 49(1).

Montgomery observed and photographed several syringes and a bong, and a large quantity of prescription medication including methadone syrup, benzodiazepines, antiepileptics and an antidepressant prescribed to Mr Semple, along with an analgesic prescribed to Ms Kalek.³⁰ No prescriptions were located at the scene.³¹

IDENTIFICATION

17. Mr Semple was visually identified by his friend, Jason Holzgal, who signed a Statement of Identification dated 6 March 2014 before police. Identity was not in issue and required no further investigation.

18. I formally find that the identity of the deceased is Daniel Isaac Semple, born on 29 December 1975, late of a North Melbourne address.

MEDICAL CAUSE OF DEATH

19. Dr Mohamed Madadin, forensic pathology trainee at the Victorian Institute of Forensic Medicine (**VIFM**), reviewed the circumstances of death as reported by police to the coroner and post-mortem computed tomography scanning of the whole body, and conducted an autopsy under the supervision of Professor Stephen Cordner.

20. Among Dr Madadin's anatomical findings were the absence of any significant injuries or pathology contributing to death other than the existence of old cerebral contusions (brain injuries) considered to be the likely cause of Mr Semple's epilepsy.

21. Routine toxicological analysis of post-mortem samples detected methadone (~0.4mg/L),³² diazepam (~0.1mg/L), oxazepam (~0.2mg/L) and their metabolites and carbamazepine (~10mg/L), levetiracetam (~7mg/L), mirtazapine (~0.1mg/L) and delta-9-tetrahydrocannabinol³³ (~6ng/mL) in blood. Temazepam,

³⁰ Coronial Brief, Statement of DSC Ryan Montgomery.

³¹ Email from DSC Montgomery dated 9 May 2016.

³² Individuals prescribed methadone as pharmacotherapy for drug addiction must have a permit issued from the Drugs and Poisons Regulation Group, Department of Health and there was a current permit in respect of Mr Semple's treatment with methadone. The recommended doses depend on the degree of tolerance and the duration of use. Doses of methadone for treatment of opioid dependence start at 10-20mg and may increase by 5-10mg/day until a maintenance dose is achieved. The terminal elimination half-life of methadone varies from 15 to 55 hours and individuals commenced on methadone are more likely to develop a toxic response than those on long term maintenance doses due to lack of opiate tolerance. Blood concentrations of methadone in patients receiving daily maintenance doses of methadone overlap considerably with the blood concentrations in deceased apparently dying from methadone toxicity.

³³ Delta-9-tetrahydrocannabinol is the active form of cannabis.

methylamphetamine (colloquially known as ice), amphetamine and tramadol were each detected only in urine.

22. The forensic pathology trainee commented that methadone has significant central nervous system depressing effects including deep sedation and respiratory depression and that these are compounded by concurrent use of benzodiazepines like diazepam and oxazepam.
23. Dr Madadin advised that the cause of Mr Semple's death was consistent with multiple drug toxicity in a man with epilepsy. He observed that epilepsy was included in the cause of death as it is 'possible that this itself caused or contributed to death'.³⁴
24. Based on Dr Madadin's advice, I find that the cause of Mr Semple's death was multiple drug toxicity involving methadone, diazepam, oxazepam, carbamazepine, levetiracetam and mirtazapine in a man with epilepsy.

CIRCUMSTANCES IN WHICH DEATH OCCURRED

25. I obtained Mr Semple's MCM consultation record, Medicare records and a Pharmaceutical Benefit Scheme (PBS) Patient Summary for the 12-months prior to his death. These documents show that Mr Semple had been a patient of MCM since about May 2009³⁵ and that for at least the year before he died, he exclusively attended MCM for primary healthcare.³⁶
26. Mr Semple was commenced on methadone maintenance therapy by Dr Jagdish Pathak in about June 2009.³⁷ Throughout the period 2009-March 2015 he was consistently prescribed high doses of methadone in addition to benzodiazepines and other medications.³⁸

³⁴ Medical Investigation Report of Dr Mohammed Madadin dated 12 June 2015.

³⁵ MCM consultation records.

³⁶ Medicare Report.

³⁷ Permit granted by Drugs and Poisons Regulation (Department of Human Services) on 4 June 2009 for Dr Pathak to prescribe methadone and buprenorphine to Mr Semple, MCM medical records.

³⁸ MCM consultation records.

Mr Semple's Clinical Management by MCM

27. The earliest electronic progress note³⁹ dated 9 March 2011 indicated that Mr Semple was prescribed 260mg methadone daily for opioid dependence, 15mg diazepam and 30mg oxazepam daily for benzodiazepine dependence and 90mg mirtazapine for depression. The methadone script specified daily pick up, meaning Mr Semple was not allowed any unsupervised doses to take away from the pharmacy for consumption.⁴⁰
28. In mid-2012, Dr Joe Chow became Mr Semple's primary clinician and prescriber. He continued diazepam, oxazepam and mirtazapine at the same dosage established by Dr Pathak, prescribed methadone between 230mg and 250mg daily (pickup only) and commenced prescription of levetiracetam and carbamazepine.⁴¹ Dr Chow ordered urine drug screening (UDS) approximately monthly and noted the absence of opiates.⁴²
29. On 14 June 2013, Dr Chow made a note about reducing Mr Semple's methadone dose, but the daily dose he prescribed was never less than 230mg.⁴³
30. In August 2013, Dr Naren Morris became Mr Semple's primary GP and continued prescribing methadone, diazepam, oxazepam, mirtazapine, levetiracetam and carbamazepine at the same levels maintained by Dr Chow. His methadone scripts stipulated daily pick up.⁴⁴
31. On 14 November 2013, Dr Morris made a note about reducing the amount of diazepam and oxazepam prescribed to Mr Semple.⁴⁵ Subsequent scripts for oxazepam

³⁹ Clinical notes made by Dr Pathak were hand-written and difficult to decipher.

⁴⁰ See generally MCM consultation record maintained by Dr Pathak.

⁴¹ See generally MCM consultation record maintained by Dr Chow between 2 March 2012 and 26 July 2013.

⁴² Ibid.

⁴³ MCM consultation record dated 14 June 2013.

⁴⁴ See generally MCM consultation record maintained by Dr Morris between 22 August 2013 and 17 October 2013.

⁴⁵ MCM consultation record dated 14 November 2013.

in November and December specified that Mr Semple was to take a half tablet each day (rather than a full tablet), and then oxazepam was ceased in late February 2014.⁴⁶

32. On 20 March 2014, Mr Semple asked that an oxazepam prescription be resumed but that he had ‘enough for the moment’.⁴⁷ Oxazepam scripts were provided by Dr Morris on 15 April 2014, absent any noted clinical rationale, with the direction that a half tablet should be picked up by Mr Semple from the Pharmacy daily.⁴⁸
33. Dr Morris ordered UDS on 20 February and 15 April 2014.⁴⁹ Unsurprisingly methadone and benzodiazepines were detected in both screens, as was cannabis and, in the April 2014 screen, methylamphetamine was also detected.⁵⁰ When the results of the later test were put to him by Dr Morris on 7 May 2014, Mr Semple denied using stimulants.⁵¹ On that occasion, Mr Semple reiterated an earlier report that he had not consumed alcohol for about seven years.⁵²
34. On 23 May 2014, Dr Shakeeb Bani Yaseen became Mr Semple’s primary clinician and prescriber. Dr Yaseen prescribed 230mg methadone daily (pick-up), 30mg oxazepam (half tablet daily pick-up), and 15mg diazepam (daily pick-up), along with 100mg levetiracetam, 1200mg carbamazepine and 90mg mirtazapine daily.⁵³
35. Dr Yaseen noted ‘for UDS next visit’ on both 4 June and 2 July 2014, though no UDS order was ever made by him and it does not appear that Mr Semple underwent urinalysis after 15 April 2014.⁵⁴

⁴⁶ MCM consultation record dated between 14 November 2013 and 20 February 2014.

⁴⁷ MCM consultation record dated 20 March 2014.

⁴⁸ MCM consultation record dated 15 April 2014 and Mr Semple’s PBS Patient Summary (though the MCM record does not reflect it, the PBS Patient Summary shows an earlier oxazepam prescription provided by Dr Morris on 1 April 2014).

⁴⁹ MCM consultation records demonstrate that urinalysis occurred regularly (every one-to-three months) during 2012 and until 2013; in addition to the methadone and benzodiazepines expected, given they were prescribed, cannabinoids were routinely present, and opiates were detected in August 2013. Urinalysis occurred at Dr Morris’ request in February and April in 2014, with methadone, benzodiazepines and cannabinoids detected on both occasions and methylamphetamines detected in April 2014.

⁵⁰ Pathology results contained in Mr Semple’s MCM consultation record.

⁵¹ MCM consultation record dated 7 May 2014.

⁵² *Ibid.*

⁵³ MCM consultation record dated 23 May 2014.

⁵⁴ See generally records of MCM consultations between 4 June 2014 and 23 February 2015.

36. During his consultation with Dr Yaseen on 28 July 2014, Mr Semple reported intravenous heroin use two days earlier.⁵⁵
37. The next MCM consultation record documents Mr Semple's attendance on Dr Morris on 11 August 2014 when the GP replaced the daily methadone dosing script with one allowing three takeaway doses per week. Dr Morris noted, 'wants TA [takeaway] doses for methadone – so he can see Heba in hosp[ital] as long as possible,'⁵⁶ likely referring to Ms Kalek's hospitalisation between August and November 2014.
38. On 18 August 2014, Mr Semple re-presented to Dr Yaseen reporting heroin use 'last week'.⁵⁷ The GP noted that Mr Semple was 'happy on 240mg methadone' and had not missed any doses recently.⁵⁸ Dr Yaseen recorded providing advice about 'safety of TA doses' and provided a further script for 240mg methadone daily, which permitted three takeaway doses per week.⁵⁹
39. Mr Semple next presented to Dr Yaseen on 8 September 2014 reporting heroin use 'last Friday'.⁶⁰ The GP made no change to Mr Semple's methadone prescription or the availability of takeaway doses.
40. On 22 December 2014, Dr Yaseen reviewed Mr Semple's medications. The notes of this consultation indicate Mr Semple's report of intravenous ice use three days earlier, benzodiazepine use only as prescribed, no heroin use for 10 weeks, and the absence of any withdrawal symptoms on 240mg methadone daily. Dr Yaseen noted advising Mr Semple to abstain from using ice, 'discuss start reduction when more stable' in relation to methadone and 'discuss start reduction' of oxazepam and diazepam. No changes were made to Mr Semple's prescribed medications.⁶¹

⁵⁵ MCM consultation records dated 28 July 2014.

⁵⁶ MCM consultation record dated 11 August 2014.

⁵⁷ MCM consultation record dated 18 August 2014.

⁵⁸ Ibid.

⁵⁹ Ibid.

⁶⁰ MCM consultation record dated 8 September 2014.

⁶¹ MCM consultation record dated 22 December 2014.

41. On 12 January 2015, Mr Semple reported intravenous use of heroin use three days earlier. Dr Yaseen made no changes to Mr Semple's methadone prescription nor the availability of takeaway doses.⁶²

Coroners Prevention Unit

42. Given the circumstances in which Mr Semple died, I sought advice from the Coroners Prevention Unit (CPU)⁶³ about dosing and prescribing practices at MCM proximate to the death, and avenues for further investigation. The CPU reviewed the coronial brief, Dr Madadin's Medical Investigation Report, Mr Semple's MCM consultation record, and his Medicare and PBS records. CPU advised:

- a. The main concern relates to Mr Semple's access to takeaway methadone doses to treat his opioid dependence.
- b. The clinical guideline for the delivery of opioid replacement therapy at the time of Mr Semple's death was the *Policy for maintenance pharmacotherapy for opioid dependence* published by the Drug and Poisons Regulation in January 2013 (the 2013 Policy).
- c. The 2013 Policy states that 'pharmacotherapy in Victoria is based on the principle of supervised dosing' but that takeaway doses can be provided to patients assessed as suitable.⁶⁴ Three levels of takeaway dosing are available: no takeaway doses are dispensed to patients assessed as requiring 'high intensity supervision'; one-to-two takeaway doses are allowed for patients who have demonstrated stability in treatment and so require 'medium intensity supervision'; and, up to five takeaway doses per week (though no more than three days' supply dispensed at once) are permitted to 'low intensity supervision' patients who have shown continuing stability in treatment.⁶⁵

⁶² MCM consultation record dated 12 January 2015.

⁶³ The Coroners Prevention Unit was established in 2008 to support the prevention role of coroners. The CPU is staffed by independent, highly skilled and experienced investigators, medical clinicians, and mental health and allied health professionals. The CPU provides advice to coroners during their investigations, assists formulation of prevention-focused comments and recommendations and monitors their effectiveness.

⁶⁴ Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, January 2013, p. 21.

⁶⁵ Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, January 2013, p. 22.

- d. The treating medical practitioner is responsible for determining whether the patient is suitable for takeaway dosing. In doing so, the clinician will consider how access to takeaway dosing may benefit the patient⁶⁶ and the risks that may manifest⁶⁷ if s/he is permitted to take methadone away from the pharmacy for consumption. The 2013 Policy offers extensive guidance about how prescribers should determine whether a patient is suitable for unsupervised dosing. Among the items included on a checklist of criteria to consider are the regularity of the patient's attendance at medical appointments, consistency of methadone dosing, provision of urine drug screens on request, concurrent use of other substances (particularly opiates, benzodiazepines and alcohol), recency of intravenous drug use, presentation in an intoxicated state, any concerns about misuse of takeaway methadone and stability of accommodation.⁶⁸
- e. Injecting methadone is a contraindication to eligibility for takeaway dosing.⁶⁹ The statements of Ms Kalek, Mr Hozigal and IMJ in the coronial brief suggest that Mr Semple was misusing/injecting takeaway doses of methadone and had been for some time.
- f. Although review of the MCM consultation record revealed no clear evidence that Dr Yaseen was aware of any contraindications to takeaway methadone dosing, the record suggests that the GP simply asked Mr Semple about his drug use and adherence to the methadone program and did not make any independent enquiries to verify Mr Semple was reporting truthfully.

⁶⁶ The 2013 Policy includes among the benefits of takeaway doses (a) an incentive for the patient to maintain engagement in treatment and so achieve sustained social and health benefits; (b) relieve the need for the patient to attend the dosing point everyday and so minimise disruption to work and family commitments; (c) enable the patient to travel away from the dosing point for recreation or work.

⁶⁷ Methadone is a particularly toxic drug and so the 2013 Policy notes that takeaway dosing creates opportunities for misuse including (a) dose hoarding and consumption outside the recommended dosing schedule; (b) injection of liquid methadone; (c) sharing and sale of takeaway doses; (d) theft of methadone from the patient's home.

⁶⁸ Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, January 2013, p. 25-26.

⁶⁹ Ibid.

- g. There is a discrepancy in the available material about how many unsupervised methadone doses Mr Semple was permitted after Dr Morris instituted three takeaways per week so he could more easily visit Ms Kalek in hospital and this pattern of prescribing was reproduced by Dr Yaseen. Pharmacist Ms Vu stated that Mr Semple's treating doctor permitted up to five takeaway doses per week.
 - h. A secondary concern is the long-term prescription of 30mg oxazepam and 15mg diazepam daily to Mr Semple to treat his benzodiazepine dependence.
 - i. The most broadly supported clinical approach for treating benzodiazepine dependence – one recommended by the Royal Australian College of General Practitioners⁷⁰ – is to shift the patient away from the use of short-acting benzodiazepines to a longer-acting form of the drug, then gradually taper use to zero. The tapering process may require months, or even years, depending on factors such as the length of use, daily amount used and individual experience of withdrawal.
 - j. Other than Dr Morris' oxazepam reduction and cessation, there is no evidence of any efforts to taper the benzodiazepines prescribed to Mr Semple.
43. CPU observed that Dr Yaseen was the primary GP responsible for treating Mr Semple in the 12 months prior to his death and was therefore most likely the practitioner who prescribed all six drugs that contributed to his death. Viewed in historical context, Dr Yaseen's prescribing to Mr Semple was largely a continuation of a prescribing practice established by Dr Pathak and embedded by Drs Chow and Morris. However, this did not diminish Dr Yaseen's clinical responsibility for his prescriptions, particularly as he conducted a full medication review on 22 December 2014 and maintained access to unsupervised methadone doses after Ms Kalek was discharged from hospital.
44. CPU recommended that further information be sought from Dr Yaseen particularly about his clinical decision-making on methadone and benzodiazepine prescribing to Mr Semple.

⁷⁰ Royal Australian College of General Practitioners, *Prescribing drugs of dependence in general practice, Part B: Benzodiazepines*, East Melbourne: Royal Australian College of General Practitioners, 2015.

Statement of Dr Yaseen

45. Dr Yaseen provided a detailed account of his management of Mr Semple in a statement dated 10 February 2020. He reported earning his medical degree in Jordan in 2012 and, having completed Australian Medical Council examinations in April 2013, commenced at MCM as ‘an observer’⁷¹ in November/December 2013. Dr Yaseen fulfilled further Australian Health Practitioner Regulation Agency requirements before commencing medical practice at MCM in April 2014 under the supervision of Dr Morris.
46. Dr Yaseen conceded that he had not appreciated at the time he prescribed methadone to Mr Semple he was required to hold his own permit to prescribe the drug to Mr Semple and could not rely on that issued to Dr Morris, even for the short term.
47. Dr Yaseen observed that Mr Semple had commenced methadone for heroin addiction in 2009. He prescribed Mr Semple 230mg-240mg doses of methadone; Mr Semple was stable on these doses and reported no withdrawal symptoms. Dr Yaseen had ‘frequent’⁷² discussions with him about dosing, but Mr Semple was resistant to a dose reduction due to the risk of relapse.
48. Takeaway methadone doses were continued after Ms Kalek’s discharge from hospital because Mr Semple (reportedly) continued to care for her due to her lack of family support and complex psycho-social needs.⁷³
49. Dr Yaseen considered that Mr Semple remained eligible for takeaway methadone doses for several reasons, including: Mr Semple’s regular attendance at medical appointments; perfect attendance at the pharmacy for methadone dosing; that he was never observed to be drug-affected including when seen outside of medical consultations; and, physical examination of Mr Semple’s forearms failed to reveal fresh injection marks.
50. Dr Yaseen permitted Mr Semple access to three takeaway methadone doses per week. He noted that the pharmacist could have unilaterally lowered the number of takeaways or ceased them if Mr Semple had presented as sedated, drug-affected or in

⁷¹ Statement of Dr Shakeeb Bani Yaseen dated 10 February 2020.

⁷² Statement of Dr Shakeeb Bani Yaseen dated 10 February 2020.

⁷³ Ibid. I note that Ms Kalek’s statement contradicts the information Mr Semple provided his doctors.

a manner otherwise indicative of dosing noncompliance. The GP was never notified of any such issues by the Pharmacy.

51. Mr Semple was always ‘pleasant, polite and cooperative’, well-groomed and ‘appeared genuine’ in discussions about overcoming heroin addiction.⁷⁴ Dr Yaseen did not consider that Mr Semple was untruthful about his drug use or suspect that he was inappropriately using methadone when unsupervised.
52. Dr Yaseen stated that he was not aware that Mr Semple was injecting takeaway methadone. If he had been aware, he would have immediately ceased Mr Semple’s takeaway doses, and provided counselling against injecting methadone and using illicit drugs.
53. Dr Yaseen observed that it was MCM policy that patients prescribed methadone undergo urinalysis every one-to-two visits and conceded that UDS had been ‘overlooked’⁷⁵ during his management of Mr Semple. He attributed this to miscommunication between himself and reception staff.
54. In relation to Mr Semple’s benzodiazepine prescriptions, Dr Yaseen noted that these were longstanding medications prescribed for benzodiazepine dependence, anxiety and alcohol dependence. Although Dr Morris had weaned Mr Semple off oxazepam for about a month (in early 2014), the medication was recommenced by him when Mr Semple experienced insomnia and worsening anxiety.⁷⁶ Dr Yaseen considered it appropriate ‘*in the short term*’⁷⁷ to continue prescribing benzodiazepines at the same rate, and with the safeguard of daily dispensing, employed by Dr Morris.
55. Dr Yaseen advised that it was ‘*not [his] intention to continue prolonged prescription*’⁷⁸ of benzodiazepines to Mr Semple. There had been ‘multiple’⁷⁹ discussions about these prescriptions. Mr Semple was stable on these medications,

⁷⁴ Ibid.

⁷⁵ Ibid.

⁷⁶ Ibid.

⁷⁷ Ibid. Emphasis added.

⁷⁸ Ibid. Emphasis added.

⁷⁹ Ibid.

had complex psychosocial issues and was resistant to engaging with treatment recommendations.

56. Nonetheless, during the December 2014 medication review, Dr Yaseen had a ‘detailed discussion’ with Mr Semple about his medications, particularly the benzodiazepines, and there was a plan to taper diazepam first and then taper oxazepam.⁸⁰ Dr Yaseen conceded that this plan, which had been hand-written and signed by him and Mr Semple, did not appear to have been scanned into Mr Semple’s MCM consultation record.
57. Dr Yaseen acknowledged the danger in commencing a patient on multiple central nervous system depressing medication and observed that as this combination of drugs had been prescribed to Mr Semple for a number of years, they did not affect him in this way; he had developed a tolerance to them. Dr Yaseen also noted the absence of any report by Mr Semple of symptoms of central nervous system depression, or observation of such effects during their consultations, and that his medications were ‘carefully controlled’⁸¹ by the Pharmacy.
58. Dr Yaseen conceded that he was a junior practitioner at the time he treated Mr Semple and that his prescribing practices and notetaking was ‘not always sufficient’.⁸² He admitted that inexperience and naivety may have led to him be deceived by Mr Semple and acknowledged that it was difficult to balance maintaining patient stability and rapport with patient safety given that if he ‘refused prescriptions, there were other practitioners who would prescribe the medications requested’.⁸³
59. Dr Yaseen advised that since 2014, he has left general medical practice for emergency medicine. He no longer provides pharmacotherapy and when he is required to prescribe Schedule 8 drugs,⁸⁴ he ordinarily consults an addiction medicine specialist. Upon reviewing Mr Semple’s case, Dr Yaseen has arranged to undertake further instruction on the prescription of Schedule 8 drugs.

⁸⁰ Statement of Dr Shakeeb Bani Yaseen dated 10 February 2020.

⁸¹ Ibid.

⁸² Ibid.

⁸³ Ibid.

⁸⁴ Schedule 8 poisons (controlled drugs) are those with strict legislative controls including opioid analgesics, two benzodiazepines and ketamine.

FINDINGS/CONCLUSIONS AS TO CIRCUMSTANCES

60. The standard of proof for coronial findings of fact is the civil standard of proof on the balance of probabilities, with the *Briginshaw* gloss or explications.⁸⁵
61. Adverse findings or comments against individuals or institutions are not to be made with the benefit of hindsight but only on the basis of what was known or should reasonably have been known or done at the time, and only where the evidence supports a finding that they departed materially from the standards of their profession and in so doing caused or contributed to the death under investigation.
62. Applying the standard of proof to the available evidence my conclusions are that:
- (a) Mr Semple was prescribed a combination of medications with central nervous system depressing effects – including methadone and benzodiazepines at relatively high doses – for a several years by MCM clinicians.
 - (b) The lack of any sustained effort by any of those clinicians to reduce Mr Semple’s daily methadone and benzodiazepine doses was suboptimal in all the circumstances. Dr Morris’ attempt to taper oxazepam in early 2014 was short-lived and despite never intending to maintain the benzodiazepine (and methadone) dosages in place when he commenced Mr Semple’s management in May 2014, no plan to taper them was ever actioned by Dr Yaseen.
 - (c) Dr Yaseen’s non-compliance with MCM’s drug screen policy for patients prescribed methadone was suboptimal and prevented independent corroboration of Mr Semple’s self-reports about the use of illicit drugs.
 - (d) Mr Semple was permitted up to three takeaway doses of methadone each week for the seven months prior to his death. Introduced by Dr Morris to facilitate Mr Semple’s carer responsibilities, takeaway doses were continued by Dr Yaseen, it seems, largely because Mr Semple never

⁸⁵ *Briginshaw v Briginshaw* (1938) 60 C.L.R. 336 esp at 362-363. “The seriousness of an allegation made, the inherent unlikelihood of an occurrence of a given description, or the gravity of the consequences flowing from a particular finding, are considerations which must affect the answer to the question whether the issues had been proved to the reasonable satisfaction of the tribunal. In such matters “reasonable satisfaction” should not be produced by inexact proofs, indefinite testimony, or indirect inferences...”

missed a methadone dose nor presented to MCM or the Pharmacy with signs of intoxication or sedation. Self-reports of heroin use on 18 August and 8 September 2014, and 12 January 2015 produced no change to his management or the availability of takeaway doses of methadone.

(e) Although Mr Semple's friends knew him to misuse takeaway methadone by injecting it, his prescribing clinicians do not appear to have shared this knowledge. There is evidence before me that Mr Semple injected an unknown quantity of methadone on 5 March 2015.

(f) Mr Semple died at 86/12 Sutton Street in North Melbourne overnight between 5 and 6 March 2015 in circumstances consistent with an inadvertent drug overdose.

COMMENTS

Pursuant to section 67(3) of the Act, I make the following comments related to the death:

1. Mr Semple's 2015 death highlighted a fundamental flaw in unsupervised dosing for methadone maintenance therapy, namely, a methadone prescriber's reliance on the patient's self-report rather than objective evidence to assess patient stability and eligibility for takeaway dosing.
2. Notwithstanding efforts made to guide clinical decision-making about access to takeaway methadone and minimise its potential harms through the 2013 Policy's *pro forma* checklist (and the earlier 2006 iteration), the coronial jurisdiction has borne witness to an increase in deaths where methadone was involved as clinical practice departed from supervised dosing.⁸⁶ Reliance on uncheckable self-reports was among the factors implicated in these deaths.⁸⁷
3. Since Mr Semple's death, the Drugs and Poisons Regulation's *Policy for Maintenance Pharmacotherapy for Opioid Dependence* has been revised and refined.⁸⁸ The most

⁸⁶ CPU research conducted 2010-2013 published as an Appendix to Coroner Audrey Jamieson's Finding into the death of Shannon Lees 2012 0485.

⁸⁷ Coroner Audrey Jamieson's Finding into the death of Shannon Lees 2012 0485.

⁸⁸ Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2016.

recent policy, published in 2016 (**2016 Policy**),⁸⁹ among other things, encourages greater use of human and technological sources of information to corroborate patient history and streamlines guidance on clinical decision-making about takeaway methadone dosing.

4. Commencing 1 April 2020, it is mandatory for prescribers to check SafeScript when writing a prescription for methadone.⁹⁰ SafeScript is a clinical support tool that can be accessed by prescribers and pharmacists to review a patient's prescription record of Schedule 8 and other high-risk medicines. The 2016 Policy recommends that SafeScript is checked each time a prescription is written or when a patient is reviewed to ensure that treatment remains safe and appropriate.⁹¹
5. Like its predecessors, the 2016 Policy is premised on individual and community harm minimisation and canvasses the serious and sometimes fatal consequences of incautious use, and misuse, of methadone and similar medications.⁹²
6. The 2016 Policy emphasises the need for careful clinical assessment and thorough risk/benefit analysis before a prescriber authorises any takeaway doses of methadone.⁹³ A four-step, sequential, decision-making process is recommended and reflected in the revised *Checklist for assessing appropriateness of take-away doses* (the **Checklist**).⁹⁴
7. Steps one and two of the Checklist requires prescribers to consider whether specified 'absolute' and 'relative' counterindications were evident during the preceding three months of pharmacotherapy. The existence of any counterindication indicates

⁸⁹ Though published in 2016, the policy refers to mandatory requirement to consult SafeScript that came into effect on 1 April 2020.

⁹⁰ Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2016, p. 28. The SafeScript requirement also applies to prescribers of buprenorphine or buprenorphine/ naloxone.

⁹¹ Ibid.

⁹² Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2016, p. 15-20.

⁹³ Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2016, p. 30.

⁹⁴ Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2016, Appendix 4.

‘increased risk and safety concern for the patient and others,’⁹⁵ with the presence of any absolute contraindication sufficient to stop supply of takeaway methadone.

Prescribers who observe relative contraindications (including evidence or report of illicit drug use or misuse of drugs or alcohol) are advised to discuss the suitability of takeaway dosing with the dosing pharmacist.⁹⁶

8. The third step, explicitly requiring prescribers to consider whether there is a ‘reasonable need’ for takeaway doses of methadone is a novel requirement in this version of the Checklist.⁹⁷ In the absence of a need for takeaway methadone, the prescriber is advised to discuss suitability of takeaway dosing with the dosing pharmacist.
9. The final step is for the prescriber to assess level of dosing supervision required by the patient (and so the number of takeaway methadone doses potentially allowed) based on the length of ‘continuous stability in treatment’.⁹⁸ Pharmacology patients with less than three months’ stability in treatment are unsuitable for takeaway methadone. That said, the 2016 Policy makes it clear that assessment of stability and suitability via the Checklist, not time in treatment, is the key consideration.⁹⁹ Moreover, assessment across all domains highlighted in the Checklist is recommended to occur regularly during a patient’s treatment and be documented.¹⁰⁰
10. Indeed, the 2016 Policy provides prescribers with specific strategies to assess a pharmacology patient’s stability in treatment. These strategies include review of the patient’s clinical records; taking the patient’s history; clinical examination; urine toxicology and liaison with other health professionals involved in the patient’s care (at a minimum this will include the pharmacy).¹⁰¹ Though the methods for assessing

⁹⁵ Ibid.

⁹⁶ Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2016, Appendix 4.

⁹⁷ Ibid.

⁹⁸ Ibid.

⁹⁹ Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2016, p. 34.

¹⁰⁰ Ibid.

¹⁰¹ Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2016, p. 37.

patient stability using the Checklist do not eliminate the prescriber's reliance on the patient's self-reports, compliance with the 2016 Policy's guidance is likely to ensure objective indicators are available to inform clinical decision-making.

11. The 2016 Policy, particularly refinements to the Checklist, appear likely to improve clinical decision-making about access to takeaway doses of methadone and so minimise the risk of harm.
12. The most obvious counterindication to takeaway methadone dosing revealed in the investigation of Mr Semple's death – injection of methadone – is one that is likely to remain very challenging for clinicians to detect in practice. That said, it is arguable that had the 2016 Policy been in place and followed prior to Mr Semple's death, his clinicians may have determined that takeaway dosing was inappropriate – on grounds other than absolute contraindication.

PUBLICATION OF FINDING

Pursuant to section 73(1A) of the Act, I order that this Finding be published on the Internet in accordance with the Rules.

DISTRIBUTION OF FINDING

I direct that a copy of this finding is provided to the following for their information:

Mr Semple's family

Dr Yaseen, c/- Cindy Tucker of Kennedys (Australasia) Pty Ltd

Department of Health and Human Services, Drugs and Poisons Regulation

DSC Ryan Montgomery (#33469) c/o OIC Melbourne North CIU

Signature:



Paresa Antoniadis Spanos

Coroner

Date: 12 June 2020

