IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2013 005788

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)
Section 67 of the Coroners Act 2008

Findings of:	**ROSEMARY CARLIN, CORONER**
Deceased:	**MELISSA JANE MAY**
Date of birth:	16 November 1969
Date of death:	17 December 2013
Cause of death:	1(a) COMBINED DRUG TOXICITY
Place of death:	Echuca, Victoria

HER HONOUR:

Introduction

1. This case highlights the importance of clear communication and good record keeping by health professionals when dealing with a prescription drug dependent person. In particular it illustrates how easily misunderstandings can occur between doctors and pharmacists in the absence of clear written instructions and how such misunderstandings can have disastrous consequences.

2. Melissa Jane May was born on 16 November 1969. She was 44 years old when she died of combined drug toxicity. At that time Mrs May lived with her husband, John May and two daughters, Emily and Mykala, in Stokes Street, Echuca.

The coronial investigation

3. Mrs May's death was reported to the Coroner as it fell within the definition of a reportable death in the *Coroners Act 2008* (**the Act**).

4. The role of a coroner is to independently investigate reportable deaths to find, if possible, identity, medical cause of death and with some exceptions, surrounding circumstances. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death. Coroners make findings on the balance of probabilities, not proof beyond reasonable doubt.[1]

5. The law is clear that coroners establish facts; they do not cast blame, or determine criminal or civil liability.

6. Under the Act, coroners also have the important functions of helping to prevent deaths and promoting public health and safety and the administration of justice through the making of

[1] In the coronial jurisdiction facts must be established on the balance of probabilities subject to the principles enunciated in *Briginshaw* v *Briginshaw* (1938) 60 CLR 336. The effect of this and similar authorities is that coroners should not make adverse findings against, or comments about, individuals unless the evidence provides a comfortable level of satisfaction as to those matters taking into account the consequences of such findings or comments.

comments or recommendations in appropriate cases about any matter connected to the death under investigation.

7. Victoria Police initially investigated this matter on my behalf and compiled a brief that included statements from John May, the investigating police officer and reports from a forensic pathologist and toxicologist. Subsequently, I obtained additional material comprising statements, records and correspondence from Mrs May's treating clinicians, dispensing pharmacist and the Victorian Department of Health and Human Services (**DHHS**). I also held a Directions Hearing and received submissions from legal representatives for the treating clinicians and dispensing pharmacist.

8. After considering all the material obtained during the coronial investigation I determined that I had sufficient information to complete my task as coroner and that further investigation was not required.

9. Whilst I have reviewed all the material, I will only refer to that which is directly relevant to my findings or necessary for narrative clarity.

Identity of the deceased

10. Mrs May was formally identified by her husband on 17 December 2013 at their home. Identity was not in issue and required no further investigation.

Background

11. In about 1994 Mrs May sustained serious injuries to both legs in a motor vehicle accident. The fracture to her right leg healed satisfactorily but her left foot was shattered and required multiple orthopaedic procedures and ankle fusion. Thereafter, Mrs May suffered chronic pain in her left foot and was prescribed opioid medication. According to her husband 'Melissa has pretty much been on pain killers since this accident happened'.

12. Mr and Mrs May married in 2001, originally living in Buninyong, but then moving to Echuca in 2005. Because of her pain Mrs May was not able to work, and Mr May started to receive a carer's pension so he could look after her.

13. Mrs May first attended the Rich River Health Group[2] in Echuca on 15 December 2004 requesting oxycodone and diazepam for her 'old left foot fracture'. Over the years she saw various doctors at that clinic for pain management, but from the end of 2007 she mainly saw Dr John Quayle. Between 2006 and 2013 she was prescribed various medications including oxycodone and diazepam. Dr Quayle noted that most of her pain problems related to her ankylosed left foot, although she did have other co-morbidities, including carpal tunnel syndrome.

14. Mrs May admitted to Dr Quayle in 2008 that she was addicted to oxycodone. She often attended the Rich River Health Group asking to receive her oxycodone early. This was usually refused. In 2011 doctors at the Rich River Health Group also became concerned that Mrs May was abusing her diazepam (in the form of Valium). She was counselled and later promised that she had reduced her intake.

15. Mrs May was a complex and difficult patient as she had chronic pain but was also addicted to her medication. Dr Quayle and his colleagues in the Rich River Health Group recognised Mrs May's opioid dependence and tried to address it in various ways, including counselling, referral to pain and other specialists, referral to rehabilitation services and controlling her supply. Dr Quayle also sought advice on how to manage Mrs May's drug dependency from the Transport Accident Commission and DHHS, but received no reply.

16. On 5 April 2013 Mrs May attended Dr Corry De Neef, a pain physician, after referral by Dr Quayle. In a letter to Dr Quayle Dr De Neef noted that Mrs May was on various medications, including 5mg diazepam in the morning[3] which she claimed assisted with her foot movement and 120 mg of oxycodone per day. He recommended the introduction of pregabalin[4] (75mg per day to be increased slowly) and possibly nortriptyline with the aim of reducing Mrs May's oxycodone. He did not comment on the diazepam.

17. In accordance with Dr De Neef's advice, Dr Quayle commenced Mrs May on pregabalin (brand name Lyrica) in August 2013. Thereafter, Mrs May attended either Dr Quayle or Dr Rifat for her prescriptions of pregabalin, diazepam and oxycodone and other matters.

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[2] General medical practice clinic.
[3] She was actually prescribed 5mg diazepam four times a day.
[4] Pregabalin is indicated for neuropathic pain. As it is a Schedule 4 drug doctors do not need a permit to prescribe it.

Circumstances Proximate to Death

18. On Wednesday 4 December 2013 Mrs May attended the Rich River Health Group and saw Dr Rifat for a repeat of her prescriptions. This was day 13 after she had received a 14 day prescription for oxycodone. Although it was 'early'[5], Dr Rifat provided her with a prescription for Lyrica (pregabalin) and OxyContin (oxycodone). The clinical records for that attendance read as follows:

> here for her scripts. AGAIN WANTS THE 40 MG OF OXY TO BE DISPENSED 2 DAYS EARLY – DENIED
> TOLERATING THE LYRICA TO 300 BD[6]
> denies any changes
> **Reason for contact:**
> Chronic pain
> **Actions:**
> LYRICA CAPSULE 150mg changed to LYRICA CAPSULE 300 mg
> Prescriptions printed:
> LYRICA CAPSULE 300 MG 1 TAB b.d. m.d.u.
> OXYCONTIN CR TABLET 40mg 1 tab b.d. STRICTLY TO BE PICKED UP FROM RICH RIVER PHARMACY ONLY
> OXYCONTIN CR TABLET 20mg 1 tab b.d. STRICTLY TO BE PICKED UP FROM RICH RIVER PHARMACY ONLY

19. After seeing Dr Rifat, Mrs May attended the Rich River Pharmacy with her prescriptions. The pharmacy dispensed 56 capsules of Lyrica and 28 tablets of OxyContin 40mg. Its records indicate the dispensing pharmacist was 'MS'.

20. On Thursday 12 December 2013 Mrs May attended Dr Quayle complaining of a bacterial infection and pain. As it was too early to provide her oxycodone prescriptions he told her to return on the Monday.

21. On Monday 16 December 2013 Mrs May returned. Dr Quayle reported that as it was only two days before she was due for her repeat prescription and as he would be unavailable on the due day, he provided Mrs May with printed[7] prescriptions for OxyContin 40mg (28 tablets, 1 tab t.i.d) and diazepam 5mg (50 tablets, 1 tab q.i.d. m.d.u.) and hand wrote on the OxyContin

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[5] There was some discussion at the Directions Hearing of the meaning of 'early' in relation to prescribing and dispensing. In this finding it means before the date the last medication prescribed or dispensed should have lasted if taken as prescribed.

[6] According to accepted abbreviations b.d. means twice daily, m.d.u. means to be used as directed, t.i.d. means three times a day and q.i.d. means four times a day.

[7] The OxyContin prescriptions obtained during my investigation were all computer generated and printed, rather than handwritten.

prescription that it was not to be dispensed until 18 December 2013. In accordance with his usual practice the OxyContin prescription contained the typed endorsement 'STRICTLY TO BE PICKED UP FROM RICH RIVER PHARMACY ONLY'. On the same day Dr Quayle prepared another referral to Dr De Neef seeking his further review and advice.

22. Following her attendance on Dr Quayle Mrs May presented her prescriptions to the Rich River Pharmacy. She also presented a repeat of Dr Rifat's prescription for Lyrica from 4 December 2013. The pharmacy dispensed the 28 OxyContin tablets, 50 diazepam tablets and 56 Lyrica capsules. Its records showed two different dispensing pharmacists, 'KF' and 'KS'.

23. Later that night Mrs May and her family were at home. According to her husband, 'Melissa was in good spirits and was looking forward to wrapping the [Christmas] presents and celebrating Christmas'. At about midnight Mrs May was still in the kitchen and Mr May went to their bedroom to watch television. At about 1.30 a.m. Mr May came out of the bedroom and found his wife lying on the hallway floor, half into the kitchen. Emily heard her father yelling and called 000. Mr May tried to resuscitate his wife to no avail. Police and ambulance officers arrived in short time, but were also unable to revive Mrs May.

24. Mr May believed his wife had been injecting OxyContin that night, as she used to do this in the bathroom so that her children could not see. He noted that the box of OxyContin prescribed by Dr Quayle on 16 December 2013 (comprising 28 tablets) was empty. Police observed and seized that empty box as well as empty blister packs of OxyContin (14 tablet) and diazepam (10 tablet), various other medications including Lyrica, a glass of opaque liquid in the bathroom and injecting paraphernalia.

Medical Cause of Death

25. Professor Noel Woodford, Director of the Victorian Institute of Forensic Medicine[8] and forensic pathologist conducted an autopsy on Mrs May on 23 December 2013. He also reviewed the results of toxicological testing of blood and urine specimens taken from Mrs May. Toxicological analysis detected **oxycodone** in blood (0.7mg/L) and urine, **diazepam** in blood (0.5mg/L) and urine (0.1mg/L), diazepam metabolites in blood and urine, **pregabalin** in

[8] At the time of the autopsy Professor Woodford was a Senior Forensic Pathologist.

blood (11mg/L), **Delta-9-tetrahydrocannabinol** in blood (4ng/mL) and its metabolite in urine. **Amoxicillin** and **paracetamol** were also detected in blood and urine respectively.

26. Whilst interpreting post-mortem blood toxicology is difficult, the levels of oxycodone and pregabalin appear considerably in excess of the expected therapeutic range[9]. The level of diazepam was consistent with therapeutic use despite the finding of the empty blister pack.

27. The reporting toxicologist commented that pregabalin can increase the depressant effects of opioid analgesics and benzodiazepines. Further, concurrent use of high amounts of oxycodone, combined with diazepam and pregabalin may lead to increased synergistic central nervous system sedation and respiratory depression.

28. The toxicologist also indicated that the ratio of diazepam to its metabolites suggested recent administration of diazepam and postulated that if not all the drug had been absorbed from the stomach at the time of death, the blood level may not reflect what was actually consumed.

29. Professor Woodford observed evidence of old and more recent intravascular access on Mrs May's upper arms consistent with injecting drugs. There was no natural disease or injuries likely to have contributed to her death. He determined her cause of death to be combined drug toxicity. I accept that opinion.

Access to the drugs

30. My investigation focused on how Mrs May was able to gain access to the drugs that killed her given Dr Rifat and Dr Quayle were both acutely aware of her drug seeking behaviour and believed they had implemented strategies to prevent it.

<u>Dr Quayle</u>

31. Dr Quayle stated that in May 2008 he arranged with the Rich River Pharmacy for Mrs May to be placed on a 'daily pick up register' so that she could not take medication in excess of the prescribed doses. He did this by letter, a copy of which he no longer had. Through his

[9] Depending on the dose of oxycodone, peak plasma therapeutic concentrations following oral administration range from 0.02-0.1mg/L. Blood concentrations of diazepam following oral dosing of 30mg daily generally range from 0.7-1.5mg/L. A single 300mg dose of pregabalin gave an average peak plasma level of 7.5mg/L.

solicitors he indicated he could not produce the letter as his clinic 'has no record of any correspondence with the Pharmacy prior to November 2008 due to an administrative error on their medical records system'[10].

32. Dr Quayle also stated that he believed that once a patient was placed on the Rich River Pharmacy daily pick up register or regime (he used the words interchangeably) he or she would remain on it unless and until removal was requested by the treating doctor. Anything in excess of the daily dose would need to be expressly approved by the doctor in writing or by telephone. In addition, to prevent Mrs May from presenting her prescription to another pharmacy commencing in June 2013 Dr Quayle added the words 'STRICTLY TO BE PICKED UP FROM RICH RIVER PHARMACY ONLY' to every OxyContin prescription for Mrs May.

33. According to Dr Quayle when he saw Mrs May on 16 December 2013, he only read the first lines of the clinical notes relating to her 4 December 2013 attendance and believed that Dr Rifat had refused to prescribe OxyContin to Mrs May on that day. However, he indicated that had he reviewed the whole record he still would have 'proceeded to print the prescription on 16 December 2013 (for collection on 18 December 2013...) as this was in fact when Melissa was next due for collection according to her two week dispensing cycle'.

34. In short Dr Quayle claimed that he believed his oxycodone prescription would not be dispensed prior to 18 December 2013 and then only on a daily basis.

35. Dr Quayle outlined other measures instituted by his clinic to address drug seeking behaviour. In particular, the clinic had software showing an alert when a patient presented early for a prescription and, since Mrs May's death, there was a policy of reviewing urine screens to assess chronic pain patient compliance with medication regimes.

Dr Rifat

36. Dr Rifat's OxyContin prescriptions also contained the words 'STRICTLY TO BE PICKED UP FROM RICH RIVER PHARMACY ONLY'. He also stated that he believed his clinic had an arrangement with the pharmacy that it would not 'fill any narcotic scripts early without

[10] Letter from TressCox Lawyers dated 13 July 2015.

notifying the practice and getting written permission'[11]. His contemporaneous clinical record supports this claim as it indicates that although he provided an early prescription for OxyContin, he denied Mrs May's request for it to be dispensed early.

37. Dr Rifat further stated that '*Dr Quayle also made arrangements to have her narcotic tablets be dispensed by Rich River Pharmacy on a daily basis for a while*'[12]. Although later he claimed differently, this statement suggests that Dr Rifat was not necessarily of the view there was a daily pick up arrangement at the time of Mrs May's death[13].

38. The pregabalin prescription Dr Rifat provided on 4 December 2013 had 5 repeats. Based on the dosage, one prescription should have lasted at least until 1 January 2014 (28 days later). Dr Rifat noted that it was not a Schedule 8 drug but there 'was no apparent need for the script to be dispensed early'[14] as occurred on 16 December 2013.

Rich River Pharmacy

39. Kara Spring, pharmacist and proprietor of Rich River Pharmacy stated that she had worked at the pharmacy since 2008. She indicated that there were periods when Mrs May was on a daily staged supply of her OxyContin. After looking at the dispensing records she believed the last time that occurred was on 2 March 2012.

40. Ms Spring was not aware of a daily pick up 'register' at the pharmacy, rather such arrangement was made by the doctor writing that instruction on the prescription. She produced three prescriptions for OxyContin in early 2011 where Dr Quayle had indeed added the words *'1 b.d. dispensed daily'* to the prescription. As the prescriptions for oxycodone on 4 and 16 December 2013 had no such endorsement she did not regard Mrs May as being on a daily pick up arrangement.

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[11] Statement of Dr Rifat dated 5 June 2015.
[12] Statement of Dr Rifat dated 5 June 2015 - my underlining.
[13] Submissions prior to and at the Directions Hearing, together with a supplementary statement dated 31 May 2016 claimed Dr Rifat, like Dr Quayle, believed Mrs May was receiving daily dispensing of her narcotic medication at the time of her death.
[14] Statement of Dr Rifat dated 5 June 2015.

41. Ms Spring stated that even if a patient was not on a staged supply of opioid medication, it was still the Pharmacy's practice to monitor dispensing to ensure opioids were not supplied early. In relation to Mrs May she said:

When Ms May was not a daily staged supply of her OxyContin, we would supply her according to her prescription, but also with close reference to her dosage and frequency, to ensure that she was not receiving her medication early. The pharmacy sought to closely monitor her supply and was in regular communications with her prescriber. If Ms May attended her doctor and requested early supply, her prescriber would provide us either with a letter confirming supply, and/or would provide a note on the prescription. If Ms May attended the pharmacy directly, without first attending her doctor, we would not make supply until we had spoken with her prescriber and confirmed that supply could be made.[15]

42. Ms Spring said that the pharmacy *'always made a contemporaneous record of any communications with a prescriber'*[16] and that such communications were *'mostly'* documented in the dispensing history.[17] She produced the dispensing history (December 2011 to 16 December 2013) and a separate record of communication and notes in relation to Mrs May with a last entry of 8 November 2013.

43. Upon my request Ms Spring forwarded to the Court a copy of Dr Quayle's 16 December 2013 OxyContin prescription which clearly contained indecipherable crossed out handwriting. Although informed of Dr Quayle's claim to have handwritten his instruction, Ms Spring stated 'there was no instruction on the prescription not to dispense it until 18 December 2013'. Further, whilst she could not say whether she or Kobie Free was the dispensing pharmacist (as neither could remember), she was *'confident that Dr Quayle was contacted to confirm the validity of the prescription before it was dispensed. Unfortunately, we cannot now produce the contemporaneous note of the communication because the records were destroyed following the death of the patient'*[18].

44. After a request for clarification, Ms Spring said that she did not know who altered the 16 December 2013 prescription which was presented that way to the pharmacist and the notes

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[15] Letter from Kara Spring dated 15 December 2014.
[16] Letter from Kara Spring dated 28 May 2015.
[17] Letter from Kara Spring dated 15 December 2014.
[18] Letter from Kara Spring dated 28 May 2015.

that were destroyed were '*notes made of the telephone communications with Ms May's prescribing doctors, Dr Quayle and Dr Rifat. These were destroyed after we learned of her death because it did not occur to us that there would be a need for these records. We acknowledge that this should not have occurred, and regret this*'[19].

The prescription for OxyContin dated 16 December 2013

45. I forwarded a copy of the prescription provided by Rich River Pharmacy to Dr Quayle who identified the crossed out handwriting as being his notation not to dispense prior to 18 December 2013. Further, he maintained that he was not contacted by the pharmacy in relation to this prescription. It was his practice that all communication with a dispensing pharmacist would be in writing and there was none.

46. I obtained the original prescription from Rich River Pharmacy. It was impossible to discern the crossed out writing with the naked eye so I submitted it for forensic examination. I received advice that because the writing underneath was totally obliterated by the same or similar ink and the latter ink was applied with considerable pressure, it was impossible to decipher it.

Directions Hearing

47. On 24 February 2016 I notified interested parties of the findings I considered available to me on the basis of all material received to date. I received submissions from all parties disputing some of the proposed findings and accepting or conceding others. As a result of these submissions I determined the matter would likely need an inquest and held a Directions Hearing in Southbank on 26 May 2016. I excused Dr Quayle, Dr Rifat and Rich River Pharmacy from attending in person on the basis they would each be represented at the hearing. Mr May was notified but did not attend.

48. At the Directions Hearing Counsel were united in submitting that an inquest was not necessary[20]. They submitted that the coronial investigation had been a learning experience for their clients causing them to reflect upon the risk posed by their past prescribing or dispensing

[19] Letter from Kara Spring and purportedly approved by Kobie Free, dated 19 June 2015.
[20] Ms B Altson of TressCox Lawyers appeared on behalf of Dr Quayle, Ms E Gardner of Counsel appeared on behalf of Rich River Pharmacy and Dr S Keeling of Counsel appeared on behalf of Dr Rifat

practices. All parties agreed that communication between the doctors and pharmacists had been lacking in relation to Mrs May.

49. Dr Quayle and Rich River Pharmacy did not agree on whether he had been contacted in relation to the 16 December 2013 prescription for OxyContin, however they did agree there was little to be gained in attempting to resolve that issue given that they had each learned from the coronial investigation and committed to improving their practices and communication. Further they doubted an inquest would resolve that issue. Ms Gardner for Rich River Pharmacy (and the individual pharmacists) submitted that the real issue was the fact that Ms May had been provided with continual access to large quantities of prescription medication and could have overdosed at any time, rather than how she obtained the medication on the last occasion.

50. Despite Ms Spring's clear wording (see paragraphs [43] and [44] above), Ms Gardner sought to explain that the records destroyed by her clients after the death of Mrs May were historical records relating to the daily pick up regime rather than any record of communication with the prescribers around the time of her death. Ms Gardner's instructions were that the relevant pharmacist omitted to make a record of her communication with the prescriber on 16 December 2013, rather than making a record which was later destroyed.

51. Submissions prior to and at the Directions Hearing highlighted the difference in opinion between doctors and pharmacists as to their respective responsibilities for ensuring prescription medications were not dispensed prior to the due date, with Rich River Pharmacy taking exception to the notion that they dispensed medications 'early' if there was no relevant limitation on the repeat prescription itself.

52. Subsequent to the Directions Hearing, I received an additional statement from Dr Rifat and Statement of Position from Rich River Pharmacy. Significantly Rich River Pharmacy acknowledged that pharmacists have an independent duty to ensure the safe dispensing of repeat prescriptions and this should have affected the decision to dispense the repeat prescription of Lyrica on 16 December 2013.

Prescribing obligations

53. Doctors who prescribe drugs of addiction have responsibilities to ensure they are not abused. Permits are required to prescribe Schedule 8 drugs, which oxycodone is. Permits are not required to prescribe Schedule 4 drugs such as diazepam, however it is still a drug of addiction.

54. At the time of Mrs May's death Dr Quayle had a valid permit to prescribe oxycodone to Mrs May. This permit was able to be used by other doctors at his clinic. The permit imposed specific obligations on Dr Quayle to take all reasonable steps to ensure that:

    1) *The medication is collected at the same pharmacy on a daily/regular pick up basis with the pharmacy's name endorsed on the script.*

    2) *There is no early supply of medication without your approval.*

    3) *There is no replacement script given for lost, stolen or otherwise misplaced scripts or medications.*

Dispensing obligations

55. It is not just doctors who have obligations to ensure drugs of addiction are not abused. Pharmacists also bear that responsibility. The obligations upon Pharmacists are enshrined in legislation[21] and are set out in various publications available on the internet. The DHHS website contains a number of such publications from which the following relevant propositions can be extracted:

    a. Pharmacists should not dispense a prescription without satisfying themselves that it is safe, appropriate and lawful to supply the medication.[22]

    b. A pharmacist is not authorized to supply multiple repeats of a Schedule 4 (such as pregabalin) or Schedule 8 (such as oxycodone) prescriptions merely because the patient

[21] Such as the *Drugs Poisons and Controlled Substances Act 1981*, the *Drugs Poisons and Controlled Substances Regulations 2006* and the *Pharmacy Regulation Act 2010*.
[22] DHHS website: *Intervening to ensure Safe Appropriate and Lawful supply.*

requests them. It is implicit that each repeat supply should occur on a separate occasion and not more frequently than a specified interval (if any).[23]

c. Pharmacists should be vigilant to identify prescription shoppers, excessive prescribing, and forged or fraudulent prescriptions and should intervene by contacting the relevant prescriber as appropriate.[24]

d. Pharmacists should make contemporaneous notes of all intervention communications with prescribers or authorities in the pharmacy dispensing records.[25]

FINDINGS

56. Melissa May died on 16 December 2013 from mixed drug toxicity including oxycodone, diazepam and pregabalin. It is likely those drugs were dispensed to Mrs May by Rich River Pharmacy on that same day and were prescribed by Dr Quayle (oxycodone and diazepam) and Dr Rifat (pregabalin).

57. On 16 December 2013 Mrs May voluntarily ingested oxycodone, pregabalin and possibly diazepam in excess of the amounts prescribed to her. In combination those three drugs can induce profound central nervous system and respiratory depression and I am satisfied that is what occurred in this case.

58. I find that her death was accidental.

59. Given Mrs May's known drug dependency, vigilance was required by the health professionals involved in her care to ensure Mrs May did not have access to dangerous quantities of prescription medication.

60. At a minimum Mrs May's oxycodone should have been dispensed on a daily basis. Instead, in the lead up to her death she was provided her full quota of oxycodone tablets whenever she presented her prescriptions to Rich River Pharmacy.

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[23] DHHS website: *Supplying multiple packs or multiple repeats.*
[24] DHHS website: *Interventions by Pharmacists.*
[25] DHHS website: *Supplying multiple packs or multiple repeats* and *Interventions by Pharmacists.*

61. As it was also a drug of addiction, ideally Mrs May's diazepam should also have been dispensed on a daily basis. If Mrs May had attended daily to collect her oxycodone it would have been a simple arrangement for her to collect her diazepam at the same time.

62. Although it is not an opioid, given its potential to interact with opioids and benzodiazepines great care was also required in relation to the prescribing and dispensing of pregabalin to Mrs May.

63. Mrs May's death might have been prevented if her oxycodone (at least) had been dispensed on a daily basis. This would have prevented her from having access to a dangerous quantity at any one time.

64. If a doctor intends a drug to be dispensed daily it is incumbent on him or her to take reasonable steps to ensure that it happens. Dr Quayle stated that he believed Mrs May was on a daily oxycodone dispensing regime at the date of her death based on a letter he sent to Rich River Pharmacy in May 2008. It was not reasonable for him to rely on a letter sent five years prior given he had not verified the existence of the regime in the intervening period. Dr Quayle conceded as much.

65. Dr Rifat relied on the Rich River Pharmacy not to dispense his 4 December 2013 OxyContin prescription early. Providing a prescription to a drug dependent patient intending that it not be dispensed prior to a specified date is a dangerous practice. If a doctor does this it is incumbent on him or her to take reasonable steps to ensure that it is not dispensed early. Simply relying on the pharmacy not to dispense early is inadequate precaution.

66. I accept Dr Quayle's assertion that the crossed out writing on the OxyContin prescription dated 16 December 2013 was his notation that it not be dispensed prior to 18 December 2013. His contemporaneous clinical notes support this finding.

67. It is likely that Mrs May crossed out this notation before presenting it to Rich River Pharmacy.

68. Presented with an altered prescription of this nature, especially by a known drug dependent person, it was incumbent on the dispensing pharmacist to enquire with the prescribing doctor.

69. Ms Spring contended that Rich River Pharmacy carefully monitored the supply of oxycodone to Mrs May to ensure she did not receive her supply early, however, perusal of the dispensing chronology indicates this did not always occur. For example the OxyContin dispensed to Mrs May on 4 and 9 December 2013 should have lasted until 18 and 23 December 2013 respectively. Yet Mrs May was dispensed more OxyContin on 16 December 2013.

70. Further, there was no reason for Mrs May to be dispensed her pregabalin on 16 December 2013 as she should not have exhausted her previous supply.

71. Poor communication and co-ordination of care between doctors at the Rich River Health Group and pharmacists at the Rich River Pharmacy enabled Mrs May to have access to large quantities of prescription drugs culminating in her fatal overdose on 16 December 2013.

COMMENTS

Pursuant to section 67(3) of the *Coroners Act 2008*, I make the following comment(s) connected with the death:

1. There is no doubt Mrs May was a complex and difficult patient and that she would have presented a challenge to both doctors and pharmacists. Further, her care was made more difficult by the fact she lived in a regional area without access to the services available in metropolitan areas.

2. This case illustrates that caring for prescription drug dependent patients requires co-operation between doctors and pharmacists as well as vigilance on the part of each of them. Clear communication is essential. Independent scrutiny is essential. Neither profession should assume the other has sufficient safeguards in place to prevent a drug dependent patient from accessing prescribed pharmaceutical drugs in ways that might create an increased risk of misuse and overdose.

3. As it was clear that Mrs May deliberately ingested drugs in excess of the amounts prescribed I did not investigate whether it was appropriate to prescribe those drugs in the quantities

prescribed, or at all.[26]. The fact I make no comment about the prescribing in this case should not be taken as an endorsement of same.

4. The healthcare providers in this case (doctors and pharmacists) were recounting their dealings with each other and Mrs May dating back some years. Given the passage of time it is understandable that some reconstruction from documents was necessary, rather than actual recall. It is also understandable that there may be faulty recall in the absence of documentation.

5. I repeat what many coroners have previously said about the importance of thorough documentation by healthcare professionals. It is essential for clear communication and may be vital to the welfare of the patient. If that is not reason enough, the possibility they may have to explain their actions years later should be.

6. There were two dispensing pharmacists on duty at Rich River Pharmacy on 16 December 2013. The dispensing records show Kara Spring's initals against the diazepam and Lyrica and Kobie Fee's initals against the OxyContin. However, according to Ms Spring this is not necessarily accurate because dispense technicians used the initials of either pharmacist on duty. This practice was unacceptable and is another example of poor record keeping. I am assured that the practice no longer exists.

7. Ms Spring's original claim that Rich River Pharmacy destroyed the notes of communications with Mrs May's doctors after she died was extraordinary and appeared unsupported by the evidence in that the Pharmacy was able to produce a complete dispensing history for Mrs May and other notes of communications and relevant matters relating to Mrs May with a last entry dated 8 November 2013. In any event the claim was later abandoned.

8. This case also illustrates the dangers of doctors writing prospective prescriptions for drug dependent patients. If they do it at all, they must ensure their precautions against early dispensing are adequate. As this case demonstrates, hand writing can be obliterated and is not

[26] Diazepam is a benzodiazepine which is highly addictive and according to published guidelines long term use is rarely justified. Further, it is known to be used by opioid users to enhance the effects of opioids. See *Therapeutic Guidelines* published on the DHHS website and *Prescribing drugs of dependence in general practice, Part B – Benzodiazepines. Melbourne: The Royal Australian College of General Practitioners, 2015.*

a failsafe precaution. Further, a handwritten notation may not be a permissible alteration to a computer generated prescription.[27]

9. Guidelines as to coordination of care between doctors and pharmacists already exist within each profession. In particular:

   The Pharmacy Board of Australia Guidelines for Dispensing of Medicines states:

   In dispensing a prescription, a pharmacist has to exercise an independent judgement to ensure the medicine is safe and appropriate for the patient, as well as that it conforms to the prescriber's intentions. Where clarification is required, the patient or their agent should be consulted and if necessary, the prescriber contacted.[28]

   The Royal Australian College of General Practitioners (**RACGP**) 4th edition of Standards for General Practices states:

   Coordination of care for individuals, families and communities is part of the accepted definition of a GP. Where relevant, practices are encouraged to coordinate patient care across the general practice setting with other health services including allied health and pharmacy as well as social, disability, indigenous health and community services. The practice needs to have readily accessible written or electronic information about local health, disability, community and mental health services and how to engage with them to plan and facilitate patient care.[29]

10. The circumstances in which Melissa May was dispensed the pharmaceutical drugs that contributed to her fatal overdose, including misunderstandings and miscommunications between prescribers and dispensers, as well as the associated issues of record keeping, script modification and prospective scripts may indicate the need for the respective guidelines to be clarified and expanded. I therefore distribute this Finding to the Royal Australian College of General Practitioners and the Pharmaceutical Board of Australia, so that each can consider,

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[27] See DHHS publication *Software to be used by health practitioners – Key requirements in Victoria* under the heading 'Forged and Fraudulent computer generated prescriptions'

[28] Page 5. Various DHHS guidelines are to the same effect.

[29] Standard 1.6: Coordination of care, Page 45.

ideally in consultation with the other, how the lessons of this case can be incorporated into future training and possible interventions to reduce pharmaceutical drug-related harms.

11. I also distribute this Finding to the Australian Health Practitioner Regulation Authority for information and to take whatever action it deems appropriate in relation to the issues revealed by this case.

RECOMMENDATIONS

Pursuant to section 72(2) of the Coroners Act 2008, I make the following recommendation(s) connected with the death:

1. The Royal Australian College of General Practitioners and the Pharmaceutical Board of Australia collaboratively consider how they might incorporate the lessons of this case into future training and the design of future interventions to reduce pharmaceutical drug-related harms.

2. The Royal Australian College of General Practitioners and the Pharmaceutical Board of Australia collaboratively consider the need for the development of a joint guideline in relation to communication between the professions to ensure the safe prescribing and dispensing of drugs of dependence, including methods of implementing daily dispensing, avoiding early dispensing and the provision of prospective prescriptions.

3. The Royal Australian College of General Practitioners consider the need for further education and training or assistance to rural general practitioners dealing with complex patients suffering chronic pain and prescription drug dependence.

Pursuant to Section 73(1A) of the *Coroners Act 2008* I direct this finding be published on the internet.

I direct that a copy of this finding be provided to the following:

The family of Mrs Melissa May;

Australian Health Practitioner Regulation Agency;

Royal Australian College of General Practitioners;

Pharmaceutical Board of Australia;

Pharmaceutical Society of Australia;

Investigating Member, Victoria Police; and

Interested Parties.

Signature:

ROSEMARY CARLIN
CORONER
Date: 26 August 2016