IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

COR 2021 001506

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2)

*Section 67 of the **Coroners Act 2008***

Findings of:	AUDREY JAMIESON, Coroner
Deceased:	Caroline Anne McCormack
Date of birth:	11 January 1947
Date of death:	22 March 2021
Cause of death:	1a: Infective exacerbation of chronic obstructive airways disease in the setting of a medication administration error (pregabalin)
Place of death:	Northern Health, Northern Hospital, 185 Cooper Street, Epping, Victoria, 3076

INTRODUCTION

1. On 22 March 2021, Caroline Anne McCormack was 74 years old when she died in hospital. At the time of her death, Caroline lived in Bundoora.

2. Caroline had a history of severe chronic obstructive airways disease, systemic lupus erythematosus, chronic lower back pain, subclinical hyperthyroidism, gastro-oesophageal reflux disease and a known right renal lesion. She was a lifelong smoker.

3. According to Caroline's general practitioner Dr James McKenzie, she was extremely unwell in the 12 months prior to her death. She required home oxygen for end-stage chronic obstructive airways disease and was supported by the Banksia Palliative Care Service at home.

THE CORONIAL INVESTIGATION

4. Caroline's death was reported to the coroner as it fell within the definition of a reportable death in the *Coroners Act 2008* (**the Act**). Reportable deaths include deaths that are unexpected, unnatural or violent or result from accident or injury.

5. The role of a coroner is to independently investigate reportable deaths to establish, if possible, identity, medical cause of death, and surrounding circumstances. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death. The purpose of a coronial investigation is to establish the facts, not to 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 comments or recommendations in appropriate cases about any matter connected to the death under investigation.

7. This finding draws on the totality of the coronial investigation into the death of Caroline Anne McCormack. 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. In the coronial jurisdiction, facts must be established on the balance of probabilities.[1]

[1] 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.

MATTERS IN RELATION TO WHICH A FINDING MUST, IF POSSIBLE, BE MADE

Circumstances in which the death occurred

8. Caroline's Webster-pak[2] containing her regular medications was collected from Pharmacy Select Lyndarum on 13 March 2021. It was unknown at this time that the Webster-pak erroneously contained pregabalin which she was no longer prescribed.

9. On 17 March 2021, Caroline had a fall in the setting of drowsiness which was witnessed by her son. The inclusion of pregabalin in the Webster-pak was discovered after Caroline had taken three or four 150mg doses. She did not want to present to hospital.

10. On 19 March 2021, Caroline was reviewed by a registered nurse from Banksia Palliative Care, in the context of increasing left hip pain since the fall. The nurse recommended she attend hospital for examination as an x-ray may be required.

11. Caroline was conveyed by ambulance to the Northern Hospital on the same day. Her Glasgow Coma Score (**GCS**)[3] was 13.

12. At 9:25pm, upon returning from an x-ray of her pelvis, Caroline's GCS dropped to 9. A MET call was initiated. Clinicians determined that this was likely her beginning the 'active dying' stage. The x-ray showed a right femoral hemiarthroplasty with no definitive acute fracture of either hip or hemipelvis.

13. At 1am on 20 March 2021, Caroline was admitted to the medical ward for end-of-life care. She was alert to voice but non-verbal and was comfortable on morphine and midazolam.

14. Caroline remained comfortable on 21 March with no changes to her medications. Preparations were being made for end-of-life care at home in accordance with her family's wishes. She became less responsive throughout the day.

15. Caroline died at 9:04am on 22 March 2021.

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[2] A Webster-pak is a dose administration aid where each medication is packed according to the day and administration time.

[3] An objective scale of neurological assessment, ranging from three (deep unconsciousness) to fifteen (no impairment). A score of less than 8 being universally accepted as the level of coma in which a person is likely to be unable to protect their airway from saliva and other secretions and is at risk of obstructing their airway. There is also agreement that at a level of GCS less than 8 a patient should be intubated to protect the airway and ensure adequate oxygenation.

Identity of the deceased

16. On 22 March 2021, Caroline Anne McCormack, born 11 January 1947, was visually identified by her granddaughter, Monique Adams, who completed a Statement of Identification.

17. Identity is not in dispute and requires no further investigation.

Medical cause of death

18. Forensic Pathologist Dr Melanie Archer from the Victorian Institute of Forensic Medicine (**VIFM**) conducted an autopsy on the body of Caroline McCormack on 26 March 2021. Dr Archer considered materials including the Victoria Police Report of Death (Form 83), post mortem computed tomography (**CT**) scan and E-Medical Deposition Form from Northern Health and provided a written report of her findings dated 29 June 2021.

19. The findings at autopsy included the following:

    a) Changes of chronic obstructive airways disease

    b) Bronchopneumonia

    c) Nodular tricuspid and mitral valves

    d) Right kidney tumour (inflammatory spindle cell lesion of unknown type)

    e) Left adrenal cortical adenoma

    f) Multinodular goitre

20. There was no evidence of any significant hip injury at autopsy. The post mortem CT scan confirmed right hemiarthroplasty and no fracture. Dr Archer considered that the fall was not likely to have contributed to the death.

21. Dr Archer commented that Caroline had emphysema which is a significant risk factor for lung infections such as bronchopneumonia, and 'infective exacerbations of chronic obstructive airways disease' are a leading cause of mortality.

22. She further commented that the pre-existence of chronic obstructive airways disease was a significant risk factor for pneumonia. However, drowsiness in the context of pregabalin administration also represented a possible risk factor for aspiration pneumonia. The origin of the pneumonia is unclear and could be linked to either or both of these risk factors.

23. Toxicological analysis of post mortem blood samples identified the presence of acetone (~ 36 mg/L), morphine (~ 0.1 mg/L) and midazolam (~ 0.06 mg/L).

24. Dr Archer provided an opinion that the medical cause of death was 1(a) INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE IN THE SETTING OF A MEDICATION ADMINISTRATION ERROR (PREGABALIN).

CORONERS PREVENTION UNIT REVIEW

25. Having identified that Caroline's death occurred in the setting of a medication administration error, I requested that the Coroners Prevention Unit (**CPU**)[4] investigate how the error occurred and advise me as to the extent the error contributed to the death.

26. As part of their investigation, the CPU sought statements from general practitioner Dr James McKenzie, Pharmacist Manager of Pharmacy Select Lyndarum, Mary Christina Rajan, and Banksia Palliative Care.

Timeline of prescribing and dispensing

27. Dr McKenzie confirmed that Caroline had been regularly prescribed pregabalin for chronic pain since 2014 and she had tolerated doses of up to 150mg twice per day. Pregabalin was first ceased in June 2020[5], but restarted in January 2021 due to difficulty controlling her chronic pain.

28. On 6 January 2021, the pharmacy received the new prescription from Dr McKenzie and subsequently dispensed the medication, after confirming the prescription with Dr McKenzie by phone call.

29. On 20 January 2021 Dr McKenzie was notified that Caroline had self-ceased pregabalin. He adjusted his records accordingly and did not provide further prescriptions.

30. On 30 January 2021, a prescription for pregabalin was received from Dr Ruwawu Medis of Banksia Palliative Care, with a dosage of 25mg at night to increase to 50mg over the next

[4] The Coroners Prevention Unit (CPU) was established in 2008 to strengthen the prevention role of the coroner. The unit assists the Coroner with research in matters related to public health and safety and in relation to the formulation of prevention recommendations. The CPU also reviews medical care and treatment in cases referred by the coroner. The CPU is comprised of health professionals with training in a range of areas including medicine, nursing, public health and mental health.

[5] Dr McKenzie states that this was conveyed on the discharge summary from the rehabilitation centre after an attendance due to a fractured hip. Ms Rajan stated that pregabalin had in fact been ceased in February 2020 by the Austin Hospital, and that Dr McKenzie was only informed in June 2020 when he wrote a repeat prescription causing the pharmacist to call him and ask him to update his records.

week. The pharmacist queried with Dr Medis whether this was in addition to the 150mg twice per day prescribed by Dr McKenzie. Dr Medis instructed the pharmacy to disregard the new prescription.

31. On 11 February 2021, Banksia Palliative Care phoned the pharmacy and requested they remove all pregabalin in Caroline's Webster-pak. On the same day, Caroline's daughter visited the pharmacy to return a Webster-pak for the period 12 February to 25 February 2021, because it contained pregabalin. Ms Rajan removed the pregabalin and delivered the updated Webster-pak to Caroline's home.

32. On 23 February 2021, another pharmacist erroneously packed pregabalin 150mg twice per day into a new Webster-pak for the following fortnight. This pack was collected on 13 March 2021.

33. On 17 March 2021, Caroline's daughter called the pharmacy to notify them of the error, and that she had removed and discarded the pregabalin.

How did the error occur?

34. Caroline's medication management was complex, and her medications changed regularly between different prescribers.

35. Ms Rajan advised that it was the usual practice at the pharmacy for prescribers to communicate medication changes in written form, though there were instances where this may be authorised verbally. The changes are then recorded on the pharmacy's changes to packing record, the packing record sheet, the packing system which prints foils for Webster-paks and the electronic patient notes.

36. Ms Rajan advised that on 11 February 2021 after taking the phone call from Banksia Palliative Care, she recorded the cessation of pregabalin on Caroline's "Changes to Packing" record. The record is a physical sheet filled out by a pharmacist with the date, changes, person authorising the changes and the pharmacist's signature or initials.

37. After Ms Rajan removed the pregabalin from the Webster-paks brought back by Caroline's daughter, she created a new packing record updated with the instructions to exclude pregabalin from future Webster-paks. This change was not recorded on the electronic packing system and subsequently was not printed onto the foil labels for future Webster-paks.

38. On 23 February 2021, another pharmacist packed Caroline's Webster-pak with reference to the old packing record, and the old electronic system which had not recorded the instructions to remove pregabalin.

39. Following the incident, the pharmacy has reviewed its process and has added an additional step of marking old packaging record sheets to indicate that they are out of date.

CPU assessment

40. The CPU considered that while there was an element of human error contributing to the medication error, the error occurred in the context of multiple prescribers and multiple forms of communication to the pharmacist.[6]

41. They noted that the statements provided to the Court depicted what could be described as an error prone environment in which the pharmacist was provided with two different prescriptions for pregabalin from two different doctors, followed by a verbal order to cease pregabalin all received in close succession. This led to the failure of the sequential transfer of multiple instructions into an electronic tracking *and* a paper-based packing order resulting in the dispensing of the incorrect medications.

42. Ultimately, the CPU advised me that Caroline was in the advanced stages of her illness and hence her death was not unexpected. It is possible, but cannot be stated definitively, that the accidental administration of pregabalin may have contributed to her increased drowsiness, despite her reported tolerance with previous usage of the medication.

COMMENTS

Pursuant to section 67(3) of the Act, I make the following comments connected with the death.

1. Medication safety is complex, with multiple risk factors potentially contributing to avoidable adverse outcomes. Whilst there was an element of human error contributing to the erroneous inclusion of pregabalin in Caroline's webster pack, I consider that the medication error was more-so due to the contributing systemic factors and could have occurred in any busy pharmacy setting.

[66] In this case there was a palliative care service, hospital service, a daughter advocate and a general practitioner with communications by phone, personal visit, and fax.

2. Communication of medication changes may rely on transmission of information between multiple clinicians often using different modes of communication. This situation is often seen in the context of a hospital admission when a medication reconciliation may not be completed on admission, or when the hospital may rely on either the patient or the GP to pass on the discharge medication list to the community pharmacy to ensure correct dispensing. While not proximate to Caroline's death, this also occurred following an admission to hospital in early 2020.

3. Any doctor can provide medication orders for any patient that they see, and, in this case, involvement of multiple doctors also increased the risk of a medication error, medication side effect and risks associated with polypharmacy. Multiple prescribers appears to have created the error prone environment which led to the critical incident when the pharmacist dispenser erroneously relied on an outdated medication list.

4. The move towards digital health solutions including real time prescription monitoring may reduce medication dispensing errors by mandating prescribers and dispensers check a real time system that allows them to see what medication is prescribed to the patient at any point in time. In Victoria, SafeScript provides access to a patient's prescription history for high-risk medicines, and it is mandatory to check SafeScript prior to writing or dispensing a prescription for medicines monitored through that system. On 3 July 2023, pregabalin was added to the medicines monitored on SafeScript.

5. Whilst not a factor in Caroline's death, I consider that medication dispensing errors may also be reduced if a dispensing pharmacy received a copy of a patient's discharge medication list upon discharge from hospital directly, rather than relying on the patient themselves, a GP or family or carer to communicate any changes to the pharmacy. I will make a recommendation to this effect.

RECOMMENDATIONS

Pursuant to section 72(2) of the Act, I make the following recommendations:

(i) With the aim of promoting public health and safety and preventing like deaths, I recommend that the Pharmacy Guild of Australia consider a means by which hospital discharge medication list could be provided directly to a patient's regular or community pharmacy, particularly where that patient relies on a Webster-pak or similar dose administration aid.

FINDINGS AND CONCLUSION

1. Pursuant to section 67(1) of the *Coroners Act 2008* I make the following findings:

    a) the identity of the deceased was Caroline Anne McCormack, born 11 January 1947;

    b) the death occurred on 22 March 2021 at Northern Health The Northern Hospital, 185 Cooper Street, Epping, Victoria, 3076;

    c) I accept and adopt the medical cause of death ascribed by Dr Melanie Archer and I find that Caroline Anne McCormack died following a medication administration error, from infective exacerbation of chronic obstructive airways disease;

2. AND, although I have found that Caroline Anne McCormack died in the setting of the accidental or inadvertent administration of pregabalin, I am unable to find with any degree of certainty whether the error was causal to her death, and accordingly whether her death was preventable.

Pursuant to section 73(1) of the Act, I direct that a copy of this finding is published on the internet in accordance with the rules.

I convey my sincere condolences to Caroline's family for their loss.

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

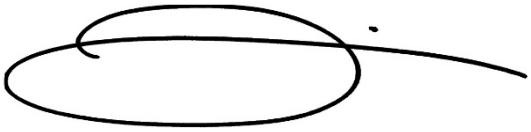
Natlee Clark, Senior Next of Kin

Meridian Lawyers on behalf of Ms Mary Christina Rajan

Pharmacy Guild of Australia

Senior Constable Priya Nataly, Coronial Investigator

Signature:



AUDREY JAMIESON

CORONER

Date: 3 March 2025

NOTE: Under section 83 of the ***Coroners Act 2008*** ('the Act'), a person with sufficient interest in an investigation may appeal to the Trial Division of the Supreme Court against the findings of a coroner in respect of a death after an investigation. An appeal must be made within 6 months after the day on which the determination is made, unless the Supreme Court grants leave to appeal out of time under section 86 of the Act.