IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2021 1330

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2)
*Section 67 of the **Coroners Act 2008***

Findings of:	Coroner Paresa Antoniadis Spanos
Deceased:	Vittorina Ipsa
Date of birth:	21 May 1928
Date of death:	13 March 2021
Cause of death:	1(a) Clozapine toxicity in a lady with terminal lung carcinoma
Place of death:	Footscray Hospital, 160 Gordon Street, Footscray, Victoria
Key words:	Clozapine, medication error, distraction, safe medication administration practices , aged care facility

INTRODUCTION

1. On 13 March 2021, Vittorina Ipsa was 92 years old when she died in hospital following a medication error. At the time, Mrs Ipsa lived in an Estia Health Aged Care Facility in Altona Meadows.

2. Mrs Ipsa's medical history included chronic obstructive pulmonary disease (**COPD**),[1] congestive cardiac failure,[2] osteoporosis, and she had been diagnosed with presumed lung malignancy.[3]

3. Mrs Ipsa initially attended Estia Health for respite care between 12 and 26 January 2021. She was discharged home but was readmitted on 2 March 2021 from Williamston Hospital for a further period of respite care due to a decline in her functional capacity. It was reported that her health had been declining over the previous two months and she was known to the Mercy palliative care and the Western Health palliative care teams.

4. Mrs Ipsa's regular medications prescribed by her general practitioner included Morphine, Apixaban (anticoagulant), Cholecalciferol (vitamin D), Brimonidine (eye drops), Coloxyl with Senna (laxative), and Spiriva Respimat Asthma mediation, among others. On 10 March 2021, she was reviewed by the Mercy palliative care team at which time it was recommended that Mrs Ipsa be commenced on injectable Morphine 2.5mg, Maxolon 10mg, Midazolam 2.5mg (sedative), and Lorazepam 0.5mg (anti-depressant).

5. Mrs Ipsa required supervision and stand-by assistance with walking and physical assistance transferring from sitting/standing and toileting. She tolerated food and fluid well but required supervision, prompting, and physical assistance during mealtime. Mrs Ipsa also required assistance from staff to administer medications due to her poor vision and decreased cognitive ability.

THE CORONIAL INVESTIGATION

6. Mrs Ipsa'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.

[1] A term used to describe a number of lung conditions that are long-term, gradually worsen and cause shortness of breath by reducing the normal flow of air through the airways.
[2] A chronic condition whereby the ability of the heart to effectively pump blood is reduced.
[3] A CT scan in November 2020 identified a large right upper lobe mass and a more recent CR angiogram showed occlusion of the right main bronchus. Mrs Ipsa had declined palliative radiotherapy.

7. 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.

8. 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.

9. As part of my investigation, I obtained a statement from Estia Health.

10. This finding draws on the totality of the coronial investigation into Mrs Ipsa's death. 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.[4]

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

Identity of the deceased

11. On 13 March 2021, Vittorina Ipsa, born 21 May 1928, was visually identified by her son, Frank Ipsa, who signed a formal Statement of Identification to this effect.

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

Medical cause of death

13. Forensic Pathologist, Dr Yeliena Baber, from the Victorian Institute of Forensic Medicine (**VIFM**), conducted an inspection on 15 March 2021 and provided a written report of her findings dated 16 March 2021.

14. The post-mortem examination revealed a large right upper lobe spiculated mass with additional radiodensity around the right hilum and right lower lobe collapse, large right pleural effusion, reduced right thoracic space, small left pleural effusion, emphysema, paraumbilical

[4] 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.

hernia, cerebral atrophy, and calcifications to coronary arteries and aorta. Other findings were in keeping with the clinical history.

15. Routine toxicological analysis of ante-mortem samples collected on 13 March 2021 detected acetone,[5] clozapine,[6] and free morphine[7] but no alcohol or other commonly encountered drugs or poisons.

16. Dr Baber provided an opinion that the medical cause of death was *"1(a) Clozapine toxicity in a lady with terminal lung carcinoma"*.

17. I accept Dr Baber's opinion.

Circumstances in which the death occurred

18. At 8.00pm on 12 March 2021, Mrs Ipsa was inadvertently administered medication prescribed for the resident in the next room. The medication consisted of clozapine 125mg, haloperidol[8] 0.5mg, and rosuvastatin[9] 20mgs.

19. At approximately 8.30pm, Mrs Ipsa was found by staff with a reduced conscious state, hypotensive, hypersalivating, and unable to maintain her own airway. She was transferred to Footscray Hospital and treated with vasopressors and non-invasive ventilation.

20. Due to Mrs Ipsa's significant medical co-morbidities a discussion between the treating medical team and her family were held and a decision was made to commence palliative care. Mrs Ipsa was kept comfortable until she passed away at 4.05am on 13 March 2021.

FURTHER INVESTIGATION INTO THE MEDICATION ERROR

21. As part of my investigation into Mrs Ipsa's death, I obtained a statement from Estia Health outlining how the medication error occurred, the guidelines in place to prevent such an error, and the changes Estia Health had implemented to prevent the error occurring in future.

[5] Low levels of acetone in the blood are likely attributable to ketosis secondary to diabetes or a fasted state.
[6] Clozapine is a second-generation (atypical) antipsychotic drug effective for treating the positive and negative symptoms of schizophrenia. It is restricted to schizophrenic patients who do not respond to first-line antipsychotics.
[7] Morphine is a narcotic analgesic used for the treatment of moderate to severe pain.
[8] Haloperidol is an antipsychotic agent used to treat schizophrenia and other psychoses, as well as symptoms of agitation, irritability, and delirium.
[9] Rosuvastatin is a lipid lowering drug that belongs to the statin class of medications used in the management of high blood cholesterol levels.

How the medication error occurred

22. According to Krishna Patel, Care Director at Estia Health Altona Meadows, Mrs Ipsa was located in room 43 of the Queen Unit. The other resident involved in this incident (normally located in room 44) was not in the facility at the time the incident occurred. Both rooms had a picture of the occupant on the door of the room and there was a corresponding photograph in the medication charts.

23. The medication trolleys have individual compartments to store medications by room for each medication round. The medication trolley is prepared by a staff member qualified to administer medications before they attend to dispense medications. The medication must be administered and signed for by the person who has checked and prepared the medication trolley. The medication room also contains a large supply of Do Not Disturb (**DND**) vests, which are to be worn by all staff undertaking a medication round to place people on notice that they are not to be disturbed to minimise the risk of errors. There is also a supply of DND vests in each medication trolley.

24. All medications are provided to Estia Health in original packaging clearly and individually labelled with the resident's name and doses. Estia Health receives two different types of medication packaging from two different pharmacies:

    (a) Webster Dose Administration Aids (Webster Packs) which provide medication in multi-dose disposable packs and single dose packs. Webster Packs are stored at the bottom of the medication trolley if they do not contain Schedule 4 or 8 Medications. However, if there are Schedule 4 or 8 Medications then the Webster Packs are stored in a locked medication cupboard in the upstairs medication room of the Queen Unit; and

    (b) MPS Sachets which provide medications in multi-dose seven-day roll in easy to tear paper packets. MPS Sachets are stored in the resident's individual partition in the medication trolley.

25. Where a resident uses the Webster Pack, their individual partition in the medication trolley may be empty as it does not contain MPS Sachets.

26. On 12 March 2021, an Endorsed Enrolled Nurse was responsible for preparing the medication trolley prior to conducting a medication round that evening at 8:00pm. The medication round usually takes one to one and a half hours to complete.

27. Mrs Ipsa's medications were provided by way of Webster Pack, while the other resident's medications were administered by way of MPS Sachets. Mrs Ipsa's medications included Schedule 4 and Schedule 8 Medications that must be stored separately in a locked cupboard or safe securely fixed to a wall and in a locked room with authorised access only.

28. The Enrolled Nurse's recollection is that she took the other resident's MPS Sachet off the roll because that resident was due to return to the aged care facility shortly and would need her usual medication administered at 8.00pm. The Enrolled Nurse placed that other resident's MPS Sachet into the medication trolley so that she would remember to give it the resident on her return to the facility.

29. It appears the Enrolled Nurse tore the other resident's MPS Sachet off the roll and inadvertently placed it in the partition in the medication trolley belonging to Mrs Ipsa, which would have been empty at the time as her medication was dispensed by a Webster Pack.

30. The Enrolled Nurse attended Mrs Ipsa's room to administer her medication at approximately 8:00pm. The Enrolled Nurse called in the Registered Nurse to assist with dispensing the Schedule 8 Medications contained in Mrs Ipsa's Webster Pack as two staff members must be present to check and administer Schedule 8 Medications, including a registered nurse.

31. The Enrolled Nurse had already administered Mrs Ipsa the medication from the other resident's MPS Sachet before the Registered Nurse came in to administer her regular Schedule 4 and 8 Medications from her Webster Pack. The MPS Sachet for the other resident did not contain any Schedule 4 or 8 medications which would require the presence of two staff members. The Registered Nurse has confirmed that she did not witness the Enrolled Nurse administer the medications from the MPS Sachet but did witness her administer the medications from the Webster Pack.

32. The Enrolled Nurse returned to check on Mrs Ipsa at approximately 8:30pm and found her unresponsive in her chair. An ambulance was subsequently called.

33. At about this time, the other resident returned to Estia Health and the Enrolled Nurse identified the MPS Sachet for the other resident was missing. She subsequently realised that she had administered this medication to Mrs Ipsa in error.

34. The ambulance for Mrs Ipsa arrived at approximately 8:45pm and paramedics were advised of the medication error.

Estia Health's policies

35. The Estia Health Medication Policy in place at the time of the incident provided that 'ten rights' of safe medication administration should be followed on every occasion of a medication being administered, namely:

    (a) right resident;

    (b) right medication;

    (c) right dose;

    (d) right route;

    (e) right time;

    (f) right date;

    (g) right of refusal for resident (who is not cognitively impaired);

    (h) right documentation;

    (i) right reason; and

    (j) right response.

36. It also generally provided procedures for the safe administration of medications to residents.

37. Following the incident, the Enrolled Nurse conceded that she did not follow the 'ten rights' of safe medication administration and also that she did not wear the DND vest during the medication round.

38. Ms Patel explained that whilst the Enrolled Nurse was not wearing a DND vest and was required to answer the front door and took one of the three telephone calls regarding the other resident during the medication round, DND vests do not preclude staff members from answering telephone calls. The evening was relatively quiet and there were no other factors that contributed to the medication error.

Training provided to nursing staff

39. The Enrolled Nurse was provided with training on Estia Health's medication management policy and processes, including the Medication Policy, during her induction. Ms Patel

confirmed that the Enrolled Nurse's theoretical knowledge was excellent and determined her competent to administer medications.

40. Ms Patel explained that those policies and procedures are reinforced by very clear prompts to ensure medication administration is undertaken in accordance with the 'ten rights' of safe medication administration. Those prompts were located directly in front of the medication trolley on the wall and in front of the folder containing all medication charts. There are also other devices to assist staff, including DND vests located at each medication trolley and in each medication room.

Estia Health's investigation into the incident

41. Estia health conducted an internal review and an external root cause analysis. These reviews identified the following contributing factors:

    (a) the Enrolled Nurse did not follow the 'ten rights' of medication administration;

    (b) there was a medication dispensing risk if the individual partition in the medication trolley was empty because the resident had a Webster Pack; and

    (c) given the Enrolled Nurse was a relatively recent graduate who was working at Estia health on a part-time basis, she may not have had the breadth of experience and knowledge of Estia Health's medication administration system.

42. Estia Health has implemented the following changes following the incident;

    (a) a system to clearly identify in the medication trolley for each resident that utilises the Webster Pack system. Stickers are now placed on each resident's medication compartment stating 'Webster Pack' as an alert for those who are medicated through the Webster Pack;

    (b) a recruitment policy rule has been implemented so that a graduate nurse or a registered nurse with less than one year of practice cannot be employed on a casual basis; and

    (c) training has been provided to staff on the importance of staff reading and being aware of Estia Health's policies and procedures, accessing these policies and procedures and acting in accordance with those policies and procedures.

Action taken against the Enrolled Nurse involved in the incident

43. Estia Health suspended the Enrolled Nurse with pay, pending the outcome of the internal investigation. Ms Patel noted that the Enrolled Nurse was very upset and very remorseful about the incident.

44. Estia Health subsequently terminated the Enrolled Nurse's casual employment on the grounds of serious misconduct. Estia Health also reported the Enrolled Nurse to the Australian Health Practitioner Regulation Agency (**AHPRA**).

45. AHPRA has informed me that as a result of the error and her reflections, the Enrolled Nurse has undergone relevant education regarding medication administration.

46. AHPRA also noted that during her medication round, the Enrolled Nurse was also expected to answer the phone and to open the doors to let visitors into the section. The Enrolled Nurse conceded that distraction was a contributing cause of the incident.

47. AHPRA has informed me that distraction is a well-known cause of medication error, and it is recognised that healthcare facilities need to provide an environment and levels of support for nursing staff so they can complete medication rounds with minimal distractions.

48. AHPRA considered there were a number of contributing factors that were beyond the Enrolled Nurse's control, such as being required to undertake competing duties concurrently with the medication round.

49. Noting the Enrolled Nurse's remorse and further training regarding medication safety, AHPRA did not take any further action against the Enrolled Nurse as she had already taken appropriate steps to address concerns an mitigate any risk.

FINDINGS AND CONCLUSION

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

    (a) the identity of the deceased was Vittorina Ipsa, born 21 May 1928;

    (b) the death occurred on 13 March 2021 at Footscray Hospital, 160 Gordon Street, Footscray, Victoria;

    (c) the cause of Mrs Ipsa's death was clozapine toxicity in a lady with terminal lung carcinoma; and

(d) the death occurred in the circumstances described above.

COMMENTS

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

51. The medication error that led to Mrs Ipsa being administered another resident's medication was clearly unintended. When the error was realised, the Enrolled Nurse immediately disclosed the incident and Mrs Ipsa was appropriately transferred to hospital. Unfortunately, given her co-morbidities, intervention was deemed inappropriate, and she passed away shortly thereafter.

52. As AHPRA has noted, distraction is a well-known cause of medication errors. During her medication round on the evening of 12 March 2021, the Enrolled Nurse noted that she had answered at least one telephone call and was also required to open the front door.

53. I note Estia Health provides DND vests for staff members undertaking medication rounds. Ms Patel explained that these vests are one way to assist staff to ensure safe medication administration. While the vests are designed to prevent others from disturbing nursing staff during medication administration, the fact that they are still required to attend to phone calls and the front door. This is not ideal and may still constitute of interruption that may lead to a medication error.

54. I am satisfied that Estia Health has conducted a relatively thorough investigation of the incident, which has identified a risk in the way Webster Pack medication is administered to patients. However, the reviews conducted following Mrs Ipsa's death have not identified distraction as a contributing factor in the incident and it appears no changes have been implemented in this regard.

55. A prevention opportunity therefore remains for Estia Health to strengthen safe medication administration practices and support nursing staff members by minimising cognitive load and the requirement to perform other duties whilst undertaking a medication round. I therefore strongly encourage Estia Health to introduce a policy or procedure mandating that staff on medication rounds should not engage in any other duties until all medication is administered to residents safely.

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

Pursuant to section 73(1A) of the Act, I order that this finding be published on the Coroners Court of Victoria website in accordance with the rules.

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

Franco Ipsa, senior next of kin

Estia Health

Western Health

Australian Health Practitioner Regulation Agency

Senior Constable Ryan Woodman, Victoria Police, reporting member

Signature:

Coroner Paresa Antoniadis Spanos

Date: 06 October 2022

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.