

IN THE CORONERS COURT OF VICTORIA AT MELBOURNE

COR 2020 001584

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2)

Section 67 of the Coroners Act 2008

Findings of: Coroner Darren J. Bracken Heather Jean LUCAS Deceased: Date of birth: 2 September 1939 Date of death: 20 March 2020 Anaphylaxis complicating chemotherapy for the Cause of death: treatment of metastatic fallopian tube cancer, in a woman with ischaemic heart disease Place of death: Cabrini Health, Cabrini Hospital, 243 New Street, Brighton, Victoria Key Words Anaphylaxis, Carboplatin

INTRODUCTION

- 1. On 20 March 2020, Ms Heather Jean Lucas was 80 years old when she died in the 'Day Oncology Unit' at Cabrini Health's Brighton premises. At the time of her death, Ms Lucas was undergoing a course of chemotherapy directed by Professor Richardson, receiving a combination of carboplatin and gemeitabine.
- 2. Ms Lucas had a medical history that included metastatic cancer, debulking surgery and experiencing a reaction to carboplatin.

THE CORONIAL INVESTIGATION

- 3. Ms Lucas's death was reported to the coroner because it fell within the definition of a reportable death in the *Coroners Act* (2008) (the Act). Reportable deaths include deaths that are unexpected, unnatural, violent or result from accident or injury as well as deaths that occur during or following a medical procedure when the death is or may be causally related to the medical procedure and a registered medical practitioner would not, immediately before the procedure was undertaken, have reasonably expected death.
- 4. The coroner's role is to independently investigate reportable deaths to establish, if possible, the deceased's identity, the cause of death, and the circumstances surrounding the death. 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.
- 5. Pursuant to the Act, coroners also have the important functions of helping to prevent deaths, promoting public health and safety and facilitating the administration of justice through the making of comments or recommendations about any matter connected to the death under investigation.
- 6. Victoria Police assigned Constable Marcus Schroen as the Coroner's Investigator in relation to Ms Lucas's death. Usually, the Coroner's Investigator conducts inquiries on my behalf, including taking statements from witnesses, collating reports including from the forensic pathologist and treating clinicians, and submitting a coronial brief of evidence.
- 7. This finding draws on the totality of the coronial investigation into Ms Lucas' death including evidence contained in the coronial brief. 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

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

Circumstances in which the death occurred

- 8. On 20 March 2020 Ms Lucas was undergoing her third treatment of carboplatin and gemcitabine, the first having been administered on 7 February 2020 and the second on 28 February 2020. During the second treatment on 28 February 2020, Ms Lucas suffered a reaction to the carboplatin. The infusion of carboplatin was stopped, Ms Lucas was given antihistamine and steroid medication and admitted, staying overnight. Cabrini staff completed an Adverse Drug Reaction Report recording that Ms Lucas experienced nausea, vomiting, light-headedness, shortness of breath, abdominal pain and an itchy rash to her face and upper limbs and torso.
- 9. On 20 March, Ms Lucas was premedicated with steroids and antihistamines, she was given gemcitabine between 1.45pm and 2.20pm and reported no difficulties. At 2.40pm, she was commenced on carboplatin. A short time (minutes) after the carboplatin was commenced, Ms Lucas developed signs and symptoms of a reaction including vomiting and redness of her face, upper limbs and torso. At 2.45pm the carboplatin was ceased and she was given more steroid and antihistamine medication. At 2.50pm a 'MET call' was made. Dr Rankin explained in his first statement that routinely there is no 'medical presence' in the Day Oncology Unit but that there is always such a presence at the adjacent hospital. An oncology registrar attended to Ms Lucas and finding that she had;
 - (a) a decreased conscious state,
 - (b) low oxygen levels,
 - (c) a rapid heart rate and

her condition further deteriorated called a 'Code Blue' was called.³

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.

² An alert to hospital staff summoning assistance because a patient's vital signs have fallen outside set criteria.

³ An alert to hospital staff summoning assistance because of a 'medical emergency' a patient being critical.

- 10. An anaesthetist from the hospital and paramedics were called and cardiopulmonary resuscitation and other treatment was undertaken. Ms Lucas's son was contacted and he spoke to his brother (Ms Lucas' other son) and attempts at resuscitation ceased in accordance with Ms Lucas's wishes. Ms Lucas was subsequently declared to be deceased.
- 11. The Medical Deposition, completed by Dr Chow, a medical oncology registrar, refers to Ms Lucas' time of death as 4.00pm 20 March 2022. The time of death in Dr Chow's progress notes seems to be 3.25pm. Those notes also refer to "anaphylactic reaction to carboplatin".

Coronial Investigation

- 12. Dr D Rankin, the Director of Clinical Governance and Informatics at Cabrini Health in 2020 provided a statement to the court in relation to Ms Lucas' treatment at Cabrini Health dated 16 July 2020 (**First Statement**), another dated 7 October 2020 (**Second Statement**) and a third dated 25 March 2021 (**Third Statement**).
- 13. In his First Statement, Dr Rankin refers to having discussed Ms Lucas' reaction to the carboplatin on 28 February 2020 with Professor Richardson. Dr Rankin refers to Professor Richardson having told him that, after 28 February but before 20 March 2020, that he told Ms Lucas that a more severe reaction may occur and that Ms Lucas decided to 'push-on' with chemotherapy because there were no other treatment options. Dr Rankin refers to Professor Richardson telling him that there were no other family members present during this discussion and makes no further reference to when this discussion was said to have occurred; there is no reference to it in Ms Lucas's medical record. Dr Rankin refers to Professor Richardson not obtaining "...formal consent..." prior to 20 March 2020.
- 14. As a result of having sought clarification from Dr Rankin about a number of matters, Dr Rankin provided the Third Statement.
- 15. Given the complexity of the circumstances surrounding Ms Lucas' death, in particular the drugs which were administered to her, I asked the Coroner's Prevention Unit (CPU) to consider Cabrini Health's treatment and management of Ms Lucas.⁴

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.

- 16. The CPU considered the content of Dr Rankin's three statements, and a considerable amount of other documentation including the Coronial Brief of Evidence and Ms Lucas' Cabrini Health medical records.
- 17. The CPU described carboplatin as a chemotherapy agent that has a recognised incidence of immunologic mediated hypersensitivity reactions, including anaphylaxis which risk of reaction is increased by repeated or continued exposure to it. The CPU referred to patients who have suffered a reaction to a prior infusion being 'pre-medicated' with antihistamine and steroid medication in the hours prior to an infusion of carboplatin. The CPU explained, however, that there is a lack of data demonstrating a pre-medication regimen that prevents infusion reactions and that 'UpToDate' refers to:
 - (a) "...most centres do not routinely administer premedication before infusion of ...carboplatin...because of the lack of data demonstrating that any premedication regimen successfully prevents infusion reactions"; and
 - (b) "... recommends not rechallenging patients who have reacted to 'agents containing platinum', such as carboplatin even after premedication when the reaction included symptoms of anaphylaxis because 'platinum drugs' are strongly associated with IgE-mediated anaphylactic reactions and cause recurrent reactions upon rechallenge in approximately 50% of cases.
- 18. The CPU notes that the 'Patient Assessment Tool', completed by nursing staff at each attendance for chemotherapy, erroneously noted that "reactions to previous therapy box" was "...ticked no" for Ms Lucas' treatment on 20 March 2020. Dr Rankin asserted in his First Statement that this was an error but that the nurse assisting with Ms Lucas' treatment was aware that Ms Lucas had a reaction to the medication on 28 February 2020 because she was also assisting then. Dr Rankin's First Statement refers to this nurse having that first reaction at the forefront of her mind when assisting with Ms Lucas' treatment on 20 March 2020.
- 19. The CPU advised me that although Cabrini Health was not using a recognised grading scale to document or communicate the severity of hypersensitivity reactions for the purpose of influencing future treatment decisions and it appeared that Professor Richardson was not present at Cabrini Health on 28 February 2020 when Ms Lucas had her original reaction, Professor Richardson considered that Ms Lucas' reaction to have been 'Grade 2'.

⁵ A subscription based information service resource designed to provide physicians with access to clinical information,

- 20. The CPU advised me that based on the assessment, including the tryptase level ascertained as a result the analysis of post mortem samples, the reaction that Ms Lucas had was likely to be anaphylactic. The CPU advised that the first drugs administered to Ms Lucas following her deterioration were hydrocortisone (steroid) and promethazine (antihistamine), both of which were not first line treatments in anaphylaxis.
- 21. The CPU advised me that Cabrini Health undertook a serious incident review as a result of Ms Lucas' death. Ms Lucas' death was reviewed at Cabrini Health as a part of a routine mortality screening process, as Serious Incident Review and also reviewed by the Cabrini Cancer Management Committee. As a result of these reviews, Cabrini Health:
 - (a) established a formal reporting process regarding treatment of reactions and made rechallenging contingent upon acknowledgement by the treating oncologist, the Day Oncology Staff and Chemotherapy Pharmacy staff;
 - (b) drafted, circulated and implemented a formal protocol for Cabrini Health site specific management of platinum hypersensitivity and established a formal protocol for the management of platinum hypersensitivity to include an internationally recognised grading system for adverse reactions. The need for specific plans arise given that for example Cabrini Malvern has a medically led MET team and Cabrini Brighton has a nurse led MET team;
 - (c) is considering a separate consent process prior to re-challenging patients by establishing a working group to develop a structured and formally documented informed consent process for rechallenging of all chemotherapeutic agents; and
 - (d) implemented multiple strategies for recognition and treatment of anaphylaxis.
- 22. The CPU advised that because the number of factors used to discriminate between grades in the 'new' Cabrini Platinum Hypersensitivity Reaction guideline are few, discerning between grades may be difficult. CPU too advised me that it was unclear upon what the guideline's grading was based what the recognised, standardised basis was for the four nominated grades. The CPU too noted that there was not a fifth grade applicable to a reaction that caused death.

Medical cause of death

23. On 25 March 2020, Dr G Young a specialist forensic pathologist practising at the Victorian Institute of Forensic Medicine performed an autopsy on Ms Lucas's body and in his resultant

- report opined that the cause of her death was "Anaphylaxis complicating chemotherapy for the treatment of metastatic fallopian tube cancer, in a woman with ischaemic heart disease".
- 24. In his report, Dr Young noted that Ms Lucas had cancer including in fallopian tubes, lymph nodes and small blood vessels in her right lung. He noted that while her serum tryptase was mildly elevated and a marker of anaphylaxis it may still have been rising at the time of her death.
- 25. Dr Young noted that whilst that result was suggestive of anaphylaxis it was not unequivocally diagnostic of it although when considering the circumstances of her death Dr Young concluded that it was most likely that Ms Lucas had a nonimmunologic anaphylaxis to carboplatin. In his report, Dr Young also noted evidence of Ms Lucas having ischaemic heart disease.
- 26. Toxicological analysis of post mortem samples supported the contention that Ms Lucas had suffered an anaphylactic reaction.
- 27. I accept Dr Young's opinion.

Identity of the deceased

- 28. On 24 March 2020 Mr Ben Lucas identified the deceased as his mother Ms Heather Jean Lucas born 2 September 1939.
- 29. Identity is not in dispute and requires no further investigation.

FINDINGS AND CONCLUSION

- 30. Having considered the material, including Dr Rankin's three statements, the CPU suggested that Cabrini Health could usefully refine their response to the circumstances of Ms Lucas' death. I set out some of the suggested refinements as recommendations below.
- 31. Pursuant to section 67(1) of the Coroners Act (2008) I find that:
 - (a) The identity of the deceased was Heather Jean Lucas, born 2 September 1939.
 - (b) Ms Lucas died on 20 March 2020 at Cabrini Hospital at 243 New Street, Brighton, Victoria, as a result of anaphylaxis complicating chemotherapy for the treatment of metastatic fallopian tube cancer, in a woman with ischaemic heart disease and
 - (c) Ms Lucas died in the circumstances described above.

RECOMMENDATIONS

- 32. Pursuant to section 72(2) of the Act, I recommend:
 - a. Cabrini Health review the grading scale utilised in the Platinum Hypersensitivity Reaction Guidline and consider implementing a recognised scale includes reference to more detailed signs and symptoms for each grade so as to facilitate a more accurate assessment of any reaction and grading with a view to reducing the possibility of underestimation of severity of assessment.
 - b. Cabrini Health review their procedures to ensure that when a patient undergoes 'rechallenge' that an appropriately qualified, trained and equipped medical practitioner is at the bedside at least for administration of the drug and for a period within which any adverse reaction would be expected to manifest taking into account that any patient who has previously experienced grade 2 or greater reactions will not be re-challenged.
 - c. Cabrini Health review its record keeping processes and procedures including the Adverse Drug Reaction System and ensure that all adverse drug reactions are recorded in a timely fashion on all databases, written and electronically held including in the patient's medical record that are accessible by clinical staff and explicitly considered before any rechallenge.
 - d. The Patient Assessment Tool Day Oncology tool be amended to allow explicit recording of allergic reactions so that staff are not required to only rely on a patient informing them of a previous allergic reaction.
 - e. Cabrini Health implement these processes and procedures across all its campuses.
- 33. 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:

Mr Ben Lucas, Senior Next of Kin

Dr D Rankin Cabrini Health

Constable M Schroen Coroner's Investigator

Signature:



Coroner Darren J. Bracken

Date: 18 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.