

IN THE CORONERS COURT  
OF VICTORIA  
AT MELBOURNE

Court Reference: COR 2019 3878

**FINDING INTO DEATH WITHOUT INQUEST**

*Form 38 Rule 63(2)*

*Section 67 of the Coroners Act 2008*

Findings of:	AUDREY JAMIESON, Coroner
Deceased:	CARL DAVID WALDON
Date of birth:	12 January 1955
Date of death:	24 July 2019
Cause of death:	1(a) Left-sided intracerebral haemorrhage associated with deep brain stimulator wire tract
Place of death:	Monash Medical Centre, 246 Clayton Road, Clayton, Victoria 3168

## INTRODUCTION

1. On 24 July 2019, Carl David Waldon was 64 years old when he died at Monash Medical Centre Intensive Care Unit subsequent to an uneventful neurosurgical procedure at Monash Medical Centre on 18 July 2019.
2. At the time of his death, Carl David Waldon lived in Edithvale with his sister Anne Morgan. Mr Waldon received a disability support pension. He had an extensive medical history which included disabling essential tremor, class III obesity<sup>1</sup> (BMI 42.5), sleep apnoea,<sup>2</sup> insulin requiring diabetes, bronchiectasis, peripheral vascular disease,<sup>3</sup> pacemaker, fatty liver,<sup>4</sup> chronic kidney disease, diabetic retinopathy,<sup>5</sup> stroke and atrial fibrillation<sup>6</sup> for which he took warfarin<sup>7</sup> as an anticoagulant.

## THE CORONIAL INVESTIGATION

3. Carl David Waldon'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.
4. 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.
5. 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

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<sup>1</sup> Previously described as morbid obesity as significant health and mortality impact.

<sup>2</sup> Requiring a Continuous Positive Airway Pressure device (CPAP).

<sup>3</sup> Impaired circulation to the lower limbs.

<sup>4</sup> Common condition in obese patient with diabetes where fatty cells interfere with liver function.

<sup>5</sup> Affecting the blood vessels at the back of the eye.

<sup>6</sup> Irregular heart beat where clots can accumulate leading to risk of stroke.

<sup>7</sup> Colloquially called blood thinners.

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

6. The Victoria Police assigned an officer to be the Coroner's Investigator for the investigation of Carl David Waldon's death. The Coroner's Investigator conducted inquiries on my behalf, including taking statements from witnesses – such as family, the forensic pathologist, treating clinicians and investigating officers – and submitted a coronial brief of evidence.
7. This finding draws on the totality of the coronial investigation into the death of Carl David Waldon, 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.<sup>8</sup>

## **MATTERS IN RELATION TO WHICH A FINDING MUST BE MADE<sup>9</sup>**

### **Circumstances in which the death occurred**

8. On 18 July 2019, Mr Waldon underwent the insertion of a deep brain stimulator (DBS) in an attempt to improve his disabling essential tremor. His warfarin was ceased prior to neurosurgery and he was prescribed shorter acting injections of enoxaparin or Clexane®, alternate anticoagulants which could continue up until immediately prior before neurosurgery and recommence immediately afterward.
9. An uneventful neurosurgical procedure at Monash Medical Centre was performed by Associate Professor (A/Prof) Andrew Danks and Mr Waldon was discharged home on 19 July 2019.
10. On 22 July 2019, Mr Waldon returned to Monash Medical Centre with slurred speech and a reported head strike. A computed tomography (CT) scan showed no brain haemorrhage and the hypothesised diagnosis was a thromboembolic stroke. The

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<sup>8</sup> 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.

<sup>9</sup> If possible.

enoxaparin dose was increased to 120mg twice per day representing ‘therapeutic anticoagulation’.

11. On 23 July 2019, Mr Waldon deteriorated again with a repeat CT scan showing a brain haemorrhage along the DBS wire tract. Whilst attempts were made to reverse the anticoagulation, Mr Waldon’s condition deteriorated further.
12. On 24 July 2019, Mr Waldon died in the Intensive Care Unit (ICU) of the Monash Medical Centre.

### **Identity of the deceased**

13. On 24 July 2019, Carl David Waldon, born 12 January 1955, was visually identified by his sister, Anne Morgan.
14. Identity is not in dispute and requires no further investigation.

### **Medical cause of death**

15. Forensic Pathologist Dr Paul Bedford from the Victorian Institute of Forensic Medicine (VIFM), conducted an autopsy on 1 August 2019, reviewed a post mortem CT scan and referred to the Victoria Police Report of Death, Form 83. Dr Bedford provided a written report of his findings dated 3 February 2020.
16. Dr Bedford stated that the internal examination was only to the brain; the neuropathologic examination and report was completed by VIFM Forensic Pathologist Dr Linda Elizabeth Iles. The internal examination confirmed the presence of a large left-sided intracerebral haemorrhage associated with deep brain stimulator wire tract. There were no other contributory injuries identified.
17. The ante-mortem toxicology sample was identified as non-contributory.
18. Dr Paul Bedford provided an opinion that the medical cause of death was ‘1(a) left-sided intracerebral haemorrhage associated with deep brain stimulator wire tract’.

## **CPU REVIEW**

19. In light of my concerns in relation to the medical management of Mr Waldon, I requested that the Coroners Prevention Unit (CPU) review this matter.<sup>10</sup> The CPU reviewed Mr Waldon's court file and Monash Medical Centre Records. They also requested statements from the Monash Medical Centre.
20. Monash Health provided three comprehensive statements from:
  - (a) Dr Carlos Scheinkestel Executive Director, Quality, Safety and Risk, Monash Health;
  - (b) Professor Henry Ma, Director of Neurology, Monash Health, and
  - (c) Associate Professor Andrew Danks, Head of Neurosurgery, Monash Medical Centre.

### Statement of Associate Professor R Andrew Danks

21. Associate Professor (A/Prof) Danks described that the neurosurgical procedure concluded without complication on 18 July 2019. He acknowledged that Mr Waldon's post-discharge anticoagulation regime was not well documented. The CPU advised that, although there is mixed documentation, it is likely that Mr Waldon continued with low dose enoxaparin (anticoagulant) injections following his discharge from pharmacy reconciliation records.
22. A/Prof Danks stated that Mr Waldon's readmission on 22 July 2019 was most likely due to a thrombo-embolic event and that no haemorrhage was detectable on the CT brain scan performed on this day. A/Prof Danks stated that, in consultation with the stroke team, he agreed that full anticoagulation<sup>11</sup> was indicated but that he did not participate in any discussions about the dosing regimen.

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<sup>10</sup> 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.

<sup>11</sup> Mr Waldon had been recommended a low dose prior to this, with full dose representing a higher dose

23. He stated that the neurosurgical team were informed of the further CT brain result of 23 July 2019 which demonstrated the new haemorrhage. A/Prof Danks opined that a neurosurgical intervention was not indicated.

Statement from Professor Henry Ma

24. Professor Ma identified that Mr Waldon was suffering from an ischaemic stroke upon his representation on 22 July 2019 and that, in consultation with the neurosurgical team, full therapeutic anticoagulation was recommended. Professor Ma wrote that the first dose of Clexane® (anticoagulant medication - 120mg to be taken twice per day) was administered at 9.00pm on 22 July 2019 and repeated at 8.00am on 23 July 2019.
25. At 6.55pm on 23 July 2019, Mr Waldon had a further neurological deterioration and an urgent repeat CT scan was arranged. Professor Ma stated that the CT scan was performed at 7.57pm. At 8.00pm on 23 July 2019, a further dose of Clexane® (120mg) was administered. At 8.10pm,<sup>12</sup> the CT scan was reviewed by the neurology team and Professor Ma stated that a new cerebral haemorrhage was identified at that time. He said that Mr Waldon deteriorated and died despite consultations with the neurosurgical team and attempts to reverse the anticoagulation.
26. Professor Ma provided the “Enoxaparin Adult Medication Guideline Full Anticoagulation” as an attachment in his statement. This guideline states that patients who weigh over 100kg should have an antiXa level at 3-5 hours post dose. AntiXa is a clotting factor product that allows measurement of the anticoagulant effect of Clexane®. A therapeutic range reassures clinicians that the appropriate dose of the anticoagulant is being administered for both therapeutic effect and to avoid excessive bleeding.
27. Professor Ma noted that there was an order written for an antiXa level at 3.45pm on 23 July 2019 but it was not drawn until 9.00pm. It was repeated at 11.20pm.<sup>13</sup> Both

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<sup>12</sup> Whilst it may not have changed the outcome, it seems that unfortunate timing that the report of the haemorrhage came through only ten minutes after another dose of anticoagulation was administered.

<sup>13</sup> Anti Xa levels are not routinely recommended as the pharmacokinetics of enoxaparin is predictable in non-obese persons with stable renal function. Levels are also recommended to be taken approximately 3-4 hours after a dose of enoxaparin. It is likely that when the decision was made that a level was indicated, this was not within the window from which a meaningful result would be available. Equally the level at 9pm also was 'too early' after the last dose of enoxaparin and hence the clinical interpretation is not possible. The 11.20pm dose represents the most accurate indication of the anticoagulant effect of the enoxaparin

levels demonstrated an elevated antiXa (2.8 and 1.38 with a therapeutic range being 0.5-1.0 U/ml for a level taken 2-4 hours post dose).

28. The guideline also requires that the dose of enoxaparin is calculated according to 'lean body weight' of patients over 100kg and that the haematology or cardiology unit ought to provide oversight of the administration. Professor Ma conceded that this did not occur and reported that both the neurology and stroke medical staff have been reminded of the importance of calculating the anticoagulant dosage by reference to a patient's lean body weight where a patient weighs more than 100kg.

Statements received from Dr Carlos Scheinkestel

29. As the executive responsible for Quality and Safety, Dr Scheinkestel reported that he had conducted an independent review of Mr Waldon's death in addition to reviews conducted by the Neurology Mortality and Morbidity meeting and by the Chair of the Venous Thromboembolism Review Committee.
30. Dr Scheinkestel concluded that whilst there were learnings to improve care, he considered Mr Waldon's death to be non-preventable. He believed that Mr Waldon's death did not meet the criteria of notification to Safer Care Victoria as a Sentinel Event.<sup>14</sup>
31. The key findings of Dr Scheinkestel's review were:
  - (a) The dose of enoxaparin prescribed was above the recommended dose for the weight of the patient with 120mg twice daily prescribed, while the correct calculated dose based on lean body mass was 107mg twice daily;
  - (b) An alternative clinical strategy obviating the need for anticoagulation was identified and discussed. This would have involved postponing the Deep Brain Stimulator (DBS) procedure until a 'Watchman Device'<sup>15</sup> was inserted, and

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<sup>14</sup> Safer Care Victoria requires reporting of significant health-care related adverse incidents and to conduct a root cause analysis.

<sup>15</sup> The Watchman™ device is a permanent implant designed to keep harmful blood clots from entering the blood stream.

- (c) The pharmacokinetics of low molecular weight heparin<sup>16</sup> is less predictable in the setting of obesity and chronic renal impairment; this was the case for Mr Waldon. Dr Scheinkestel said that these two factors should have prompted a discussion with the Haematology Unit<sup>17</sup> around monitoring the antiXa level. He stated that obese patients with poor renal function typical had unpredictable antiXa levels.

32. Dr Scheinkestel's review recommendations were:

- (a) Education of the Neurology Unit clinical staff in the correct procedure for use of low molecular weight heparin, especially in an obese patient. This has been completed;
- (b) Education of the Neurology Unit clinical staff about the need for documentation of a clear plan following DBS procedures. This has been completed;
- (c) Education of the Neurology Unit clinical staff about the management options for atrial fibrillation including the insertion of a Watchman Device in elective cases of DBS insertion to avoid the need for post-procedure anticoagulation. This has been completed; and
- (d) In response to this and other cases, a Hospital-wide anticoagulant stewardship<sup>18</sup> program partnering with pharmacy to oversee patients such as this is being considered; a proposal for this was presented to Clinical Council on 9 June 2020.

## COMMENTS

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

1. The Monash Medical Centre Neurology Unit did not follow their local guideline "Enoxaparin Adult Medication Guideline Full anticoagulation" resulting in the administration of a higher than recommended dose of enoxaparin and in a delay in

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<sup>16</sup> Enoxaparin is in the class of low molecular weight heparins

<sup>17</sup> Specialists in blood and blood clotting

<sup>18</sup> To provide clinical oversight, expert advice and reduce variation in practice and compliance to guidelines in high risk areas. Common other stewardship programs include antibiotic and opioid prescribing stewardship programs.



obtaining the results of Mr Waldon's antiXa assay.<sup>19</sup> This departure from best practice may have contributed to Mr Waldon's increased bleeding tendency and subsequent risk of developing a post-operative haemorrhage along the deep brain stimulator tract. However, this cannot be known with any degree of certainty.

2. The complexity of clinical decision making in weighing up the competing risks of anticoagulation and thrombosis represents a significant and ongoing challenge for clinicians treating patients with multiple comorbidities.
3. In light of the specific issues raised in Mr Waldon's medical management, I support Dr Scheinkestel's endorsement of an anticoagulant stewardship program at the Monash Medical Centre. This would guarantee a systemic, collaborative approach to promote safe and optimal anticoagulant therapy for patients at the Centre. Anticoagulant stewardship programs have been adopted in healthcare systems throughout Australia. A pertinent recommendation will follow.
4. I direct that copies of my Finding are provided to Safer Care Victoria and the Pharmacy Guild to share ongoing learning in the dangers of high-risk<sup>20</sup> medications.

## **FINDINGS**

1. Pursuant to section 67(1) of the *Coroners Act 2008* I make the following findings:
  - (a) the identity of the deceased was Carl David Waldon, born 12 January 1955;
  - (b) the death occurred on 24 July 2019 at the Monash Medical Centre, 246 Clayton Road, Clayton, Victoria 3168;
  - (c) I accept and adopt the medical cause of death ascribed by Dr Paul Bedford and I find that Carl David Waldon died from left-sided intracerebral haemorrhage associated with deep brain stimulator wire tract; and
  - (d) the death occurred in the circumstances described above.

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<sup>19</sup> An assay is an investigative procedure in laboratory medicine, mining, pharmacology, environmental biology and molecular biology for qualitatively assessing or quantitatively measuring the presence, amount, or functional activity of a target entity.

<sup>20</sup> <https://www.safetyandquality.gov.au/our-work/medication-safety/high-risk-medicines>

## RECOMMENDATIONS

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

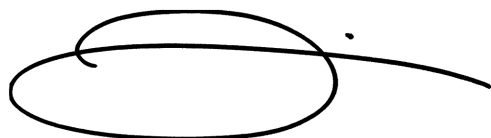
1. In the interests of public health and safety and preventing like deaths, I recommend that the Monash Clinical Council supports the proposed Hospital-wide anticoagulant stewardship program.

Pursuant to section 73(1B) 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:

Anne Morgan, Senior Next of Kin  
Ms Lanii Birks of Monash Health  
Safer Care Victoria  
Pharmacy Guild of Australia, Victorian Branch

Signature:



**Audrey Jamieson**



**CORONER**

Date: 5 February 2021

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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.

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