MAGISTRATES COURT TASMANIA

MAGISTRATES COURT *of* TASMANIA

CORONIAL DIVISION

Record of Investigation into Death (Without Inquest)

Coroners Act 1995
Coroners Rules 2006
Rule 11

I, Robert Webster, Coroner, having re-investigated the death of Vivienne Lorraine Wallace

Find, pursuant to Section 28(1) of the *Coroners Act* 1995 (the Act), that

a) The identity of the deceased is Vivienne Lorraine Wallace ("Ms Wallace");

b) Ms Wallace died in the circumstances set out below;

c) Ms Wallace's cause of death was due to natural causes, namely atherosclerotic and hypertensive coronary vascular disease; and

d) Ms Wallace died between 21 August and 23 August 2021 at Blackmans Bay, Tasmania.

Introduction

1. In making the above findings I have had regard to the evidence gained in the investigation into Ms Wallace's death which includes:

- Police Report of Death for the Coroner;
- Affidavits establishing identity and life extinct;
- Affidavit of Dr Donald Ritchey, forensic pathologist;
- Medical records obtained from Ms Wallace's general practitioner;
- Medical records obtained from Calvary Hospital;
- Report of Dr Anthony Bell, coronial medical consultant, dated 9 November 2021;
- Records obtained from the cardiologist Dr Warrick Bishop;
- Letter from Hobart Pathology dated 22 February 2022;
- Report of Dr Anthony Bell, coronial medical consultant, dated 2 March 2022.
- Letters from Dr Warrick Bishop dated 14 April 2022 and 10 May 2022 and
- Report and curriculum vitae of Professor Richard Harper consultant and interventional cardiologist dated 6 May 2022.

2. Because of the advice from the forensic pathologist, Dr Ritchey, Coroner Andrew McKee advised Ms Wallace's daughter and senior next of kin, Mrs Stolp, in writing on 23 September 2021 that her mother's death was due to natural causes, namely atherosclerotic and hypertensive coronary vascular disease. He also advised that in these circumstances an inquest was not required and that his function as coroner had concluded.

3. Subsequently, Dr Anthony Bell reviewed this file and provided a report dated 9 November 2021. In that report he says the decision to use flecainide, which is an anti-arrhythmic drug, in this case was an unusual one. He indicated that further information was required to determine whether or not it was appropriate to use that medication. Dr Bell's report was brought to my attention on 9 November 2021 and on that day I advised the Chief Magistrate that consideration should be given to reopening the investigation into the death of Ms Wallace.

4. I received a written direction from the Chief Magistrate dated 26 January 2022 to reopen this investigation and re-examine the findings made by Coroner McKee. Mrs Stolp was advised of this development on 7 February 2022. I therefore sought, via s59 of the Act, any medical records in the possession of Hobart Pathology and the cardiologist, Dr Bishop, who prescribed flecainide. Dr Bishop's records were received on about 10 February 2022 and by letter, received on 24 February 2022, Hobart Pathology advised they had no records on file for Ms Wallace between 1 July and 1 September 2021[1]. Those records were given to Dr Bell for comment. In addition I wrote to the cardiologist Dr Paul MacIntyre on 8 March 2022 and I provided him with the relevant documentation. Dr Bell then conferred with Dr MacIntyre. Dr Bell provided a subsequent report of 2 March 2022 in which he confirmed his previous opinion.

5. Because of Dr Bell's opinion procedural fairness dictated that I afford Dr Bishop an opportunity to comment on that opinion. This he has done in his letters of 14 April 2022 and 10 May 2022. In addition his professional indemnity insurer has, via its solicitor Mr Charles Law of Murdoch Clarke, provided an independent medical opinion of Professor Harper which is set out in his report of 6 May 2022.

Health history

6. Ms Wallace was aged 73 years at the date of her death. The records of the general practitioner disclose she had a number of medical conditions of significance which included depression, hypertension dermatomyositis, Raynaud's phenomena, fibrosing alveolitis and osteopenia.

[1] Dr Bell recommended any pathology results between those dates be obtained.

Those records also indicate a heart murmur was noted in 2013, colonic polyps were found that same year and 2 polyps were removed in 2019. In 2020 it was noted Ms Wallace had asthma and chronic obstructive pulmonary disease (COPD) and gastro-oesophageal reflux disease (GORD). The Calvary Hospital records reveal that in 2018 an ACAT assessment was conducted the assessment being she required basic care. Those records also indicate Ms Wallace smoked 40 cigarettes a day up until approximately 1974 and she suffered vertigo and tinnitus in 2021.

The circumstances leading to Ms Wallace's death

7. In April 2021 Ms Wallace suffered a fracture of the tibia and fibula. Immobilisation resulted in the healing of the tibia but the fracture to the fibula did not heal. Accordingly surgery was recommended.

8. A pre-admission electrocardiogram (ECG) was performed at the Calvary Cardiac Centre. This study showed a normal sinus rhythm and an auto read algorithm suggested consideration of left ventricular hypertrophy. Professor Harper's interpretation of that study is that it was within normal limits.

9. On 16 August 2021 Ms Wallace was admitted to Calvary Healthcare at its Lenah Valley campus. An open reduction and internal fixation of the fractured fibula was performed that day. During surgery Ms Wallace developed atrial fibrillation whereby her heart rate increased to 110 bpm but it was slowed to 60 bpm with intravenous metoprolol. On the ward an ECG was performed and it showed atrial fibrillation with a ventricular rate of 88 bpm. That afternoon Ms Wallace was reviewed by Dr Bishop and he obtained a trans-thoracic echocardiogram, which showed normal left ventricular size, wall thickness, systolic function and no evidence of left ventricular hypertrophy. Professor Harper points out that an echocardiogram is a far more sensitive test for the determination of left ventricular hypertrophy than an ECG. Professor Harper's interpretation of the echocardiogram is that it showed a structurally normal heart. Metoprolol and flecainide were prescribed orally. Overnight Ms Wallace's vital signs were stable however the atrial fibrillation continued.

10. On 17 August 2021 further testing was conducted but the results were unchanged. Ms Wallace was discharged on her usual medication with the addition of flecainide 50 mg daily, metoprolol 50 mg twice daily and rivaroxaban. Dr Bell notes there are no blood tests associated with this admission.

11. On 21 August 2021 Mrs Stolp visited her mother. Ms Wallace complained of increasing shortness of breath and fatigue over a few days. A doctor's appointment which had been made was brought forward and was scheduled to take place on 25 August 2021. At approximately 11 AM on 23 August 2021 Mrs Stolp found her mother deceased at home.

Post-mortem examination

12. Dr Ritchey performed a post-mortem examination in this case on 25 August 2021. After performing an external and internal examination and after considering the histology Dr Ritchey says:

"The cause of death for the 73-year-old woman, Vivian Lorraine WALLACE, was atherosclerotic and hypertensive coronary vascular disease.

Ms WALLCE was unexpectedly found deceased in her home several days after discharge from the Calvary Hospital where she underwent an orthopaedic procedure to repair stress fractures in the left foot.

The autopsy revealed a normally developed and nourished elderly woman with advanced natural disease of the heart and its major blood vessels. No pulmonary thromboemboli or deep vein thrombi were identified at autopsy."

13. I accept Dr Ritchey's opinion.

Information With Respect to the Use of Flecainide

14. Flecainide is effective in treating both ventricular and supraventricular arrhythmias. However, its use is limited by concern about toxicity, particularly its pro-arrhythmic effects.

15. The Pharmaceutical Benefits Scheme in Australia limits the use of flecainide to serious supra-ventricular arrhythmias and treatment with this drug must be commenced in hospital.

16. In the USA there is a black box warning in respect of this drug. Such a warning is required by the US Food and Drug Administration for certain medications that carry serious safety risks. A review of the world literature revealed reports of 568 patients treated with oral flecainide for paroxysmal atrial fibrillation/flutter (PAF). Ventricular tachycardia was experienced in 0.4% of these patients. Of 19 patients in the literature with chronic atrial fibrillation (CAF), 10.5% experienced ventricular tachycardia (VT) or ventricular fibrillation (VF). Flecainide is not

recommended for use in patients with CAF. Case reports of ventricular pro-arrhythmic effects in patients treated with flecainide for atrial fibrillation/flutter (AF) have included increased premature ventricular contractions (PVCs), VT, VF, and death. Furthermore the rate of ventricular arrhythmias (new or exacerbated) is 7 to 13%. Worsening heart failure occurs at a rate of approximately 9%.

17. Other warnings are included in the drug information leaflet. These leaflets are written for both healthcare providers and patients so that medications are used safely and effectively in order to reach the required therapeutic outcomes. Flecainide use in patients with structural heart disease (heart failure, myocardial infarction/ischemia) may exacerbate pro-arrhythmic events (ventricular arrhythmias) and increase the risk of death. Acute decompensated worsening of heart failure is possible in patients with chronic heart failure.

18. In addition there is an interaction between flecainide and sertraline. In this case Ms Wallace was prescribed 1x 50mg tablet of sertraline daily. Sertraline may slow down how quickly a patient's liver processes flecainide which may result in the level of flecainide increasing in a patient's blood which in turn may cause more side-effects than normal. In this case Dr Bell is of the view, given the dose of flecainide was low, that this is probably not a significant issue. Dr Bishop noted the low dose of sertraline and did not consider the dose to be clinically significant given the low dose of flecainide he prescribed which was in keeping with the Cardiac Society of Australia and New Zealand (CSANZ) recommendations for the management of atrial fibrillation that flecainide is prescribed in conjunction with an AV nodal blocker; metoprolol.

19. Data from the Cardiac Arrhythmia Suppression Trial (CAST)[2] suggested that the increase in malignant arrhythmias was due to the use of flecainide in the setting of ischaemia and/or cardiac structural abnormalities (scar from a prior infarction). Flecainide did not increase mortality when used for the treatment of supraventricular arrhythmias in structurally normal hearts.

[2] The **Cardiac Arrhythmia Suppression Trial** (**CAST**) was a controlled study designed to test the hypothesis that suppression of premature ventricular complexes (PVC) with class I anti-arrhythmic agents after a myocardial infarction (MI) would reduce mortality. The study was conducted in the United States between 1986 and 1989 and included over 1700 patients in 27 centres. The study found that the tested drugs increased mortality instead of lowering it as was expected. The publication of these results in 1991/92, in combination with large follow-up studies for drugs that had not been tested in CAST, led to a fundamental change in the treatment of MI patients.

20. European guidelines on this drug's use include a section on how to commence flecainide therapy. The current guidelines say flecainide is indicated in patients with a normal heart, hypertension, minor heart disease, and good left ventricle function, and this likely applied to some 80% of the patients with PAF and 50% of the patients with persistent AF. Overall, the use of flecainide in practice is low: the Euro Heart Survey on AF indicates that around 13% of persistent AF patients and 17% of PAF patients are treated with class IC antiarrhythmic drugs including flecainide or propafenone. Prior to initiating flecainide treatment, patients should be examined for contraindications including structural heart disease, second- or third-degree AV block, left bundle branch block, right bundle branch block (when associated with left hemiblock), asymptomatic non-sustained ventricular tachycardia, cardiogenic shock, reduced cardiac output, post-MI, and significant renal or hepatic impairment. ECG parameters determined should include PR, QT, and QRS interval prolongation (≤120 milliseconds). In addition, the presence of ischemia and tolerance to exercise should be determined. Dr Bishop says he tends to refer to the Australian guideline however he contends he fulfilled the European guidelines' recommendation for patient assessment prior to commencement of the medication. I agree with that contention. He excluded structural heart disease, second or third-degree AV block, left bundle branch block, right bundle branch block, he noted there was no evidence of asymptomatic non-sustained ventricular tachycardia nor cardiogenic shock, nor reduced cardiac output, Ms Wallace was not post myocardial infarction and there was no significant renal or hepatic impairment.

The Use of Flecainide in this case

21. The first issue which must be considered before flecainide is used is whether a patient has a serious supra-ventricular arrhythmia. In this case the rhythm was well tolerated and not life-threatening. The AF appeared to be paroxysmal (not chronic) and therefore flecainide was used to restore and maintain a normal sinus rhythm.

22. Next, prior to use, the fact a patient has a structurally normal heart and good heart function should be demonstrated. In addition a patient's levels of electrolytes in the blood should be normal so that electrical impulses can be conducted in the body. In this case the pre-operative ECG suggested consideration of left ventricular hypertrophy; it did not confirm that condition. Dr Bell says this was a warning sign. Professor Harper disagrees. He says both the ECG and echocardiogram showed a structurally normal heart. The post mortem examination showed significant cardiac disease including left ventricular hypertrophy (2.2 cm concentric), cardiomegaly (500 gm heart, normal weight 285 gm), stenotic atherosclerosis of a diagonal

branch of the left anterior descending coronary artery (80% narrowing) and congestive cardiac failure.

23. The symptoms recorded by Mrs Stolp when she visited her mother on 21 August 2021 (shortness of breath and fatigue) were indicative, in Dr Bell's view, of impairment of cardiac function by flecainide (and metoprolol). This, Dr Bell says, increases the risk of sudden death. On this point Dr Bishop disagrees strongly with Dr Bell's opinion. Dr Bishop says the more likely scenario is Ms Wallace was developing an acute coronary syndrome, or possibly even an episode of atrial fibrillation. Professor Harper says Dr Bell's assessment that the shortness of breath was indicative of the use of flecainide is unreliable. He says her lung disease could have caused the shortness of breath. In addition atrial fibrillation, particularly if the heart rate was fast, could have caused shortness of breath and fatigue or alternatively it could have been a premonitory symptom of an acute coronary syndrome.

24. Dr Bishop performed an echocardiogram which was essentially normal, with mild aortic valve regurgitation and mild left atrial enlargement which Dr Bishop says are a consequence of hypertension and ageing. Dr Bell says the lack of blood tests was probably of no consequence in this case. Dr Bishop says he had results of blood tests from May 2021 and he had no reason to believe in the intervening period there would have been any reason to think these results would have appreciably changed.

25. The post mortem examination showed the extent of cardiac disease which was not appreciated clinically or on the echocardiogram. One example of this, according to Dr Bell, was the left ventricular cardiac wall thickness which was 1.2 cm on the echocardiogram but it was measured at 2.2 cm during the post mortem. Dr Bishop suggests the difference might be due to significant inflammation and swelling as a result of the acute atherosclerotic ischaemic event.

26. Dr Bell concludes by saying Ms Wallace had heart disease which was not detected either on clinical examination or on the echocardiogram which was performed. Accordingly there was no specific indication that flecainide should not be used. However in all the circumstances it is Dr Bell's opinion that the choice to use this drug in this case was a poor one. Dr Bishop disagrees. He says in the absence of a prior diagnosis of coronary artery disease in which Ms Wallace demonstrated no symptoms and had no clear-cut risk factors other than a history of hypertension in the treatment of paroxysmal atrial fibrillation, the European, American and Australian guidelines all suggest use of an anti-arrhythmic and those guidelines do not include

beta blockade or calcium channel blocker as first line anti-arrhythmic therapy. Dr Bishop says the use of flecainide in this case was in keeping with the CSANZ guideline as a first line treatment. Had there been a clear indication of previous significant coronary artery disease with uncontrolled ischaemic symptoms or abnormality of left ventricular function then he agrees that flecainide would not be a logical first choice; however this was not the case. He notes other antiarrhythmics such as amiodarone and sotolol that could have been chosen have limitations which limit the use in a patient such as Ms Wallace.

27. Professor Harper says the fact an ECG showed sinus rhythm prior to Ms Wallace's surgery and she subsequently developed atrial fibrillation indicates to him her atrial fibrillation was likely to be paroxysmal in nature. In those circumstances he says the correct treatment was to start Ms Wallace on an anticoagulant to reduce the risk of thromboembolic stroke, to start her on a medication to prevent her heart beating too fast when she was in atrial fibrillation and to start an anti-arrhythmic drug to try and restore sinus rhythm and hopefully prevent further episodes of atrial fibrillation. He notes Dr Bishop prescribed rivaroxaban as the anticoagulant, metoprolol to reduce the heart rate in atrial fibrillation and flecainide as an anti-arrhythmic agent. Professor Harper says all 3 prescriptions were entirely appropriate. He says the dose of flecainide was low, namely 50 mg twice daily. He says an initial low dose is worth trying but to achieve satisfactory control of atrial fibrillation many patients require a higher dose and the typical dose of flecainide as an anti-arrhythmic agent is 100 mg twice daily. He explains there are only 3 anti-arrhythmic drugs available in Australia to treat atrial fibrillation, namely amiodarone, sotalol and flecainide. Flecainide is typically used as a first line anti-arrhythmic agent in patients with structurally normal hearts on the echocardiogram, a normal or near normal ECG and without a history of coronary artery disease and in particular without a history of prior myocardial infarction which is the main contraindication for the use of flecainide. Professor Harper says Ms Wallace fulfilled all the criteria for the safe prescription of flecainide. Sotalol can be used as a first-line anti-arrhythmic agent and it is not contraindicated if there is left ventricular dysfunction but it is generally less well-tolerated than flecainide and has side-effects of its own including respiratory side-effects. He says in a small proportion of patients sotalol can prolong the QT interval and cause serious ventricular arrhythmias. Amiodarone has many long term adverse side-effects and would never be used as a first-line anti-arrhythmic agent in Ms Wallace's circumstances[3]. It is generally reserved for patients with severe structural heart disease and life-threatening arrhythmias. Professor Harper is of the opinion the majority of Australian cardiologists would have treated Ms

[3] This is because of Ms Wallace's history of pulmonary fibrosis/fibrosing alveolitis.

Wallace in exactly the same way as Dr Bishop did. He says Dr Bishop's prescription of flecainide in conjunction with metoprolol and rivaoxiban was entirely consistent with the CSANZ guidelines on the use of flecainide and it was consistent with the European and American guidelines as well. He says some cardiologists may have used sotalol initially and then switched to flecainide if sotalol was ineffective or caused side-effects and vice versa but Professor Harper is confident that those who would have initially used sotalol would not be critical of those who first used flecainide.

28. Professor Harper confirms that in this case amiodarone would never be used by cardiologists in Australia as a first-line drug treatment. He says if flecainide, an appropriate dose of say 100 mg bd, had failed to control Ms Wallace's proximal atrial fibrillation, sotalol would be considered as the next choice in preference to amiodarone. If sotalol failed, then consideration would be given to other measures to control atrial fibrillation such as catheter electrode ablation or AV node ablation and pacing rather than long-term amiodarone.

Conclusion and Comments

29. Professor Harper therefore says Dr Bell's opinion is incorrect. *"The echocardiogram clearly showed that there was no significant structural abnormality of the heart that would be a contraindication to the use of flecainide nor was there any abnormality on the ECG that would contraindicate the use of flecainide."* He does not believe the ECG showed evidence of left ventricular hypertrophy and the echocardiogram, which is more accurate than the ECG in determining left ventricular hypertrophy, did not show left ventricular hypertrophy. Given Professor Harper's training, experience and qualifications in cardiology span approximately 45 years[4] and Dr Bell's experience is confined to emergency medicine I accept the opinion of Professor Harper over that of Dr Bell. To be clear then there was nothing unusual about Dr Bishop's treatment of Ms Wallace. Dr Bishop's choice of flecainide **was not** a poor decision. To the contrary Dr Bishop's treatment of Ms Wallace was consistent with all relevant guidelines and with clinical practice in Australia.

30. The circumstances of Ms Wallace's death are not such as to require me to make any comments or recommendations pursuant to Section 28 of the Act.

31. I convey my sincere condolences to the family and loved ones of Ms Wallace.

[4] See Professor Harper's Curriculum Vitae.

Dated: 4 July 2022 at Hobart in the State of Tasmania.

Robert Webster
Coroner