IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2014 6263

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)

Section 67 of the Coroners Act 2008

Amended pursuant to *Section 76 of the Coroners Act 2008* on 10 November 2016[1]

Findings of:	CAITLIN ENGLISH, CORONER
Deceased:	Beverley Joy Leggett
Date of birth:	3 April 1935
Date of death:	9 December 2014
Cause of death:	1(a) Pulmonary thromboembolism in the setting of right elective total hip replacement
Place of death:	The Royal Melbourne Hospital 300 Grattan Street, Parkville, Victoria

[1] This document is an amended version of the finding into Beverley Leggett's death dated 28 October 2016. Typographical corrections have been made pursuant to Section 76 of the *Coroners Act 2008 (Vic)*, in response to a telephone call from Senior Next of Kin Glenn Leggett received on 9 November 2016.

Background

1. Beverley Joy Leggett was born on 3 April 1935. She was 79 years old at the time of her death. Ms Leggett was retired and lived alone at 88 Noga Avenue, East Keilor in Victoria. Mrs Leggett's husband had suffered a stroke some seventeen years previously and resided in a residential facility. The couple had three children, and eight grandchildren. Mrs Leggett was supported on the aged pension.

2. Mrs Leggett lived independently in her own home. Although she was becoming frail, she shopped and cooked for herself, enjoyed walking with the neighbours and attended a weekly crochet club. Mrs Leggett had a current Victorian drivers licence and continued to drive herself. Mrs Leggett's daughter lived in Adelaide. She did have local support in her son, who lived in nearby Rosanna, who would mow her lawns and generally keep in telephone contact each week.

3. Mrs Leggett had a medical history of hypertension, hypercholesterolemia, osteoarthritis and possible mild cognitive impairment. She had also reportedly had cataracts removed from both eyes. Otherwise she had no other significant, known medical conditions. She had been prescribed aspirin, celebrex, crestor and panadol osteo.

4. On 20 January 2014, Mrs Leggett presented to her general practitioner, Dr Tai Wai Kang with significant right hip pain. Investigation found severe osteo arthritis and she was referred to the Royal Melbourne Hospital (RMH) Orthopaedic Department for a hip replacement to be performed by Department head, Associate Professor Andrew Bucknill.

5. Mrs Leggett underwent a preoperative physiotherapy assessment by Ms Bernada Cavka. On 25 March 2014, Ms Cavka wrote Mrs Leggett presented with a two year history of right hip pain with an insidious onset, recently aggravated by a fall down some steps. She was limited to walking for fifteen minutes at a time and had difficulty negotiating steps and completing domestic duties.[2] Mrs Leggett was then referred for preoperative physiotherapy and hydrotherapy which she attended between 15 April and 6 June 2014. She was scheduled for a right total hip replacement on 1 December 2014, with instructions to withhold aspirin and celebrex for seven days prior to the surgery.

The coronial investigation

6. Mrs Leggett's death was reported to the Coroner as it fell within the definition of a reportable death in the *Coroners Act 2008.*

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

[2]Royal Melbourne Hospital Allied Health Department correspondence dated 25 March 2014.

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. As part of the coronial investigation, a report has been obtained from the forensic pathologist who examined Mrs Leggett, as well as a statement from Associate Professor Andrew Bucknill and Mrs Leggett's medical records from the Royal Melbourne Hospital.

9. I have based this finding on the evidence contained in above materials. In the coronial jurisdiction facts must be established to the standard of proof which is the balance of probabilities.[3]

Circumstances in which the death occurred

10. On 1 December 2014, Mrs Leggett underwent a right total hip joint replacement, performed by A/Prof Andrew Bucknill at the RMH. The procedure was uncomplicated and the operation uneventful although Mrs Leggett had suffered from delirium in the post-operative recovery stage and this no doubt affected her ability to mobilise. On 3 December 2014, she was able to sit, stand and walk fifteen metres with the assistance of two staff and a two wheel frame but she was still noted to have residual delirium.[4] A brain CT scan was performed on 5 December 2014, which confirmed the provisional diagnosis of underlying Alzheimer's Dementia,[5] and she was scheduled for further cognitive assessments during her rehabilitation stay.

11. The operation report on 1 December 2014, recorded that an explanation of the complications and risks of hip surgery were explained to Mrs Leggett by A/Prof Andrew Bucknill, including *'Leg length discrepancy, DVT, PE (inc. fatal), infection, neurovascular injury, anaemia requiring transfusion, dislocation, pain, stiffness, wear, loosening.'*

12. Mrs Leggett was discharged to the Royal Melbourne Hospital Aged Care Rehabilitation Unit on 5 December 2014. She was prescribed aspirin for six weeks post operatively for deep vein thrombosis prophylaxis. On admission she was noted to be *'pleasantly confused'* albeit alert by nursing staff and noted to be at risk of falling due to her mental state by the physiotherapist. Mrs Leggett's mobility appeared to have been somewhat compromised by her confused mental state and hence I note her increased risk of developing a blood clot.

13. RMH discharge notes on 5 December 2014, noted the gaols for discharge were *'aim to discharge home with services, prevention of ulcer, prevention of DVT/PE, maintain upper limb strength*

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[3] This is 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.

[4] The delirium was noted to have improved but was still only scoring 5/10 as assessed by Dr Eric Seal.

[5] TRAC Assessment – RMH (City) consultant assessment and opinion by Dr Eric Seal dated 5 December 2014.

through exercises'.[6] The management plan for admission to the rehabilitation unit, noted *'DVT prophylaxis with aspirin as per orthopaedics'* and to optimise analgesia which would aid in mobility.

14. Mrs Leggett was still disorientated to time and place on the 6 December 2014 and alert but confused as to the day and month on 8 December 2014, but managing to mobilise with a four wheeled frame with supervision. This mild confusion continued the following day although Mrs Leggett used her four wheel frame to ambulate to the toilet.

15. Five minutes after Mrs Leggett had left her bedside, she was found by nursing staff to be unresponsive, lying on the bathroom floor, having also hit her head on the wall during the fall. A Code Blue cardiac arrest was instigated and Mrs Leggett was resuscitated and transferred to the Intensive Care Unit.

16. A transthoracic echocardiogram of Mrs Leggett's heart was subsequently performed to investigate the cause of her collapse. This investigation showed right ventricular dilation of the heart and severe tricuspid valve regurgitation, which suggested to her treating practitioners she had suffered from a massive pulmonary embolus. She was then give anti-thrombotic treatment using the pharmacological agent t-PA.[7] Mrs Leggett subsequently developed multi organ failure, found to be unresponsive to maximum medical support. In consultation with Mrs Leggett's family and her treating medical team, a decision was taken to cease active management. Mrs Leggett was palliated and passed away at 10.20 pm on 9 December 2014.

Post mortem examination

17. On 11 December 2014, Dr Victoria Francis, Forensic Pathologist at the Victorian Institute of Forensic Medicine, conducted a post mortem inspection on Mrs Leggett. Dr Francis completed a report on 13 February 2015 in which she formulated the cause of death as 'pulmonary thromboembolism in the setting of right elective total hip replacement.' I accept Dr Francis' opinion as to the medical cause of death.

18. Dr Francis reported a presumptive diagnosis of thromboembolus was made, the thrombus was thrombolysed and multi organ failure ensued. A post mortem whole body computed tomography scan showed only a right hip prosthesis and a right pleural effusion. Dr Francis commented the cause of death was framed on the basis of the information available to her in the absence of a full post mortem examination.

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[6] Royal Melbourne Hospital Admission and Discharge SUMMARY, page 4.

[7] T-PA is an abbreviation of 'Tissue Plasmin activator' which is a protein involved in the breakdown of clots.

Finding

19. I find that Beverley Joy Leggett died on 9 December 2014 from a pulmonary thromboembolism in the setting of right elective total hip joint replacement at the Royal Melbourne Hospital in Parkville, Victoria.

Venous thromboembolism prophylaxis in Victoria

20. Mrs Leggett was exposed to a number of known risk factors in embarking upon her hip surgery, not the least of which was her elderly age. She was the recipient multi-modal venous thromboembolism (VTE) prophylaxis in the preoperative, intra-operative and post-operative phases of her care, which included early mobilisation and oral aspirin therapy.

21. Mrs Leggett was given a provisional diagnosis of thromboembolism at the time of her collapse. Indeed, she was treated with anti-thrombolytic agents, and a presumptive diagnosis of pulmonary embolus was made by Dr Francis.

22. Deep vein thrombosis and pulmonary embolism are well known complications arising from hip replacement surgery. VTE prophylaxis has generally been known to focus on early post-operative mobilisation and anti-coagulant therapy such as heparin, clexane and aspirin. In light of Mrs Leggett's cause of death as formulated by Dr Francis, a statement was requested from the Royal Melbourne Hospital to address some of the questions raised in relation to current VTE prophylaxis protocol for patients such as Mrs Leggett.

23. On 21 April 2015, the Head of the Department of Orthopaedic and Trauma Surgery, Associate Professor Andrew Bucknill (A/Prof Bucknill) provided a response to the coroner regarding what thromboprophylaxis therapy plan had been in place for Mrs Leggett post-surgery. A/Prof Bucknill advised Mrs Leggett was prescribed a multi-modal venous thromboembolism (VTE) prophylaxis. This includes pre-operative, peri-operative and post-operative measures:

    a. The pre-operative measures include risk screening and cessation of any medications that might increase the risk of bleeding;

    b. Peri-operative measures include hypotensive anaesthesia, mechanical prophylaxis with pneumatic foot compression, minimisation of femoral work time and minimisation of surgical duration through the use of efficient surgical technique;

    c. Post-operative measures include instructions on the operation report regarding DVT prophylaxis, including early mobilisation, intermittent foot compression and chemoprophylaxis of Aspirin 100 milligrams, orally every six hours.

24. A/Prof Bucknill indicated that this regime was carried out in Mrs Leggett's case:

a. Prior to surgery Mrs Leggett was screened for additional risk factors for VTE, of which none were found. She was asked to cease her usual Aspirin and Celebrex (to decrease the risk of intraoperative or post-operative bleeding) one week before the surgery;

b. Mrs Leggett underwent hypotensive anaesthesia using a Spinal Anaesthetic, a foot pump was used, applied to the contralateral foot during surgery and reduced surgical time using an un-cemented implant system.

c. Post-operative instructions were for early mobilisation and Mrs Leggett was assisted out of bed the morning after surgery, the earliest possible time after spinal anaesthetic and evening surgery. Intermittent foot compression were applied to the contralateral foot at the completion of the surgery and continued on the ward, documented to still be applied on 5 December 2014. The foot compression pumps were discontinued after transfer to the rehabilitation unit on 5 December 2014, possibly as a result of Mrs Leggett's confused state. Aspirin was prescribed and commenced on the morning after the surgery.

25. RMH was asked how RMH guidelines for thromboprophylaxis of VTE differed from the National Health and Medical Research Council (NHMRC) guidelines (2009) for the prevention of venous thromboembolism in a patient admitted to Australian hospitals. A/Prof Bucknill advised there are many differing guidelines for prophylaxis of VTE around the world and much controversy concerning the interpretation of evidence of the efficacy and risks. Many Australian orthopaedic surgeons considered the NHMRC guidelines, published in 2009 to be out of date. Since the NHMRC guidelines were published there has been much further literature and discussion, especially within orthopaedic surgery. As a consequence of this, many arthroscopy centres around Australia use guidelines that do not match the NHMRC guidelines.

26. A/Prof Bucknill reported the rate of fatality from pulmonary embolus (PE) had dramatically fallen and is no longer the leading cause of death after a total hip replacement. Since the implementation of multi modal prophylaxis such as screening for risk, improved surgical and anaesthetic techniques and early mobilisation, fatal PE now accounts for 26% of the total cause of death after total hip replacement. Cardio-pulmonary complications account for 47%, mostly due to myocardial infarction. The risk of fatal PE is 0.1-0.2% in large series which include high risk patients and without the use of anti-coagulants.

27. A/Prof Bucknill further advised despite many large trials examining the use of anticoagulants like low molecular weight heparin (LMWH) for prophylaxis of VTE, there is not a single study that has shown that the routine use of LMWH leads to a reduction in the risk of a fatal PE. There is no evidence that the use of potent anti-coagulants like heparins lead to a reduced risk of fatal PE or to reduced all-cause mortality either. However, there is some evidence that risk of all-cause mortality is lower with the use of multi-modal prophylaxis as received by Mrs Leggett. In the absence of extra-

ordinary risk factors for VTE, the relative risk of mortality (all causes) is 2.5 times higher with potent anti-coagulants than with multi-modal prophylaxis as received by Mrs Leggett.

28. The orthopaedic literature has documented a proliferation of safety and efficacy concerns about the routine use of anticoagulants. Severe problems like persistent wound drainage and haematoma formation lead to surgical site infection, leading to multiple surgical revisions over many months, which in turn leads to catastrophic complications such as amputation, fatal bleeding and neurological injury. A/Prof Bucknill reports the serious nature of such complications in not well recognised by the wider medical community or the NHMRC. As a result of the more recent literature, RMH does not follow the current NHMRC guidelines for VTE prophylaxis.

Coroners Prevention Unit Review

29. The Coroners Prevention Unit[8] (CPU), at my direction, reviewed the adequacy of the National Health and Medical Research Council (NHMRC) Clinical Practice Guidelines for the Prevention of Venous Thromboembolism and Pulmonary Embolism (Deep Vein Thrombosis and Pulmonary Embolism) in Patients admitted to Australian Hospitals (2009) for procedures in orthopaedic surgery.

30. The CPU found the proportion of deaths after arthroplasty that are due to PE is low[9][10]and does not seem to be prevented by the routine use of anticoagulants[11] which may well result in higher all-cause mortality.[12] Multimodal prophylaxis appears to be safer and more effective.[13] Described in one recent review of VTE thromboprophylaxis for hip and knee surgery as essential,[14] multimodal prophylaxis has now been recommended by the American College of Foot and Ankle Surgeons instead of chemical prophylaxis.[15]

31. In correspondence with the CCOV on 13 October 2015, the NHMRC advised the VTE guidelines, developed to provide clinical advice on the management of patients admitted to Australian hospitals, were designed to be current for a period of up to five years in order to ensure that guidelines reflect advances in relevant scientific evidence. As the VTE guideline is no longer current the NHMRC has requested an update of the guideline from the Australian Commission on Safety and Quality in Health Care in its capacity as the agency leading the national review of the prioritisation of clinical

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[8] The Coroners Prevention Unit (CPU) is a specialist service created to strengthen their prevention role and provide them with assistance on issues pertaining to public health and safety.
[9] Cusick LA, Beverland DE. The incidence of fatal pulmonary thromboembolism after primary hip and knee replacement in a consecutive series of 4253 patients. J Bone Joint Surg [Br] 2009;91-B:645-8.
[10] Venous Thromboembolism (VTE) Risk Screen *in* Medication Chart. The Royal Melbourne Hospital, Parkville 2015.
[11] Dahl OE, Gudmundsen TE, Bjornara BT, Solhei DM. Risk of clinical pulmonary embolism after joint surgery in patients receiving low-molecular weight heparin prophylaxis in hospital. A 10 year prospective register of 3,954 patients. Acta Orthop Scand 2003; 74(3): 299-304.
[12] Sharrock NE, Della Valle AG, Go G, Lyman S, Salvati S,. Potent Anticoagulants are Associated with a Higher All-cause Mortality Rate After Hip and Knee Arthroplasty. Clin Orthop Relat Res 2008;66:714-721
[13] Dealla Valle AG, serota A, Go G et al. Venous Thromboembolism Is Rare with Multimodal Prophylaxis after Total Hip Arthroplasty. Clinical Orthopaedics And Related Research 2006;444:146-153.
[14] BudhiparamaNC Abdel MP, Ifran NN, Parratte S. Venous Thromboembolism (VTE) Prophylaxis for Hip and Knee Arthroplasty: Changing Trends. Curr Rev Musculoskelet Med. 2014 Jun;7(2):108-16.
[15] Fleischer AE, Abicht BP, Baker JR, Boffeli TJ, Jupiter DC, Schade VL. American College of Foot and Ankle Surgeons' clinical consensus statement: risk, prevention, and diagnosis of venous thromboembolism disease in foot and ankle surgery and injuries requiring immobilization. J Foot Ankle Surg. 2015 May-Jun;54(3):497-507.

practice guideline development in Australia. The commission, following a period of public consultation, will submit a final draft list of priority guidelines to the Australian Health Minister's Advisory Council for is approval.

Comments

Pursuant to section 67(3) of the *Coroners Act 2008*, I make the following comments connected with the death:

The National Health and Medical Research Council (NHMRC) Clinical Practice Guideline for the Prevention of Venous Thromboembolism (Deep Vein Thrombosis and Pulmonary Embolism) in Patients Admitted to Australian Hospitals (2009) appears to be out of date and does not reflect current evidence. In particular, the Guideline does not appear to adequately reflect the requirements for thromboprophylaxis of patients undergoing orthopaedic surgical procedures, taking into account the complications of therapy with potent anticoagulants.

In light of the response from the Royal Melbourne Hospital and a review of the literature by the CCOV it is evident the current VTE guidelines require review in order to bring them into line with current global best practise as identified in the most recent literature available referred to in Associate Professor Bucknill's response to the CCOV.

Recommendations

Pursuant to section 72(2) of the *Coroners Act 2008*, I make the following recommendation connected with the death:

I recommend the NHMRC request the Australian Commission on Safety and Quality in Health Care expedite its review of current VTE guidelines to provide relevant, evidenced based, best practice guidelines for Australian clinicians in 2016, with a particular focus on consideration of the risks verses the benefits of thromboprophylaxis for this group of patients, taking into account complications after surgery related to the use of routine anticoagulants.

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

Mr Glenn Leggett, Senior Next of Kin

Associate Professor Andrew Bucknill, Royal Melbourne Hospital

Professor Anne Kelso, AO, National Health and Medical Research Council

Constable A Minichiello, Coroner's Investigator, Victoria Police

Signature:

CAITLIN ENGLISH
CORONER
Date: 10 November 2016