CORONERS COURT
OF NEW SOUTH WALES

Inquest:	Inquest into the death of Madeline Newcombe
File number:	2015/214041
Hearing dates:	24 – 26 August 2020
Date of findings:	2 October 2020
Place of findings:	Coroners Court, Lidcombe
Findings of:	Deputy State Coroner E. Truscott
Catchwords:	Coronial Law – Cause and manner of death – Pulmonary Thromboembolism within 24 hours Bilateral Total Knee Arthroplasty – Aspirin and Mechanical Prophylaxis – Anti-coagulants – Body Mass Index (BMI) – Risk Factors and Assessment– Hospital Guidelines – Surgeon's Standing Orders – Multi-modal innovations to reduce the occurrence of fatal venous thromboembolism (VTE)
Representation:	**Counsel Assisting** Dr K Sant instructed by Ms C Healey-Nash of the NSW Crown Solicitor's Office **Nepean Private Hospital and EEN Ms D Jarvis** Mr D Lloyd instructed by Ms Ms I Kristiansen of Kennedys Law **Dr P Sunner** Mr M Lynch instructed by Mr J Vijayaraj of Avant Law **EN Ms J Tunks and RN Ms M Berroya** Ms L Toose, solicitor advocate, NSW Nurses and Midwives' Association

Findings:	**Identity** Madeline Newcombe **Date of Death** 21 July 2015 **Place of Death** Nepean Public Hospital **Cause of death** Pulmonary Thromboembolism **Manner of death** Madeline Newcombe died in hospital having undergone bilateral knee replacement in a single surgical procedure at Nepean Private Hospital the previous day. She developed a deep vein thrombosis in her lower right leg which subsequently migrated to her lungs resulting in her collapse when mobilising the following morning. This was a rare event despite the administration of aspirin and mechanical prophylaxis.

IN THE CORONERS COURT
LIDCOMBE
NSW

Section 81 Coroners Act 2009

REASONS FOR DECISION

Introduction

1. This is an inquest into the death of Madeline Newcombe (Madeline) on 21 July 2015 at the Nepean Public Hospital following a bilateral knee replacement performed in a single surgical procedure[1] by Dr Pavitar Sunner at Nepean Private Hospital (the Hospital) on 20 July 2015.

2. An autopsy concluded the cause of death was pulmonary thromboembolism (a blood clotting in the lungs). It was noted that many large and smaller pulmonary emboli were identified originating from the right leg, in particular within the veins of the deep calf muscles as well as within the popliteal vasculature (which is behind the knee).[2]

3. Whilst a venous thromboembolism (VTE), including pulmonary embolism, is a recognised complication of total knee replacement, a fatal pulmonary thromboembolism within 24 hours is apparently and thankfully a very rare event.

4. The focus of the inquest was whether the thromboembolism could have been prevented, or detected earlier, so as to prevent Madeline's death.

Background

5. Madeline was 63 years of age, having been born on 5 August 1951. She was from a large family and had three brothers and three sisters, most of whom were able to

[1] Bilateral knee surgery is the term used in these findings to indicate the performance of total knee replacement in a single surgical procedure distinct from having two separate surgeries where a single knee is replaced successively.
[22] Post Mortem Report, Dr J Duflou, Tab 2.

attend the hearing but unfortunately due to Covid-19 restriction protocols viewed the proceedings via video link in another court room. Madeline met her husband Thomas in 1970 and they married in 1973. Thomas and Madeline had two children, Michael and Amanda, and Madeline was grandmother to Amanda and her partner Brendan's four children and Michael and his partner Alex's two children. She was very family focussed and had a strong work ethic. Michael described her as always supportive, she rarely complained and she wasn't one to make a fuss, particularly about herself. She was always up to giving something a go, never shying away from a challenge.

6. Madeline and Thomas worked together running small businesses such as a newsagency and a post office which occupied at least six days a week while raising their children. Madeline was as adept at balancing the books as she was in laying a foundation for the house she and Thomas built.

7. Michael spoke of the great love and adoration between his parents Thomas and Madeline during their 42-year marriage and that they had spent most of their married life working together and being together day and night. The most important thing for Madeline was the love she shared with her family. It is so terribly sad she is no longer with them and Thomas is not able to spend his retiring years with his beloved wife.

Arthritic Knees

8. Thomas describes that Madeline was very active throughout her life but she suffered an injury to her right knee in 2011 which was corrected by arthroscopic surgery the same year. About 18 months later Madeline experienced pain in her right knee which she managed through light exercise and walking. After about another year she began to experience increased pain and reduced mobility in her right knee and gradually gained weight and developed arthritic pain in her left knee.

9. By 2015, walking for 10 minutes or doing the shopping caused Madeline significant pain. Madeline had experienced pain and stiffness in both her knees

for some time, the right one being the more severe.[3] As a result, she was referred by her doctor to an imaging facility and to see Dr Sunner, an orthopaedic surgeon.

10. In June 2015, Madeline attended Dr Sunner with the X-ray images. Dr Sunner explained that the images showed advanced arthritis in both knees. He advised that knee replacement surgery was the ultimate treatment.[4]

11. Dr Sunner discussed with Madeline the options of either having each knee replaced in two separate successive surgeries some months apart or having the surgery and hospitalisation completed in one round. Dr Sunner said in his statement that he explained the procedure, the post-operative rehabilitation as well as the risks associated with the surgery. Dr Sunner said that he told Madeline that there was a risk of blood clot in her legs and the clot going to her lungs. He said at that point he had not carried out any assessment of risk of Madeline developing a deep vein thrombosis (DVT) because he does that on the day of the surgery. Accordingly, he did not discuss with her the level of risk nor the prophylaxis to mitigate that risk.[5]

12. Whilst Madeline was in Dr Sunner's rooMs she decided to proceed with the bilateral procedure. This seeMs to be much in keeping with Michael's description of her approach to life - of "leaning in", of getting things done that needed to be done. Dr Sunner booked Madeline in to have the surgery on 20 July 2015.

Surgery and Post-Operative Orders

13. The surgery was successfully performed and Madeline was transferred to the post-surgical orthopaedic ward with patient controlled analgesia (PCA). Dr Sunner was assisted by anaesthetist Dr Philip Corke during surgery. Dr Sunner set out post-operative orders of "Routine Limb Observations, IV antibiotics, Analgesia, ice, Aspirin, calf compressors, x-rays, FBC (full blood count) MFC". These orders were consistent with Dr Sunner's standing orders.

14. Madeline was prescribed aspirin 150mg daily the first given at 18:00 on 20 July 2015. The aspirin was prescribed by Dr Corke on the direction of Dr Sunner who

[3] Dr Sunner's statement of 22 February 2017, Tab 5, paragraph 1.
[4] Dr Sunner's statement of 22 February 2017, Tab 5, paragraph 3.
[5] T34.30-T35.25 25/8/2020.

made the choice of aspirin for VTE prophylaxis (with mechanical prophylaxis) and decided not to prescribe a low molecular weight heparin (LMWH).[6]

15. Madeline was returned to the ward at 12.15 pm with a Pico dressing, crepe bandage and tubi-grip on each knee.[7] Sequential compression devices (SCDs) (the mechanical prophylaxis) were applied and at 6 pm the aspirin was administered. Madeline also used her PCA. Madeline appeared to be recovering well though she complained of some pain to her right lower-thigh which had apparently resolved by the following morning.

Madeline's Collapse on Mobilisation

16. At about 10 am on 21 July 2015 Madeline was attended to by the physiotherapist. It was anticipated that Madeline would mobilise by walking after which she would have a shower and the TED stockings would be fitted. She completed a number of in bed exercises and then out of bed exercises with good effect and within tolerable pain levels. These including marching on the spot and walking five metres. It was whilst walking the second five metres that Madeline collapsed and despite immediate and appropriate resuscitative treatment, she was unable to be revived.

The Issues for Inquest

17. The Coroner must make findings in accordance with section 81 of the *Coroners Act 2009* (the Act) in relation to the person's identity, date, place and manner and cause of death. The focus of the inquest was the manner of Madeline's death in terms of the risk and prevention of VTE; the other issues were not controversial.

18. Under s 82 of the Act a Coroner can determine whether any recommendations are necessary or desirable.

19. An issues list was provided to the parties as follows:
    (a) Was Madeline given adequate prophylaxis for VTE?
        With specific consideration of the following:

[6] The medication chart can be found in the Nepean Private Hospital records at page 92, Tab 15 and also at annexure F of Ms Tunks' statement (Tab 8), amongst other places.
[7] Pico dressing is a Negative Pressure Wound Therapy device to keep the wound free of excess fluid.

i. Was Madeline correctly assessed as being at high risk of VTE?
ii. Was aspirin alone adequate chemoprophylaxis, taking into account that mechanical prophylaxis was also utilised?
iii. Was mechanical prophylaxis used appropriately, including consideration of any use of graduated compression (or TED) stockings?

(b) Could the DVT have been detected earlier?

20. Expert evidence from two orthopaedic surgeons, Dr Stephen Quain and Dr David Campbell, and from a haematologist, Dr Steve Flecknoe-Brown was given concurrently or in a "conclave". There were two main issues – the general or standard protocols for prophylaxis of VTE when performing total knee arthroplasties and, more specifically, the best approach in Madeline's case. This involved a discussion about the assessment of risk, taking into account her weight and that she was having both knees replaced.

21. In relation to the general protocols in 2015, guidelines in the brief and a number of tendered medical research papers and journals about whether a LMWH such as Clexane would have been more appropriate than aspirin suggest there was a variation in recommended medication regimes globally at that time.

22. Indeed, the issue as to how best to respond to the risk of VTE while balancing other risks, particularly wound bleeding, remains an ongoing discussion to this day. These findings should not be considered in any way a resolution of that discussion or an endorsement of any particular approach.

23. It is necessary to deal with issue (b) first as it involves setting out some relevant events on the ward and background to this investigation.

Could the Deep Vein Thrombosis (DVT) Have Been Detected Earlier?

24. During the coronial investigation a number of matters relating to the nursing practices in carrying out the post-operative instructions were unclear particularly in relation to the application of compression stockings and Madeline's pain management.

25. The inquest had the benefit of receiving statements clarifying those issues and nursing expert reports which addressed, amongst other things, whether Madeline's pain warranted further action. That matter involved consideration of any complaint of pain, the scores on the pain chart and the doses of analgesia she required.

26. When Thomas returned to visit on 21 July 2015 at about 9:45 am he observed that the dressing was no longer covering the thigh on the right leg. The coverings on that side were about 5 to about 10 cm lower than the coverings on the left leg. Madeline told him, "They moved the bandage down and it's much better now".[8] That she had little or no pain by that time is consistent with the pain charts and the evidence of the physiotherapist, Jessica Wheatley.

27. At around 10:00 am Madeline commenced some exercises under Ms Wheatley's supervision. Ms Wheatley has provided a statement in which she noted that Madeline had informed her she was feeling well and had minimal pain.[9] Ms Wheatley assisted Madeline out of bed to have her first walk which is consistent with early mobilisation treatment. Whilst standing close to Ms Wheatley, Madeline reported "seeing stars", her eyes rolled, and she fell to the floor.[10]

28. At 10:30 am a Rapid Response Team was called, arriving at 10:32 am. Resuscitation, involving cardiopulmonary resuscitation (CPR) and thrombolysis, was commenced and continued for about an hour and forty minutes.[11]

29. At 11:55 am Madeline was transferred to Nepean Public Hospital's Intensive Care Unit. However, Madeline did not recover and at 12:09 pm a decision was made to cease CPR and Madeline was declared deceased at Nepean Public Hospital at 12:10 pm.

Compression Stockings

30. It was initially thought that thigh-high TED stockings may have been used as Thomas described Madeline as wearing compression stockings when he visited

[8] Supplementary statement, Tab 4.1, paragraph 12.
[9] Tab 11.1, paragraph 5. She noted that in the record on the day.
[10] Ms Wheatley's statement at Tab 11.1, paragraph 5 and attached entry in the progress notes.
[11] The emergency response data collection form is at pages 66-77, Nepean Private Hospital records, Tab 15.

Madeline after the operation. He said that they went above Madeline's knee to high on her thigh[12] but when he visited again the next morning, the covering had been removed from her right thigh and she expressed that she felt more comfortable because it had been rolled down and/or removed.

31. Progress Nursing notes entered at 3:15 pm on 20 July 2015 had recorded ticks next to TEDs and SCDs.[13] The overnight nurse who had care of Madeline, Endorsed Enrolled Nurse (EEN) Deborah Jarvis had documented at 4:20 am in her Progress Note, that Madeline had *"TEDS and SCDS insitu"*.[14] EEN Jarvis provided a statement dated 12 December 2017 in which she confirmed that she had *"carried out lower limb observations at around 0010 and 0545 on 21 July 2015 and also observed that Mrs Newcombe had TED stockings fitted as well as sequential compression devices activated".*[15]

32. That was potentially a matter of some significance as TED stockings are tightly fitted so if rolled down they may have the potential to act as a tourniquet in the sense of compressing the veins. However, following further investigation of this issue, statements from nursing staff who worked on the ward, the Director of Nursing at the Hospital and Ms Wheatley reported that thigh-high TED stockings were neither in stock nor used at the time. Only ankle-to-knee TED stockings were available at the Hospital at the time.[16] The Director of Nursing, Jill McEvoy-Williams, has provided documents establishing the ordering details.[17]

33. The nurse who cared for Madeline in the evening after her surgery, Enrolled Nurse (EN) Jade Tunks, also explained in her supplementary statement that Madeline had mid-thigh to mid-calf dressings on both legs, consisting of a crepe bandage and tubi-grip.[18] Registered Nurse (RN) Maria Patricia Berroya, who nursed Madeline in the morning of 21 July 2015, agreed, describing the tubi-grip as a

[12] Mr Newcombe's statement, Tab 4, paragraphs 14 & 17.
[13] Brief of Evidence, Volume 2, Tab 15, page 58.
[14] Brief of Evidence, Volume 2, Tab 15, page 59.
[15] Brief of Evidence, Volume 1, Tab 9, paragraph 21.
[16] See supplementary statement of Ms Rushton at Tab 7.1, paragraph 2; supplementary statement of Ms Tunks at Tab 8.1, paragraph 10; supplementary statement of Ms Jarvis at Tab 9.1, paragraph 5; supplementary statement of Ms Berroya at Tab 10.1, paragraph 10; statement of Ms Wheatley at Tab 11.1, paragraph 9.
[17] Tab 14.1, annexure B.
[18] Tab 8.1, paragraph 7. I note that Ms Tunks said in both of her statements that TEDs would not be applied until a day after surgery after the removal of the bulky dressings.

"tubular bandage".[19] RN Berroya gave evidence and explained that Madeline had a Pico dressing directly on the surgical site to absorb any fluids. This was covered by a crepe bandage and the tubi-grip, which kept the crepe bandage in place. This is consistent with the Recovery Ward Report.[20]

34. After information that thigh-high TED stockings were not then used by the Hospital, a further statement was obtained from Thomas clarifying that he was not specifically indicating that Madeline was wearing TED stockings. Indeed, he has since seen TED stockings and does not believe that is what he saw on Madeline after the operation.[21]

Madeline's Thigh Pain

35. Madeline arrived on the ward at about 12:35 pm on 20 July 2015. Thomas visited Madeline at about 1:30 pm. Thomas stayed for the afternoon and at about 4 pm he observed the SCDs (the mechanical compression device) being applied to both of Madeline's lower legs. At about 5 pm and again when he visited in the evening at about 7 pm, Madeline told Thomas that she had pain in her lower right thigh area.[22] Thomas encouraged her to discuss it with the nurses and she said she would.[23] None of the nurses who looked after Madeline recall her doing so.

36. Amanda visited in the afternoon between around 4 and 5 pm and she confirms that she was present when Madeline complained of pain in her right thigh and that Thomas advised Madeline to tell the nurse. Amanda said that she told a nurse her mother was experiencing pain in her thigh and she says the nurse responded that she would be back soon to check Madeline's vitals and that she would check the pain then.

37. During the inquest Amanda was present when EN Tunks gave evidence about the nursing care she provided Madeline from 2 pm to 10 pm on 20 July 205, including recording her vital observations and her pain management. Amanda reported to those assisting me that EN Tunks was not the nurse she spoke with about Madeline's pain.

[19] Tab 10.1, paragraph 6.
[20] Brief of Evidence, volume 2, Tab 15, page 55.
[21] Supplementary statement, Tab 4.1, paragraph 7.
[22] Statement at Tab 4, paragraphs 15-16.
[23] Supplementary statement, Tab 4.1, paragraph 10.

38. The significance of Madeline's leg pain relates to whether it was an early warning sign that she was developing a blood clot in her leg. However, a total knee replacement is a procedure well known to be accompanied by significant pain. Dr Quain, orthopaedic surgeon, provided an expert report, in which he remarks "knee replacement is regarded as a painful procedure and clearly bilateral knee replacements even more so".[24] The experts gave universal support to this proposition and said that Madeline's report of pain would not have been a matter sufficient to alert the nursing staff to consider seeking a medical review (by a doctor).

39. Nursing staff looking after Madeline that evening (20 July 2015) and overnight completed the usual pain management observation chart, which can be found in the Hospitals records.[25] Madeline's pain score at rest varied from 3 to 5 over that period and was zero at 8:00 am the morning of 21 July 2015. Pain with movement, when recorded, varied between 4 and 6. It also appears to have been zero at 8:00 am on 21 July 2015.

40. The nursing staff who gave evidence attested that the pain scores together with the identification of thigh pain would not cause them to suspect that their patient was developing a DVT because they would expect the pain to be in the calf area not the thigh.

41. Dr Sunner said that he tells his patients that knee replacement is a very painful procedure. He said that a DVT occurs more commonly a few days after the operation rather than within 24 hours. He said pain in that area of the thigh near or just behind the knee would not be the usual sort of pain that would indicate the possibility of a DVT. It was his practice to review his patient the day following the surgery and have his patients undergo an ultrasound on the third day after surgery.[26]

42. Dr Quain opined that mid-thigh pain could be explained if there had been a tourniquet used during surgery. The Intra-Operative Nursing Care completed

[24] Tab 12, page 2.
[25] Tab 15, volume 2, page 86.
[26] T13.5-34 25/08/2020.

during surgery indicates that Madeline's right leg had a tourniquet applied for 62 minutes and then her left leg for 59 minutes[27].[28]

43. I note that EN Tunks was asked what she would have done if her patient had complained of thigh pain and she said: "*I would have assessed the thigh area and like, palpated it, checked for any bruising. I would have then discussed with the patient that the doctor uses a tourniquet during the procedure, so it can be common to have some thigh pain. I would have then notified the RN in charge, and then notified the CMO and VMO (medical officers)".* Ms Tunks clarified that the medical officers would only be notified if there was a finding out of the ordinary and a complaint of thigh pain was not something out of the ordinary, depending on the pain level.[29]

44. In terms of the pain scores of 3 and 4 in the afternoon of 20 July 2015, the experts were in agreement that they were scores which would not cause alarm bells in any event. Finally, in response to the query whether the pain was indicative of the development of a DVT, Dr Campbell remarked, *"Most thromboses are asymptomatic and certainly in the first few days it would be undetectable clinically because the knee replacement pain so overwhelms any peripheral pain. So in our world we anticipate DVT to be asymptomatic observation".*[30]

45. Dr Flecknoe-Brown said that the development of DVTs usually took longer than 24 hours but that experience from long haul flights demonstrate that they can develop within that period of time.

46. EEN Jarvis, who was the nurse caring for Madeline overnight, was asked about the level of pain Madeline reported as well as her use of the PCA. She reported that Madeline used the PCA twice on her shift and that her use was well below the maximum allowed. Madeline's reported pain scores of 6 on movement and 3 on rest were well within normal limits.[31] She said that only a complaint of pain if significant would be recorded in a progress note.

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[27] Tab 15, page 53.
[28] Dr Quain also remarked that "these days the tourniquet usage is generally decreased to the actual timing of cementing the prosthesis."
[29] T28.5-37 24/08/2020.
[30] T5.1-5 25/08/2020.
[31] T4.41-50, T5.27 25/08/2020.

47. The evidence is such that even if there had been a record made of Madeline's report of specific right-sided lower-thigh pain as witnessed by Thomas and Amanda; it was not a matter that would cause nursing staff to request a medical review. Indeed given the evidence that the development of DVT can be asymptomatic, the pain in Madeline's thigh was likely not to be indicative let alone related to the development of the DVT.

48. The answer to issue (b) is no.

Was Madeline Given Adequate Prophylaxis For VTE?

49. Dr Sunner considered that daily 150mg aspirin was the appropriate chemical prophylaxis but had Madeline been at increased risk of VTE he would have prescribed LMWH. One factor which can increase the risk of developing a venous thrombosis is being overweight.[32]

50. The experts prepared their reports on the basis of Madeline's weight identified by the post mortem examination which appears anomalous to a number of other varying weights recorded on Madeline's medical records so it is important to resolve this issue first.

Body Mass Index (BMI) - a Risk Factor

51. There are three classes of obesity. Class 1 BMI is 30-34.9, Class 2 BMI is 35-39.9 and Class 3 BMI is 40 or greater. Those classes may also be described respectively as mild, moderate or severe.

52. The Post Mortem report identified that Madeline's BMI was 38.3 kg/m^2. This was calculated on the basis of measurements taken upon her admission to the Department of Forensic Medicine then at Glebe where Madeline's weight was recorded as 94.5 kg and her height as 1.57 m.

53. Accordingly, based on the Post Mortem Report, Madeline's BMI was at the upper end of Class 2. Dr Sunner disputed that measurement and it is apparent that it is highly anomalous with other records including pathology, Madeline's self-report,

[32] Dr Flecknoe-Brown said that obesity increases the risk of developing venous thrombosis about threefold. (T25.6 26/08/2020)

Thomas' knowledge, pre-assessment nursing records and admission nursing records.

54. On 6 July 2015, in preparation for the surgery Madeline attended a pathology unit where her bloods, weight and height measurements were taken. The pathology records dated 7 July 2015 were forwarded to Dr Sunner and are on the hospital file. They identify Madeline's height as 159 cm (5'2") and weight as 79.7 kg.

55. Thomas estimates that by the time Madeline had her surgery her usual weight of about 75 kg had increased by about 10 kg. He thought Madeline's height was 5'1"-5'2".[33]

56. Madeline was admitted to the Hospital the day prior to the surgery and as part of the admission process she completed a "Patient Health History" recording her height and weight as 155 cm and 78 kg[34] respectively.

57. Madeline was attended to by RN Claudine Rushton who completed a number of documents. One of them was called *"Screening your patient for Malnutrition"*. That document records that Madeline's weight on 19 July 2015 was 80 kg, though the "0" appears to be written over the figure "6" as if the initial figure recorded was 86. A similar entry appears in a document "Operation Check List" completed by a ward nurse.

58. Another hospital document likely completed by RN Rushton was the first part of the *Pre-Operative Assessment* section of the *"Anaesthetic Record"* which identifies Madeline's weight as 86 kg. I note that the anaesthetist Dr Corke in his statement identifies that he used the weight recorded on that document to prescribe the doses of Tranexamic Acid.[35]

59. The weight recorded at post mortem must be incorrect[36] as it is 15 kg heavier than the pathology record taken just 2 weeks earlier. It is likely that Madeline's weight was about 80-85 kg at the time she had surgery. This is consistent with

[33] Supplementary statement, Tab 4.1, paragraphs 18-19.
[34] Though the handwriting is difficult to read, counsel assisting suggested it could be 72kg.
[35] Tab 6, paragraph 6.
[36] Likely a handwriting/transcription error from triage to examination preparation.

Madeline's self-report, Thomas' statement, Dr Sunner's assessment and most of the documents completed by RN Rushton.

60. Regardless of the precise weight, at the time Madeline had her surgery her weight placed her within the classification of Class 1 or mild obesity with a BMI of 31.6–33.6.

Assessment of Madeline's Risk of Developing a VTE

Issue (a) (i) whether Madeline was correctly assessed as being at high risk of VTE.

61. Dr Sunner's position is that Madeline was a routine or low risk of VTE and accordingly his "Standing Orders" were appropriate and prevailed over the hospital assessment identification that Madeline was a high risk of VTE.

62. This issue ultimately became whether Madeline's risk of VTE was assessed by Dr Sunner and if so was his assessment correct?

Assessment of Risk and Applicable Guidelines and Policy

63. Dr Sunner provided four statements (22 February 2017, 18 January 2020, 19 May 2020 and 10 July 2020[37]) and he gave evidence at the hearing.

64. In his first statement Dr Sunner did not say that he had carried out any risk assessment. In this statement Dr Sunner said that his post-operative orders included aspirin and calf compressors. He said that it is his practice for knee replacement patients not to have enoxaparin (anticoagulant heparin) because aspirin with other physical modalities such as calf compressors is acceptable DVT prophylaxis in total knee replacement as per the Australian Orthopaedic Association (AOA) guidelines as well as the American Academy of Orthopaedic Surgeons (AAOS) and the American College of Chest Physicians (ACCP) guidelines.[38]

[37] Tabs 5–5.3.
[38] Attached to his final statement was a copy of those August 2012 Standing Orders/Protocol of Treatment and Care for his patients undergoing a Total Knee Replacement.

65. In his second statement in January 2020 Dr Sunner referred to the Arthroplasty Society of Australia (ASOA) 2010 guidelines for VTE prophylaxis for hip and knee arthroplasty (2010 ASOA guidelines). He said that the risk assessment was carried out in accordance with those guidelines. He did not say that he carried out an assessment. He did not describe the level of risk other than saying that Madeline did not fit the criteria for increased risk of pulmonary embolus (PE) and then referred to the criteria against that found in the 2010 ASOA guidelines. He did say that Dr Corke the anaesthetist did not express any reservations about the use of the aspirin as he (that is, Dr Corke) did not consider her to be at high risk of a DVT/PE.

66. In his third statement Dr Sunner addressed a question asked by those assisting me: *"Please indicate the location of any individualised risk assessment for thromboembolic disease in the records, explaining all the factors taken into account and the weight given to each if this is not evident from the record. Please note this should only include factors taken into account at the time."* Dr Sunner replied: *"I have previously set out, in my prior statements, the factors I had considered when making an assessment, however I did not document these as individual risk factors when making a decision with Ms Newcombe"*.[39]

67. In his evidence Dr Sunner said that he assessed Madeline by reference to the pathology reports which included her blood coagulation results (which were within normal limits) and her height and weight, those results had been sent to his rooms which he took to the Hospital. He said he assessed Madeline's risk on the day of but prior to the surgery.[40] He said he assessed that her risk was routine[41] or low.[42] He did not document his assessment nor did he make notes to calculate her BMI or record what it was.[43]

68. In his second statement when he addressed the 2010 ASOA guidelines criteria, which includes "marked" obesity, Dr Sunner identified this definition as being synonymous with Class 3 or "severe" obesity. He was of the opinion that Madeline did not have marked obesity.[44] In his evidence he adhered to describing the term

[39] Tab 5.2, paragraph 4.
[40] T32.12 25/08/2020.
[41] T35.5-25 25/08/2020.
[42] T38.28 25/08/2020.
[43] T32.47 25/08/2020.
[44] Tab 5.1, paragraph 4.

"marked obesity" to mean "severe obesity" though there was no literature that he had read to support such description.[45]

69. Dr Sunner said in his evidence that at the time when Madeline had her surgery he used and still uses LMWH for patients who are at high risk of DVT/PE.[46]

70. The Hospital requires their Nursing Staff to carry out an assessment of the risk of a patient developing VTE and that assessment identified that Madeline was at high risk. That assessment was solely reliant on the nature of the surgery Madeline was having consistent with the position of both the AOA and the AAOS that *"Patients undergoing elective hip or knee arthroplasty are already at high risk for venous thromboembolism".*

71. In his second statement Dr Sunner referred to the most recent 2018 ASOA guidelines for VTE prophylaxis for hip and knee arthroplasty (2018 ASOA guidelines) which suggest that a patient would require three or more minor risk factors to be considered high risk of VTE. He identified that Madeline had two such risk factors being a BMI of greater than 30 and knee replacement. He identified under these new 2018 ASOA guidelines she would not be considered a high risk of VTE.

72. Dr Sunner did not consider that the fact Madeline was having bilateral knee arthroplasty increased her risk of developing a DVT/VTE, and in his evidence he said that if it did increase risk it was only by a factor of one or two,[47] which in his opinion did not place Madeline in the high risk category.

<u>Arthroplasty – a Risk Factor</u>

73. In addition to the issue of obesity, the discussion about the risk of Madeline developing VTE involved the fact that her surgery was for both knees as opposed to a single knee.

[45] T37.49 25/08/2020.
[46] T18.25 25/08/2020.
[47] T22.3 25/08/2020.

74. RN Rushton completed a "VTE Risk Assessment Form" (Risk Form) where she ticked "Hip or knee arthroplasty e.g. Joint Replacement surgery".[48] The Nepean Private Hospital Policy identifies all patients who are undergoing this surgery as being at high risk of VTE.

75. The Risk Form has a number of other criteria to evaluate the risk but given that Madeline's risk, by virtue of the nature of the surgery, was already assessed as high, it was unnecessary for RN Rushton to complete the form any further.

76. RN Rushton affixed a red sticker on the first page of the nursing progress notes and on the relevant medication records and fluid charts. The purpose of the sticker is to provide a clear and consistent alert to nursing staff that Madeline was a high risk VTE patient.

77. The Risk Form has a number of guidelines set out on page 2. Those guidelines recommend that a person undergoing hip or knee arthroplasty surgery should receive the following treatment: *"Low Molecular Weight Heparin e.g. Enoxaparin 40mg / day OR Dalteparin 5000U / day AND Sequential compression devices (SCDs) / with or without TED Anti-Embolism Stockings (TEDs)".*

78. The guidelines apparently apply to employees of the Hospital but where a surgeon, none of whom are hospital employees, has "standing orders" for post-operative care, their orders prevail over the Hospital's guidelines.

79. Dr Sunner was taken to the NSW Health Policy for Prevention of Venous Thromboembolism which applies to NSW Public Hospitals and Affiliated Health Organisations.[49] It is unclear whether such policy applies to private hospitals but in any event Dr Sunner conceded he was not aware of the content of that policy and relevantly he was unaware that it recommended against the use of aspirin in a total knee replacement. He said it had never been suggested to him by anyone at the Hospital there was an issue about not complying with their policy.

[48] Nepean Private Hospital records, Tab 15, pages 32-33. It was labelled as a 'Trial Form', noted to have been implemented from November 2013.
[49] Brief of Evidence, Volume 2, Tab 17.

Tranexamic Acid

80. Before addressing the issues dealt with by the experts there is a matter which needs to be documented. Immediately prior to surgery, anaesthetist Dr Corke administered 1g of tranexamic acid. He also prescribed two 1g doses to be given at 16:00 on 20 July 2015 and 24:00 on 20 July 2015. To use Dr Corke's words, tranexamic acid is an *"antifibrinolytic agent, which basically means that it stops the new clots that are formed from dissolving and it's given because these procedures, arthroplasties, whether they be single or bilateral, and have an associated blood loss. So it's an attempt to reduce the amount of bleeding and, therefore, reduce the amount of transfusion requirements".*[50]

81. Despite its function, tranexamic acid apparently does not increase the likelihood or risk of thrombus and/or pulmonary embolus. According to all expert evidence, post-surgical doses of tranexamic acid played no role in Madeline developing thrombus.

The Expert Conclave

82. Dr Johan Duflou, the forensic pathologist who carried out the autopsy gave evidence further to his report. He clearly set out from his examination and the analysis of the histology that the thrombus was recent and there was no evidence to suggest that Madeline had any DVT prior to her surgery. It was accepted by all experts that the aetiology of the fatal PE was from the development and migration of a post-surgical DVT in at least Madeline's right calf.[51]

83. In his expert report Dr Flecknoe-Brown remarked that Madeline had a very active thrombotic reaction to the surgery and, according to his understanding of the applicable guidelines pertaining to the now discredited weight at autopsy, he suggested that she should have been administered a LMWH 12 hours prior to surgery but even if that had occurred it may not have prevented the outcome. In his evidence he said that he took no issue with a standard risk patient being prescribed aspirin as per the ASOA guidelines.[52]

[50] T45.25 24/08/2020.
[51] It may be both calf muscles but only her right was examined at autopsy.
[52] T23.9 26/08/2020.

84. In his evidence Dr Flecknoe-Brown premised the pre-surgical prophylaxis provided that the surgery was under spinal anaesthetic; which Madeline's was not, it was under general anaesthetic. After hearing from Dr Campbell and Dr Quain that any LMWH would be given after rather than before general surgery Dr Flecknoe-Brown withdrew his opinion that a LMWH should have been administered. Dr Campbell added that the dose of an LMWH would have been prophylactic rather than a treatment dose and all experts agreed that this would not have prevented Madeline developing VTE. In examination by Mr Lynch, Dr Flecknoe-Brown re-stated his preference that LMWH with the multi-modal components, rather than aspirin with the multi-modal components, was employed.

85. Dr Flecknoe-Brown provided a brief explanation of three factors that can lead up to a patient developing venous thrombosis following surgery. The first relates to the physical thickness or *"constitution of the blood…the way the person normally deals with the balance between the need to form a clot where it's needed at a site of injury and the need to make sure that that clot doesn't extend beyond that point".*

86. The second is *"injury to the blood vessels themselves and, of course, this could be just a bump but in the case of surgery the injury - it's obvious that there's injury to …the blood vessel wall which does tend to stimulate the formation of a normal clot. That's what clots are for, they seal off injured blood vessels*".

87. The third factor in thrombosis is stasis, which is *"the blood flow slowing down either because the patient…is immobile, or the limb or the part of the patient has compromised circulation"*.[53]

88. He said that an "*overweight person moves less and their veins are being compressed by … folds in the groins that you see when there's a bit more fat around the thigh and the abdomen"*.[54]

89. Dr Flecknoe-Brown spoke of some of the innovations which he described as "multi-modal" measures to decrease the incidence of VTE which are now employed. They are directed at improving a patient's stasis such as maintaining fluid and blood volume and introducing pre-warmed fluids during surgery and

[53] T24 26/08/2020.
[54] T25.7 26/08/2020.

anaesthetic techniques such using spinal anaesthetic instead of general anaesthetic and engaging the patient in early post-surgical mobilisation.[55]

90. Dr Quain added that lessening or foregoing the use of a tourniquet in more recent times has assisted a patient's stasis.[56] Dr Campbell suggested the motivation behind the decreasing use of a tourniquet was to decrease the pain experienced by the patient and thus the use of analgesia[57] which would in turn improve a patient's mobilisation.

91. Dr Flecknoe-Brown acknowledged that around the time of Madeline's death the use of aspirin rather than LMWH was controversial and he thought that LWMH was still protective and that there were many surgeons who would not use aspirin over a LWMH. He described that there had been a move by the Australian Orthopaedic Community towards aspirin rather than LWMH and he felt that due to the multi-modal improvements that this use is less controversial that it was five years ago.[58]

92. Dr Campbell said that DVTs are more commonly experienced by patients who have a knee rather than a hip replacement. Some 40% (perhaps more) of knee replacement patients develop some below the knee DVT and it is understood that many, if not most, of these asymptomatic DVTs resolve without any extra intervention. The PE mortality rate however, is about the same between hip and knee replacement patients.[59] He said that the likelihood that a below knee DVT may become a PE in *"one in a thousand".*[60]

93. Dr Quain opined that the risk of a knee replacement causing a PE is 0.5% and if the patient is having a bilateral knee replacement, that risk would double to 1% which he remarked was a very low risk and one which multi-modal practices made a reasonable risk in orthopaedic practice. Dr Flecknoe-Brown said that the risk is multiplied rather than added so it would be 0.5 x 0.5 which provides a risk factor of 2.5%. Dr Quain disputed this "four-fold" calculation.[61]

[55] T25.3-26.7 26/08/2020.
[56] T28.10 26/08/2020.
[57] T29.10 26/08/2020.
[58] T30.3-9 26/08/2020.
[59] T17.15-18.15 26/08/2020.
[60] T17.27 26/08/2020.
[61] T31.3-15 26/08/2020.

94. Dr Quain described that Madeline had a borderline or just over borderline increased risk in developing a VTE due to her Class 1 obesity and having both knees replaced in the one surgery.[62] His approach to mitigating that risk was not to prescribe LMWH over aspirin but to proceed with single knee surgery only. He remarked that a lot of colleagues would not change to LMWH over aspirin just because the knee surgery was bilateral rather than single. He acknowledged there were a lot of reasons for a patient to consent to bilateral surgery but it definitely increased the risk and should be taken into account in the decision on how to proceed.[63]

95. Dr Campbell said that 30% of the knee replacement patients in Australia fall within Class 1 obesity and 17% within Class 2. He said that obese middle-aged women are the standard patient for knee replacement surgery.[64] Both Dr Quain and Dr Campbell agreed that Madeline did not present as a patient with an increased risk as she was a standard (or routine) patient.[65]

96. Dr Campbell and Dr Quain both said that the SCDs or the mechanical devices are usually put on in recovery or as soon as possible. I note that Thomas described that he saw them being put on at 4 pm which was 2 ½ hours after Madeline returned to the ward. Whether that was the case or whether they had been put on in recovery is unclear as indicated in the discussion regarding the TEDs. In any event both doctors said that the timing would not affect the outcome in this case.[66]

97. Dr Flecknoe-Brown noted that the ASOA Guidelines did not identify that bilateral as opposed to single knee replacement increased the risk of developing VTE. Dr Campbell agreed and said that it should apply though it is not stated.[67] Given the discussion involved I would anticipate an addition to the Guidelines to include this issue. The definition of marked obesity should also be understood by the readers of the Guidelines. Dr Sunner took marked obesity to mean Class 3 obesity but any surgery on a patient with a BMI over 40 is deemed palliative surgery, so marked obesity is less than that. It would be helpful if the term could

[62] T32.37 26/08/2020.
[63] T31.25-47 26/08/2020.
[64] T33.4 26/08/2020.
[65] T42.25-40 26/08/2020.
[66] T48.30 26/08/2020.
[67] T40.25 26/08/2020.

be, at least, broadly determined but on the evidence it appears probable to mean at least Class 2 obesity.

98. Finally, both Dr Quain and Dr Campbell spoke about patient-driven decision making in opting for the one surgery to replace both knees. The risks to successive surgeries include cardio-vascular strain as well as other factors such as doubling hospitalisation periods, rehabilitation periods, aggravating the non-replaced knee and so on. Dr Flecknoe-Brown acknowledged the balance and said that the conversation with the patient and the obtaining of informed consent was important.

99. There was no issue with Dr Sunner's evidence that minimising bleeding at the surgical site addressed the risk of revisionist surgery, nor that it was a balancing of risks, the important aspect is that the risk was considered and appropriately addressed.

100. To answer the questions raised by issue (a): was Madeline correctly assessed as being at high risk of VTE? The answer to this question is that the Hospital assessed Madeline as high risk due to her having knee replacement surgery. That component, particularly taking into account the increased risk due to having bilateral knee surgery, was not a consideration that exercised Dr Sunner's mind at the time. He approached the task not by carrying out an individual assessment but rather treating Madeline as a standard or routine patient as she fitted within that demographic described by Dr Quain and Dr Campbell. Dr Sunner's discussion with Madeline on the day she decided to have bilateral knee surgery did not involve a discussion of any increased risk factors.

101. Was aspirin alone adequate chemoprophylaxis, taking into account that mechanical prophylaxis was also utilised? The answer to this question, on balance, was that at the time aspirin had become an emerging Orthopaedic choice which as time has progressed has become a choice adopted by the Hospital in its current VTE assessment guidelines. With the development of better multi-modal components the use of aspirin is less controversial. I note at the time, Madeline's surgery did not necessarily involve many of those multi-modal components identified and described by Dr Flecknoe Brown, Dr Quain and Dr Campbell, indeed her surgery was both under general anaesthetic with prolonged use of tourniquet. However, it is apparent that had Dr Sunner determined that Madeline was at a

high risk or increased risk of developing VTE, the prophylactic use of a LMWH would not likely have changed the outcome.

102. Was mechanical prophylaxis used appropriately, including consideration of any use of graduated compression (or TED) stockings? The answer to this question is yes. The SCDs were placed on and operating by 4 pm on 20 July 2015 and remained on as was required. The TEDs were due to be placed on Madeline at a later stage appropriate with the removal of the dressings on the day following surgery. Unfortunately, Madeline experienced a rare event and sadly collapsed and could not be revived.

103. I have not set out the closing submissions made by each representative because ultimately much of the evidence at inquest was resolved and is uncontroversial and no criticism is warranted of the nursing or hospital care provided to Madeline.

104. Mr Lynch addressed counsel assisting's submissions in relation to whether Dr Sunner in fact carried out a risk assessment and whether he took into account the risk having bilateral knee replacement involved. Mr Lynch said that Dr Sunner correctly identified the risk as being somewhat increased due to bilateral surgery though such risk was still within acceptable limits. He said that Dr Sunner was a credible witness and that I should accept his evidence that he applied his assessment as he asserted in evidence.

105. Dr Sunner's evidence was that he considered that Madeline was a standard risk patient. Dr Sunner suggested in his second statement that it was Dr Corke who assessed Madeline's risk of DVT. That was the statement in which he addressed the criteria of the ASOA Guidelines. It was not until when he was giving evidence that he was confronted with ASOA policy citing the need to carry out an individualised risk assessment that he sought to impress that he did so on the day of surgery.

106. He did not refer to those guidelines as informing his development of his Standing Orders/Protocol, though he relied on the AOA guidelines and AAOS guidelines to explain his use of aspirin over LMWH. Dr Sunner did not refer to any of the multi-modal components other than TEDs and SCDs and early mobilisation, the surgery techniques did not apparently incorporate any of the more recent innovations to minimise vessel injury or to address a patient's stasis.

107. From hearing from the experts in this case and the discussion surrounding the development of the AOSA Guidelines and the more recent development and implementation of the multi-modal approach taken in surgery to address the issue of VTE risk, particularly for orthopaedic patients, and specifically where surgery involves joint replacement, the decision about what chemical prophylaxis to use for a particular patient requires a consideration of many issues.

108. Those issues include not only the patient's personal risk factors such as age, fitness, weight and blood constitution but also the nature of the surgery such as whether it is single or bilateral replacement in addition to a consideration about what multi-modal techniques are going to be employed in carrying out that surgery such as minimal use of tourniquet, spinal rather than general anaesthetic, warmed fluids in addition to the timing and nature of post-operative devices such as SCDs.

109. The consideration of those matters should not be left to the day of surgery particularly as it may involve a decision to change from bilateral to single joint replacement and they are matters which should be fully discussed with the patient in a timely manner so that, as Dr Flecknoe-Brown, remarks the patient understands the risks.

110. Having heard from Madeline's family about her personality to take things on and having heard from the experts, particularly Dr Quain that even if a 4 in 1000 risk is considered a risk within acceptable limits, Madeline would likely have made the same decision to have both knees replaced at the same time so she could get on with things and live an active and full life with her family.

111. That Madeline did not survive the procedure is so extremely sad and unexpected but it is a reminder that this kind of surgery is not without risk. If a "standard patient" is an overweight middle aged woman who is electing to have a single surgery so she can keep moving and get on with life, it is important that the full suite of multi-modal innovations also becomes "the standard" in addition to the appropriate chemical prophylaxis so that VTE deaths are completely minimised.

112. I again extend my condolences to Madeline's family and thank them for their patience in having this long overdue inquest finally completed.

113. I now enter my findings:

Identity: Madeline Newcombe

Date of Death: 21 July 2015

Place of Death: Nepean Public Hospital

Cause of death: Pulmonary Thromboembolism

Manner of death: Madeline Newcombe died in hospital having undergone bilateral knee replacement in a single surgical procedure at Nepean Private Hospital the previous day. She developed a deep vein thrombosis in her lower right leg which subsequently migrated to her lungs resulting in her collapse when mobilising the following morning. This was a rare event despite the administration of aspirin and mechanical prophylaxis.

114. I close this inquest.

Magistrate E Truscott
Deputy State Coroner
2 October 2020