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**JURISDICTION** : CORONER'S COURT OF WESTERN AUSTRALIA  
**ACT** : CORONERS ACT 1996  
**CORONER** : BARRY PAUL KING, DEPUTY STATE CORONER  
**HEARD** : 20 SEPTEMBER 2018 and 28 FEBRUARY 2020  
**DELIVERED** : 19 OCTOBER 2020  
**FILE NO/S** : CORC 701 of 2015  
**DECEASED** : RUYZING, RENEE DESIREE

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*Catchwords:*

Nil

*Legislation:*

Nil

**Counsel Appearing:**

Mr J T Bishop assisted the Coroner on 20 September 2018

Ms K A Heslop assisted the Coroner on 28 February 2020

Mr M L Williams (Minter Ellison) appeared for Dr Khorshid and Dr Lam

Mr B D Nelson (State Solicitor's Office) appeared for South Metropolitan Health Services on 20 September 2018

Ms R M Hartley (State Solicitor's Office) appeared for South Metropolitan Health Services on 28 February 2020.

**Case(s) referred to in decision(s):**

Nil

Coroners Act 1996  
(Section 26(1))

**RECORD OF INVESTIGATION INTO DEATH**

*I, Barry Paul King, Deputy State Coroner, having investigated the death of **Renee Desiree Ruyzing** with an inquest held at Perth Coroner’s Court on 20 September 2018 and 28 February 2020 find that the identity of the deceased person was **Renee Desiree Ruyzing** and that death occurred on 14 June 2015 at Rockingham General Hospital from pulmonary thromboembolism in association with deep vein thrombosis in the recently injured left leg in the following circumstances:*

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## INTRODUCTION

1. Venous thromboembolism (VTE) is a disease process that includes deep vein thrombosis (DVT) and pulmonary embolism (PE). DVT occurs when blood pools and thickens to form blood clots in the deep veins of the legs or in the pelvis. PE occurs when a blood clot breaks off and moves through the veins to block blood vessels in the lungs. If the clot blocks enough blood vessels in the lungs, the person can die.<sup>1</sup>
2. Ms Ruyzing fractured her ankle accidentally on 9 May 2015. After swelling of her ankle had decreased, she underwent surgery at Fiona Stanley Hospital (FSH) to repair the fracture. She was discharged home on 16 May 2015 with a cast on her lower left leg and instructions not to bear weight on her left leg. She was not prescribed an anticoagulant despite having risk factors for VTE.
3. Over the next three or four weeks, Ms Ruyzing had no adverse signs or symptoms, but on 14 June 2015 she went to her doctor with shortness of breath, chest pains and vomiting. The doctor sent her to the emergency department (ED) at Rockingham General Hospital (RGH). When Ms Ruyzing arrived at RGH on the evening of 14 June 2015, her heart arrested, and the emergency medical team were unable to revive her. She was 21 years old.
4. Forensic pathologists identified the cause of her death to have been PE in association with DVT.
5. Following a police investigation into Ms Ruyzing's death, on 8 December 2016 Coroner Linton approved the holding of an inquest into the death given that it was the second recent death of a young woman from PE following a leg injury.
6. Counsel Assisting, Mr Bishop, then obtained statements from relevant witnesses and an opinion by Dr Ramdas Tampi, a laboratory and clinical haematologist.
7. I held the inquest on 20 September 2018. The documentary evidence adduced on that day comprised:

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<sup>1</sup> Exhibit 15 1

- a. a brief of evidence containing, among other things, medical reports, VTE clinical guidelines and medical records for Ms Ruyzing from FSH;<sup>2</sup>
- b. a report by Dr John Anderson, the Acting Director Clinical Services, Fiona Stanley and Fremantle Hospitals Group;<sup>3</sup>
- c. a report from Ms Ruyzing's doctor;<sup>4</sup>
- d. a 2013 report by Dr Omar Khorsid, consultant orthopaedic surgeon, in relation to another woman who died from PE and DVT of the left leg;<sup>5</sup>
- e. a statement by Dr Li-on Lam, the consultant orthopaedic surgeon who carried out the surgery on Ms Ruyzing's ankle;<sup>6</sup>
- f. a statement by Dr Khorshid in relation to Ms Ruyzing's care at FSH;<sup>7</sup>
- g. a framework for the prevention of venous thromboembolism, produced by the NSW Clinical Excellent Commission, and a VTE risk assessment tool produced by the NSW Department of Health;<sup>8</sup>
- h. a research paper 'Do isolated calf deep vein thrombosis need anticoagulant treatment?' *Journal of Thoracic Disease*, 2016 Dec;<sup>9</sup>
- i. a 2012 clinical practice guideline produced by the American College of Chest Physicians: 'Antithrombic Therapy and Prevention of Thrombosis';<sup>10</sup> and
- j. an email dated 19 September 2019 from forensic pathologist Dr C T Cooke to Mr Bishop.<sup>11</sup>

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<sup>2</sup> Exhibit 1

<sup>3</sup> Exhibit 2

<sup>4</sup> Exhibit 3

<sup>5</sup> Exhibit 4

<sup>6</sup> Exhibit 5

<sup>7</sup> Exhibit 6

<sup>8</sup> Exhibit 7

<sup>9</sup> Exhibit 8

<sup>10</sup> Exhibit 9

<sup>11</sup> Exhibit 10

8. Oral evidence was provided by (in order of appearance):
  - a. Dr Tampi;<sup>12</sup>
  - b. Dr Khorshid;<sup>13</sup> and
  - c. Dr Lam.<sup>14</sup>
9. During the inquest, it became apparent that there was a lack of consensus among medical specialists about the aetiology of VTE and the best ways to reduce the risk of VTE in hospital patients, and it was clear that further expert opinion would be necessary to address those issues. The court was also informed that a revised guideline for managing risks of VTE was being produced and that the guideline would, potentially, have a direct bearing on the question of how possible VTE should be managed.
10. In addition, the court learned from friends of Ms Ruyzing's family that her father (Mr Ruyzing) had a history of VTE and that he had asked the doctor who had discharged Ms Ruyzing from FSH whether she should be prescribed an anticoagulant.
11. I therefore adjourned the inquest pending the receipt of further evidence.
12. Once the inquest was adjourned, there was a regrettable delay in listing the continuation. The inquest was finally re-commenced on 28 February 2020 for one day. The documentary evidence adduced on that day was:
  - a. a letter dated 10 November 2018 from Mr Ruyzing to the court;<sup>15</sup>
  - b. a report by Professor Ross Baker, consultant haematologist;<sup>16</sup>
  - c. a chart and image related to DVT and PE trends, produced by Dr Cooke;<sup>17</sup>

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<sup>12</sup> 20/9/2018 ts 10 – 34

<sup>13</sup> 20/9/2018 ts 37 – 58

<sup>14</sup> 20/9/2018 ts 59 - 62

<sup>15</sup> Exhibit 11

<sup>16</sup> Exhibit 12

<sup>17</sup> Exhibit 13

- d. a report by Dr Dominic Pepperell, consultant haematologist at FSH;<sup>18</sup> and
  - e. a venous thromboembolism prevention clinical care standard produced by the Australian Commission on Safety and Quality in Health Care in January 2020.<sup>19</sup>
13. Oral evidence was provided by (in order of appearance):
- a. Professor Baker;
  - b. Dr Cooke; and
  - c. Dr Anderson.
14. Following the oral evidence, I indicated to counsel that I did not intend to make any adverse comments about any person or organisation. Ms Hartley indicated that a relevant document at FSH was in draft form, and that she would provide a copy of the final version when it became available.
15. The court has since received Ms Hartley's submissions together with a copy of a VTE information pamphlet for patients. Ms Hartley has also advised that a long-awaited VTE Risk Assessment eForm is being officially launched at FSH on 11 November 2020.

**RENEE DESIREE RUYZING**

16. Ms Ruyzing was a pharmacy assistant who lived in Waikiki with her parents and her younger brother.<sup>20</sup>
17. Ms Ruyzing was a non-smoker. She was overweight, with a body mass index of about 35 kg/m<sup>2</sup>.<sup>21</sup> She had a past medical history of depression and a slipped femoral epiphysis. She had an inverted left ankle injury in March 2014 and dysfunctional uterine bleeding in October 2014 for which she was prescribed

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<sup>18</sup> Exhibit 14

<sup>19</sup> Exhibit 15

<sup>20</sup> Exhibit 1.5 1

<sup>21</sup> Exhibit 1.3

the triphasic oral contraceptive pill.<sup>22</sup> She was also taking the antidepressant sertraline.<sup>23</sup>

### **ROCKINGHAM GENERAL HOSPITAL**

18. At about 2.00 am on 10 May 2015, Ms Ruyzing presented at the RGH ED with an injury to her left leg that she sustained while dancing in high heels. She was unable to bear weight on the left leg and there was an obvious deformity and a graze to her left ankle. A plaster cast was applied to her leg and an X-ray showed a tri-malleolar fracture.<sup>24</sup>
19. Ms Ruyzing was given a tetanus booster and analgesia, and she was started on intravenous antibiotics because of the skin wound over the fracture. At 2.52 pm was transferred to FSH for further assessment.<sup>25</sup>

### **FIONA STANLEY HOSPITAL AND FREMANTLE HOSPITAL**

20. Ms Ruyzing was admitted to FSH under Dr Khorshid's 'bed card' though Dr Khorshid had no direct involvement in her treatment.<sup>26</sup> Her leg was considered to be too swollen for surgery, so she was provided with a below-the-knee cast, analgesia and elevation of her ankle. The antibiotics were continued, and she was administered subcutaneous low molecular weight heparin (enoxaparin) for three days for DVT prophylaxis.<sup>27</sup>
21. On 13 May 2015, Ms Ruyzing was transferred to Fremantle Hospital (FH) to await the further reduction of the swelling in her leg. The enoxaparin was continued, as was her regular contraceptive pill.<sup>28</sup>
22. Mr Ruyzing said in his letter that he had spoken to a staff member of FH and had explained that he had a past history of blood clots in his lungs in 2000 and had been prescribed warfarin for two years. He asked if Ms Ruyzing would be

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<sup>22</sup> Exhibit 3

<sup>23</sup> Exhibit 1.13B

<sup>24</sup> Exhibit 1.9 FSH Medical Admission

<sup>25</sup> Exhibit 1.9 FSH Medical Admission

<sup>26</sup> Exhibit 6 2-3

<sup>27</sup> Exhibit 1.9 FSH Discharge Summary 13/5/2015

<sup>28</sup> Exhibit 1.9 FH Integrated Progress Notes

given blood thinners, and the staff member told him that they were giving her blood thinners every night.<sup>29</sup>

23. By the morning of 14 May 2015, the swelling had reduced enough to transfer Ms Ruyzing back to FSH for surgery.

### **RETURN TO FIONA STANLEY HOSPITAL**

24. Ms Ruyzing was re-admitted to FSH at 8.30 pm on 14 May 2015. She was not given enoxaparin that night, presumably in preparation for surgery the next morning.
25. At approximately 10.50 am on 15 May 2015, an orthopaedic registrar in FSH performed an open reduction and internal fixation of Ms Ruyzing's ankle fracture. The operation took just under two hours to complete.<sup>30</sup> Ms Ruyzing was on Dr Lam's 'trauma list' of surgeries that were scheduled for that day, but as her surgery was not complicated, he had allocated it to one of his registrars.<sup>31</sup>
26. The post-operative instructions on the operation report were:
- a. elevation of the leg that night;
  - b. discharge home the next day if safe;
  - c. a wound check in two weeks;
  - d. no weight bearing for six weeks;
  - e. a full cast at two to six weeks; and
  - f. diastasis screw out at 12 weeks.<sup>32</sup>
27. Dr Lam said in a statement that the surgeon who performs a surgery provides the post-operative orders for the patient. Dr Lam stated that the usual practice was for a patient's need for ongoing thromboprophylaxis to be considered at

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<sup>29</sup> Exhibit 11

<sup>30</sup> Exhibit 1.9 Intra-operative Nursing Assessment

<sup>31</sup> Exhibit 5

<sup>32</sup> Exhibit 1.9 Operation Report

the time that the patient's discharge was ordered.<sup>33</sup> It is therefore not surprising that the post-operative orders make no mention of thromboprophylaxis.

28. Ms Ruyzing was returned to the ward at about 3.00 pm and given analgesia.<sup>34</sup>
29. At the time of Ms Ruyzing's surgery, there were two relevant guidelines for thromboprophylaxis at FSH:
  - a. the FSH guideline for thromboprophylaxis for lower limb fracture with immobilisation, which recommended enoxaparin commencing at six hours after the surgery followed by enoxaparin for the entire period of immobilisation; and
  - b. the orthopaedic departmental guideline for thromboprophylaxis for lower limb trauma, which recommended the use of enoxaparin on the next morning after surgery followed by aspirin 150 mg on discharge for patients with restricted weight bearing. For high risk patients, this guideline recommended enoxaparin at six hours after surgery and the use of warfarin for six weeks from the day after surgery.<sup>35</sup>
30. The FSH anticoagulation chart for Ms Ruyzing indicates that she was administered enoxaparin at 9.15 pm on 15 May 2015 in accordance with the FSH guideline.<sup>36</sup>
31. On the morning of 16 May 2015, a physiotherapist and an occupational therapist reviewed Ms Ruyzing and deemed her safe for discharge. An on-call register also reviewed her and was happy to discharge her. There was a plan that accorded with the post-operative instructions but no mention in the notes of aspirin or enoxaparin.<sup>37</sup>
32. The last nursing note of the day indicates that Ms Ruyzing was given a medical certificate, discharge medications and 'educational material'.<sup>38</sup>

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<sup>33</sup> Exhibit 5

<sup>34</sup> Exhibit 1.9 Inpatient Progress Note - Nursing

<sup>35</sup> Exhibit 5B

<sup>36</sup> Exhibit 1.9

<sup>37</sup> Exhibit 1.9 Medical Progress Note

<sup>38</sup> Exhibit 1.9 Inpatient Progress Note - Nursing

33. Ms Ruyzing's father said in his letter that, when Ms Ruyzing was discharged, he asked a doctor who introduced himself as one of the surgeons who had operated on her whether Ms Ruyzing would be sent home with 'blood thinners'. The doctor said, 'No, her heart is good, she is young and strong like an ox.'<sup>39</sup> No anticoagulant was prescribed.

#### **OUTPATIENT CLINIC AT FIONA STANLEY HOSPITAL**

34. On 29 May 2015, Ms Ruyzing attended the FSH outpatient clinic where the stitches on her ankle were removed and her cast was replaced with a below knee fibreglass cast. The wound on her leg was reported to have healed well.<sup>40</sup>

#### **ROCKINGHAM GENERAL HOSPITAL ED**

35. On the evening of 14 June 2015, Ms Ruyzing attended her GP with complaints of palpitation, pleuritic chest pain worsened by deep breathing, shortness of breath and vomiting. She had experienced a similar episode on the previous evening. Her GP was concerned that she may have a PE, so he advised her to present to the RGH ED and provided her with a referral letter.<sup>41</sup>
36. Ms Ruyzing went to the RGH ED, but she collapsed in the waiting room at about 7.45 pm before being triaged. She was initially gasping and had a weak pulse, but her heart then arrested. Given her history of a recent surgery, immobilisation, oestrogen use and pleuritic chest pain, she was treated for a suspected PE. She was administered CPR and transferred to the resuscitation area, but she could not be revived. Her life was certified extinct at 9.10 pm.<sup>42</sup>

#### **HOW DEATH OCCURRED AND THE CAUSE OF DEATH**

37. On 17 June 2015, forensic pathologist Dr C T Cooke and forensic pathology registrar Dr V Kueppers performed a post mortem examination of Ms Ruyzing's body and found recent injury of the left leg, PE, and DVT in the

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<sup>39</sup> Exhibit 11

<sup>40</sup> Exhibit 1.9 Outpatient Progress Note

<sup>41</sup> Exhibit 1.13C

<sup>42</sup> Exhibit 1.12

left calf. They formed the opinion, which I adopt as my finding, that the cause of death was PE in association with DVT in the recently injured left leg.<sup>43</sup>

38. As the PE arose from the accidental injury and consequent immobilisation of Ms Ruyzing's left leg, I find that death occurred by way of accident.

### **VTE PROPHYLAXIS AND MS RUYZING'S MANAGEMENT AT FSH**

#### ***Dr Tampi***

39. Given the existence of the FSH guideline and the orthopaedic department guideline, and the opinion of Dr Cook and Dr Kueppers, the issue of whether an anti-coagulant should have been prescribed to Ms Ruyzing following her lower leg injury was significant.
40. In 2009, the National Health and Medical Research Council (NHMRC) produced a clinical practice guideline for the prevention of VTE in patients admitted to Australian hospitals. In relation to lower leg fractures and injuries with immobilisation, the guideline recommended the use of enoxaparin for all patients in a brace or plaster cast for the entire period of immobilisation.<sup>44</sup>
41. However, Dr Tampi provided a report and gave evidence in which he noted that there was no clear evidence that thromboprophylaxis reduced the risk of VTE in patients undergoing ankle surgery. Numerous researchers argued that routine use of thromboprophylaxis was not justified, but that patient-specific risk factors should be considered in assessing patients individually.<sup>45</sup>
42. Dr Tampi said that the VTE prevention guidelines issued by the NSW health department provide clear guidance on patients in either the high or low risk groups, but patients having intermediate risk factors such as immobility, oestrogen therapy, family history and/or obesity require balanced judgement which is difficult without strict guidelines.<sup>46</sup>

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<sup>43</sup> Exhibit 1.3A

<sup>44</sup> Exhibit 1.15

<sup>45</sup> Exhibit 1.7

<sup>46</sup> Exhibit 1.7

43. Dr Tampi said that a lack of consensus indicates the need for a position statement regarding thromboprophylaxis in the lower leg trauma setting, particularly since risk stratification appears to be required in order to judge whether thromboprophylaxis should be considered. Risk stratification and algorithms may be useful, but in practice, junior staff may be filling in the necessary forms and guidelines, so effective management policy needs to be put in place early in the course of a patient's admission.<sup>47</sup>
44. In oral evidence, Dr Tampi said that Ms Ruyzing's risk factors of lower limb immobilisation, use of the contraceptive pill, and obesity would have led him to prescribe enoxaparin.<sup>48</sup> He said that the orthopaedic department at FSH favoured aspirin, but that the evidence supporting the use of aspirin was poor.<sup>49</sup>
45. As to the purported connection between DVT and PE, Dr Tampi could see no problem with saying that, if a person has DVT and gets PE, the PE came from the DVT. He agreed that it was highly unlikely to have come from somewhere else.<sup>50</sup>
46. Dr Tampi agreed that the use of an anticoagulant would not have guaranteed that Ms Ruyzing would not develop a PE, but it would have reduced the likelihood.<sup>51</sup>
47. Dr Tampi was taken to the framework and the VTE risk assessment tool produced by the NSW Clinical Excellence Commission.<sup>52</sup> He considered that a discharge patient information leaflet as recommended in the framework was urgently needed in WA and that the risk assessment tool would have been extremely useful.<sup>53</sup>

***Dr Khorshid***

48. Dr Khorshid said that the issue of the effect of thromboprophylaxis on DVT and PE is extremely complicated and is frequently debated in the setting of

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<sup>47</sup> Exhibit 1.7

<sup>48</sup> 20/9/2018 ts 20-23

<sup>49</sup> 20/9/2018 ts 23, 18

<sup>50</sup> 20/9/2018 ts 27

<sup>51</sup> 20/9/2018 ts 31

<sup>52</sup> Exhibit 7

<sup>53</sup> 20/9/2018 ts 33-34

orthopaedic surgery. He said that the evidence that thromboprophylaxis prevents DVT is reasonably strong, but the evidence is weaker with respect to PE, and the evidence is almost non-existent in relation to fatal PE.<sup>54</sup> He said that evidence of enoxaparin being effective in preventing PE is very weak in relation to lower leg injuries.<sup>55</sup>

49. Dr Khorshid said that the members of the FSH orthopaedic department considered the relevant literature and determined that, rather than not prescribing anything for lower leg injuries as suggested by the influential College of Chest Physicians guideline,<sup>56</sup> they would prescribe aspirin for the period of immobilisation as it was easy to administer and cheaper for the patient and the health system. On that basis, they developed their own guidelines instead of using the FSH guidelines.<sup>57</sup>
50. Dr Khorshid said that it appeared to be accepted in the medical profession that calf DVTs were not big enough to cause significant PE's. Instead, it was suspected that the big PEs may arise from the pelvic veins or a thigh vein. He said that, if the guidelines are based on evidence that only relates to the calf, they may not prevent PEs.<sup>58</sup>
51. Dr Khorshid said that all junior doctors in the FSH orthopaedic department were aware of their guidelines.<sup>59</sup> He did not believe that there was a deliberate decision not to prescribe a prophylaxis. Rather, it was possible that not prescribing one was an omission rather than a failure of the guidelines.<sup>60</sup>
52. Dr Khorshid said that the guidelines in place at the time were reasonable and would have normally resulted in the prescription of a prophylactic agent.<sup>61</sup> Ms Ruyzing had risk factors, and he said that he would have categorised her overall risk as medium.<sup>62</sup> He said that, at the time when he was giving his oral

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<sup>54</sup> 20/9/2018 ts 37

<sup>55</sup> 20/9/2018 ts 37-38

<sup>56</sup> Exhibit 9

<sup>57</sup> 20/9/2018 ts 38

<sup>58</sup> 20/9/2018 ts 53-54

<sup>59</sup> 20/9/2018 ts 40

<sup>60</sup> 20/9/2018 ts 46

<sup>61</sup> 20/9/2018 ts 45-46

<sup>62</sup> 20/9/2018 ts 41

evidence, he would prescribe her enoxaparin but that he would discuss it with her and would agree to give her aspirin if she preferred it.<sup>63</sup>

53. Dr Khorshid said that a strong family history of DVT or PE, especially a diagnosed genetic abnormality, increases the risk of VTE by orders of magnitude more than the other risk factors. For that reason, it was appropriate to ask a patient if they have a history of DVT or if there is a history of DVT in the family.<sup>64</sup>
54. Dr Khorshid did not think that there was enough evidence to implement the NSW framework and risk assessment tools, but he thought that it would be reasonable for a working group of experts from different perspectives to evaluate the evidence and develop a guideline.<sup>65</sup>

*Dr Cooke*

55. Dr Cooke said that he did not check the thigh veins, but he did check the pelvis veins and found no blood clots.<sup>66</sup> He said that he thought that a thrombus develops in the calf and then propagates and grows upward in the leg where part of it breaks off and goes into the lungs. What is left in the veins of the calf is a residual clot. He said that it is commonly understood that DVT is potentially dangerous and can lead to PE.<sup>67</sup>

*Dr Lam*

56. Dr Lam was not involved with the decision to discharge Ms Ruyzing, so he was unaware of any discussions that might have taken place with her about post-discharge thromboprophylaxis.
57. In his statement, Dr Lam said that, had he been involved, he would have assessed Ms Ruyzing as having a moderate risk of developing DVT due to the facts that she was female, was on the oral contraceptive pill, was obese and

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<sup>63</sup> 20/9/2018 ts 42-43

<sup>64</sup> 20/9/2018 ts 57

<sup>65</sup> 20/9/2018 ts 47-49

<sup>66</sup> 28/2/20 ts 27

<sup>67</sup> 28/2/20 ts 28

had undergone lower limb surgery. He would have then prescribed aspirin for six weeks in accordance with the orthopaedic department guideline.<sup>68</sup>

58. In oral evidence, Dr Lam said that he would also have classed Ms Ruyzing at moderate risk of VTE and he also agreed that a hereditary condition of blood clots would have put her at a higher risk.<sup>69</sup>
59. Dr Lam believed that a working group should develop simple guidelines based on evidence rather than on what is thought to be correct by extrapolating from lower limb joint replacement surgery.<sup>70</sup>
60. It is noteworthy that an attachment to Dr Lam's statement, *American College of Foot and Ankle Surgeon's Clinical Consensus Statement: Risk, Prevention, and Diagnosis of Venous Thromboembolism Disease in Foot and Ankle Surgery and Injuries Requiring Immobilisation*,<sup>71</sup> advised that routine chemical prophylaxis is not warranted, but patients should be stratified and have a prevention plan tailored to their individual risk level.<sup>72</sup> Patient-specific risk factors included obesity, oral contraceptive pill, family history of VTE, injuries involving a fracture, surgery and prolonged immobilisation.<sup>73</sup> Enoxaparin was considered to be effective at reducing the rate of VTE disease (VTE and PE), and there was insufficient evidence to support the use of aspirin as an isolated measure of prophylaxis in high-risk patients.<sup>74</sup>
61. Before the inquest was adjourned following Dr Lam's evidence, Mr Nelson advised that the NHMRC's guideline had been rescinded in 2016 and that a replacement guideline was expected to be published in October 2018. He said that FSH would consider the new guideline once it was published.<sup>75</sup> The new guideline was published in 2018 and was updated with minor revision in January 2020.<sup>76</sup>

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<sup>68</sup> Exhibit 5

<sup>69</sup> 20/9/2018 ts 59

<sup>70</sup> 20/9/2018 ts 62

<sup>71</sup> Exhibit 5C; *Journal of Foot & Ankle Surgery* 54 (2015) 497-507

<sup>72</sup> Exhibit 5C; *Journal of Foot & Ankle Surgery* 54 (2015) 499

<sup>73</sup> Exhibit 5C; *Journal of Foot & Ankle Surgery* 54 (2015) 499-502

<sup>74</sup> Exhibit 5C; *Journal of Foot & Ankle Surgery* 54 (2015) 503

<sup>75</sup> 20/9/2018 ts 63

<sup>76</sup> Exhibit 15

*Professor Baker*

62. In his report, Professor Baker stated that there is vast medical literature suggesting a strong association between lower limb DVT and PE, and that the risk increases with proximity of the vessels to the heart. Thromboprophylaxis, particularly anticoagulation with enoxaparin or direct acting oral anticoagulants, reduces the risk by about 60-80%, but it also increases the risk of bleeding. Aspirin reduces the risk of DVT and PE by about 20-30%.<sup>77</sup>
63. In relation to clinical risk analysis, Professor Baker referred to a recent publication which had identified a new risk score called the TIP (trauma, immobilisation and patient characteristics) Score that can be used in EDs to assess the need for VTE prophylaxis for patients with lower limb trauma and cast or brace immobilisation. He said that, if it is further validated, it could be widely adopted since it identifies the people at the highest risk,<sup>78</sup> and you would almost want those people to be 100% compliant for risk assessment.<sup>79</sup>
64. In oral evidence, Professor Baker explained the causes and origins of DVT and PE. Contrary to Dr Khorshid, he said that it is wrong to consider that a calf DVT would be too small to block a lung vein because it is not an all or nothing effect. A calf vein thrombosis may be from an isolated event or it may be associated with a larger clot that has already disappeared into the lungs. He said that one in five people with calf vein thromboses progress if the risk factors are still present, and that can lead to more proximal thrombosis in the legs and PE.<sup>80</sup>
65. Professor Baker said that the prevention mechanism option that has been championed in hospitals is risk assessment since it determines the application of all the other options.<sup>81</sup> The risk factors include the oral contraceptive pill, lower limb fracture and being immobile. Family history is very important so should always be ascertained as part of a risk assessment.<sup>82</sup> There is no one

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<sup>77</sup> Exhibit 12

<sup>78</sup> 28/2/20 ts 13

<sup>79</sup> 28/2/20 ts 14

<sup>80</sup> 28/2/20 ts 5-6

<sup>81</sup> 28/2/20 ts 6

<sup>82</sup> 28/2/20 ts 11

risk factor; rather, it is an accumulation of risk factors that each slowly increases the risk.<sup>83</sup>

66. Professor Baker disagreed that there was insufficient evidence to support using the NSW framework and risk assessment tools. He said that 80% of people who have VTE come to our hospitals, so we need to do better to identify those at risk and to prevent it. We also need to identify those at low risk so as not to cause them harm by giving them medicine that may not provide any benefit. He said that the NSW tool was the one to do it.<sup>84</sup>
67. Professor Baker said that, if he applied the TIP score to Ms Ruyzing, she was at risk, so there would have been a discussion with her about possible preventative measures.<sup>85</sup> That is, she was within the high risk group and would not have been a moderate risk patient.<sup>86</sup> He said that, if she had been taking enoxaparin, her risk would have been reduced by 60 to 80%, and if she had been taking aspirin her risk would have been reduced by 20 to 30%.<sup>87</sup>
68. Professor Baker suggested that I recommend that hospital EDs increase VTE awareness by providing a glossy information pamphlet on VTE risk and symptoms to every patient discharged with lower limb injury, and that there be consideration of implementation and further research to validate the TIP score.<sup>88</sup>

***Dr Pepperell***

69. In his report dated 26 February 2020, Dr Pepperell agreed with Professor Baker that there is a well-accepted association between DVT and PE and that proximal DVTs are more likely to result in PEs. He said that it is accepted that pharmacological prophylaxis can reduce the risk of VTE in certain categories of hospitalised medical, surgical and orthopaedic patients, but that controversy still exists about which patients truly benefit from prophylaxis because some large, recent studies failed to show a meaningful reduction. In addition, any

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<sup>83</sup> 28/2/20 ts 9-10

<sup>84</sup> 28/2/20 ts 14

<sup>85</sup> 28/2/20 ts 15

<sup>86</sup> 28/2/20 ts 22

<sup>87</sup> 28/2/20 ts 25

<sup>88</sup> Exhibit 12 3

benefit may be counterbalanced by a significant increase in bleeding caused by anticoagulants.<sup>89</sup>

70. Dr Pepperell said that current opinion supports a practice of attempting to individualise treatment in order to identify which patients would benefit from prophylaxis and to balance that benefit with the risk of bleeding. Unfortunately, there is no clinical data to prove that the practice actually works, and it has not been possible to create a scoring system that integrates thrombosis risk and bleeding risk.<sup>90</sup>
71. However, Dr Pepperell said that there has been health data from England which showed that the use of risk assessment has led to a reduction in VTE events.<sup>91</sup>
72. Dr Pepperell said that the risk of symptomatic VTE appears low in patients like Ms Ruyzing who have lower limb fracture, immobilisation and non-weight bearing after discharge. There appear to be risk factors which include: previous VTE, age greater than 75 years, oestrogen therapy or pregnancy, cancer, surgery, first degree relative with VTE, and obesity.<sup>92</sup>
73. Dr Pepperell noted that the TIP score has yet to be validated and may prove to be too unwieldy for routine clinical use. He also pointed out that it is for non-operative patients, so may not be directly applicable to Ms Ruyzing's case.<sup>93</sup>
74. After referring to the College of Chest Physicians guideline<sup>94</sup> and the 2019 American Society of Haematology guidelines, which provide no advice on the issue, Dr Pepperell concluded that the optimal management in Ms Ruyzing's case remains unclear.<sup>95</sup>

***Dr Anderson***

75. Dr Anderson provided a report dated 23 August 2018. In it, he described the policies and risk assessments used at FSH in the course of Ms Ruyzing's

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<sup>89</sup> Exhibit 14 1

<sup>90</sup> Exhibit 14 2

<sup>91</sup> Exhibit 14 2

<sup>92</sup> Exhibit 14 2

<sup>93</sup> Exhibit 14 2

<sup>94</sup> Exhibit 9

<sup>95</sup> Exhibit 14 2

admissions, and he provided his assessment as to whether the documents had been followed. He concluded that, apart from Ms Ruyzing receiving no enoxaparin or aspirin for the period of immobilisation of her leg after discharge, the risk assessments were followed but not fully completed.<sup>96</sup>

76. Dr Anderson agreed with Dr Tampi that managing patients within the intermediate level of risk requires balanced judgement which is difficult without strict guidelines. He said that developing such guidelines will be difficult given the lack of clear-cut evidence and the continuing uncertainty in the debate over relative risk versus benefit.<sup>97</sup>
77. Dr Anderson added that producing guidelines without convincing evidence could lead to large numbers of patients being placed on pharmacologic agents, with cost and adverse outcome implications.<sup>98</sup>
78. In oral evidence, Dr Anderson explained that, as well as being the deputy director of clinical services at the Fiona Stanley and Fremantle Hospitals Group, he was a practising specialist anaesthetist at the coalface and that the implications of risk exposure to VTE was a day-to-day issue for surgical staff and anaesthetic staff.<sup>99</sup>
79. Dr Anderson confirmed that, despite the indication in the FSH documentation that a VTE risk assessment was appropriately done for Ms Ruyzing, the VTE guidelines applicable to her at FSH were not followed.<sup>100</sup> He also said that the documentation at FSH does not support a conclusion that Ms Ruyzing was asked about a family history of VTE.<sup>101</sup>
80. Dr Anderson acknowledged that the FSH orthopaedic department had their own guideline which recommended aspirin for uncomplicated lower limb surgery, but he said that he had not seen evidence in the international literature

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<sup>96</sup> Exhibit 2 4-6

<sup>97</sup> Exhibit 2 7

<sup>98</sup> Exhibit 2 8

<sup>99</sup> 28/2/2020 ts 32

<sup>100</sup> 28/2/2020 ts 54

<sup>101</sup> 28/2/2020 ts 33

that aspirin changes the outcome of VTE risk in cases of lower limb injury in association with immobilisation.<sup>102</sup>

81. Dr Anderson said that the incidence of VTE in an uncomplicated lower leg injury such as Ms Ruyzing's with or without surgery is 0.6%; that is, very low.<sup>103</sup> At the same time, if you put a person who is at low risk of VTE onto enoxaparin, the incidence of severe haemorrhage doubles and it is difficult to reverse the effect of enoxaparin or the new oral anticoagulants, so clinicians are particularly concerned about prescribing it in the post-operative period.<sup>104</sup>
82. He said that clinicians know what to do with patients who do not have any risk and with patients who have a high risk, but trying to work out what to do with patients who have intermediate risk is intensely problematic.<sup>105</sup>
83. Dr Anderson said that the potential for inadvertent complications associated with anticoagulant has led to a search for a scorecard that could identify a recipe approach to patients like Ms Ruyzing who had moderate risk of VTE. He said he had hoped for clear guidance from the latest report of the Australian Commission of Safety and Quality in Health Care (ACSQHC),<sup>106</sup> but the report just recognised that the information from all the latest research did not lead to a real guideline. Instead, health providers must note that there may be additional risk stratification that requires conversation with the patient, formation of a management plan, formation of a management plan downstream at point of alternative care distribution, and a potential to revise and refine the treatment plan as you go along in agreement with the treatment team and the patient. It is a matter for every individual.<sup>107</sup>
84. Dr Anderson said that the ongoing inability of developing that guideline is at the top of the Health Department's major problems and that the difficulty in

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<sup>102</sup> 28/2/2020 ts 47

<sup>103</sup> 28/2/2020 ts 43

<sup>104</sup> 28/2/2020 ts 43

<sup>105</sup> 28/2/2020 ts 35-36

<sup>106</sup> Exhibit 15

<sup>107</sup> 28/2/2020 ts 36, 44, 50

solving it is the greyness of the information.<sup>108</sup> He said that it requires a whole of Health solution.<sup>109</sup>

85. As to the TIP score, Dr Anderson said that it is a piece of the puzzle but that he was not as enthusiastic about it as Professor Baker was. It was designed for an analysis of a patient sub-group involving lower leg injury without operative intervention, so it does not have direct application to Ms Ruyzing's case. He said that a low TIP score could identify patients who probably would not benefit from prophylaxis, but there is nothing to indicate that a high TIP score can rightly be held as an indication for pharmacological intervention.<sup>110</sup>

### **CHANGES AT FSH FOLLOWING MS RUYZING'S DEATH – THE EFORM AND LEAFLET**

86. Dr Anderson said in oral testimony that, partly as a result of Ms Ruyzing's case, FSH realised that there was a discrepancy between the FSH VTE risk assessment guideline and the orthopaedic department's guideline. To bring those two guidelines into conformity, they did a review of the process in 2017. The resultant policy was due for review, but FSH had been awaiting the ACSQHC standard to provide guidance on that review process. At the time of the inquest, FSH was heading into that process.<sup>111</sup>
87. Dr Anderson also said that the Health Department initially attempted to improve the compliance with VTE risk analysis documentation at all tertiary hospitals, but they soon became aware that junior medical staff felt unsupported by their mentors and by the information that was available. The Health Department considered that the only way to address that situation was by formalising a process of risk assessment in accordance with the ACSQHC standard.<sup>112</sup> That risk assessment was then built into a VTE risk assessment eForm developed at FSH after consultation across FSH in 2019.<sup>113</sup>

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<sup>108</sup> 28/2/2020 ts 50

<sup>109</sup> 28/2/2020 ts 49

<sup>110</sup> 28/2/2020 ts 35

<sup>111</sup> 28/2/2020 ts 33

<sup>112</sup> 28/2/2020 ts 38; Exhibit 14 4

<sup>113</sup> Exhibit 14 4

88. Dr Pepperell said that the eForm was to become part of the electronic medical admission form for all patients at FSH and saved in the patients' medical notes. It was based on validated VTE risk and bleeding scores.<sup>114</sup>
89. The eForm requires a junior medical officer to ask a patient all of the questions, step by step, that were charted in the old-style medical admission forms in relation to VTE risk assessment, and it takes the place of almost all other forms. The questions will include reference to the patient's family history of clotting disorders.<sup>115</sup> If the answers are to positive fields, the form will lead to relevant eForms for analysis of alternatives for recipe-type arrangements for management of low, medium and high-risk patients.<sup>116</sup>
90. Unfortunately, according to Dr Anderson, the eForm will not be available to most of WA's health facilities because the digital environment at FSH will not be applicable to other facilities apart from FH, RGH and probably Bunbury Hospital.<sup>117</sup> In any event, the eForm had been delayed at FSH due to funding and resource issues.<sup>118</sup>
91. In September 2020, Ms Hartley informed the Court that the VTE risk assessment eForm will be officially launched at FSH on 11 November 2020, and Dr Pepperell is currently delivering presentations of the use of the eForm to various specialities in FSH.<sup>119</sup>
92. Ms Hartley also advised that, in accordance with Professor Baker's suggestion<sup>120</sup> and foreshadowed by Dr Pepperell,<sup>121</sup> FSH had recently finalised a VTE patient information leaflet, a copy of which is to be provided to all inpatients and patients being discharged at risk of VTE. It is proposed that patients will be directed to the leaflet at admission and will be encouraged to ask their clinicians about the issue. Dr Pepperell had been working towards

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<sup>114</sup> Exhibit 14 4

<sup>115</sup> Exhibit 14 6; *Submissions on Behalf of the South Metropolitan Health Service and Department of Health* [2]

<sup>116</sup> 28/2/2020 ts 39

<sup>117</sup> 28/2/2020 ts 49

<sup>118</sup> 28/2/2020 ts 37-39

<sup>119</sup> *Submissions on Behalf of the South Metropolitan Health Service and Department of Health* [6]

<sup>120</sup> Exhibit 12 3

<sup>121</sup> Exhibit 14 5

having the leaflet available for distribution by 13 October 2020, which was World Thrombosis Day.<sup>122</sup>

93. The evidence supports a conclusion that these changes, once implemented, will considerably increase the likelihood at FSH that patients in similar situations to those facing Ms Ruyzing will be treated appropriately for the risk of VTE.
94. The Department of Health has acknowledged that the South Metropolitan Health Service, which includes FSH, is leading the way in addressing the assessment and prevention of VTE.<sup>123</sup> The evidence did not provide a clear answer to the question of why FSH's eForm or another suitable resolution of the issue of VTE prevention is not also being adopted across all Western Australian hospitals.
95. In a Clinical Focus Report on hospital-associated VTE published by the NSW Clinical Excellence Commission in 2015, the following statistics from 2008 were cited:

VTE is a leading cause of morbidity and mortality in Australia with more than 14,000 Australians diagnosed with a VTE each year and more than 5,000 cases resulting in death. VTE has been shown to cause more deaths than all transport accidents and falls combined and more deaths than bowel or breast cancer. In 2008, the total hospital inpatient expenditure on VTE in Australia was estimated as \$82.2 million. This does not take into account health care costs associated with long-term effects of VTE once patients are managed within the community setting.

Hospitalisation has been found to be a major risk factor in the development of VTE, where the incident of VTE among hospitalised patients was found to be more than 100 times greater than the incidence among community residents. Of all deaths in Australian hospitals, seven per cent are due to VTE.<sup>124</sup>

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<sup>122</sup> *Submissions on Behalf of the South Metropolitan Health Service and Department of Health* [4]-[5]

<sup>123</sup> *Submissions on Behalf of the South Metropolitan Health Service and Department of Health* [8]

<sup>124</sup> NSW Clinical Excellence Commission *Clinical Focus Report on hospital-associated VTE*, 2015 1

96. Similar statistics are cited in the ACSQHC clinical care standard,<sup>125</sup> and Professor Baker said that 80% of people who have VTE come to our hospitals.<sup>126</sup> The NSW Emergency Care Institute website states that symptomatic or asymptomatic PE occurs in about 50% of patients with proximal (popliteal and above) DVT and in about 5% of those with distal DVT.<sup>127</sup>

### RECOMMENDATION

97. In these circumstances, I make the following recommendation:

That the Department of Health place a high priority on ensuring that an appropriate system is implemented in all Western Australian hospitals to ensure as far as practicable that VTE risk is prevented.

98. As part of the implementation of that system, it would be appropriate for the TIP score to be considered as suggested by Professor Baker.

### CONCLUSION

99. It is shocking that a 21 year old person could die from PE following an uncomplicated operation for a fractured ankle, especially in circumstances where her risk factors for developing VTE were known. No parent should have to endure such a loss.
100. The evidence in this inquest makes clear that the issue of the assessment and prevention of VTE at the time was marked by controversy and uncertainty.
101. Even today, there is no guarantee that Ms Ruyzing would have been prevented from developing VTE had she had been assessed as requiring prophylaxis and managed accordingly.
102. However, what is clear is that she was not treated in accordance with FSH's own guidelines and was thereby exposed to a much higher risk of developing a PE than would otherwise have been the case.

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<sup>125</sup> Exhibit 15 4

<sup>126</sup> 28/2/2020 ts 4, 6

<sup>127</sup> [www.aci.health.nsw.gov.au/networks/eci/clinical/clinica--resources/clinical-tools/thromboembolism/dvt](http://www.aci.health.nsw.gov.au/networks/eci/clinical/clinica--resources/clinical-tools/thromboembolism/dvt)

103. It is commendable that FSH and other hospitals in the South Metropolitan Health Service network are about to implement an assessment process that should improve the standard of VTE assessment and risk reduction.
104. It is clearly imperative that an effective assessment process be implemented in all hospitals in Western Australia as soon as reasonably possible.

B P King  
Deputy State Coroner  
19 October 2020