Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 22HDC00815)

Introduction

1. This report is the opinion of Dr Vanessa Caldwell, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

2. The report discusses the care provided to the late Ms A by Te Whatu Ora (formerly a district health board[1]).

3. Ms A, aged in her sixties at the time of events, underwent surgery after sustaining a broken ankle.

4. Following Ms A's surgery, she was discharged from hospital. Sadly, she died five days later from a pulmonary embolism[2] (PE).

5. The following issue was identified for investigation:

- *Whether Te Whatu Ora provided Ms A with an appropriate standard of care in 2021.*

[1] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Te Whatu Ora|Health New Zealand. All references in this report to the district health board now refer to Te Whatu Ora.
[2] Occurs when a piece of a deep vein clot breaks off, travels through the bloodstream, and becomes stuck in a blood vessel in the lungs.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

6. The parties directly involved in the investigation were:

Ms B	Consumer's daughter
Te Whatu Ora	Provider

7. Further information was received from the Coroner.

How the matter arose

Medical history

8. Ms A had a medical history of venous thromboembolism[3] (VTE). In 2008, she developed a right leg deep vein thrombosis[4] (DVT) following Achilles tendon repair surgery. In 2013, she developed another DVT following a long car journey.

9. Ms A also had high blood pressure and an elevated body mass index[5] (BMI).

Surgery

10. In 2021, Ms A had a fall and injured her left ankle. She presented to the Emergency Department (ED) at a public hospital.

11. Imaging showed a bimalleolar fracture, which means that both the tibia[6] and fibula[7] were broken. Te Whatu Ora explained that this was an unstable injury, most commonly treated with surgery to align and stabilise the fractures.

12. Te Whatu Ora said that Ms A received medication for pain relief, and that aspirin[8] once daily was given orally for chemical VTE prophylaxis[9] starting on her arrival at the ward. Te Whatu Ora stated that it also instituted mechanical VTE prophylaxis [10] with a sequential compression device[11] (SCD) on Ms A's left leg.

13. Prior to the surgery, Ms A completed an Acute Theatre Health Questionnaire, indicating that she had had DVTs previously.

14. Ms A underwent surgery for her ankle fracture.

[3] Occurs when a blood clot, or thrombus, forms in a deep vein. VTE describes two separate but often related conditions — deep vein thrombosis and pulmonary embolism.
[4] Occurs when a blood clot forms in a deep vein in the body, usually in the legs.
[5] A measure of the proportion of body fat to total body weight, which is used to define healthy and unhealthy weight ranges. Ms A's BMI was 38.1. A BMI of greater than 30 is considered obese.
[6] Shinbone.
[7] The smaller bone of the lower leg.
[8] 100mg aspirin is used for the prevention of blood clots.
[9] The use of medication to prevent blood clots.
[10] The use of compression stockings and intermittent pneumatic compression devices to prevent blood stasis in the legs.
[11] A method of DVT prevention that improves blood flow in the legs.

15. Te Whatu Ora said that use of an SCD on Ms A's left leg continued during surgery, and a tourniquet was used, as 'is standard for this type of procedure'. Te Whatu Ora said that the surgery was 'uneventful and not of prolonged duration'.

16. Following the surgery, Ms A's left ankle was immobilised in a controlled ankle motion walking boot (CAM boot), and she was advised not to weight bear for a period of six weeks. Te Whatu Ora stated that Ms A was also advised to remove the CAM boot for ankle movement exercises around two weeks after the surgery, once the soft tissue healing was adequate.

17. Postoperatively, as an inpatient, Ms A continued to receive mechanical VTE prophylaxis in the form of an SCD on her left leg. Ms A also received chemical VTE prophylaxis in the form of enoxaparin[12] (Clexane) and daily aspirin from the date of her surgery until her discharge.

Discharge

18. Ms A was discharged from hospital. Te Whatu Ora stated that Ms A was advised to continue using oral aspirin daily for a period of six weeks.

19. On discharge, Ms A did not receive any other chemical VTE prophylaxis, or any mechanical VTE prophylaxis.

20. In response to the provisional decision, Ms A's daughter, Ms B, noted that following her mother's surgery, the bandage on her leg 'kept falling off'. Ms B told HDC:

> 'I spoke to [my mother] about the bandage on her leg as I would have expected to see a stocking to help with the swelling but she only had a [wrap-around] bandage that kept coming loose and falling down and she was told to keep her moon boot on for swelling which didn't make a lot of sense to me.'

21. As Ms A resided outside the region of the hospital where the surgery was undertaken, follow-up care was arranged at another hospital. The stitches were to be removed within two weeks, and an X-ray was to be done within six weeks from the date of discharge.

Events following discharge

22. Five days following Ms A's discharge from hospital, Ms B telephoned her mother at her home. Ms A was having difficulty breathing. Ms B contacted an ambulance and set out for Ms A's home.

23. On arrival, the emergency responders commenced CPR,[13] but Ms A was unable to be revived, and she was declared deceased at the scene.

24. The post-mortem examination found that the direct cause of Ms A's death was 'bilateral pulmonary thromboemboli', and that the antecedent cause was 'Left lower extremity [DVT]'. The post-mortem report states:

[12] 40mg enoxaparin (Clexane) is used to treat and prevent blood clots.
[13] Cardiopulmonary resuscitation.

> 'It is my opinion that the cause of death was bilateral pulmonary thromboemboli due to a left lower extremity deep vein thrombosis. Hypertension, obesity, and recent surgery would have been significant contributory factors to the cause of death.'

Serious Event Analysis

25. Following Ms A's death, Te Whatu Ora undertook an investigation of the events, and completed a Serious Event Analysis (SEA). The SEA states:

> 'The patient completed an Acute Theatre Health Questionnaire form, indicating she had previously had a blood clot/embolism/DVT. It is not clear who reviewed this form once it was completed prior to surgery. The patient may have assumed this information was known to all staff. There is no evidence to show on this admission that the orthopaedic team/anaesthetist team/nursing staff were aware of past VTE events or specifically asked the patient …
>
> A more robust VTE assessment on admission (as occurs on discharge) may have led to this patient being identified as having a high risk of developing VTE and receiving an altered management plan eg: rivaroxaban[14]/clexane on discharge which potentially could have altered the outcome for the patient.'

26. The SEA reported the following findings:

> 'At the time of admission, there was no robust assessment process for VTE risk assessment until a patient was discharged.
>
> The VTE [electronic learning] module is currently unavailable.
>
> There is no current RMO[15] teaching session on VTE or VTE risk assessment.
>
> Information on the Acute Theatre Health Questionnaire form indicated she had previously had blood clot/embolism/DVT was not documented elsewhere within the clinical notes, indicating the form was not seen/referred to by staff.'

27. The SEA states:

> 'The absence of a) a robust assessment (on admission) for VTE risk and b) teaching opportunities, increased the likelihood of the patient not being identified or treated as being high risk of VTE which potentially led to the development of pulmonary embolisms.'

Protocol

28. Te Whatu Ora's protocol in relation to 'Thromboprophylaxis for orthopaedic patients' (dated April 2020) (VTE Policy) states that patients with 'isolated lower extremity injury/surgery requiring immobilisation with significant risk factors' are considered to be at 'moderate' risk of VTE. The VTE Policy states that patients are considered to be at 'high' risk of VTE if they

[14] An anticoagulant that is used to treat and prevent clots in the blood.
[15] Resident medical officer.

have undergone a total hip joint replacement or a total knee joint replacement, or have had multi trauma or bilateral joints are involved.

29. The VTE Policy states that the mechanical prophylaxis required for patients at moderate risk of VTE are 'TEDS[16] and SCDs' unless contraindicated, early mobilisation if possible, and good hydration. Chemical prophylaxis in the form of aspirin or rivaroxaban or enoxaparin (Clexane) is also required. If rivaroxaban or enoxaparin is used, aspirin should be considered after five days.

30. The VTE Policy states that the mechanical prophylaxis required for patients at high risk of VTE is intermittent pneumatic compression (IPC[17]) or SCDs unless contraindicated, TEDs unless contraindicated, early mobilisation if possible, and good hydration. Chemical prophylaxis in the form of aspirin or rivaroxaban or enoxaparin (Clexane) is also required, as above.

31. For both moderate-risk patients and high-risk patients, the VTE Policy states that prophylaxis should be continued until hospital discharge, except where the patient has had major cancer surgery or previous VTE, in which case it should be continued for up to 30 days.

Further information

32. Te Whatu Ora stated:

> 'There remains no universally agreed guideline as to whether chemoprophylaxis is of benefit in these injuries, with the majority agreement in current literature being that most patients with these isolated lower limb injuries do not receive chemoprophylaxis, but that consideration should be given to assessing individual risks. Various methods of prophylaxis may be employed but no method completely protects against VTE.'

33. Te Whatu Ora referred to a position statement by the American Orthopaedic Foot & Ankle Society, 'The Use of Venous Thromboembolic Disease Prophylaxis in Foot and Ankle Surgery', dated 11 February 2020 (AOFAS statement). The AOFAS statement includes:

> 'The exact risk of VTED[18] in patients undergoing foot and ankle surgery remains unclear due to the wide variation in injuries, treatments and rehabilitation protocols. There is currently insufficient data to make broad recommendations for or against the use of routine VTED prophylaxis in patients undergoing foot and ankle surgery.
>
> We can recommend that a comprehensive assessment of risk factors should be performed to aid in the decision-making process. If sufficient risk factors are present, VTED prophylaxis through mechanical and/or chemical interventions should be considered and weighted against the potential risks of prophylaxis. Exactly what

[16] Thromboembolism deterrent stockings.
[17] IPC devices use cuffs around the legs that fill with air and squeeze the legs, which increases blood flow through the veins of the legs and helps prevent blood clots.
[18] Venous thromboembolic disease.

> constitutes sufficient risk, however, remains undetermined, especially in those patients without a strong risk factor.'

Responses to provisional opinion

34. Ms B was given an opportunity to respond to specific sections of the provisional opinion. Ms B's comments have been incorporated into this opinion where relevant and appropriate.

35. Te Whatu Ora was given an opportunity to respond to the provisional opinion. Te Whatu Ora's comments have been incorporated into this opinion where relevant and appropriate.

36. Te Whatu Ora acknowledged that its processes did not meet the standards of care for VTE prophylaxis for Ms A and apologised unreservedly to her family. Te Whatu Ora told HDC:

> '[P]ost-operative VTE is part of the surgical checklist for theatre; for this patient it appears no members of the team were aware of the patient's high risk from two previous thromboembolic events, despite the patient having recorded this in her admission documents. We acknowledge that there will continue to be VTE cases presenting to our hospitals, and a good system in place to assess risk and use it consistently will assist us all.'

37. Te Whatu Ora agreed with the recommendations made.

Opinion: Te Whatu Ora — breach

38. First, I express my sincere condolences to Ms A's family for their loss. I acknowledge that this was a traumatic experience, and that these events had a significant impact on Ms A's family.

39. Te Whatu Ora acknowledged that Ms A recorded her medical history of DVTs on the Acute Theatre Health Questionnaire upon admission, but that there is no evidence to suggest that the orthopaedic team, anaesthesia team or nursing staff were aware of this information, or specifically asked Ms A about this. Te Whatu Ora said that it was not clear who reviewed the Questionnaire prior to surgery.

40. Ms A's history of DVTs was highly relevant to guide the clinical decision-making. I am critical that the surgical staff were not aware of this information and did not specifically ask Ms A about her history of DVTs prior to the surgery. In addition to her history of DVTs, Ms A had other factors that suggested that she was at risk of developing a DVT. Her BMI was elevated (obese) and she had high blood pressure. However, it appears that these factors were also overlooked.

41. I acknowledge the difficulty in determining the exact risk of VTE in patients undergoing foot and ankle surgery. However, a comprehensive assessment of risk factors should be performed to aid the decision-making process. If sufficient risk factors are present, appropriate steps should then be taken, including chemical and mechanical prophylaxis. I note that Te Whatu Ora has acknowledged that a more robust VTE assessment on admission may have led to Ms A being identified as having a high risk of VTE.

42. The VTE Policy states that patients at either high or moderate risk of VTE should receive mechanical prophylaxis in the form of TEDS and SCDs, both during and following their admission to hospital. However, although Ms A received SCDs as an inpatient, there is no evidence that TEDS were considered or utilised at any point during her care, and I am critical that this did not happen.

43. In addition, Te Whatu Ora has acknowledged that had Ms A been assessed as high risk, she may have received an altered management plan on discharge (eg, rivaroxaban/enoxaparin), and this may have altered her outcome. I note that when Ms A was discharged, the only chemical prophylaxis she was told to continue was aspirin (daily, for a period of six weeks). Further, the mechanical prophylaxis was discontinued. This was despite the VTE Policy stating that prophylaxis should be continued for up to 30 days after discharge for patients who had had a previous VTE.

44. As discussed above, although Ms A indicated a prior history of DVT on the acute theatre admission form, the surgical staff were unaware of Ms A's history of DVTs, resulting in Ms A not being assessed as having a higher risk of developing a VTE.

45. I acknowledge Te Whatu Ora's comments that various methods of prophylaxis may be employed, and that no method completely protects against VTE. However, in this case, Ms A was not assessed at all. As a result, Ms A's management on discharge was inadequate and fell below the expected standard of care.

Conclusion

46. In summary, I consider that the assessment process for VTE on admission was inadequate, and that Ms A's specific conditions or risk factors were not considered by staff appropriately. As a result, Ms A's management on discharge was inadequate.

47. There were missed opportunities for staff to assess Ms A's condition critically, and to put in place a management plan to address the risks appropriately. As multiple staff members and teams (the orthopaedic team, the anaesthesia team, and the nursing staff) had the opportunity to assess and review Ms A's clinical history, I consider this to be a service delivery failure for which, ultimately, Te Whatu Ora is responsible. Accordingly, I find that Te Whatu Ora breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[19]

Changes made since events

48. Following Te Whatu Ora's analysis of the events, the following recommendations were made, which have all been implemented:

- A mandatory field for VTE assessment has been included on the electronic admission document;
- Mandatory e-learning about VTEs for RMOs has been reinstated;

[19] Right 4(1) states: 'Every consumer has the right to have services provided with reasonable care and skill.'

- VTE risk and assessment have been included in the RMO orientation and teaching; and
- The preoperative process regarding the use of the Acute Theatre Health Questionnaire has been reviewed.

49. Further to the above, Te Whatu Ora advised HDC of the following:

a) This case will be presented at the orthopaedic team's next Morbidity and Mortality meeting and will be shared with the anaesthetic team.

b) The anaesthetic team noted that VTE prophylaxis is discussed at 'sign-out' in theatre, which should be an opportunity to assess and address the perioperative risk of VTE.

c) If not underway already, senior nursing staff will remind house officers about VTE prophylaxis.

d) An Orthopaedic Ward VTE nursing champion will follow up on compliance with TEDs and will submit an updated teaching plan for nursing and healthcare assistant staff, which will form part of the VTE nursing champion's expert PDRP[20] quality project.

e) A Ward Quality Board will be set up in the corridor to provide information for staff, patients, and their whānau regarding VTE prevention.

f) The VTE information booklet 'You are at risk — Blood Clots' is now more accessible for staff to give to patients.

Recommendations

50. As recommended in my provisional opinion, Te Whatu Ora has provided a formal written apology to Ms A's family for the failings identified in this report. Taking into account the apology provided and the changes made by Te Whatu Ora, I recommend that Te Whatu Ora:

a) Review its VTE Policy to improve the assessment of VTE risk and the recommended prophylaxis, by including a requirement for all patients to be assessed for VTE risk on admission and discharge, as well as identifying the parties responsible for the assessment. Evidence of this is to be provided to HDC within six months of the date of this decision.

b) Provide training to all current staff who were involved in Ms A's care, including an awareness of VTEs, the assessment processes for VTEs, and the associated risks for patients undergoing foot and ankle surgery. Evidence of this is to be provided to HDC within six months of the date of this decision.

c) Following the amendment and implementation of the new VTE Policy (as set out in (a) above), undertake an audit of at least 15 patients to determine the degree of compliance with the new VTE Policy. The summary of findings is to be provided to HDC within six months of the date of implementation of the new VTE Policy.

[20] Professional Development Recognition Programme.

d) Use an anonymised version of this report for staff learning and provide HDC with evidence that this has been completed, within six months of the date of this decision.

Follow-up actions

51. A copy of this report will be sent to the Coroner.

52. A copy of this report with details identifying the parties removed will be sent to Te Whatu Ora and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.