SCOTTISH PUBLIC SERVICES OMBUDSMAN

People Centred | Improvement Focused

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

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Scottish Parliament Region: Lothian

Case ref: 202209575, Lothian NHS Board - Acute Division

Sector: Health

Subject: Hospitals / clinical treatment / diagnosis

Summary

The complainant (C) complained to my office about the treatment provided to their late sibling (A) by Lothian NHS Board (the Board). A was 51 years old. They ruptured the patella tendon of their left knee in a fall and underwent surgery at Royal Infirmary of Edinburgh (RIE) to repair the patella tendon tear. They were discharged the following day with a hinged knee brace and instructed to weight bear as able to.

A attended the Orthopaedic Fracture Clinic for follow-up review two weeks later, as arranged. The clips were removed from the wound and a plan was made for A to progress gradually with a hinged knee brace with follow up in clinic four weeks later.

A died suddenly at home the day after attending the Fracture Clinic. Following investigation by the Scottish Fatalities Investigation Unit (SFIU), A's cause of death was found to be:

- 1a) pulmonary thromboembolism,
- 1b) deep vein thrombosis (DVT) and
- 1c) recent leg surgery

C complained that A was not appropriately assessed and treated for blood clot risk.

In their complaint response the Board said that A's blood clot risk was assessed. They said A was not prescribed blood-thinners as they had no high-risk features for blood clots and had no weight-bearing restrictions placed upon them. When A attended the fracture clinic for review, they were not displaying any signs or symptoms of a DVT or pulmonary embolism (PE), such as leg or thigh swelling, calf pain, chest pain or shortness of breath.

In response to our enquiries the Board acknowledged that there was no record of a risk assessment having been carried out. The Board said a further investigation by the service identified that A was in fact prescribed and administered one dose of DVT/ anticoagulant medication. They apologised for the inaccurate information

previously provided but provided no further evidence or documentation in support of their position.

The Board said that the case was discussed at the Trauma Department morbidity and mortality meeting and there was agreement that post-operative pulmonary embolism is a recognised complication of lower limb surgery and no alteration in practice was recommended.

During my investigation I took independent advice from a consultant orthopaedic surgeon (specialist in conditions involving the musculoskeletal system).

Having considered and accepted the advice I received, I found that the Board:

- failed to carry out a risk assessment for A's blood clot risk.
- failed to note A's BMI (body mass index) of >/= to 30, which was a risk factor.
- failed to identify the additional risk associated with the anaesthesia time, which in A's case was in excess of 90 minutes.
- did not have a venous thromboembolism (VTE) prophylaxis protocol in place in their orthopaedic department.
- failed to undertake a Significant Adverse Event Review (SAER) for an unexpected death, in line with national guidance.

I also found failings in the Board's complaints handling:

- the Board's complaint response sought to provide reassurance that A's personal blood clot risk was assessed, and that A did not have any high-risk features despite there being evidence which clearly indicates this was not the case.
- the Board provided conflicting accounts in relation to whether A received anticoagulant medication.

Taking all of the above into account, I upheld C's complaint.

Redress and Recommendations

The Ombudsman's recommendations are set out below:

What we are asking the Board to do for C:

Rec number	What we found	What the organisation should do	What we need to see
1	Under this point of the complaint I found that the Board's treatment fell below a reasonable standard. In particular I found that the Board should have: i. carried out an appropriate risk assessment for VTE. ii. identified that A was high risk for VTE because of their BMI and that the anaesthetic time was an additional risk factor. iii. identified the risk of VTE outweighed the risk of bleeding.	Apologise to C for the failings identified in this investigation. The apology should meet the standards set out in the SPSO guidelines on apology available at www.spso.org.uk/informationleaflets	A copy or record of the apology. By: 24 June 2024

Rec number	What we found	What the organisation should do	What we need to see
	iv. carried out a SAER in relation to this case as this was an unexpected death. I also found it was unreasonable that the Board did not have in place a relevant VTE policy for the orthopaedic department and that the Board's complaint handling was unreasonable.		

We are asking the Board to improve the way they do things:

Rec number	What we found	Outcome needed	What we need to see
2	Under this this point of the complaint I found that the Board's treatment fell below a reasonable standard. In particular I found that the Board should have: i. carried out an appropriate risk assessment for VTE.	Patients undergoing orthopaedic surgery should be appropriately risk assessed for VTE. This should include an assessment of BMI and anaesthetic time.	Evidence that the Board have: carried out a sample audit of orthopaedic trauma patients at RIE to ensure that the assessment and documentation of risk for

Rec number	What we found	Outcome needed	What we need to see
	ii. identified that A was high risk for VTE because of their BMI and identified that the anaesthetic time was an additional risk factor. iii. identified the risk of VTE outweighed the risk of bleeding.	The assessment should be documented on the clinical record.	VTE is being appropriately carried out. Details of the findings of the audit and any actions identified to be included. reviewed the training needs for relevant staff in relation to the assessment and documentation of risk for VTE. Details of the review findings and how any actions identified will be taken forward to be included. shared the findings of my investigation with relevant staff in a supportive manner for reflection and learning. By: 22 August 2024

Rec number	What we found	Outcome needed	What we need to see
3	A Significant Adverse Event Review for an unexpected death should have been held in line with national guidance.	Where adverse event(s) occur an adverse event review should be held in line with relevant guidance to ensure there is appropriate learning and service improvements that enhance patient safety.	Evidence that the Board's systems for carrying out critical and adverse event reviews have been reviewed to ensure they are carried out in line with national guidance. By: 22 August 2024

We are asking the Board to improve their complaints handling:

Rec number	What we found	Outcome needed	What we need to see
4	There was a failure to fully investigate and identify the significant failings in this case in accordance with the Board's complaint handling procedure and the NHS Model Complaints Handling Procedure. The complaint response also contained inaccuracies in relation to the assessment of A's risk for VTE.	Complaints should be investigated and responded to in accordance with the Board's complaint handling procedure and the NHS Model Complaints Handling Procedure. Complaints investigators should fully investigate and address the key issues raised, identify and action appropriate learning. The complaint response should be factually accurate.	Evidence that these findings have been fed back to relevant staff in a supportive manner that encourages learning, including reference to what that learning is (for example, a record of a meeting with staff; or feedback given at one-to-one sessions). By: 22 July 2024

Evidence of action already taken

The Board told us they had already taken action to fix the problem. We will ask them for evidence that this has happened:

Complaint number	What we found	Outcome needed	What we need to see
a)	The Board should have had a relevant VTE protocol for the orthopaedic department in place.	The Board told us they were drafting a protocol.	Evidence of the VTE protocol and any supporting documents. By: 22 July 2024

Feedback

Points to note

My investigation found the medical records in relation to whether anticoagulation was prescribed and given to be unclear. This is unsatisfactory. I am highlighting this for the Board to reflect on and action as required. I expect the Board to give this serious consideration.

Who we are

The Scottish Public Services Ombudsman (SPSO) investigates complaints about organisations providing public services in Scotland. We are the final stage for handling complaints about the National Health Service, councils, housing associations, prisons, the Scottish Government and its agencies and departments, the Scottish Parliamentary Corporate Body, water and sewerage providers, colleges and universities and most Scottish public authorities. We normally consider complaints only after they have been through the complaints procedure of the organisation concerned. Our service is independent, impartial and free. We aim not only to provide justice for the individual, but also to share the learning from our work in order to improve the delivery of public services in Scotland.

The role of the SPSO is set out in the Scottish Public Services Ombudsman Act 2002, and this report is published in terms of section 15(1) of the Act. The Act says that, generally, reports of investigations should not name or identify individuals, so in the report the complainant is referred to as C. The terms used to describe other people in the report are explained as they arise and in Annex 1.

Introduction

1. The complainant (C) complained to me about the treatment provided to their late sibling (A) by Lothian NHS Board (the Board).

2. A was 51 years old. They ruptured the patella tendon of their left knee in a fall and underwent surgery at Royal Infirmary Edinburgh (RIE) to repair the patella tendon tear on 2 September 2022. They were discharged the following day with a hinged knee brace and instructed to weight bear as able to. Follow-up was arranged in two weeks.

3. A attended the Orthopaedic Fracture Clinic for review on 15 September 2022. The clips were removed from the wound and a plan made for A to carry out two weeks at 0 to 30 degrees in the hinged knee brace, increasing to 0 to 50 degrees after two weeks, with follow-up in clinic in four weeks' time.

4. A died suddenly at home on 16 September 2022. Following investigation by the Scottish Fatalities Investigation Unit (SFIU), their cause of death was found to be:

1a) pulmonary thromboembolism,

1b) deep vein thrombosis (DVT) and

1c) recent leg surgery.

5. C complained to me about aspects of A's treatment in RIE in September 2022. In particular, that A was not appropriately assessed and treated for blood clot risk.

6. The complaint from C I have investigated is that:

(a) The treatment provided to A fell below a reasonable standard (***upheld***).

Investigation

7. In order to investigate C's complaint, I and my complaints reviewer considered all of the documentation submitted to us by C and by the Board including A's medical and nursing records, and complaint correspondence. I also obtained medical advice from an appropriately qualified medical adviser (the Adviser: a consultant orthopaedic surgeon). The Adviser had full access to A's relevant medical records and the Board's complaint file.

8. In this case, I have decided to issue a public report on C's complaint to reflect my concerns about the failings identified in A's treatment, which were not identified by the Board in their own investigation, including the Board's failure to carry out a

Significant Adverse Event Review (SAER); the significant personal injustice caused by the failings identified; and the potential for wider learning from the complaint.

9. This report includes the information that is required for me to explain the reasons for my decision on this case. Please note, I have not included every detail of the information considered. My complaints reviewer and I have reviewed all of the information provided during the course of the investigation. C and the Board were given an opportunity to comment on a draft of this report.

10. Explanations for the medical terms referred to are provided in Annex 1 and/ or the report.

Key events (compiled from information provided by both C and the Board)

Date of event	Details of event
26 August 2022	A was taken by ambulance to the Emergency Department (ED) of RIE after being found unconscious with injuries to their nose and leg. A went home before being fully assessed.
27 August 2022	A attended the Minor Injuries Unit at the Western General Hospital with signs and symptoms of a patella tendon rupture of the left knee. The notes report that there was swelling mainly at the front of the knee with bruising extending into the thigh and calf. An ultrasound (US) scan was requested to confirm a diagnosis of the patella tendon rupture. A was discharged home with a splint and it was documented they were mobilising well with crutches without any weight-bearing restrictions applied.
1 September 2022	A attended RIE for a US scan which confirmed a patella tendon tear.
2 September 2022	A was admitted to RIE for surgery to repair the patella tendon tear. This was performed by a Senior Registrar with no complications.
3 September 2022	A was assessed by Physiotherapy and discharged from RIE in a hinged knee brace locked in full extension with instructions to weight bear as able to.

Date of event	Details of event
	Drugs listed in the discharge letter: • Dihydrocodeine (an opioid painkiller) 30 mg as required four hourly, maximum four times daily • Paracetamol 1000 mg four times daily • Ibuprofen 400 mg as required maximum three times daily • Macrogol (medication to treat constipation) 1 x sachet as required
15 September 2022	A was reviewed in the Orthopaedic Surgeon's fracture clinic by a different Registrar, who removed the clips and documented that A had been mobilising well and had no concerns.
16 September 2022	A died suddenly at home.
21 September 2022	A postmortem examination was carried out. Cause of death was noted as: pulmonary thromboembolism pending further investigation.
8 November 2022	Following investigation by the SFIU a final postmortem report was issued. The postmortem report said there appeared to be some swelling and yellow bruising of the lower leg with a degree of pitting oedema[1]. The report notes medical cause of death to be: • 1a Pulmonary thromboembolism • 1b Deep vein thrombosis • 1c Recent leg surgery (left patella tendon repair 2/9/22) A's death certificate was amended accordingly.

[1] Pitting oedema occurs when excess fluid builds up in the body, causing swelling. When pressure is applied to the swollen area a "pit" or indentation will remain. Although it can affect any part of the body it usually occurs in legs; feet and ankles.

Concerns raised by C

11. C complained to the Board after receiving the postmortem result. Noting that A was seen for outpatient review less than 12 hours before their sudden death, C questioned whether clinical or nursing staff had noticed any change in A's leg on examination.

12. C questioned why A's leg had not been X-rayed.

13. A was asthmatic. C was concerned that A had been prescribed ibuprofen, as they thought this may cause blood clots.

14. C questioned why A was not given any blood-thinning injections to prevent blood clots, as they were in a leg brace and unable to bend their knee for a week before the surgery and two weeks after surgery.

15. They advised the death of A has devastated their family. C believes that if A had received appropriate treatment, they would still be alive.

The Board's complaint response

16. The Board offered their sincere condolences.

17. The Board said A was not prescribed blood-thinners as they had no high-risk features for blood clots and had no weight-bearing restrictions placed upon them.

18. When A was seen in the fracture clinic by a registrar on 15 September 2022 it was documented that they had been mobilising well and had no concerns. It was documented that a thorough examination was made and they did not report any unexpected swelling in the leg or thigh, any colour change, or any excessive pain. Some swelling would be expected around the knee at this post-operative stage. Excessive swelling or calf/ thigh swelling was not recorded.

19. X-ray was not required to assess this soft tissue injury at two weeks.

20. It is standard to immobilise the knee in a hinge knee brace for six weeks following a patella tendon rupture to allow the tendon to heal. During this time, the patient's knee flexion is limited so that the tendon heals without rupturing the repair. The flexion allowed is typically increased in 30 degree increments every two weeks. This was intended to be the case for A. Weight-bearing is not typically restricted and was not restricted in A's case.

21. It is not routine practice in the Orthopaedic Department to provide patients with anticoagulants who do not have any other risk factors for blood clots (deep vein

thrombosis (DVT) or pulmonary embolism (PE)) after a patella tendon repair. They wished to reassure C that A's personal blood clot risk was assessed. A did not have any high-risk features, and therefore was not prescribed anticoagulation medication.

22. Routine anticoagulation of patients who are not high risk can be associated with significant side effects from blood thinning medication such as unexpected bleeding. All patients are consented prior to undergoing any surgery and they are made aware of the risks of DVT/ PE.

23. When A attended the fracture clinic on 15 September 2022, they were not displaying any signs or symptoms of a DVT or PE, such as leg or thigh swelling, calf pain, chest pain or shortness of breath. A did not complain of shortness of breath during the consultation.

24. Noting that A had died suddenly the following day, and that the postmortem had confirmed the cause of death was from a PE, the Board said PE is a rare complication following surgery which can be devastating.

The Board's response to our enquiries

25. We noted that the Board's complaint response contained reference to a risk assessment for VTE but the risk assessment in the records was blank. We asked the Board to confirm when and where the risk assessment was carried out and where it was documented. The Board said the VTE risk assessment had not been documented in A's orthopaedic notes. They said there may have been a risk assessment at the time of attendance in the ED when the injury was diagnosed and the knee brace was first applied, but there is no record of this.

26. We noted that the postmortem report notes a BMI > 30, which the Adviser confirmed was a risk factor. We asked the Board to comment on why A's BMI was not recorded as a risk factor. The Board responded by stating that the clinical team were unable to confirm why A's BMI was not recorded as a risk factor, for which they apologised. They commented that the association between obesity and thrombosis is controversial, setting out a statement made in a recent British Medical Journal (BMJ) Best Practice publication as follows:

> "The relationship between VTE and obesity is controversial. No association was found in the Heart and Estrogen/ Progestin Replacement Study (HERS), but a 2.9-fold increase in pulmonary embolism with a body mass >29 kg/m2 was documented in Nurses' Health Study".

27. When responding to our enquiries, the Board said the patient electronic record states A was prescribed DVT/ - anticoagulation. In contrast, the Board's complaint response states blood thinners were not given, and the Adviser noted that anticoagulant was prescribed on the Kardex and then scored off so did not believe it was given. We highlighted the conflicting information and asked the Board to confirm their position. The Board said a further investigation by the service identified that A was in fact prescribed and administered one dose of DVT/ anticoagulant medication on 3 September 2022. They apologised for the inaccurate information previously provided. No further evidence or documentation was provided in support of the Board's position.

28. We asked why no SAER was carried out in relation to this case. The Board replied that the clinical team confirmed the case was discussed at the Trauma Department morbidity and mortality meeting and there was agreement that post-operative pulmonary embolism is a recognised complication of lower limb surgery and no alteration in practice was recommended. In light of this, it would not be expected that a "Serious [sic] Adverse Event Review" would be undertaken in this case.

29. We asked the Board to provide a copy of their policy on VTE prophylaxis. They initially provided a copy of a Major Trauma VTE prophylaxis protocol. As A was not a major trauma patient, we asked the Board for their protocol for generic orthopaedic inpatient/ day case patients. The Board confirmed that A was an orthopaedic emergency trauma patient. They said such patients are not treated on the Major Trauma Ward or by the Major Trauma service, therefore the Major Trauma VTE protocol is not followed. The Board said at present there is not an agreed VTE protocol for Orthopaedic Trauma patients. Each patient will be risk assessed on a case by case basis by the team who are treating them, which the Board said is what happened with A.

30. The Board confirmed that they were in the process of writing a VTE protocol for the orthopaedic department, which is at the draft stage.

Relevant guidance

31. Overview | Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism | Guidance | NICE

Non-arthroplasty orthopaedic knee surgery

> 1.11.11 Be aware that VTE prophylaxis is generally not needed for people undergoing arthroscopic knee surgery where:

- total anaesthesia time is less than 90 minutes **and**
- the person is at low risk of VTE. **[2018]**

1.11.12 Consider LMWH[2] 6 to 12 hours after surgery for 14 days for people undergoing arthroscopic knee surgery if:

- total anaesthesia time is more than 90 minutes **or** the person's risk of VTE outweighs their risk of bleeding. **[2018]**

  In March 2018, the use of LMWH in young people under 18 was off label. See NICE's information on prescribing medicines.

1.11.13 Consider VTE prophylaxis for people undergoing other knee surgery (for example, osteotomy or fracture surgery) whose risk of VTE outweighs their risk of bleeding. **[2018]**

32. Building a national approach to learning from adverse events through reporting and review (healthcareimprovementscotland.scot)[3]

Medical advice

Risk assessment

33. The Adviser noted that the Board's complaint response suggested that a risk assessment was done for VTE. They highlighted that in A's notes, the pre-operative assessment short stay: Risk Assessment of venous thromboembolism (VTE) had not been filled in. They advised the risk assessment should have been completed by nursing staff.

34. The Adviser said the Board's risk assessment tool itself is reasonable and notes a BMI >/= to 30 as being a risk factor. The Adviser could find no record of BMI in the clinical notes and said this is unreasonable. The postmortem report notes A had a BMI > 30, which is a risk factor.

35. With reference to the above-noted NICE guidance, the Adviser said in this case there was a risk factor for VTE (BMI >30) and a further risk was anaesthetic time > 90 minutes (anaesthetic started 13:45 and finished 15:30). Therefore, according to the relevant guidance VTE prophylaxis should have been considered and in A's case it was not. The adviser stated that, in this case, the risk of VTE outweighed the risk of bleeding.

[2] Low-molecular-weight heparin- a class of anticoagulant medications used in the prevention of blood clots and treatment of VTE.
[3] from 1 January 2020, all significant adverse event reviews commissioned by the NHS boards for a Category 1 adverse event should be reported to Healthcare Improvement Scotland (HIS) in alignment with the national notification system.

36. They noted that the Board's risk assessment included sections for 'pre-existing thrombosis risk or other risk factor for VTE' and 'does VTE risk factor need to be highlighted to responsible medical staff because of risk factors?' The adviser commented that risk factors did need to be highlighted to medical staff but were not.

Policy on VTE prophylaxis

37. The Adviser said it was unreasonable for the Board not to have a VTE protocol for the orthopaedic department. In relation to their comment that a risk assessment was carried out in A's case, the Adviser stated this was not done which was unreasonable.

Anticoagulant medication

38. The Adviser noted a ward round note dated 2 September 2022, stating 'DVT/ Anticoagulation prescribed on KARDEX: Yes'. We were not originally provided with the KARDEX and requested this from the Board. As noted at paragraph 27, the Board provided a KARDEX record on which dalteparin (an anticoagulant) was prescribed and then scored off. The Adviser was unclear as to whether one dose was given but did not believe it was.

39. In response to the Board's later clarification that one dose of dalteparin had been given, the Adviser commented that it would be very unusual for a patient to be given just one dose of dalteparin post-operatively.

40. When commenting on my draft report, the Board said it is possible to receive only one dose of dalteparin whilst an in-patient as A had an overnight stay and dalteparin is usually given as a once daily medication. They said it is also common practice to give this medication in the evening. As such, A would have been discharged home before getting a second dose. The Board noted that A was not planned to receive, and therefore did not get, extended treatment of prophylactic dalteparin where this is continued following hospital discharge. The Board accepted that inadequate documentation meant that it is not known whether dalteparin was administered.

41. We shared these comments with the Adviser, who maintained that it would be very unusual for a patient to be given just one dose of dalteparin post-operatively. Noting the comment that A was not planned to receive an extended treatment, the Adviser said this was unreasonable because the Board had not carried out a risk assessment and had not identified a risk factor (BMI >30).

Significant Adverse Event Review (SAER)

42. The Adviser considered it unreasonable that the Board had not undertaken a SAER in accordance with the above-noted national guidance. They confirmed an unexpected death is a Category 1 event under this guidance and should automatically trigger a SAER.

43. When commenting on my draft report, the Board accepted that a DATIX report should have been submitted when they received C's complaint in January 2023, which would have triggered an appropriate adverse event review.

Review in Fracture Clinic on 15 September 2022

44. The Adviser agreed with the Board's position that the clinic note documented that A had been mobilising well and had no concerns. However, they said it was not documented that a thorough examination was made, as stated by the Board (see paragraph 18). The Adviser agreed with the Board's statement that excessive swelling or calf/ thigh swelling was not recorded.

Ibuprofen prescription

45. The Adviser considered the Board's position regarding ibuprofen to be reasonable. They said that a small number of people with severe asthma can have a reaction to ibuprofen but that it is commonly prescribed following trauma surgery and is not associated with blood clots.

Adviser's conclusions

46. In conclusion, the Adviser reiterated that the Board failed to:

a. carry out an appropriate risk assessment for thromboembolic events.

b. identify A as being high risk for thromboembolic events due to their high BMI.

c. carry out a SAER for an unexpected death as per national guidance.

Decision

47. The basis on which I reach conclusions and make decisions is 'reasonableness'. My investigation looks at whether the actions taken, or not taken, were reasonable in the circumstances and in light of the information available to those involved at the time.

48. In investigating this complaint, I have obtained professional advice from the Adviser (as outlined above). I have carefully considered this advice, which I accept in full, along with the other information and evidence we hold.

49. C was concerned about ibuprofen being prescribed to A. I am satisfied that the Board have responded to this aspect of complaint appropriately. I accept that while a small number of people with severe asthma can have a reaction to ibuprofen it is commonly prescribed following trauma surgery and is not associated with blood clots. On this basis, I consider the use of ibuprofen to treat A was reasonable.

50. Nevertheless, taking into account the clinical records and advice I have received, I have significant concerns about the Board's assessment of A's risk for VTE.

51. My investigation has found the risk assessment in the records was blank and there is no evidence that A's blood clot risk was assessed as it should have been. In addition, the Board's risk assessment tool notes BMI >/= to 30 as being a risk factor. The Board failed to note A's BMI, which was reported in the postmortem report as greater than 30. A's BMI was therefore a risk factor which the Board failed to identify.

52. In their response to our additional enquiries on this point, the Board said the link between obesity and VTE is controversial. Whilst observing that this is the Board's position, the fact remains that BMI >/= to 30 is noted as a risk factor on the Board's own risk assessment tool; and the advice I have received which I accept is that BMI > 30 is a risk factor. I am in no doubt that had the Board's risk assessment tool been appropriately completed, A's risk factor would have been identified. I consider the failure to do so was unreasonable.

53. It is also of significant concern that the Board did not identify the additional risk associated with the anaesthesia time, which in A's case was in excess of 90 minutes. According to the relevant NICE guidance, VTE prophylaxis should have been considered in A's case as the anaesthetic time was in excess of 90 minutes. The advice I have received is clear that the risk of VTE outweighed the risk of bleeding in A's case and so anticoagulation medication should have been considered. I consider the failure to do so was unreasonable.

54. It is important that complaints responses are accurate, and it is concerning that the Board's complaint response sought to provide reassurance that A's personal blood clot risk was assessed, and that A did not have any high-risk features despite there being evidence, as noted above, which clearly indicates this was not the case. I consider this more fully under complaint handling below.

55. Further to this, the Board have provided conflicting accounts in relation to whether A received anticoagulant medication. The Board advised C that A did not receive anticoagulant medication yet their response to this office is that A received one dose. The Board have not provided evidence to substantiate this and, given the lack of clarity in the records on this point, I am unable to conclude definitively whether A received anticoagulant medication. It is unsatisfactory that the clinical records are not clear on this point.

56. While I am unable to conclude definitively from the records whether A received anticoagulation medication, the advice I have received is that receiving one dose would be unusual. When commenting on a draft of this report, the Board have said that it is possible to receive only one dose of dalteparin whilst an in-patient as A had an overnight stay; dalteparin is usually given as a once daily medication and A was not planned to receive, and therefore did not get, extended treatment of prophylactic dalteparin. In noting the Board's position, I consider the significant learning point is not whether it is possible or unusual to receive only one dose of dalteparin; it is that a risk assessment was not carried out for A as it should have been and a risk factor (BMI >30) was not identified. I consider this was unreasonable.

57. A's death was unexpected and ought to have been identified as a Category 1 event, triggering a SAER which should have been reported to HIS. The failure to undertake a SAER is also of significant concern. This was a lost opportunity for the Board to identify and take forward the appropriate learning from this serious adverse event at the appropriate time. It is unreasonable this did not happen.

58. Finally, while I welcome that the Board are in the process of preparing a VTE protocol for the orthopaedic department this should have been in place from the outset. It is unreasonable such a protocol was not in place at the time of these events.

59. Taking account of the advice I have received and in view of the failings identified, I uphold this complaint.

60. I recognise the devastating impact of these events on C and their family and that my investigation sadly cannot change what occurred in this case. Nevertheless, I am making several recommendations for action to ensure that appropriate learning from this tragic case is noted and acted on, so that a similar situation does not reoccur. I very much hope that C receives some comfort from this, and that their complaint will have made a difference for others.

61. I am not making a specific recommendation that a SAER now be carried out, but I am recommending that the Board review their systems for considering and

deciding whether to carry out adverse and critical event reviews to ensure such reviews are appropriately carried out in the future. I also intend to send a copy of my investigation report to HIS when it is published given this case relates to a Category 1 adverse event which should have been reported to HIS. My recommendations are set out below.

Complaint handling

62. Section 16 G of The Scottish Public Services Ombudsman Act 2002 requires me to monitor and promote best practice from complaint handling. This means I can make recommendations on complaints handling issues without a specific complaint having been made by the complainant.

63. In terms of the NHS Model Complaints Handling Procedure, the Board's investigation of a complaint should fully address all the issues raised and demonstrate that each element has been fully and fairly investigated. It should also include an apology where things have gone wrong.

64. Complaints are not only about addressing the concerns people raise, they are also a source of learning, and fundamental to building confidence in services and the relationship between service users and the organisations providing those services.

65. I have found that the Board's complaint response wrongly reassured C that A's personal blood clot risk was assessed when there is no record of this and that A did not have any high risk features, when this was not the case. It also stated that A was not prescribed any anticoagulant medication although the Board later advised my office that A had received one dose of anticoagulant medication. (As noted above, I have found the Board's clinical records in relation to this point to be unsatisfactory). These were fundamental aspects of C's complaint. I am deeply concerned that the Board's own investigation failed to appropriately address these concerns and identify failings including the additional failures listed above. I have also found it was not documented that a thorough examination was made on 15 September 2022, as stated in the Board's complaint response to C.

66. In view of this, I am making an additional complaint handling recommendation.

Recommendations

Learning from complaints

The Ombudsman expects all organisations to learn from complaints and the findings from this report should be shared throughout the organisation. The learning should be shared with those responsible for the operational delivery of the service as well as the relevant internal and external decision-makers who make up the governance arrangements for the organisation, for example elected members, audit or quality assurance committee or clinical governance team.

What we are asking the Board to do for C:

Rec number	What we found	What the organisation should do	What we need to see
1	Under this point of the complaint I found that the Board's treatment fell below a reasonable standard. In particular I found that the Board should have: v. carried out an appropriate risk assessment for VTE. vi. identified that A was high risk for VTE because of their BMI and that the anaesthetic time was an additional risk factor.	Apologise to C for the failings identified in this investigation. The apology should meet the standards set out in the SPSO guidelines on apology available at www.spso.org.uk/informationleaflets	A copy or record of the apology. By: 24 June 2024

Rec number	What we found	What the organisation should do	What we need to see
	vii. identified the risk of VTE outweighed the risk of bleeding. viii. carried out a SAER in relation to this case as this was an unexpected death. I also found it was unreasonable that the Board did not have in place a relevant VTE policy for the orthopaedic department and that the Board's complaint handling was unreasonable.		

We are asking the Board to improve the way they do things:

Rec number	What we found	Outcome needed	What we need to see
2	Under this point of the complaint I found that the Board's treatment fell below a reasonable standard. In particular I found that the Board should have: iv. carried out an appropriate risk assessment for VTE. v. identified that A was high risk for VTE because of their BMI and identified that the anaesthetic time was an additional risk factor. vi. identified the risk of VTE outweighed the risk of bleeding.	Patients undergoing orthopaedic surgery should be appropriately risk assessed for VTE. This should include an assessment of BMI and anaesthetic time. The assessment should be documented on the clinical record.	Evidence that the Board have: carried out a sample audit of orthopaedic trauma patients at RIE to ensure that the assessment and documentation of risk for VTE is being appropriately carried out. Details of the findings of the audit and any actions identified to be included. reviewed the training needs for relevant staff in relation to the assessment and documentation of risk for VTE. Details of the review findings and how any actions identified will be taken forward to be included. shared the findings of my investigation with relevant staff in a supportive manner for reflection and learning. By: 22 August 2024

Rec number	What we found	Outcome needed	What we need to see
3	A Significant Adverse Event Review for an unexpected death should have been held in line with national guidance.	Where adverse event(s) occur an adverse event review should be held in line with relevant guidance to ensure there is appropriate learning and service improvements that enhance patient safety.	Evidence that the Board's systems for carrying out critical and adverse event reviews have been reviewed to ensure they are carried out in line with national guidance. By: 22 August 2024

We are asking the Board to **improve their complaints handling**:

Rec number	What we found	Outcome needed	What we need to see
4	There was a failure to fully investigate and identify the significant failings in this case in accordance with the Board's complaint handling procedure and the NHS Model Complaints Handling Procedure. The complaint response also contained inaccuracies in relation to the assessment of A's risk for VTE.	Complaints should be investigated and responded to in accordance with the Board's complaint handling procedure and the NHS Model Complaints Handling Procedure. Complaints investigators should fully investigate and address the key issues raised, identify and action appropriate learning. The complaint response should be factually accurate.	Evidence that these findings have been fed back to relevant staff in a supportive manner that encourages learning, including reference to what that learning is (for example, a record of a meeting with staff; or feedback given at one-to-one sessions). By: 22 July 2024

Evidence of action already taken

The Board told us they had already taken action to fix the problem. We will ask them for evidence that this has happened:

Complaint number	What we found	Outcome needed	What we need to see
a)	The Board should have had a relevant VTE protocol for the orthopaedic department in place.	The Board told us they were drafting a protocol.	Evidence of the VTE protocol and any supporting documents. By: 22 July 2024

Feedback

Points to note

My investigation found the medical records in relation to whether anticoagulation was prescribed and given to be unclear. This is unsatisfactory. I am highlighting this for the Board to reflect on and action as required. I expect the Board to give this serious consideration.

Terms used in the report **Annex 1**

A	the aggrieved
the Adviser	the consultant orthopaedic surgeon who provided independent advice on this case
anticoagulant	blood-thinning medication
BMI	body mass index, a measure using height and weight to assess whether a person is of a healthy weight for their height.
the Board	Lothian NHS Board
C	the complainant
DVT	deep vein thrombosis - a blood clot in a vein, usually in the leg
ED	emergency department
HIS	Healthcare Improvement Scotland
NICE	National Institute for Health and Care Excellence, which provides guidance for health and care practitioners
PE	pulmonary embolism (also referred to as pulmonary thromboembolism) - a life-threatening condition where a blood clot from another part of the body travels to the lungs and blocks an artery.
RIE	Royal Infirmary of Edinburgh
SAER	Significant Adverse Event Review - a national approach to learning from adverse events through reporting, review and the sharing of learning.
VTE	Venous thromboembolism – a condition that occurs when a blood clot forms in a vein.

VTE includes deep vein thrombosis and pulmonary embolism.