SCOTTISH PUBLIC SERVICES OMBUDSMAN

People Centred | Improvement Focused

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

SPSO
Bridgeside House
99 McDonald Road
Edinburgh
EH7 4NS

Tel **0800 377 7330**
Web **www.spso.org.uk**

Scottish Parliament Region: Mid Scotland and Fife

Case ref: 202105840, Fife NHS Board

Sector: Health

Subject: Hospitals / Clinical treatment / diagnosis

Summary

The complainant (C) complained to my office about the care and treatment they received from Fife NHS Board (the Board) between April and May 2021.

C received Dalteparin injections, a heparin-based treatment, from the Board's outpatient Deep Vein Thrombosis (DVT) clinic for a superficial vein thrombophlebitis (SVT: inflammation of a vein near the surface of the skin). Around nine days after commencing the injections C reported to the clinic new onset of symptoms of weakness, numbness and difficulty moving their leg. C was admitted to hospital where they received investigations to rule out either peripheral nerve entrapment or a stroke. C's symptoms continued to worsen including new onset of severe leg pain, and it was later confirmed that C had developed limb ischaemia (inadequate blood supply due to blockage of the blood vessels) due to Heparin Induced Thrombocytopenia (HIT), a serious complication associated with heparin-based products. Although C was transferred to another health board for emergency vascular surgery which saved their leg, they have been left with permanent nerve damage and suffer from chronic pain and reduced mobility.

C complained the delay in treating them for HIT resulted in the permanent harm caused to their leg, and their outcome would have been better had the condition been diagnosed and treated earlier. C also complained that the Board's handling of their complaint had been unreasonable.

The Board said that C's presentation of limb ischaemia was unusual, alongside an unusual but not unrecognised, side effect of heparin injections. Ruling out a stroke or spinal problem was the clinical priority. There was a missed opportunity to review C at the DVT clinic in light of the blood tests taken, and there was a failure to consider HIT earlier, timeous screening of which could have prompted an earlier prescription of a different anticoagulant drug to treat or prevent a blood clot.

C complained to SPSO about this episode of care and the Board's handling of their complaint, which they said had failed to recognise the harm caused to them by this incident. When my office contacted the Board about C's complaint, the Board advised that a decision had been taken to undertake a Local Adverse Event Review

(LAER). The complaint was closed by my office as it was considered the outcome of the LAER may resolve C's remaining concerns. C contacted my office again some months later as they were yet to receive a copy of the LAER report and as the Board were unable to commit to a timescale for its completion. I made enquiries of the Board about the LAER and decided to investigate. The Board subsequently issued the LAER report, 11 months after the decision was made to commence the review process.

I sought independent advice from a Consultant Haematologist (the Adviser). The Adviser told me HIT is an infrequent rather than unusual complication of heparin injections and all patients receiving this treatment should be routinely monitored for this. The DVT clinic appointments were a key opportunity to manage C's condition before harm had happened, particularly in light of the blood results which were available indicating that C's platelet count had dropped. HIT is a very difficult condition to treat even when treatment is commenced immediately, however, had action been taken earlier, in their view, it may have significantly changed the outcome for C. It would be usual to treat for HIT urgently until proven otherwise, however, the investigations C received were focused on nerve entrapment or stroke. Had it been the case that C was suffering from a stroke, it would likely have occurred as a consequence of HIT, not as an independent occurrence. The link between HIT and the presence of a stroke had not been made and there was a failure to recognise the need to act on the likely diagnosis of HIT and start treatment straight away.

The Adviser noted the Board's LAER report did not recognise that the haematology experts, both the DVT clinic and the on-call haematologist, failed to identify the significant change in C's blood results which had occurred even before C first presented with leg symptoms. It was of significant concern that although junior and general medical staff correctly suspected HIT, they did not then receive appropriate specialist support and advice which meant C was not urgently treated for HIT as they should have been.

The Adviser further said that they considered this incident to be a serious adverse event. As C was left with a permanent harm, the incident met the requirements for a category one Significant Adverse Event Review, as set out in guidance issued by Healthcare Improvement Scotland. The grounds on which a LAER or SAER would be commissioned were unclear in the Board's policy, however, on balance it was unreasonable that this had not been investigated as a SAER.

i. In light of the evidence I have seen and the advice I have received and considered, I found that:

i. There was a failure to appropriately review and monitor C's platelet count at the DVT clinic;

ii. There was a failure to appropriately assess and diagnose C for suspicion of HIT; provide appropriate haematology advice to medical staff and review and document C's response to pain relief; and

iii. the Board's handling of C's complaint was unreasonable including their handling of the LAER

As such, I upheld C's complaints.

Redress and Recommendations

The Ombudsman's recommendations are set out below:

What we are asking the Board to do for C:

Complaint number	What we found	What the organisation should do	Evidence SPSO needs to check that this has happened and the deadline
(a)	The care and treatment provided by the Board to C in April and May 2021 was unreasonable. Specifically, the Board failed to: i. appropriately review and monitor C's platelet count at the DVT clinic. ii. appropriately assess and diagnose C for suspicion of HIT taking into account the timeframe of onset of symptoms or consider the working diagnosis of stroke as a likely manifestation of HIT.	Apologise to C for the failings identified in this report The apology should meet the standards set out in the SPSO guidelines on apology available at www.spso.org.uk/information-leaflets.	A copy or record of the apology. By: 24 January 2024

Complaint number	What we found	What the organisation should do	Evidence SPSO needs to check that this has happened and the deadline
	iii. provide appropriate haematology advice to medical staff iv. appropriately review and document C's response to pain relief medication once their pain had escalated.		

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

Complaint number	What we found	What should change	Evidence SPSO needs to check that this has happened and deadline
(a)	Under complaint (a) I found that the Board did not appropriately review and monitor C's blood test results.	Bloods results should be appropriately reviewed and patients receiving heparin injections appropriately monitored. Patients should receive appropriate, timely review if any new onset symptoms are reported.	Evidence that the findings of this investigation have been fed back to relevant staff in a supportive way for learning and improvement and to avoid a similar mistake being made again.

Complaint number	What we found	What should change	Evidence SPSO needs to check that this has happened and deadline
			Evidence that the Board have reviewed the DVT clinic's management and review of patients receiving heparin injections to ensure blood results are timeously reviewed and acted on appropriately. Confirmation of the action taken and details of any resulting action points or procedural changes. By: 20 March 2024
(a)	Under complaint (a) I found that the Board did not i. appropriately assess and diagnose C for suspicion of HIT taking into account the timeframe of onset of symptoms or consider the working	Patients presenting symptoms as in C's case should be appropriately reviewed by general and speciality medical staff with reference to the timeframe of onset of symptoms and likely manifestations of HIT,	Evidence that my findings have been shared with relevant staff in a supportive way for feedback and reflection. Evidence that consideration has been given as to whether guidance is required for the

Complaint number	What we found	What should change	Evidence SPSO needs to check that this has happened and deadline
	diagnosis of stroke as a likely manifestation of HIT. ii. provide appropriate haematology advice to medical staff.	such as stroke, with treatment commenced as appropriate.	management and treatment of suspected cases of HIT. By: 20 March 2024

We are asking the Board to improve their complaints handling:

Complaint number	What we found	What the organisation say they have done	Evidence SPSO needs to check that this has happened and deadline
(b)	I found the Board's handling of C's complaint was unreasonable. Specifically the Board failed to consider activating the Duty of Candour process at an appropriate time.	When an incident occurs that falls within the Duty of Candour legislation, the Board's Duty of Candour processes should be activated without delay and the individual notified within the prescribed timescales. If there is a delay in notification a full explanation should be provided.	Evidence that the findings on the Board's complaint handling have been fed back in a supportive manner to relevant staff and that they have reflected on the findings of this investigation. Evidence that the Board have reviewed their Duty of Candour processes, including timescales for activating the process and

Complaint number	What we found	What the organisation say they have done	Evidence SPSO needs to check that this has happened and deadline
			notifying the individuals concerned with details of how the guidance, and any changes, will be disseminated to relevant staff By: 20 March 2024
(b)	I found that the Board failed to undertake a reasonable adverse event review that identified key learning from C's complaint. i. It failed to keep C informed of the process and the reasons for selecting a LAER, rather than SAER. ii. It failed to identify key learning from the circumstances of C's complaint. iii. Significant (rather than a Local) adverse event review should have been held in line with relevant guidance.	Local and Significant adverse event reviews should be reflective and learning processes that ensure failings are identified and any appropriate learning and improvement taken forward. The Board's adverse event policy should be consistent with HIS guidance, and the type of investigation undertaken should be appropriate to the level of category identified.	Evidence that the Board have reviewed the Adverse Event Policy, the conclusions of the review and any actions taken as a result. By: 17 April 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	What the organisation say they have done	Evidence SPSO needs to check that this has happened and deadline
(b)	The Board's handling of C's complaint was unreasonable	The outcome of the local adverse event review had been shared with the key individuals involved for reflection and learning to include improvement in documentation. Teaching sessions were in progress, commencing in July 2022	Evidence that the Board have taken action in relation to this By: 21 February 2024

Feedback

Points to note

The Adviser noted that the policy for the management of superficial vein thrombophlebitis does not include information about the monitoring of blood results which should be done for patients being treated with heparin. If this information is included in a separate policy, it is suggested that consideration is given to including a link or reference to the relevant policy that gives such detail, or to include the detail in the SVT policy itself.

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 states 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. C complained to me about the care and treatment that they received from Fife NHS Board (the Board) between 14 April and 16 May 2021. C said that there had been a failure to timeously diagnose and treat a blood clot in their leg caused by the heparin (medication used to prevent blood clots) medication that they had been prescribed at the outpatient Deep Vein Thrombosis (DVT) clinic (the DVT clinic). They had been attending the DVT clinic for the treatment of a left lower leg superficial vein thrombophlebitis (SVT: inflammation of a vein near the surface of the skin).

2. C's GP subsequently arranged direct admission to hospital following a worsening of their symptoms. C complained that there was a delay in receiving a medical review during their hospital admission, despite reporting persistent and worsening pain which had not resolved with strong painkillers. C was later transferred for emergency vascular surgery to another health board. C complained to me that there was a delay in diagnosis and failure to review them appropriately which they said had resulted in permanent nerve damage to their left leg. They advised that this had significantly affected their mobility and continues to cause them severe and chronic pain. C also complained that the Board's handling of their complaint about the episode of care had been unreasonable.

3. The complaint from C I have investigated is:

(a) The care and treatment provided by the Board to C from April 2021 was unreasonable *(upheld);* and

(b) The Board's handling of C's complaint was unreasonable *(upheld)*.

Investigation

4. 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 C's medical and nursing records, and complaint correspondence. We also obtained medical advice from an appropriately qualified medical adviser (the Adviser: a Consultant Haematologist, specialising in diagnosing, treating and managing diseases that affect the blood). In advising on the case, the Adviser had full access to C's relevant medical records and the Board's complaint file.

5. I appreciate that at the time the actions investigated took place, and at the time of reporting, the NHS was and continues to be under considerable pressure due to the impact of COVID-19 and other significant issues. Like others, I

recognise, appreciate and respect the huge contribution everyone in the NHS (and public services) has made, and continues to make. However, much as I recognise this, I also recognise that patient safety, personal redress, and learning from complaints are as relevant as ever and it is important that collectively we do not miss opportunities to learn and improve for the future.

6. In this case, I have decided to issue a public report on C's complaint because of the significant personal injustice suffered by C and my concerns about the failings I have identified, including complaint handling failures. I also consider there is the potential for wider learning from the complaint.

7. 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.

(a) The care and treatment provided by the Board to C from April 2021 was unreasonable

Timeline of care and treatment provided by the Board

8. This section contains a summarised chronology of C's care and treatment.

   i. 14 April 2021 C was referred to the DVT clinic by their GP on suspicion of having a left lower leg DVT. A diagnosis of SVT was made, and C was commenced on Rivaroxaban (a medicine used to thin the blood to treat and prevent blood clots). C's platelet (cells in the blood which clot to prevent excess bleeding) count at this appointment was 230 (x 10^9/L).

   ii. 5 May 2021 C attended a review appointment at the DVT clinic. C reported having an urticarial skin rash (hives) on both legs. It was thought this had been caused by a reaction to the Rivaroxaban and C's treatment was changed to Dalteparin injections (a heparin-based medicine that helps to prevent the formation of blood clots by thinning the blood). A plan was made to review C and check their bloods at the next scheduled appointment on 13 May 2021.

   iii. 13 May 2021 C attended the DVT clinic. It was noted that the rash to C's legs had resolved. C was to continue on Dalteparin injections and an ultrasound scan of their leg was planned for 27 May 2021. C's platelet count at this appointment was reported as 106 (x 10^9/L).

iv. 14 May 2021 C phoned the DVT clinic for advice due to the onset of new symptoms of weakness, numbness and difficulty moving their leg. C was advised by the DVT nurse (the Nurse) to attend the Accident & Emergency (A&E) Department on suspicion of them having a stroke. C had also contacted their GP about the same matter, who subsequently arranged direct admission to the assessment unit, AU1. C's platelet count was reported as 27 (x 10^9/L).

v. 15 May 2021 C received a CT scan (Computerised Tomography: an imaging technique used to obtain detailed internal images of the body) in the early hours of the morning which ruled out a haemorrhagic stroke (a stroke caused by bleeding). C was reviewed on the ward by medical staff at 05:00. C's symptoms were still thought to be clinically in keeping with a stroke. C's case was discussed with the on-call consultant haematologist. Advice was given to stop the Dalteparin injections and a plan was made for further tests to be taken after discussion at the medical ward round the next morning. C was seen on the medical ward round at 09:30.

A plan was made for further haematology (the branch of medicine concerned with diseases related to blood) review and an MRI scan (Magnetic Resonance Imaging scan: an imaging technique used to obtain detailed internal images of the body) was arranged to rule out other head or spinal causes of C's symptoms. C was moved to the stroke ward. A junior doctor (Doctor 1) discussed C's case with the on-call haematology consultant.

At 18:23 Doctor 1 documented that the plan to arrange an MRI scan had been agreed by haematology, which would take place after the weekend. Doctor 1 documented the advice given not to restart anticoagulant (medicines used to thin the blood to prevent clots) treatment at that time. C was to remain in hospital for monitoring of blood results and symptoms. C's platelet count was reported as 26 (x 10^9/L).

vi. 16 May 2021 C was reviewed at 00:12 for new onset of severe leg pain by a different junior doctor (Doctor 2). C was prescribed oramorph (liquid morphine) analgesia which they received at 01:09. On examination, C's pulses and temperature were documented as normal. Advice was given by Doctor 2 to the ward nursing staff to escalate if C's pain did not improve following analgesia.

At 12:47 Doctor 1 documented in the medical notes that they had been asked to review C for continuing and worsening leg pain. On examination changes to colour, temperature and a lack of leg pulses are noted. The medical

registrar was informed of concern regarding a lack of blood supply to C's leg. C attended an urgent CT scan which confirmed a blockage to the blood supply to C's left leg. Advice was given by haematology to start a specialist prescription anticoagulant drug, Argatroban. C's transfer to another health board for emergency vascular surgery was arranged that same day. C's platelet count was reported as 29 (x 10^9/L).

Concerns raised by C

9. C told us that they considered the Board had failed to provide them with reasonable care and treatment for the following reasons:

   i. There had been too much focus on a stroke being the likely cause of their symptoms due to them having reported a headache two days prior to the onset of their leg symptoms. C considered it was unreasonable for other causes not to have been considered and investigated at the same time. C considered that the treatment they were receiving for SVT and their recently diagnosed reaction to Rivaroxaban should have pointed more toward a diagnosis of an ischaemic (inadequate blood supply due to blockage of the blood vessels) leg.

   ii. C considered their outcome would have been better had leg ischaemia been diagnosed and treated earlier. C explained that their mobility has been significantly reduced and they suffer from chronic leg pain. C told us that their leg is disfigured and claw-like in appearance which has seriously reduced their quality of life. C was the sole carer for their partner, however, the loss of mobility and function of their leg had affected their ability to look after them. C's partner has sadly died in the time since making the complaint.

The Board's position

10. I have not repeated the content of the Board's original response to C's complaint, as all parties are aware of it. However, the main points of their response were that:

   i. C's presentation of limb ischaemia was unusual, alongside an unusual but not unrecognised, side effect of heparin injections. The Board said ruling out a stroke or spinal problem was the clinical priority.

   ii. There was a missed opportunity to review C at the DVT clinic given the reduction in their platelet count between their appointments in April and May 2021.

iii. There was a failure to document C's leg pulses on admission to AU1, with recording of the same being considered best practice.

iv. A possible diagnosis of Heparin Induced Thrombocytopenia (HIT: a serious complication associated with heparin products) should have been considered in light of C's recent clinical history, timeous screening of which could have prompted an earlier prescription of a different anticoagulant drug to treat or prevent a blood clot.

v. The new leg pain C experienced overnight was not in keeping with the working diagnosis of stroke or spinal problems, which should have prompted re-assessment of their symptoms. Over the following 12 hour period, there was no documentation in the medical record of C's response to analgesia having been reviewed, nor update on their condition generally. The medical and nursing notes did not say whether C's condition had been discussed or escalated to senior staff for review.

11. In response to our further enquiries, the Board provided a retrospective statement obtained from the Nurse on 28 July 2021 as part of the Board's own investigation into the complaint. The statement advised that:

i. C had been independently mobile on attending the clinic appointment on 13 May 2021.

ii. A blood test was taken on 13 May 2021 and C's platelets were recorded as 106 (x 10^9/L).

iii. It was acknowledged that there had been a failure to notice the drop in C's platelet count from the previous results.

iv. On receiving the phone call from C on 14 May 2021 reporting the new onset of leg symptoms, the statement advises C was directed to attend A&E as little could be done at the DVT clinic.

Relevant policies, procedures, and legislation

12. The British Society for Haematology Guideline, 'Diagnosis and Management of Heparin Induced Thrombocytopenia[1]'.

13. NHS Fife Policy for the management of superficial vein thrombophlebitis (DVT-01).

[1] Diagnosis and Management of Heparin Induced Thrombocytopenia: Second Edition (b-s-h.org.uk)

Medical advice

14. The Adviser was asked to consider the treatment that C had received from the DVT clinic. The Adviser told us that:

i. Heparin (Dalteparin) injections were commenced at the clinic on 5 May 2021. Follow-up was appropriately scheduled for just over a week later on 13 May 2021.

ii. A full blood count (FBC) was taken on 13 May 2021 with C's platelet count reported as 106 (x 109/L). The Adviser noted the previous recorded platelet result of 230 (x 109/L) on 14 April 2021.

iii. The Nurse's statement obtained by the Board in response to C's complaint said that they had failed to notice the drop in the platelet count at that time. The Nurse had explained that they had told C to attend A&E during the phone call of 14 May 2021 as there was little the DVT clinic could do for C.

iv. It was unclear whether the Nurse did not realise the implications of the platelet count having more than halved, or whether they had not checked the FBC to see what the platelet count was at that point. If the former, the Adviser said recommending the patient to attend A&E rather than arranging for an urgent haematology review would have been unreasonable on the basis that it would have been appropriate, even if further assessment was to be undertaken in the A&E setting, to highlight that C required an urgent haematology (and not a general medical) review on attending the A&E department. In the latter case, if the situation was that the Nurse had referred C to the A&E having failed to check the results of the FBC, then this would also have been unreasonable on the grounds that HIT as a possible complication of the heparin injections should have been considered, particularly as the reason for checking a FBC one week after starting heparin is specifically to check for the possibility of HIT.

v. The outpatient appointments were a key opportunity to manage C's condition before harm had happened. Given the blood results which were available and which showed a drop in C's platelet count, the Adviser considered this was a missed opportunity to act before any symptoms had occurred. Instead, C remained on Dalteparin injections until 15 May 2021, and the Adviser noted the failure by the DVT clinic to urgently start an alternative anticoagulant treatment in response to C's platelet results. HIT was an infrequent rather than unusual complication of heparin injections and all patients receiving this treatment should be routinely monitored for this.

vi. HIT is a very difficult condition to treat even when treatment is commenced immediately, however, had action been taken at this point, they considered it may have significantly changed the outcome for C. The Adviser further explained that in cases of HIT the effect of the heparin is to activate platelets through an immune response which increases the chance of the blood clotting which is the opposite intended effect of the drug. Stopping the heparin alone does not stop the platelet activation immediately as the antibodies remain present for some time. This means the risk of arterial or venous clots persist which are often life threatening, as was the case for C.

vii. Had an alternative anticoagulant been administered, this may have been sufficient to avoid any blood clots forming and there may have been no adverse effects for C at all. However, HIT is unpredictable and, even if appropriate alternative treatment had been started sooner, platelet activation can be so significant in some individuals that administration of an alternative anticoagulant may not have fully worked. The Adviser said it was not possible to say that there would have been no consequences for C had the correct treatment been started immediately, however, there was a significant chance that that the consequences would have been less severe.

15. The Adviser was asked to consider the initial assessment of C at the AU1.

i. The Adviser said a possible diagnosis of HIT was considered by Doctor 1 who had assessed C, but was excluded following discussion with the on-call haematologist. As it was known that C's platelet count was already at more than 50 percent less than their baseline count, HIT should have been high on the differential diagnosis for C at this point. The Adviser said it would be usual to treat for HIT urgently until proven otherwise. However, C's leg weakness was thought to be caused by a stroke or nerve entrapment, with a plan made for C to have a head CT and MRI scan of their spine.

ii. The Adviser noted that the on-call haematology consultant had confirmed C's platelet count to be genuinely low, and they considered that this should have pointed toward a likely diagnosis of HIT. An alternative anticoagulant should have been started straight away, rather than waiting for the results of the MRI scan before investigating the likelihood of HIT further.

iii. The Adviser noted that consideration had been given clinically to C's symptoms possibly being due to a stroke. The Adviser explained that the presence of a stroke would likely have been as a result of HIT (due to a blood clot) and not that of a further independent occurrence. The Adviser said that the link between HIT and the presence of a stroke had not been made at all.

This meant there was a consequent failure to recognise the need to act on the likely diagnosis of HIT and start treatment straight away. In light of this, the Adviser considered the initial assessment carried out by Doctor 1 to be reasonable, however, they considered the advice provided by the on-call haematologist at this time to be unreasonable.

iv. The Adviser highlighted that there had been other occasions during C's admission when the general medical doctors had considered a diagnosis of HIT, however, it remained the specialist haematology advice to not urgently treat C for this. The Adviser said that they did not think that the general medical team had been guided sufficiently by the on the on-call haematology specialist. The Adviser considered that the general medical staff had acted reasonably based on the specialist haematology advice that they had been given.

v. The Adviser explained that C should have been urgently started on an alternative blood thinner given that a significant drop in their platelet count had been noted, and as no alternative reason for this drop had been identified. The Adviser pointed out that the timing of this drop at nine days from the time of C starting on heparin (4 May – 13 May 2021) was typical for the onset of HIT. Based on this, the Adviser said that the plan of care made by haematology for C had been unreasonable.

16. The Adviser was asked to consider whether or not C had received reasonable treatment from the point at which they had reported the new onset of leg pain on 16 May 2021.

i. The Adviser said, given the working diagnosis made by senior colleagues of peripheral nerve entrapment or stroke, and as suspicion of HIT had not been realised, it was reasonable for Doctor 2 to attempt pain relief as a first line treatment for C's leg pain. On 16 May 2021, it was noted that Doctor 2 had documented at 00:12 that they had checked C's pulses and temperature which were found to be normal. The Adviser said that this suggested that Doctor 2 had considered a vascular supply issue as a cause of C's leg pain. The Adviser noted that Doctor 2 had then prescribed oramorph (liquid morphine) and given advice to escalate if there was no improvement following the pain relief.

ii. The Adviser highlighted that there was no further documentation in the medical or nursing records for the next 12 hours until 12:47. Therefore, it was not possible to know from the information available whether C's pain had been assessed by the ward staff following administration of the pain

medication. Given the degree of pain being described, the Adviser said it was reasonable to expect the ward nursing staff to have checked whether the pain relief had worked and if not, then there would have been the expectation that the medical staff would have been called back to assess and review further. From the documentation available, there did not appear to have been any further assessment soon after or for at least twelve hours after the pain relief had been administered. The Adviser considered the lack of documentation following administration of the pain medication to be unreasonable.

iii. The Adviser said, by the time C's symptoms had escalated later on 16 May 2021, the onward care documented in the medical record from 12:47 appeared to have been managed promptly. The Adviser reiterated that, had treatment for HIT commenced earlier, it may have led to a different outcome for C.

17. I have considered and accepted this advice to inform my decision making.

(a) Decision

18. C complained to my office that the care and treatment that they received from the Board from April 2021 was unreasonable. I recognise and acknowledge at the outset the very significant impact these events have had and continue to have on C and the importance of the issues raised for them.

19. In investigating this complaint, I have obtained professional advice from the Adviser as outlined above. I have carefully considered this advice, which, as stated above, I accept.

20. It is clear from the evidence and the advice that I have received, that the DVT clinic failed to recognise the drop in C's platelet count, and in turn failed to provide reasonable advice to C when they phoned the clinic to report the new onset of leg symptoms. In light of the heparin injections that they were receiving and the drop in their platelet count, I accept the advice I have received that the DVT clinic should have either arranged for C to receive an urgent haematology review or provided them with appropriate advice when re-directing them for review at the A&E.

21. I consider it was unreasonable that this did not happen. While acknowledging that HIT is a difficult condition to treat even when recognised early, the Adviser has said C's outcome may have been significantly different had it been treated immediately. I understand this will be a very difficult conclusion for C to learn

given the significant difficulties that they have experienced since these events. They have my utmost sympathy.

22. On being admitted to hospital, the Adviser considered HIT should have been high on the list of differential diagnoses for C in light of them receiving active treatment for a recent onset SVT with daily Dalteparin injections. The evidence indicates that HIT was suspected by junior and general medical staff. However, while the specialist haematology advice was to stop the Dalteparin injections, no advice was given to commence an alternative anticoagulant treatment. In light of the blood tests available which supported the diagnosis of HIT and the timeframe of the onset of C's symptoms, the advice I have received and accept is that it would have been usual to urgently treat C in these circumstances on suspicion of HIT until proven otherwise. I am extremely critical that this did not happen.

23. It is of significant concern to me that although junior and general medical staff correctly suspected HIT, they did not then receive appropriate specialist support and advice which led to C not being urgently treated for HIT as they should have been.

24. I am also concerned that it does not appear to have been understood that, had C suffered a stroke, it would likely have occurred as a consequence of HIT and not as a separate independent occurrence. In this context, I understand C should have urgently commenced on an alternative anti-coagulant treatment. Again, I am critical that this did not happen.

25. Referring to the ward's management of C's pain, in light of the advice and working diagnosis given by senior colleagues, I consider that it was reasonable for Doctor 2 to have trialled pain relief as a first line management of C's leg pain. Nevertheless, I am critical that there is no documentation in the medical record of the ward staff assessing C's response to the pain relief or evidence of re-referral back to the medical staff when their pain had not improved. This was another missed opportunity to take urgent action in relation to C's symptoms.

26. While I accept C received reasonable care from the point at which the deterioration in the blood supply to their leg was recognised, taking account of the above, I consider a diagnosis of HIT should have been considered far earlier in C's admission and appropriate treatment commenced. Additionally, based on the advice I have received (which I accept), there was a failure to recognise the significance of the drop in C's platelet count at the DVT clinic prior to admission which was a missed opportunity to act before any symptoms had occurred. I consider this was a further serious failing.

27. The advice I have received is that HIT is an infrequent rather than unusual complication of heparin injections and all patients receiving this treatment should be routinely monitored for this. Unfortunately this does not appear to have happened in C's case and I consider this was a significant omission in care.

28. Overall, I consider that the care and treatment provided by the Board to C fell below a reasonable standard and I uphold this complaint.

29. In making this decision, I am cognisant that the Board's Local Adverse Event Review (LAER) report recognises that, 'a different plan and/or delivery of care may have resulted in a different outcome [for C]'. While I acknowledge and welcome that the Board have identified and accepted some failings, it is my view that this falls short of the comprehensive review and learning I would expect to see in such a case. I have provided further comment on this under the decision section of complaint (b) below.

30. I have made a number of recommendations to address the issues identified and these are set out at the end of this report. The Board have accepted the recommendations and will act on them accordingly. My complaints reviewer and I will follow up on these recommendations. I expect evidence to demonstrate appropriate action has been taken before I can confirm that the recommendations have been met.

(b) The Board's handling of C's complaint was unreasonable

Timeline of complaint handling

31. The following dates are not intended as a complete summary of the communication between C, the Board and SPSO. Rather, the timeline is intended to highlight key dates in the complaint handling process.

    i. 21 July 2021 C submitted a formal complaint to the Board about the care and treatment received in respect of their left lower leg symptoms.

    ii. 11 October 2021 the Board issued their stage 2 complaint response letter to C.

    iii. 12 October 2021 C complained to SPSO.

    iv. 22 November 2021 C attended a complaints meeting with the Board. The Board decided to undertake a LAER of C's case, however, C explained to SPSO that they were not made of aware of this decision at the time.

v. 18 January 2022 the Board wrote to C advising that, following the stage 2 complaint and subsequent contact with SPSO, a further internal investigation and review of their complaint will take place (the LAER).

vi. 18 January 2022 my complaints reviewer closed the complaint on the grounds that the outcome of the LAER might answer C's remaining questions. C was provided with advice that they could return to my complaints reviewer should they remain unhappy with the Board's response.

vii. 5 July 2022 C emailed my complaints reviewer advising that they are still to receive the outcome of the LAER from the Board.

viii. 6 July 2022 my complaints reviewer contacted the Board requesting an update on the completion of the LAER. The Board responded that the case had been discussed on 9 June 2022, however, further clarification was required from the clinical teams before the investigation could be closed. Due to pressure on the services, the Board advised that they were unable to commit to a timescale for completion.

ix. 7 July 2022 - 10 August 2022 my complaints reviewer made further enquiries of the Board which were not responded to. The complaint was subsequently escalated and managed in line with SPSO's Support and Intervention Policy[2].

x. 21 October 2022 a copy of the LAER report and summary were received by my complaints reviewer.

xi. 26 October 2022 my complaints reviewer contacted the Board to confirm that a copy of the LAER had been sent to C. The Board advised that it had not yet been sent.

xii. 31 October 2022 C confirms that they have received a copy of the LAER report from the Board.

xiii. 3 November 2022 the Board issued a Duty of Candour letter to C. The letter acknowledged C's experience as a safety incident and that the Board did not provide the standard of care that C should be able to expect. It stated that the incident had been investigated with it being recognised that there must be an improvement in documentation, with reference to the failure to document the significant change in C's leg pain and the lack of escalation to the

[2] Support and Intervention Policy | SPSO

Hospital at Night Team. The Board offered C a meeting for them to discuss the incident and to explain the actions taken in response.

32. During our initial assessment of C's complaint and in light of the permanent harm C reported, my complaints reviewer contacted the Board seeking clarification on the processes under which C's complaint had been reviewed. Specifically, the Board were asked whether C's complaint had been considered in line with Duty of Candour legislation or if the circumstances of the complaint were considered to meet the criteria for a Significant Adverse Event Review.

Concerns raised by C

33. C told us the reasons they felt the Board's handling of their complaint was unreasonable were that:

    i. C had attended a complaint meeting with the Board on 22 November 2021 to discuss the episode of care during which several areas for learning had been identified. Nevertheless, it remained their view that the Board had failed to take responsibility for the harm and the long term damage that had been caused.

    ii. On complaining to my office, C said that they were not aware of the Board's plan to carry out the LAER until being informed of this by my complaints reviewer. C was subsequently informed about the LAER by the Board at our request in January 2022. In July 2022, C contacted my complaints reviewer again as the Board were still to conclude the LAER and they would not confirm a timeframe of when it would be completed. C considered the time taken by the Board to complete the LAER was unreasonable.

The Board's position

LAER

34. I have noted the following key points from the LAER of C's complaint completed in October 2022.

    i. The decision to undertake a LAER was made by the Head of Nursing in November 2021 following the complaints meeting between the Board and C.

    ii. A probable diagnosis of HIT had been made on a background of 10 days treatment with low molecular weight heparin for thrombophlebitis. A differential diagnosis of stroke was considered, and a CT scan was

requested which did not show any bleeding or other changes. A further examination confirmed that C had some weakness and loss of sensation that could still be in keeping clinically with a stroke.

iii. C was reviewed on the post-take ward round at 09:30 on 15 May 2021 and given the concern regarding HIT, a further haematology opinion and MRI scan (head and spine) were considered to rule out any more unusual pathology in the brain or spinal cord. As MRI scans are not routinely carried out at the weekend, the plan was made for C to remain in hospital for monitoring with a view to them having the scan after the weekend.

iv. The LAER noted a gap in documentation and no evidence of escalation until 12:47 on Sunday 16th May 2021, where it was noted that C was experiencing worsening leg pain despite receiving morphine medication. On examination, changes were noted including temperature changes and loss of pulses which prompted escalation to senior doctors. A CT angiogram scan was urgently arranged to rule out a blockage to the blood supply of C's leg. The scan confirmed a blockage and an alternative anticoagulant was commenced, with C being transferred to another health board for emergency vascular surgery on their leg.

v. On conclusion of the LAER, the review team considered C's case was an unusual presentation of leg ischaemia, complicated by an unusual but not unrecognised side effect of the Dalteparin injections. The review team considered, had staff at the DVT clinic checked C's blood results from the previous day, it would have been noted that the platelet level had dropped from 230 to 106 (x 10^9/L) and that this should have prompted a medical review and possibly earlier involvement by the consultant haematologist.

vi. On the evening of 16 May 2021, at the point at which a change and deterioration had occurred, the diagnosis should have been reviewed, noting new pain to the degree described would not be in keeping with the working diagnosis of a stroke or spinal problem. The review team considered that C's pain had not been appropriately managed as the ischaemia progressed, and staff failed to document this or escalate it appropriately.

vii. The Board reported that the complaint had been presented as a teaching opportunity to the junior doctors and other health care professionals on the importance of recognising and managing change and deterioration, especially around the issue of developing new pain which would have changed the working diagnosis. The outcome of the LAER had been shared with the key individuals involved for reflection and learning to include

improvement in documentation. The Board advised of teaching sessions being in progress, commencing in July 2022 and they said awareness of the potential for HIT and the management of this condition had increased as a result of this.

viii. In response to our further enquiries, the Board explained that the delay in completing the LAER had been caused by the pressures on the service at that time, however, they provided reassurance that C's concerns were being taken seriously.

ix. The Board were asked to clarify the type of adverse review process followed for C's complaint, noting the Board's Adverse Events Policy offers two types of review: a LAER, and a Significant Adverse Event Review (SAER). The Board advised of the difference between each process: LAER is carried out by the local team involved in the incident whereas SAER will have an Executive Sponsor.

x. LAER is carried out by the team within the service/ department where the event happened, the review team will be independent of the episode of care that resulted in the adverse event. The LAER report and its learning is reviewed and approved by the senior management team for that service/ department.

xi. SAER is carried out predominately by the same team that would carry out a LAER within the service/ department where the event happened. The difference between the two levels of reports being that the SAER will have a member of the executive team who is responsible for the review and approval process.

xii. Both SAER and LAER are commissioned by Medical Director and Director of Nursing.

35. The Board were unable to provide evidence supporting the decision-making in respect of the type of review undertaken in this case.

Relevant policies, procedures, and legislation

36. Healthcare Improvement Scotland. Learning from adverse events through reporting and review. A national framework for Scotland: December 2019[3]

[3] Learning from adverse events through reporting and review - A national framework for Scotland: December 2019 (healthcareimprovementscotland.org)

37. NHS Fife Adverse Events Policy.

i. This policy includes instruction on the process to be followed for LAERs. The policy provides 90 working days for completion from the reporting date.

38. Scottish Government. Organisational duty of candour: guidance. March 2018[4]

i. The Organisational Duty of Candour guidance is founded on legislation which advises the procedure must be activated when:

> ‘an unintended or unexpected incident has occurred that results in death or harm (or additional treatment is required to prevent injury that would result in death or harm)’.

ii. The circumstances where this would apply are given as:

> in the reasonable opinion of a registered health professional not involved in the incident that:
>
> a) that incident appears to have resulted in or could result in any of the outcomes mentioned below; and
>
> b) that outcome relates directly to the incident rather than to the natural course of the person’s illness or underlying condition.

iii. The outcomes referenced at ii) being as follows:

> a) The death of the person.
>
> b) Permanent lessening of bodily, sensory, motor, physiologic or intellectual functions (including removal of the wrong limb or organ or brain damage) (‘severe harm’).
>
> c) Harm which is not severe harm but which results in one or more of the following criterion:
>
> an increase in the person’s treatment.
>
> changes to the structure of the person’s body.
>
> the shortening of the life expectancy of the person.

[4] Organisational Duty of Candour guidance: March 2018 (www.gov.scot)

an impairment of the sensory, motor or intellectual functions of the person which has lasted, or is likely to last, for a continuous period of at least 28 days.

the person experiencing pain or psychological harm which has been, or is likely to be, experienced by the person for a continuous period of at least 28 days.

d) The person requires treatment by a registered health professional in order to prevent:

the death of the person;

any injury to the person which, if left untreated, would lead to one or more of the outcomes mentioned at b) or c).

iv. In terms of the processes in relation to notifying the relevant person about the incident:

a) The relevant person should be notified as soon as possible (with good practice being notification within 10 days).

b) Where the procedure is activated more than a month after the incident, the organisation must provide a reason for this.

c) The notification must include an account of the incident as far as is known at the time, and an explanation of the action the organisation plans to take in response to the incident.

v. The organisation must apologise for the duty of candour incident.

vi. The relevant person must be invited to a meeting.

vii. The organisation must carry out a review of the circumstances which they consider led or contributed to the unintended or unexpected incident. They must seek the views of the relevant person and take account of any views expressed.

viii. The organisation must prepare a written report of the review, to include a description of how the review was conducted, a statement of any actions to be taken in terms of learning and improvement by the organisation, and a

list of actions taken for the purpose of the procedure in respect of the incident and the date each action took place.

Medical Advice

39. The Adviser was asked to consider the LAER carried out by the Board:

i. The Adviser noted that the LAER report did not give due consideration to the role and responsibility of the DVT clinic in this incident. The Adviser said that the DVT clinic had been managing C's SVT, yet the report contained limited comment on the management and assessment C received from this service. As noted under complaint a), the Adviser said that the outpatient appointments were a key opportunity to manage C's condition before harm had happened. Given the blood results which were available and which showed a drop in C's platelet count, the Adviser considered that this was a missed opportunity to act before any symptoms had occurred. Rather, C remained on Dalteparin injections until 15 May 2021, and they noted the failure by the clinic to urgently start an alternative anticoagulant treatment in response to C's platelet results.

ii. The Adviser highlighted that the LAER had described the incident as, '…an unusual presentation of limb ischaemia complicated by an unusual (but not unrecognised) side effect of the Dalteparin injections'. The Adviser said, as noted above, HIT was an infrequent rather than unusual complication of heparin injections and reiterated that all patients receiving this treatment should be routinely monitored for it.

iii. The Adviser noted the LAER had described an omission to check C's leg pulses on admission as a failure in care, with it being said that this should have been recorded as good practice. The Adviser said, while C's pulses could have been recorded on admission, given the pedal pulses (the pulse palpable at the top of the foot) were checked and present on 16 May 2021 at 00:16, the failure to check them on admission was less significant as they would also have been present had they been checked earlier in the admission. As such, the Adviser said this omission was less significant in the context of C's case than the LAER report suggested.

iv. The Adviser noted the LAER's comments in relation to the failure to escalate C's condition when their pain had not improved following the morphine analgesia. As noted under complaint a), the Adviser considered the plan made by Doctor 2 to trial pain relief was reasonable in the circumstances of HIT not being considered in this case. The Adviser noted that there was no

evidence to suggest C had been escalated back to Doctor 2 when it was known that the pain relief had had little effect. The Adviser said that this pointed toward a failure at ward level rather than a failure by Doctor 2 to take appropriate action.

v. The Adviser said that it was concerning that the LAER report does not appear to have identified that the haematology experts, both the DVT clinic and the on-call haematologist, failed to identify the significant platelet drop that happened even before the patient first presented as a likely diagnosis of HIT. The Adviser said it was unreasonable that the learning actions put in place were aimed at the junior doctors and the general medical service and, while this was relevant and important, there were other learning needs which could have been identified for the haematology service.

vi. Of note, the Adviser said the LAER report did not include recognition of the need for blood results to be routinely reviewed, and for there to be a clear understanding of the implications of a significant drop in platelet count in any patient receiving any type of heparin, including Dalteparin injections.

vii. The Adviser also said that there appeared to be a lack of understanding that HIT could lead to strokes. The documentation suggested that the clinical team were considering both HIT and stroke as possible causes of C's symptoms, but not stroke as a manifestation of HIT, noting that stroke in the setting of HIT would require even more urgent treatment with an alternative blood thinner.

viii. The Adviser provided wider context to the circumstances of this complaint. The Adviser said, where clinical advice is given by a specialist consultant, it is very difficult for junior staff to challenge this advice. The Adviser noted that senior clinical staff from other specialties were also accepting of the haematology advice that they received, despite also documenting that HIT could be the cause of C's symptoms. The Adviser reiterated that the junior doctors had acted reasonably, based on the senior clinical advice given at the time. They were clear that the haematology service had failed to provide reasonable care and treatment to C, at both the DVT clinic prior to admission and in the advice given once C was admitted to hospital. Overall, given the points above, the Adviser considered the LAER of C's complaint completed by the Board to be unreasonable.

ix. The Adviser also considered the type of review process chosen by the Board to review this incident. Given the permanent harm caused to C, the Adviser considered Duty of Candour should have applied in this case. Had it been

followed, the legislation would have required formal notification to C within 10 working days, and the processes would have ensured a much quicker response to C on the matter.

x. The Adviser further said that they considered this incident to be a serious adverse event. Having reviewed the Board's policy for adverse events, they considered the grounds on which a LAER or Significant Adverse Event Review (SAER) would be conducted were unclear, as was the difference between each type of review. To inform their view, the Adviser explained that they had referred to the SAER guidance issued by Healthcare Improvement Scotland (HIS).

xi. The Adviser said that Category 1 events are defined as occurrences which may have contributed to or resulted in permanent harm. As C was left with a permanent harm, the Adviser considered that this met the definition of a Category 1 SAER. However, the Board's policy indicated that Category 1 events can be investigated as either a LAER or a SAER, with there being no clear explanation on how to select one over the other. The Adviser considered that this was inconsistent with the HIS guidance and, as Category 1 events require a SAER, on balance they considered it unreasonable for this incident to be reviewed as a LAER. In light of this, it was the Advisers' view that the Board's policy should be reviewed.

40. I have considered and accepted this advice to inform my decision making.

(b) Decision

41. C complained to the Board in July 2021 and attended a complaint meeting on 22 November 2021, with SPSO being informed that a plan was made to undertake a LAER as an outcome of this meeting. I am critical that C was not informed of this plan, with it only being known to them at the point of being advised by the SPSO following our enquiries.

42. From the evidence provided it appears the LAER commenced in or around November 2021, but the Board did not complete the LAER until October 2022. While I accept the Board were working, and continue to work, under challenging circumstances as a result of the ongoing impacts of the COVID-19 pandemic, I am critical that the Board took 11 months to complete and report on the LAER. The Board's Adverse Events Policy states the timeframe for completing a LAER is 90 working days from the date of reporting. In C's case, it took around 317 days, which is a significant breach of the timescale, and in my view, wholly unreasonable.

43. I am also concerned that the Board did not proactively seek to provide updates to C about the progress of the LAER during this time, or provide a working timeframe by which to conclude the matter. Once the LAER was completed, it is notable that the report was sent to SPSO, with a copy being sent to C once being prompted to do so by my office. Given the above, I am extremely critical of the way in which the LAER was managed by the Board as an outcome of C's complaint.

44. In addition, the advice I have received and accept is that the circumstances of the complaint should have activated Duty of Candour processes with formal notification issued as soon as possible and, as a matter of good practice, within 10 working days. Had this happened, and had the process been followed as it should have been, this would have ensured a much quicker response to C on the matter.

45. While the Board eventually activated the Duty of Candour process and wrote to C on 3 November 2022 acknowledging C's experience as a safety incident this was after the involvement of my office; approximately 18 months after the events taking place and more than a year after C made their complaint. I am extremely critical this process was not activated far sooner in line with the relevant legislation. I also note that when C was eventually notified, no specific explanation was provided for the delay as required under the legislation.

46. It is clear to me from the advice I have received and accepted that the LAER failed to identify key points in relation to the role and responsibility of the DVT clinic in this incident.

47. Given C was under the care of the DVT clinic for treatment of their lower leg SVT, the LAER should have included comment on the management and assessment C received from this service. Of note, the Adviser highlighted key concerns with the failure to

    i. document the outcome of some of C's appointments,

    ii. recognise or act on the drop in their platelet count (which had occurred before the onset of symptoms of HIT had occurred), and

    iii. urgently start C on an alternative anticoagulant treatment at the point of them flagging new onset of lower leg symptoms to the clinic.

48. I also accept the advice that the LAER failed to consider the failure by the on-call haematologist to identify the drop in platelets, and failed to consider the unreasonable advice given to the general medical service and junior doctors.

49. Given the above, I consider that the Board's handling of C's complaint was unreasonable in respect of the length of time taken to complete the LAER; the lack of notification of the LAER and updates to C as the LAER progressed; and the failure of the LAER to consider and identify key failings in the care and treatment C received from the DVT clinic and haematology service.

50. I am also critical that the Duty of Candour responsibilities placed on the Board were not initially considered and that instead the process was only implemented at a very late stage. Had it been applied at the appropriate time C would have received a much quicker response.

51. Finally I am critical that the Board did not consider conducting a SAER given C's primary concern that they had suffered permanent harm.

52. I uphold this complaint.

53. I have made a number of recommendations to address the issues identified and these are set out at the end of this report. The Board have accepted the recommendations and will act on them accordingly. My complaints reviewer and I will follow up on these recommendations. I expect evidence to demonstrate appropriate action has been taken before I can confirm that the recommendations have been met.

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

Recommendation number	What we found	What the organisation should do	What we need to see
1	The care and treatment provided by the Board to C in April and May 2021 was unreasonable. Specifically, the Board failed to: v. appropriately review and monitor C's platelet count at the DVT clinic. vi. appropriately assess and diagnose C for suspicion of HIT taking into account the timeframe of onset of symptoms or consider the working diagnosis of stroke as a likely manifestation of HIT.	Apologise to C for the failings identified in this report The apology should meet the standards set out in the SPSO guidelines on apology available at www.spso.org.uk/information-leaflets.	A copy or record of the apology. By: 24 January 2024

Recommendation number	What we found	What the organisation should do	What we need to see
	vii. provide appropriate haematology advice to medical staff iii. appropriately review and document C's response to pain relief medication once their pain had escalated.		

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

Recommendation number	What we found	Outcome needed	What we need to see
2	Under complaint (a) I found that the Board did not appropriately review and monitor C's blood test results.	Bloods results should be appropriately reviewed and patients receiving heparin injections appropriately monitored. Patients should receive appropriate, timely review if any new onset symptoms are reported.	Evidence that the findings of this investigation have been fed back to relevant staff in a supportive way for learning and improvement and to avoid a similar mistake being made again. Evidence that the Board have reviewed the DVT clinic's management and review of patients receiving heparin injections to ensure blood results are timeously reviewed and acted on appropriately.

Recommendation number	What we found	Outcome needed	What we need to see
			Confirmation of the action taken and details of any resulting action points or procedural changes. By: 20 March 2024
3	Under complaint (a) I found that the Board did not iii. appropriately assess and diagnose C for suspicion of HIT taking into account the timeframe of onset of symptoms or consider the working diagnosis of stroke as a likely manifestation of HIT. iv. provide appropriate haematology advice to medical staff.	Patients presenting symptoms as in C's case should be appropriately reviewed by general and speciality medical staff with reference to the timeframe of onset of symptoms and likely manifestations of HIT, such as stroke, with treatment commenced as appropriate.	Evidence that my findings have been shared with relevant staff in a supportive way for feedback and reflection. Evidence that consideration has been given as to whether guidance is required for the management and treatment of suspected cases of HIT. By: 20 March 2024

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

Recommendation number	What we found	Outcome needed	What we need to see
4	I found that the Board's handling of C's complaint was unreasonable. Specifically the Board failed to consider activating the Duty of Candour process at an appropriate time.	When an incident occurs that falls within the Duty of Candour legislation, the Board's Duty of Candour processes should be activated without delay and the individual notified within the prescribed timescales. If there is a delay in notification a full explanation should be provided.	Evidence that the findings on the Board's complaint handling have been fed back in a supportive manner to relevant staff and that they have reflected on the findings of this investigation. Evidence that the Board have reviewed their Duty of Candour processes, including timescales for activating the process and notifying the individuals concerned with details of how the guidance, and any changes, will be disseminated to relevant staff. By: 20 March 2024
5	I found that the Board failed to undertake a reasonable adverse event review that identified key learning from C's complaint.	Local and Significant adverse event reviews should be reflective and learning processes that ensure failings are identified and any	Evidence that the Board have reviewed the Adverse Event Policy, the conclusions of the

Recommendation number	What we found	Outcome needed	What we need to see
	iv. It failed to keep C informed of the process and the reasons for selecting a LAER, rather than SAER. v. It failed to identify key learning from the circumstances of C's complaint. vi. Significant (rather than a Local) adverse event review should have been held in line with relevant guidance.	appropriate learning and improvement taken forward. The Board's adverse event policy should be consistent with HIS guidance, and the type of investigation undertaken should be appropriate to the level of category identified.	review and any actions taken as a result. By: 17 April 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	What the organisation say they have done	What we need to see
b)	The Board's handling of C's complaint was unreasonable.	The outcome of the Local adverse event review had been shared with the key individuals involved for reflection and learning to include improvement in documentation. Teaching sessions were in progress, commencing in July 2022.	Evidence that the Board have taken action in relation to this. By: 21 February 2024

Feedback for Fife NHS Board

Point to note

1. The Adviser noted that the policy for the management of superficial vein thrombophlebitis does not include information about the monitoring of blood results which should be done for patients being treated with heparin. If this information is included in a separate policy, it is suggested that consideration is given to including a link or reference to the relevant policy that gives such detail, or to include the detail in the SVT policy itself.

Terms used in the report **Annex 1**

A&E	the Accident and Emergency Department at Victoria Hospital, Kircaldy
Anticoagulant	medicines used to thin the blood
Argatroban	an anticoagulant medicine used to manage heparin-induced thrombocytopenia
AU1	assessment unit 1
C	the complainant
CT scan	computerised tomography scan: an imaging technique used to obtain detailed internal images of the body
Dalteparin	a heparin-based anticoagulant that helps to prevent the formation of blood clots
Duty of Candour	legislation which sets out the procedure that organisations providing health services, care services and social work services in Scotland are required to follow when an unexpected or unintended incident has occurred that results in death or harm, or additional treatment to prevent death or harm
DVT	deep vein thrombosis: a blood clot in a vein
Full Blood Count	a blood test taken to check the types and number of cells in the blood
GP	General Practitioner
HIS	Healthcare Improvement Scotland: the national authority for the development of evidence-based advice, guidance and standards for health and care settings.
HIT	heparin induced thrombocytopenia: a complication associated with heparin products where there is an increased tendency for the blood to clot
haematology	the branch of medicine concerned with diseases related to blood

haemorrhagic stroke	a stroke caused by bleeding
heparin	medication used to prevent blood clots
ischaemic stroke	a stroke caused by a clot
LAER	local adverse event review
MRI	magnetic resonance imaging scan: an imaging technique used to obtain detailed internal images of the body
Rivaroxaban	an anticoagulant medicine used to treat and prevent blood clots
SAER	significant adverse event review
SVT	superficial vein thrombophlebitis: inflammation and clotting in a superficial vein
The Adviser	a consultant haematologist who provided independent advice on this case
The Board	Fife NHS Board
The Doctor	The junior doctors providing ward based care to C
The Nurse	the nurse C attended at the Board's outpatient DVT clinic

List of legislation and policies considered **Annex 2**

The British Society for Haematology Guideline, ‘Diagnosis and Management of Heparin Induced Thrombocytopenia’.

Healthcare Improvement Scotland. Learning from adverse events through reporting and review. A national framework for Scotland: December 2019

NHS Fife Adverse Events Policy

Scottish Government. Organisational duty of candour: guidance. March 2018

Scottish Public Services Ombudsman Support and Intervention Policy