SCOTTISH PUBLIC SERVICES OMBUDSMAN

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The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

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Scottish Parliament Region: North East Scotland

Case ref: 201911632, Grampian NHS Board

Sector: Health

Subject: Hospitals / Clinical treatment / diagnosis

Summary

C complained about the care and treatment their spouse (A) received while undergoing kidney dialysis in Aberdeen Royal Infirmary (the Hospital). A had progressive kidney failure, and had an arteriovenous fistula formed in anticipation of complete kidney failure. A fistula requires surgery to join an artery to a vein so that blood goes directly into the vein rather than going down to the small blood vessels of the hand before returning. If successful, the vein becomes larger and "tougher" which allows needles to be inserted three times a week to circulate blood out of the body to a dialysis machine.

A was admitted to Aberdeen Royal Infirmary with worsening symptoms attributed to severe kidney failure, with the intention of starting dialysis using the fistula. During dialysis treatment three days later, A started to lose blood from the needle insertion site. Staff attempted to control the bleeding but were unable to and sought assistance from medical staff. The vascular surgery team attended and were able to stitch the bleeding vessel, which stopped further blood loss, but A's condition deteriorated and clinical staff were unable to stabilise them. A died of a myocardial infarction (heart attack) at 20:00 that evening. C complained that assistance was not sought quickly enough by staff working in the dialysis room. They complained that there was a delay in stitching A's arm.

We took independent advice from a consultant nephrologist (the Adviser). The Adviser noted A's complex medical history. They had advanced chronic kidney disease and focal segmental glomerular sclerosis (FSGS, a disease of the kidneys usually diagnosed by kidney biopsy), among other medical conditions, and were prescribed a range of medication including warfarin (an anti-coagulant, or blood thinner, used to treat or prevent blood clots) for atrial fibrillation (an abnormal or rapid heart rate, occurring when the heart's upper and lower chambers beat out of coordination). A was also on aspirin which may increase bleeding risk by its effect on platelets, key to blood clotting.

We found a number of failings in A's care and treatment. Medicines reconciliation on A's admission failed to pick up a recent dose change in warfarin, resulting in A being given a higher dose than they had been prescribed by their GP. There was

insufficient monitoring of International Normalised Ratio (INR, a measure of how long it takes the blood to clot used to determine the effects of anticoagulants on the clotting system). The Adviser told us that A's admission to hospital, recent decline in functional status, elevated C-reactive protein (CRP, inflammation marker), low albumin (a protein produced by the liver that circulates in blood plasma and temperature) were all triggers for more frequent monitoring. Additionally, A was on aspirin, which in combination increases the bleeding risk.

We found that a number of individual risk factors and errors combined to cause profound bleeding and death. The confusion surrounding warfarin dosing and insufficient INR monitoring were significant in causing such extensive bleeding. Other warning signs, which may or may not have contributed to A's death, were not noticed and considered by the medical team. The lack of escalation of A's blood loss meant that time was lost before clinical staff attended.

Grampian NHS Board (the Board)'s response and learning focused on warfarin prescription and monitoring. We saw no evidence of changes of practice or policy regarding fistula bleeds. We found that staff did not have a clear escalation policy of when and whom to call when they were unable to control the bleeding.

These deficiencies in care contributed to A's death, which we found was entirely preventable.

In conclusion, we found that the Board's care and treatment fell below a reasonable standard, and we upheld C's complaint.

We also found that the Board failed to investigate C's complaint appropriately or adequately. It took several enquiries before the Board provided all the information we were asking for. We noted that statements of certain members of staff were obtained by the Board in response to our enquiry, rather than during the Board's own investigation which was when we would have expected them to be taken. There were also some records which were only provided to us after the Board had received our draft report, which impeded our investigation process. All the relevant information should have been reviewed in the course of the Board's original investigation, then provided to this office in response to our initial enquiry.

Redress and Recommendations

The Ombudsman's recommendations are set out below.

What we are asking the Board to do for C:

What we found	What the organisation should do	Evidence SPSO needs to check that this has happened and the deadline
• The Board failed to adequately monitor A's INR levels. • Staff did not communicate with each other the risks associated with A's warfarin and aspirin medication. • There were documentation failings in respect of the dialysis. • Clinical staff failed to note and act upon other risk factors at the time of dialysis, including raised CRP, low albumin levels and raised temperature. • When A's fistula started bleeding, staff failed to escalate this promptly	Apologise to C for the failings in A's care and treatment. The apology should meet the standards set out in the SPSO guidelines on apology available at www.spso.org.uk/leaflets-and-guidance	A copy or record of the apology. By: One month of final decision

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

What we found	What should change	Evidence SPSO needs to check that this has happened and deadline
• The Board failed to adequately monitor A's INR levels. • Staff did not communicate with each other the risks associated with A's warfarin and aspirin medication. • There were documentation failings in respect of the dialysis. • Clinical staff failed to note and act upon other risk factors at the time of dialysis, including raised CRP, low albumin levels and raised temperature. • When A's fistula started bleeding, staff failed to escalate this promptly	Staff are aware of the importance of monitoring INR levels. There is a policy in place in respect of frequency of monitoring and staff should be appropriately trained and supported to apply it. Staff are appropriately trained and so aware of the risks associated with warfarin and other medications including aspirin, in the context of blood clotting. Dialysis documentation is thorough and includes details of all pertinent information, in particular needle size used and staff are appropriately informed of this. Staff ensure blood test results are considered and acted upon, and are appropriately trained and supported to do this. Staff are trained and aware of what to do in the event of a fistula bleed	Evidence that our findings have been fed back to relevant staff in a supportive manner that encourages learning. Evidence that the Board has taken measures to improve the clinical knowledge of the staff concerned in relation to warfarin (and other) monitoring, fistula bleeding and dialysis documentation. By: Three months of final decision

What we found	What should change	Evidence SPSO needs to check that this has happened and deadline
A's death was a serious adverse event that was preventable	The Board shares learning with the wider kidney community (Scottish Renal Association, Renal Association, British Renal Society)	Evidence of the learning having been shared. By: Three months of final decision

We are asking the Board to improve their complaints handling:

What we found	What the organisation say they have done	Evidence SPSO needs to check that this has happened and deadline
The Board's complaint investigation failed to identify the significant failures in A's care and treatment, and failed to identify adequate learning	The Board's complaint handling monitoring and governance system should ensure that complaints are appropriately investigated and that failings (and good practice) are identified and learning from complaints are used to drive service development and improvement	Evidence that the findings on this complaint have been fed back in a supportive manner to the staff involved in investigating C's complaints and that they have reflected on the findings of this investigation. (For instance, a copy of a meeting note or summary of a discussion.) By: One month of final decision

What we found	What the organisation say they have done	Evidence SPSO needs to check that this has happened and deadline
The Board failed to provide all relevant information during our investigation	All information relevant to a complaint under investigation is provided at the appropriate time	Evidence that the Board has reflected on its responses to this office and made any necessary changes to its approach to ensure that relevant information is identified and shared timeously. By: Three months of final decision

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. C complained to my office about the care and treatment their spouse (A) received in March 2019 while undergoing kidney dialysis in Aberdeen Royal Infirmary. During dialysis treatment on 15 March 2019, A started to lose blood from the needle insertion site. A's condition deteriorated and clinical staff were unable to stabilise them. A died of a myocardial infarction (heart attack) at 20:00 the same day. After their death it was noted that A had been on a higher dose of warfarin than had been prescribed by their GP.

2. The complaint from C I have investigated is that the care and treatment provided to A between 12 and 15 March 2019 fell below a reasonable standard *(upheld).*

Investigation

3. In order to investigate C's complaint, my complaints reviewer obtained the clinical records relevant to the time of the complaint and we took independent clinical advice from an appropriately qualified adviser, a Consultant Nephrologist. In this case, I have decided to issue a public report on C's complaint given the significant personal injustice to C, the systemic failures our investigation has identified and significant learning points of a wider public interest.

4. 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.

5. I recognise that this report may be distressing for C and A's family to read, and cannot begin to imagine how difficult it must have been for C to witness their spouse's deterioration and subsequent death. My colleagues and I offer our sincere condolences.

Background

6. This section contains a background leading to A's admission to hospital, which is the subject of C's complaint. A was in their sixties at the time of their death. They had a complex medical history. They had advanced chronic kidney disease, which was said to be due to high blood pressure and focal segmental glomerular sclerosis (FSGS, a disease of the kidneys usually diagnosed by kidney biopsy).

7. A was being seen in a local hospital clinic for their progressive kidney failure. Anticipating complete kidney failure, they had an arteriovenous fistula formed on 30 January 2019. A fistula requires surgery to join an artery to a vein so that blood goes directly into the vein rather than going down to the small blood vessels of the hand before returning. If successful, the vein becomes larger and "tougher" which allows needles to be inserted three times a week to circulate blood out of the body to a dialysis machine.

8. A had worsening symptoms attributed to their severe kidney failure: itching from build-up of waste products normally disposed of by the kidneys, lethargy, lack of energy and breathlessness worse than normal. This was considered to be due to fluid build-up as the kidneys were not passing out as much urine and fluid being taken in drinking.

9. A was admitted to Aberdeen Royal Infirmary on 12 March 2019 with these symptoms, and with the intention of starting dialysis using the fistula. A's treatment between 12 and 15 March 2019 will be detailed under the Board's response below, and in the medical advice we received.

Complaint: The Board's care and treatment fell below a reasonable standard

Concerns raised by C

10. C complained about the events leading to A's death. C had left the dialysis room for a period of time on 15 March 2019 and when they came back in they witnessed a healthcare support worker (HCSW) swabbing A's arm where the needle had been. C recalled the HCSW having said the needle had just fallen out.

11. The HCSW continued to swab the area and C was concerned as A's face had turned grey and they reported feeling sick. C noticed the blood pressure machine appeared not to be working and asked the HCSW if A's blood pressure could be low. The HCSW said they would ask someone to check.

12. As the HCSW started walking away, A appeared to be having a seizure and clinical staff rushed in. C was kept updated in respect of the efforts being made to stabilise their spouse but was later told A was unlikely to survive.

13. One of the doctors treating A acknowledged the high level of warfarin in A's system, which prevented their blood from clotting. C complained that A's warfarin levels were only checked once on admission.

14. C complained:

a. that the dialysis needle should not have come out of A's arm so easily, and questioned why assistance was not sought sooner.

b. that the blood pressure monitor did not appear to be operational and questioned why it was not connected.

c. about the way staff handled the situation, which C said heightened the stress and upset caused to them.

15. C believed there was a delay in inserting a stitch in their spouse's arm. C told us the Board said in their original complaint response that this had been done immediately but C said this was not the case. (The Board have clarified the exact terms of their response regarding the stitching, which can be found at paragraph 17 below.)

The Board's response

16. The content of the Board's original response is known to both parties, and I will therefore not repeat it in full here. In summary, they said at the end of the period of dialysis on 15 March 2019, A suffered bleeding from their dialysis fistula and into the tissues of the fistula arm. It was noted there was bleeding coming from one of the dialysis needles at the end of the session, and the nursing staff removed this dialysis needle, as is standard procedure, to apply pressure to the area. Despite this, the bleeding worsened both from the fistula site and into the tissues. As a result, A's blood pressure dropped and treatment was commenced with intravenous fluids, a blood transfusion, and intravenous medication to improve blood clotting.

17. The Board explained that the on-call vascular surgery team attended quickly and were able to stitch the bleeding vessel which stopped further blood loss. Despite the blood loss being controlled and an initial response to the other treatments, A's blood pressure continued to fall which resulted in them suffering a heart attack. This they thought to be the event which resulted in A's death later the same day.

18. One of A's medications at the time of death was warfarin and a review of these events revealed that A was at increased risk of bleeding because their International Normalised Ratio results (INR, a measure of how long it takes the blood to clot used to determine the effects of anticoagulants on the clotting system) were raised. When the blood test had been checked three days earlier, the result had been within the target set for warfarin treatment. However, when checked at the time of bleeding on the day of A's death, the INR had changed substantially, and much more than would

be expected given the warfarin doses that were prescribed during their admission. This was recognised by the Board as contributing to the bleeding A suffered.

19. In response to our enquiry, the Board provided a detailed chronology as set out below. A was admitted to Ward 108 (Renal Speciality Ward) in the Hospital on 12 March 2019, for a planned start of haemodialysis. A's INR at the time was reported as 2.4. After admission A was assessed by medical and nursing staff. A Renal Specialty Registrar assessed A and noted their symptoms of uraemia (kidney failure) and fluid overload (also as a result of their kidney failure) and made a plan for A to have their first haemodialysis session. This took place at 16:45 hours for two hours via A's fistula using a single needle, and 0.4 litres of fluid was removed by ultrafiltration. No complications were reported.

20. On 13 March 2019, A was reviewed on the daily ward by a locum Consultant Nephrologist. They noted that the fistula was bruised after A's first dialysis the preceding day, which was common when used for the first time. The fistula was functioning with a good thrill and bruit (the sensation and sound which indicate how well dialysis access is functioning). The Consultant Nephrologist decided to 'rest' the fistula that day to allow the bruising to settle. A had been prescribed oral furosemide 40 mg twice daily for fluid overload prior to admission and the Consultant Nephrologist changed this to bumetanide 3 mg twice daily, as this can be more effective in this context.

21. A was seen on the daily ward round on 14 March 2019 by the Renal Specialty Registrar, who noted that A was stable (National Early Warning Score (NEWS) of 0) and planned for A to have their second dialysis session the following day. No changes were made to A's medication.

22. On 15 March 2019 A was seen again by the Renal Specialty Registrar, and their second dialysis session was planned for three hours with 0.5 – 0.75 litres ultrafiltration. A commenced haemodialysis at 11:40 hours. Intravenous heparin, often administered during dialysis to prevent clotting of the circuit, was not administered. Standard monitoring was carried out during A's dialysis with blood pressure (using the cuff which is integrated within the dialysis machine rather than a separate monitor), heart rate, oxygen saturations and dialysis parameters, including arterial pressure, venous pressure and transmembrane pressure. This was recorded on the acute dialysis recording sheet with no concerns and haemodynamically stable until near the end of the session.

23. No concerns were noted until minutes before the end of treatment (14:10 hours) when an appropriately trained dialysis HCSW noted that the arterial needle was bypassing (i.e. blood was oozing from around the needle insertion site). They

therefore terminated the dialysis treatment, returned all blood that was in the dialysis circuits to A (as is standard practice), removed the arterial needle and applied pressure. On needle removal, A's fistula continued to bleed and the HCSW continued to apply direct pressure, as it is not unusual for fistulas to bleed for a period at the end of dialysis and is routinely managed with direct pressure.

24. The HCSW became concerned that the bleeding time was longer than they would expect and informed the Staff Nurse (SN). Together they applied a Kaltostat dressing but this did not reduce the bleeding. The SN reports that A was conversant with their spouse and stable at this point, but they noted A's colour had changed and became concerned about their condition and attempted to inform medical staff of their concerns.

25. There was a brief delay (around ten minutes) in obtaining help from medical staff, as the Renal Specialty Registrar was reviewing patients on another ward and was not carrying the pager that the SN originally contacted. The SN therefore left the dialysis room briefly to contact medical staff in person (the dialysis room is within the ward area). Shortly thereafter the Renal Specialty Registrar and locum Consultant Nephrologist arrived back on the ward together and immediately attended to A at 15:10 hours.

26. A became haemodynamically unstable with low blood pressure and low oxygen saturations. There was a period when their blood pressure was so low that the machine could not record a reading. There was no evidence that the equipment malfunctioned, as this was in keeping with the clinical assessment. As a result, A experienced cerebral irritation and became agitated. They did not have a tonic clonic seizure.

27. It was challenging to administer oxygen therapy due to A's agitation. It was noted that their right arm was swollen; in keeping with bleeding into the tissues of their arm in addition to the visible blood loss. Peripheral venous access was obtained and fluid resuscitation given, initially with 500 ml 0.9% saline, followed by 1.5 units of O-negative emergency blood. Larger volumes were not administered due to A's renal failure and vascular disease. A initially responded to these measures; they became less agitated and their blood pressure improved.

28. The vascular team, comprising two Consultant Vascular Surgeons and a Vascular Registrar, were in Ward 108 reviewing another patient when A deteriorated. They were alerted and promptly attended to assess the fistula. A had a second episode of cerebral irritation and agitation whilst the vascular surgeons were in attendance. The Vascular Registrar sutured the arterial cannulation site to directly control the bleeding and this was successful. The second venous needle was then

removed and the exit site was also sutured. There was no further external blood loss, and no further swelling of A's arm was observed.

29. The renal team simultaneously took emergency blood tests including venous blood gas and INR. The venous blood gas available at 16:02 hours demonstrated that A's haemoglobin was 73 g/L and lactate was within the normal range, which suggested that their tissues were being perfused.

30. Given the clinical picture of prolonged bleeding and A's prolonged warfarin therapy, a raised INR was suspected. Emergency treatment with intravenous vitamin K and Beriplex was administered without waiting for the formal INR result to be reported. Dosing was discussed with the on-call Haematology Registrar. After the administration of resuscitation fluids, advised medication to correct any clotting abnormality and suturing of the bleeding site, A initially improved and it appeared that the treatment had been effective, however shortly thereafter they sustained a further clinical deterioration with acute breathlessness in keeping with a clinical diagnosis of acute pulmonary oedema (an accumulation of fluid in the lungs).

31. A was assessed by an Intensive Care Consultant who considered that ICU care was not appropriate in view of their comorbidities and functional status. Therefore, the consultant on duty for Medical High Dependency Unit (HDU) was contacted to assess A.

32. A repeat venous blood gas (at 17:52 hours) demonstrated that A's lactate level had risen from 2.4 to 9.7. The HDU Consultant assessed A and then spoke with C, along with the locum Consultant Nephrologist. After discussion with C, the HDU Consultant's assessment was that A was unlikely to have the physiological reserve to survive this event, and therefore it would not be appropriate to pursue an aggressive treatment plan with invasive monitoring and ventilation. C and subsequently A's son were in agreement with this decision. A was transferred to a ward side room so that they and their family could have privacy. They died at 20:00 hours on Friday 15 March 2019.

33. Laboratory results subsequently confirmed that A's INR at the time of the bleeding was >11. The locum Consultant Nephrologist informed C and A's son of the elevated INR on the evening of 15 March 2019, and explained that it had contributed to the bleeding that A had experienced. It transpired that A had been receiving 4 mg dose of warfarin during their admission in error, as the dose had been reduced from 4 mg to 3 mg daily by their GP a few days prior to admission to Ward 108. The locum Consultant Nephrologist also explained this to C and A's son at that time.

34. The locum Consultant Nephrologist submitted a report to the Procurator Fiscal on Monday 18 March 2019 and had a discussion with the Procurator Fiscal's Office. A's family did not wish for a hospital post mortem to be performed. The Procurator Fiscal Office stated that given that A's family had been fully informed regarding the events surrounding their death and did not wish a post mortem, a death certificate could be issued without investigation. The death certificate was issued with the following cause of death:

1a Myocardial infarction

1b Haemorrhage from Arteriovenous dialysis fistula

1c Bleeding diathesis secondary to anticoagulation

II End stage kidney disease

Abdominal Aortic Aneurysm

Hypertension (high blood pressure)

35. They confirmed that A's INR was checked on the day of admission, 12 March 2019, and found to be within the therapeutic range at 2.4 (target INR 2.5, acceptable range 2.0-3.0). Four mg of warfarin was prescribed, which was believed to be A's stable dose. They said cannulation of an AV fistula is not considered a high-risk procedure where a pre-cannulation INR check is mandated, and this is not routinely undertaken. This is in contrast to other renal procedures, such as a renal biopsy where pre-procedure coagulation is routinely checked.

36. The Board noted that INR levels can change if medications are commenced that interact with warfarin. The only change made to A's medication after admission was stopping furosemide and commencing bumetanide. A had been admitted to hospital to be established on dialysis, was not acutely unwell, and there was no clear indication to increase the frequency of INR monitoring. On the basis of the information available at the time, there was no reason to suspect that the INR would rise significantly and the frequency of monitoring of A's INR level was not outwith standard practice.

37. The Board said that their subsequent investigation had highlighted specific issues that may have contributed to A's bleeding and elevated INR. A's GP reported that their INR had been variable in the community, though it had been within therapeutic range the day prior to admission. The Board said they were unfortunately unaware of this issue. A had been taking a regular dose of 4 mg warfarin for some time, but their GP had reduced their dosage to 3 mg daily a few

days prior to admission. The dose of 4 mg daily was recorded on their renal electronic patient record from their last admission (at the time of fistula formation) and was used as part of the reconciliation process in error.

38. The medicine reconciliation process was followed with a medicine reconciliation form being completed by a fifth-year medical student under supervision (with three sources used for the reconciliation: the patient, the repeat prescription list and the renal electronic patient record). This was checked by a pharmacist. The alteration in dose was not detected or documented to alert staff to this change. This led to the administration of three daily doses of 4 mg rather than 3 mg i.e. a total extra dose of 3 mg over three days. Given that this had been A's stable dose for some time previously, it is still unexplained how this dose could lead to such an elevated level of INR within three days.

39. The Board noted that the warfarin administration chart has the INR of 2.4 documented for 12 March 2019, however the entry for 13 March has '2' written in the INR box. There was no INR checked on 13 March 2019. They said this would appear to be a transcription error. This did not lead to a change in warfarin dose and was discussed at the Renal Morbidity and Mortality meeting, and the consensus opinion of those present was that this error is unlikely to have influenced the prescriber's decision-making, as an INR of 2 was within therapeutic target range, and therefore, the prescriber would have continued the regular dose, as previously charted.

40. In response to this incident the Board reported having undertaken three changes in practice to improve the safety of anticoagulation in the renal ward:

- They have sought to increase awareness of warfarin administration in the ward by formally identifying patients taking warfarin (or therapeutic doses of heparin or other anticoagulants) and having a list of names prominently displayed in the doctors' area of the ward in order to prompt daily consideration for the need for INR monitoring.

- They have changed the way warfarin is prescribed on the renal electronic patient record so that a specific dose is not stated, as it can quickly become out of date and contributed to the error in this case.

- They have switched to alternative software for their renal ward discharge documentation (from using the renal electronic patient record to using the hospital wide Core Discharge Document). This allows for the entry of free text so that the dose can be described as 'variable according to INR' and annotations, such as recent INR levels, can be included.

41. In the longer term, the Board are participating in the North of Scotland Hospital Electronic Prescribing and Medicines Administration (HEPMA) project, which will lead to electronic prescribing across the Board, and includes built-in electronic safety checks for a large range of medication including warfarin, therefore leading to safer prescribing.

Complaint handling

42. The Board's original response to C's complaint was brief and lacking in detail; given the circumstances, it would have been reasonable to expect a more in-depth analysis and explanation of what had happened.

43. It is worth highlighting that it took several requests for information from the Board before they provided us with everything we asked for, including only providing some information in response to our draft report. We noted that statements of certain key members of staff appeared to have been taken in response to our enquiry, rather than at the time of the incident.

44. Even after the Board provided us with their detailed chronology, we noted some of the assertions they made (particularly in relation to timing) were not supported by staff statements they provided later on. We had to request repeatedly copies of these statements when it became evident that information was missing from the initial response to our enquiry.

Medical advice

45. I asked the Adviser to assess whether A was provided with a reasonable standard of care and treatment on 15 March 2019. I have summarised their views as in paragraphs 46 to 78 below.

46. A was in their sixties at the time of their death, and had a complex medical history.

- They had advanced chronic kidney disease (CKD, stage five), which was said to be due to high blood pressure and FSGS.
- They had a pulmonary embolism and atrial fibrillation (irregular heart rhythm) in 2016, both of which are indications for anticoagulation (blood thinning treatment) with warfarin.
- They had an abdominal aortic aneurysm treated by endovascular aneurysm repair (EVAR) in 2018. This is a minimally invasive way of introducing a stent to support the aorta without requiring major surgery.

- They had chronic obstructive pulmonary disease (COPD, a group of chronic lung conditions that cause breathing difficulties) for which they were taking inhalers. They were on two medications for high blood pressure.

- They were also on aspirin which may increase bleeding risk by its effect on platelets, key to blood clotting.

47. The Adviser also explained that usually the non-dominant arm is used and there is a usual hierarchy of veins used. In this case A's left arm veins were poor and they required a right arm fistula (dominant hand). This was more complex, having to use the basilic vein which runs on the inside of the upper arm. The surgery was successful, and they were reviewed in the surgical clinic on 27 February 2019 when it was deemed suitable for use.

Warfarin

48. The admission clerking on 12 March 2019 notes all A's medical issues and specifically comments on the combination of aspirin and warfarin. The medication list was compiled by a final year medical student and checked by a pharmacist.

49. The dose of warfarin was recorded as 4 mg. This dose was (as explained) previously correct, but the most recent prescribed dose was 3 mg by the GP changed three to four days before admission. It is unclear if the patient-held record, which should document the blood test results and dose changes, was reviewed. The measurement used to monitor the effectiveness of warfarin is INR. Depending on the indication for the warfarin (in this case pulmonary embolism and atrial fibrillation), each patient has a target INR between 2 and 4. Above 4 is over anticoagulated and significantly increases risk. Below 2 and it is not sufficient to reduce blood clotting risk.

50. Warfarin was being managed by the GP, and a wide variation in levels is noted in the mortality review meeting presentation. It is unclear why this was. Sometimes it can be caused by the patient not taking the prescribed dose regularly; other causes include variation in diet, alcohol intake, other illnesses or interactions with other medications (including over the counter).

51. INR was 2.8 on 11 March 2019 and 2.4 on admission. It was next checked at the time of the bleed and found to be massively elevated >11.

52. The warfarin was prescribed on the Inpatient Warfarin Prescription Chart. It was prescribed at 4 mg daily which was a 1 mg dose increase from the GP dose. The indication ticked was atrial fibrillation for which the target INR is 2.5.

53. Therefore, once the initial dose error was made it would have seemed appropriate to continue at 4 mg as the level was effectively on target. The chart is geared towards new start of warfarin and does not give any guidance on when to recheck blood tests for patients already taking it and with INR in the target range.

Other abnormal blood tests

54. A number of blood tests were taken on admission. A was anaemic (Hb 101) which is not uncommon in advanced CKD. Their CRP was significantly elevated at 73. This is a non-specific indicator of inflammation or infection. It is not an expected finding in CKD unless there is a second process going on. It is noted in the records but there is no indication that it was felt to be significant. Infection can influence INR.

55. One of the blood proteins, albumin, was very low at 26g/l (the normal range is 35—50). The cause for this is not clear but it does not seem to have been flagged up in the medical notes. It may be significant because warfarin in the bloodstream is bound to albumin and low albumin is a risk factor for bleeding.

First dialysis, undertaken on the day of admission

56. The nursing note is on a stamp template. It appears to have happened as prescribed for two hours with fluid removed. No mention is made of needling issues.

57. In the notes from the next day, 13 March 2019, it is noted A found the needling very painful. In the nursing documentation from 12 March 2019 it is noted they only used a single needle. The standard practice is two needles and one is used only when there are such difficulties that two cannot be inserted. This can be because the fistula is small or deep. The fistula arm was found to be bruised and swollen but the fistula was working. It was appropriately planned to rest the fistula (not dialyse). A stronger diuretic dose was prescribed (bumetanide rather than furosemide).

58. On 14 March 2019, A was feeling better, with no temperature or change of physical signs. The plan was to dialyse the next day if blood results were fine. Early warning score NEWS was zero.

59. On 15 March 2019 A was feeling the same. They were noted to have a temperature, 37.8 NEWS 3. There were no signs or symptoms of infection, and no other investigations were planned. Dialysis was planned for that day. The records contain no mention of warfarin dosing or checking the INR.

60. Aside from the warfarin dosage, there were three points that did not trigger an appropriate response from the medical team:

- The raised CRP suggested an inflammatory process which did not trigger any obvious discussion on cause. An undiagnosed infection could have influenced the result of warfarin on INR.

- The albumin level was extremely low in the bloodstream. From whatever cause this is a poor prognostic marker and it is unclear if it was noticed. There is no evidence that it was acted on. It may have influenced the INR. The Board told us the serum albumin was at a similar level on admission to that noted in clinic on 12 December 2018, but there is no evidence that the admission level was reviewed and considered to be a stable finding. In the medical records of 12, 13 and 14 March 2019 there is no mention of low albumin levels, which gives no assurance that the medical team had noticed the low levels, compared them to what the Board states were historically low levels, and determined they were not clinically relevant.

- The temperature was elevated on two readings prior to dialysis but does not seem to have triggered any action.

Dialysis on 15 March 2019

61. The Adviser noted that dialysis seems to have been initially uneventful, with two needles inserted into the fistula to allow conventional continuous flow of blood into the artificial kidney. The treatment was undertaken by a HCSW and SN, which is appropriate. The dialysis was stopped early when blood was noted to be leaking out around the “arterial” needle.

62. The needle is not in an artery but in the fistula vein, but it is the needle that removes blood from the body, which is returned via the “venous” needle.

63. The Adviser explained that needle size is important: larger needles allow better blood flow but make a larger hole in the fistula vein, hence increased risk of bleeding afterwards. It is generally advised that smaller (17G) needles are used for the first sessions and the size increased (up to 14G) after several sessions. The Adviser noted that 17G needles were used on 15 March 2019.

64. The needle was removed and pressure exerted on the needle site. The pressure clearly did not stop either internal or external bleeding. It is difficult to know if there was any lack of technique or if the warfarin effect would have stopped any reasonable attempt.

65. The HCSW escalated to the SN and they used a topical swab designed to stop bleeding, which was unsuccessful. It is likely that A was inevitably going to die once blood pressure dropped to the point of cerebral irritation.

66. If the bleeding did not stop with direct pressure (thumb covering a hole around 2mm diameter) this should have been regarded as unusual and triggered escalation to more senior staff. The volume of blood lost externally was not measured but seems to have been significant, and more was lost internally. It does not seem that the blood loss as such triggered a call for medical help; only the collapse. The bleeding was not controlled until the vascular surgical team arrived, initially controlling with pressure then stitching both needle sites. This suggests that better technique was able to stop the external bleeding, although it may have been easier at this point as A's blood pressure had dropped.

67. The Adviser was concerned that staff did not have a clear escalation policy of when and whom to call. They said a fistula "blow" causing some local swelling is not uncommon (as in A's first dialysis) but a significant swelling of the arm as was noted by the medical team should trigger rapid review.

68. The Adviser noted no evidence that communication between medical and nursing staff, or medication review informed the dialysis nurses of the increased risk of bleeding from warfarin and aspirin (even if the warfarin had been correctly prescribed and monitored). The Adviser also noted the Board's comment that no additional anticoagulation (heparin) was used, and that the paper prescription is annotated "on warfarin and aspirin". The Adviser said this may suggest that the nursing team correctly avoided additional heparin because of this but there is no other text explaining the rationale. The prescription sheet for the second dialysis (with no entry on the prescription side) indicated no heparin used but there is no mention of warfarin or aspirin. The Adviser said the documentation does not confirm that the nursing staff were aware of the warfarin on this occasion.

69. The Adviser was asked to comment on the warfarin levels and impact on the bleeding A experienced. They noted that the Board said the frequency of monitoring of A's INR level was not outwith standard practice. The Adviser explained there is no absolute instruction on the frequency of monitoring INR in SIGN or NICE guidelines but it is suggested to increase frequency during illness. A's admission to hospital, recent decline in functional status, elevated CRP, low albumin and temperature were all triggers for more frequent monitoring. Additionally, A was on aspirin, which in combination increases the bleeding risk.

70. When asked to consider the measures taken by the Board in response to the complaint, the Adviser said the changes put in place in terms of the prescription,

flagging up patients on warfarin in the kidney ward, and more regular testing were appropriate and largely address the deficiencies of care. However, they noted the response did not address the possible educational deficiencies in the medical team as it did not address issues that may have influenced the grossly abnormal INR. They said they would look for assurance that warfarin is prescribed by doctors with sufficient knowledge of using the drug.

71. The Adviser noted the very low albumin was not commented on anywhere in the notes or complaints response. If it was seen and not commented on, the Adviser would regard this as a deficiency of care. If it was not seen, the Adviser would ask for assurances that blood results are properly reviewed; ordering tests and not reviewing them is a deficiency of care.

72. The Adviser's view was that neither the original nor subsequent responses from the Board seemed to address the main issue. In their view, this was an avoidable death and there were deficiencies of care that contributed to it. The response detailed the individual issues but did not provide sufficient assurance that this would not happen again. The Adviser considered there to be no recognition that bleeding to death on a dialysis unit is something that should never happen. They saw no reflection on the practices of the dialysis unit and if anything different would be done in a similar scenario in future.

73. The Adviser noted that the Board's learning seemed to concentrate on warfarin prescribing and monitoring. They saw no evidence of changes of practice or policy regarding fistula bleeds.

74. The Adviser noted the in-patient anticoagulation chart does not give any guidance on the expected frequency of check blood test for patients already on warfarin. They considered assurance was needed that this will be rectified in the new prescribing structure mentioned in the complaint response.

75. The Adviser commented that the dialysis note in the medical record appears to be a stamp which provides fields to be filled in by hand. They said it was crowded and did not prompt for comments such as difficulties needling. Neither the stamp nor the electronic records had a specific field for needle size, which the Adviser said may be regarded as a long term issue of documentation. The Adviser highlighted that the note for the first dialysis on 12 March 2019 does not provide evidence of needle size but the electronic record of dialysis on 15 March 2019 does, indicating 17G needles were correctly used.

76. We originally noted that blood test results do not appear to have been reviewed by the medical team; this was based on the information the Board had sent us during

our investigation. After we issued our draft report the Board supplied print-offs of the blood results, indicating that they were signed off in the electronic patient management system (Trakcare). Noting that the failure to supply these with the original file hindered the investigation process, the Adviser's view (which I very much agree with) was that demonstrating these had been seen did not amount to evidence they had been considered and reflected upon. The Adviser highlighted that there is a comment section in the electronic record which was not completed in any of the recently supplied records.

77. In summary, the Adviser identified the following areas where there was a need for learning and improvement:

- Prescribing and monitoring warfarin, including adequate drugs reconciliation with General Practice, training for prescribers, documentation and policy for frequency of monitoring.
- Medical staff not noticing or acting on abnormal blood tests and physical signs (CRP, albumin, high temperature).
- Dialysis records keeping and documentation.
- Assurance that there is a policy (and supporting education) for new fistula needling.
- Assurance that there is a policy (and education) for post dialysis fistula bleeding.
- Sharing of learning from the case (once it has been implemented) with the wider kidney community (Scottish Renal Association, Renal Association, British Renal Society).

78. The Adviser concluded by saying A's death was, in their view, entirely preventable, occurring as a result of issues arising from A's management in hospital. They said bleeding from a fistula causing death does happen, but it is usually once the patient has gone home and the fistula starts to bleed and the patient is unaware or unable to control it until too late. The Adviser said that in over 25 years of kidney medicine they had never come across, or heard of, bleeding on a dialysis unit leading to death. They noted a number of individual risk factors and errors combined to cause profound bleeding and death:

- A had poor veins and a basilic fistula had to be formed in their dominant arm.
- A was on both aspirin and warfarin.

- Their warfarin control had been erratic, with wide ranges of INR and recent changes to dosage.
- Medicines reconciliation failed to pick up a dose change.
- Warfarin/INR monitoring was not sufficient.
- Other health issues that may have influenced the response to warfarin were not picked up or acted on.
- The bleeding was both out of the body and internally which masked the severity.
- Staff did not respond with urgency in escalating the bleeding. A tolerated the bleeding very badly, dropping their blood pressure and failing to respond to resuscitation with blood and stitching the external bleeding points.

Decision

79. The advice I have received, which I accept, is that the care and treatment A received on 15 March 2019 was unreasonable. The Adviser considered A's death was preventable and should never have happened. It is a matter of significant concern that the Board do not appear to have acknowledged this, nor have they provided evidence of sufficient learning to ensure such an event never happens again.

80. It is clear that a number of factors combined to cause A's death. The confusion surrounding warfarin dosing and insufficient INR monitoring were significant in causing such extensive bleeding. There was also a failure to recognise other warning signs such as raised CRP, low blood albumin and raised temperature. Whilst these additional factors may or may not have contributed to A's death, I accept the advice that they should have been noticed and considered adequately by the medical team.

81. I recognise that those tending to A on the day they died were faced with an unexpected and challenging set of circumstances, and that the event, and my decision on it will likely have a significant impact on them. However, the lack of escalation meant that time was lost before clinical staff attended. That there appears to be a need for policy and training on fistula bleeds suggests that those tending A were inadequately supported by the Board's systems. I also recognise that those tending and caring for A were acting in the context of the Board's existing policy and systems.

82. The Board's position is that the HCSW made the decision to remove the needle early due to bleeding, whilst C recalls having been told that the needle fell out of A's arm. I am unable to make a finding on this particular matter as I cannot verify either version of events.

83. It took several enquiries from my complaints reviewer before the Board provided all the information we were asking for. It concerns me that, given the seriousness of the event, they did not appear to have taken contemporaneous statements from all the staff involved in A's care on the day they died. Statements of certain members of staff were obtained by the Board in response to our enquiry, rather than during the Board's own investigation which is when I would have expected them to have been taken. It was not until they had received our draft report that the Board provided full records in respect of this incident. This has impeded our investigation process. All the relevant information should have been reviewed in the course of the Board's original investigation, then provided to my office in response to our initial enquiry.

84. We asked the Board what steps they had taken in terms of their Duty of Candour obligations. The Board said at the time of the Datix submission it was not considered by the reviewing clinical manager that this incident fell within the scope of the legislation, but the renal team practised a similar approach with the family providing an apology, describing the circumstances, findings and proposed approach at the time by the Consultant in Charge.

85. While I recognise the actions taken were in step with Duty of Candour obligations, I am unclear as to why this case was not identified as falling within the scope of the legislation. I am asking the Board to reflect on this and consider whether there is a need for additional training on the relevant obligations.

86. In light of the failings identified, I uphold this complaint. My recommendations for action by the Board are set out at the end of this report. The Board have accepted the recommendations and will act on them accordingly. We will follow up on these recommendations. The Board are asked to inform us of the steps that have been taken to implement these recommendations by the date specified. We will expect evidence (including supporting documentation) that appropriate action has been taken before we can confirm that the recommendations have been implemented.

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:

What we found	**What the organisation should do**	**What we need to see**
• The Board failed to adequately monitor A's INR levels. • Staff did not communicate with each other the risks associated with A's warfarin and aspirin medication. • There were documentation failings in respect of the dialysis. • Clinical staff failed to note and act upon other risk factors at the time of dialysis, including raised CRP, low albumin levels and raised temperature. • When A's fistula started bleeding, staff failed to escalate this promptly	Apologise to C for the failings in A's care and treatment. The apology should meet the standards set out in the SPSO guidelines on apology available at www.spso.org.uk/leaflets-and-guidance	A copy or record of the apology. By: One month of final decision

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

What we found	Outcome needed	What we need to see
• The Board failed to adequately monitor A's INR levels. • Staff did not communicate with each other the risks associated with A's warfarin and aspirin medication. • There were documentation failings in respect of the dialysis. • Clinical staff failed to note and act upon other risk factors at the time of dialysis, including raised CRP, low albumin levels and raised temperature. • When A's fistula started bleeding, staff failed to escalate this promptly	Staff are aware of the importance of monitoring INR levels. There is a policy in place in respect of frequency of monitoring and staff should be appropriately trained and supported to apply it. Staff are appropriately trained and so aware of the risks associated with warfarin and other medications including aspirin, in the context of blood clotting. Dialysis documentation is thorough and includes details of all pertinent information, in particular needle size used and staff are appropriately informed of this. Staff ensure blood test results are considered and acted upon, and are appropriately trained and supported to do this. Staff are trained and aware of what to do in the event of a fistula bleed	Evidence that our findings have been fed back to relevant staff in a supportive manner that encourages learning. Evidence that the Board has taken measures to improve the clinical knowledge of the staff concerned in relation to warfarin (and other) monitoring, fistula bleeding and dialysis documentation. By: Three months of final decision

What we found	Outcome needed	What we need to see
A's death was a serious adverse event that was preventable	The Board shares learning with the wider kidney community (Scottish Renal Association, Renal Association, British Renal Society)	Evidence of the learning having been shared. By: Three months of final decision

We are asking the Board to improve their complaints handling:

What we found	Outcome needed	What we need to see
The Board's complaint investigation failed to identify the significant failures in A's care and treatment, and failed to identify adequate learning	The Board's complaint handling monitoring and governance system should ensure that complaints are appropriately investigated and that failings (and good practice) are identified and learning from complaints are used to drive service development and improvement	Evidence that the findings on this complaint have been fed back in a supportive manner to the staff involved in investigating C's complaints and that they have reflected on the findings of this investigation. (For instance, a copy of a meeting note or summary of a discussion.) By: One month of final decision

The Board failed to provide all relevant information during our investigation	All information relevant to a complaint under investigation is provided at the appropriate time	Evidence that the Board has reflected on its responses to this office and made any necessary changes to its approach to ensure that relevant information is identified and shared timeously. By: Three months of final decision

Terms used in the report **Annex 1**

A	the complainant's spouse, whose care and treatment is the subject of this investigation
C	the complainant
the Adviser	a Consultant Nephrologist who provided an independent assessment of the case
the Board	Grampian NHS Board
the Hospital	Aberdeen Royal Infirmary
abdominal aortic aneurysm	a swelling in the lower part of the aorta, the large artery that runs through the torso
albumin	a protein produced by the liver that circulates in blood plasma
arteriovenous fistula	a surgically created connection between an artery and a vein in the arm. When the artery and vein are joined, blood flow increases from the artery into the vein, resulting in the vein getting bigger over time. The enlarged vein provides easier access to the blood for treatment for kidney failure (dialysis)
atrial fibrillation	an abnormal or rapid heart rate, occurring when the heart's upper and lower chambers beat out of coordination
bumetanide	a diuretic, used to treat the build-up of fluid in the body (oedema)
C-reactive protein (CRP)	a blood test marker for inflammation in the body. CRP is produced in the liver and its level is measured by testing the blood
focal segmental glomerular sclerosis (FSGS)	a disease in which scar tissue develops on the parts of the kidneys that filter waste from the blood (glomeruli)

furosemide	a diuretic, used to treat oedema and high blood pressure
International Normalised Ratio (INR)	a measure of how long it takes the blood to clot, used to determine the effects of anticoagulants on the clotting system
kidney dialysis	a procedure to remove waste products and excess fluid from the blood when the kidneys stop working properly
myocardial infarction	heart attack, when the heart muscle does not receive an adequate supply of oxygen
nephrologist	a doctor specialising in treating diseases of the kidney
National Early Warning Score (NEWS)	a scoring system used to identify and respond to patients at risk of clinical deterioration
vascular surgery	specialism in diagnosing and treating disorders of the arterial, venous and lymphatic systems
warfarin	an anti-coagulant, or blood thinner, used to treat or prevent blood clots

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

SIGN 129 Antithrombotics: indications and management. Updated June 2013

5.2.2 Monitoring should be performed or supervised by experienced staff; and clinical performance should be monitored.

Cumulative records of INR and warfarin dose should be maintained.

A reliable patient recall and review system should be kept.

A well stabilised patient may need an INR check only every four to eight weeks.

Any change in clinical state or in medication should prompt more frequent checks.

Healthcare professionals monitoring anticoagulant treatment should be aware of the indication for treatment, target therapeutic range, and the planned duration of therapy.

GMC Good Clinical Practice

Domain 3: Communication partnership and teamwork

Continuity and coordination of care

44 You must contribute to the safe transfer of patients between healthcare providers and between health and social care providers. This means you must:

share all relevant information with colleagues involved in your patients' care within and outside the team, including when you hand over care as you go off duty, and when you delegate care or refer patients to other health or social care providers.