SPSO Scottish Public Services Ombudsman

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

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Scottish Parliament Region: Lothian

Case ref: 201305461, Lothian NHS Board
Sector: Health
Subject: Hospitals; clinical treatment; diagnosis

Summary

Mrs A was transferred from Victoria Hospital, Kirkcaldy, which is the responsibility of Fife NHS Board, to the Royal Infirmary of Edinburgh for heart surgery. Following one postponement in mid-December, the operation went ahead on 21 December 2012. Mrs A's niece (Mrs C) said that two days after the operation, her aunt was having a blood transfusion shortly after which she began to very rapidly decline. Mrs A was admitted to intensive care and died on 26 December 2012. The cause of Mrs A's death was recorded as multi-organ failure due to sepsis of unknown source in association with recent prosthetic aortic valve replacement and known ischaemic heart disease (a condition that affects the supply of blood to the heart). Mrs C complained that her aunt did not receive appropriate care and treatment from Lothian NHS Board.

In investigating this complaint, I took independent clinical advice from a cardiothoracic surgeon (specialising in chest, heart and lung surgery). The advice I received was that the heart surgery appeared to have been performed to a high standard, and Mrs A's initial recovery was good. Following a routine observation, Mrs A was recommended to have a blood transfusion. Her condition quickly deteriorated, and the board said that staff suspected a transfusion reaction and implemented their procedures for this. My adviser said that all teams reacted appropriately and promptly in response to Mrs A's condition.

Tests were taken to determine the cause of Mrs A's change in condition and I am satisfied that the blood Mrs A received was not contaminated. Her deterioration was coincidental with her developing a bacteria entering into her blood stream in association with sudden acute liver failure. However, I understand that it must have been very distressing for Mrs A's family to witness her sudden deterioration given the early signs that her heart surgery had been successful.

My investigation identified a number of areas that I am critical of. My adviser told me that communication between the two hospitals treating Mrs A should

have been better given her status as a high-risk patient with other pre-existing medical conditions and a history of previous heart surgery. Related to this, given Mrs A's case was a high-risk and complex case, this should have been discussed at a pre-operative multi-disciplinary team meeting, which did not happen – the board said that when Mrs A was transferred to the Royal Infirmary she was fit for surgery and there were no alternative treatments to discuss.

My adviser noted that some documentation was not completed appropriately, particularly around consent for the procedure. Following Mrs A's death, there is no evidence that her GP was notified, as should have happened. I also acknowledge that there was an early retraction of Mrs A's death certificate which, according to my adviser, had been inappropriately completed by a junior doctor. I recognise the additional distress that this would have caused Mrs A's family.

Finally, during the course of my investigation I identified that there was a positive result from an umbilical (navel) swab taken on 12 December 2012, the day of the initial scheduled operation, which may have been the source of the subsequent bacteraemia (the presence of bacteria in the blood) and septicaemia responsible for Mrs A's death. My adviser said that although the positive result was acted upon and antibiotics prescribed to Mrs A, it is not apparent that the potential relevance of this positive finding for Mrs A, who was who was due to undergo high-risk re-do cardiac surgery, was fully realised by the cardiac team treating her and whether consideration was given to potentially delaying Mrs A's surgery in view of the risk of the subsequent sepsis.

I made a number of recommendations to address the failings I identified in the care and treatment provided to Mrs A. I also found that the board's handling of Mrs C's complaint was not reasonable. There were delays in responding which I accept the board have apologised for, but the apology letter was brief, lacked empathy and did not fully address the reasons for the delay. I note, however, that process changes have since been implemented so I have not made a recommendation about this.

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) ensure that the comments of the Adviser in relation to the issues of consent and proper and accurate	30 November 2015

	record-keeping are brought to the attention of the relevant staff and a review is carried out;	
(ii)	ensure the comments of the Adviser in relation to the positive umbilical swab taken from Mrs A on 12 December 2012 are brought to the attention of relevant staff and they reflect on this;	30 November 2015
(iii)	apologise to Mrs C and the other members of Mrs A's family for the failings identified in complaint (a); and	30 October 2015
(iv)	apologise to Mrs C and Mrs A's daughter for the failings identified in the apology letter initially issued to Ms A's family.	30 October 2015

The Ombudsman recommends that the Board and Fife NHS Board:

(v)	ensure the comments of the Adviser in relation to the lack of clear cardiology referral documentation between Hospital 1 and Hospital 2 are brought to the attention of relevant staff.	30 November 2015

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 Mrs C and her late aunt, who is the subject of the complaint, is referred to as Mrs A. The terms used to describe other people in the report are explained as they arise and in Annex 1

Introduction

1. Mrs C's aunt (Mrs A) was transferred from Victoria Hospital, Kirkcaldy (Hospital 1) to the Royal Infirmary of Edinburgh (Hospital 2) on 28 November 2012 for investigations into a heart condition. Mrs A underwent cardiac surgery on 21 December 2012.

2. On 23 December 2012 Mrs A was given a blood transfusion, during which her condition suddenly deteriorated. Mrs A's condition continued to deteriorate thereafter and she died on 26 December 2012.

3. Lothian NHS Board carried out an investigation into the cause of Mrs A's death and a post-mortem was carried out. Lothian NHS Board said errors in the blood transfusion given to Mrs A and contamination of the blood used were ruled out. The cause of Mrs A's death was multi-organ failure due to sepsis of unknown source, in association with recent prosthetic aortic valve replacement and known ischaemic heart disease. However, my investigation of Mrs C's complaint, as I set out in further detail in paragraphs 32, 47 and 58 of this report, has identified that a positive result from an umbilical swab taken from Mrs A on 12 December 2012 by Lothian NHS Board, may have been the source of the bacteraemia and septicaemia responsible for Mrs A's death. The advice I have received is that although the positive result was acted upon and antibiotics (metronidazole) prescribed to Mrs A, it is not apparent that the potential relevance of this positive finding for Mrs A, who was due to undergo high risk re-do cardiac surgery, was fully realised by the cardiac team treating her and whether consideration was given to potentially delaying Mrs A's surgery in view of the risk of the subsequent sepsis.

4. Mrs C, acting on behalf of Mrs A's family, complained that Mrs A did not receive appropriate care and treatment while she was a patient in Hospital 2 and, in particular, raised concerns about Mrs A's sudden deterioration during the blood transfusion and her subsequent death following cardiac surgery.

5. Mrs C was not satisfied that Lothian NHS Board responded reasonably to her complaint.

6. The complaints from Mrs C which I have investigated are that Lothian NHS Board:

(a) did not provide reasonable care and treatment to Mrs A in November and December 2012 (*upheld*); and

(b) did not respond reasonably to Mrs C's complaint of 18 September 2013 (*upheld*).

Investigation

7. In order to investigate Mrs C's complaint, my complaints reviewer examined copies of Mrs A's clinical records and Lothian NHS Board's complaint correspondence and made written enquiries of Lothian NHS Board. My complaints reviewer also reviewed copies of Mrs A's clinical records from Fife NHS Board, where Mrs A had also been treated. In addition, independent clinical advice was obtained from a consultant cardiothoracic surgeon (the Adviser), who reviewed Mrs C's clinical records, Lothian NHS Board's complaint file and Lothian NHS Board's response to our enquiries.

8. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. Mrs C and Lothian NHS Board were given an opportunity to comment on a draft of this report. In addition, Fife NHS Board, who have responsibility for Hospital 1, were also given an opportunity to comment on the draft report.

(a) Lothian NHS Board did not provide reasonable care and treatment to Mrs A in November and December 2012

What Mrs C told Lothian NHS Board

9. Mrs A, who was 70 years of age at the time, was admitted to Hospital 1 after suffering a cardiac arrest on 15 November 2012. Mrs C told us that Mrs A had previously had surgery to have a cardiac valve replaced several years earlier. Mrs A was transferred to Hospital 2 on 28 November 2012 and underwent replacement cardiac valve surgery on 21 December 2012. According to Mrs C, Mrs A appeared to be recovering well from her surgery. However, on 23 December 2012 Mrs A was given a blood transfusion during which her condition suddenly deteriorated. Mrs C told us that she and another family member were with Mrs A when this occurred and were 'shocked' at what had occurred.

10. Mrs C said that Mrs A continued to deteriorate. Mrs C said that she was told by a member of the nursing staff that the blood used in the transfusion Mrs A had received may have been contaminated. Mrs C said that Mrs A's death had 'devastated' her family.

What Mrs C told us

11. Mrs C told us that Mrs A was recovering well after her cardiac surgery on 21 December 2012. On 23 December 2012 Mrs A was given a blood transfusion. Mrs C said this had happened in her presence and also other members of Mrs A's family. Mrs A said that within ten to 15 minutes of the start of the transfusion, Mrs A's disposition changed drastically. Mrs C said the colour drained from Mrs A's face and she could no longer communicate with them.

12. According to Mrs C, blood tests carried out on Mrs A on 23 December 2012 had shown her blood to be infected. Mrs C questioned when and why this had occurred; whether Mrs A should have undergone cardiac surgery when she did; and whether Mrs A should have been moved to ward level care so soon after undergoing surgery. Mrs C also questioned if the blood transfusion had in some way been connected to Mrs A's death and was also the cause of her sudden deterioration and subsequent death.

13. Mrs C told us that the manner of Mrs A's death and the subsequent investigations which had been carried out to establish the cause of her death had been very stressful and difficult for the family to cope with. Members of Mrs A's family had met with Mrs A's consultant cardiac surgeon (Consultant 1) but this had failed to answer their concerns and questions about Mrs A's care and treatment and the cause of her death.

Lothian NHS Board's response to Mrs C

14. Lothian NHS Board, in response to the concerns raised by Mrs A's family, stated that Consultant 1 had confirmed that Mrs A had been transferred from Hospital 1 to the Cardiology Unit of Hospital 2 on 28 November 2012 for further investigations, which had led to Mrs A having cardiac surgery on 21 December 2012. Lothian NHS Board said that Mrs A had a complex cardiac disease and treatment history, including undergoing surgery in May 2009 and the placement of stents in blocked heart arteries in August 2012.

15. According to Lothian NHS Board, Consultant 1 had confirmed that Mrs A's early recovery was good and she was transferred back to ward level care on the morning of 23 December 2012. A blood transfusion was ordered in the afternoon, following a review of Mrs A's morning blood test results. Lothian NHS Board explained that, from time to time, a blood transfusion can be required at this point in a patient's recovery. Lothian NHS Board said that

Mrs A's condition changed very soon after the transfusion was started. Lothian NHS Board said that ward staff had followed the procedures for suspected transfusion reaction, which included stopping the transfusion, reporting to medical staff and sending the blood bag, the intravenous administration set used for the transfusion, together with the required documentation and blood samples to the Blood Transfusion Service for analysis.

16. Lothian NHS Board stated that on the same day, 23 December 2012, Mrs A was initially transferred back to the high dependency ward and then to the intensive care ward when her condition deteriorated further. The critical care team had continued to investigate the cause of the sudden change in Mrs A's condition, which included performing an echocardiogram to check the aortic valve, which was shown to be working well.

17. Lothian NHS Board said that on 24 December 2012 surgeons carried out a laparoscopy procedure to see Mrs A's abdominal organs. They noted a degree of pre-existing liver damage and had advised continuing all the body systems supports and treatments already in place. However, despite breathing support, kidney support, antibiotics and other medications, Mrs A's condition continued to deteriorate and she died on 26 December 2012.

18. Lothian NHS Board said the cardiothoracic team were unable to explain what had happened in Mrs A's case. Therefore, Mrs A's death was reported to the procurator fiscal, which Lothian NHS Board explained was standard procedure in situations where medical staff are unclear about the underlying cause of the patient's death. A post-mortem examination was carried out and the procurator fiscal had agreed with the cardiothoracic team that investigation into the blood used for transfusion was required. The associate medical director, Hospital 2's most senior doctor, and senior managers were kept informed of the investigation.

19. Lothian NHS Board stated that the blood used in Mrs A's blood transfusion was tested comprehensively. The final results, which were confirmed several weeks after Mrs A's death, had shown that the blood used was not contaminated and also that it had been correctly cross-matched to Mrs A's blood type. A consultant haematologist who co-ordinated the blood testing had confirmed this to the procurator fiscal in April 2013. The associate medical director and senior managers were also told of the test results. In light of the test results, the consultants involved in Mrs A's care had concluded that the

timing of her sudden deterioration in relation to the blood transfusion was coincidental.

20. Lothian NHS Board also stated that a blood sample taken on 23 December 2012 from Mrs A had shown she had an infection in her blood. While a specific source for this was not found, Consultant 1 had explained that patients who are already very ill and who are or have been in hospital shortly before being admitted for surgery are particularly susceptible to serious infection, which may go on to cause the severe post-operative complications and systems failures which Mrs A experienced.

21. Lothian NHS Board said that Consultant 1 had met with Mrs A's family but this had failed to answer their very understandable concerns and questions. Lothian NHS Board had also advised Mrs A's family that a further meeting with Consultant 1 and the clinical nurse manager for cardiothoracic surgery could be arranged. Lothian NHS Board stated that the entire cardiothoracic team had been very upset by the sudden change in Mrs A's condition and her subsequent deterioration and death and offered their sincere sympathies.

Lothian NHS Board's response to SPSO

22. Lothian NHS Board stated that Mrs C's case was not discussed at a multi-disciplinary team meeting prior to her surgery. They explained the reasons for this were because Mrs C had presented with an out of hospital cardiac arrest and her previously inserted mechanical aortic valve was malfunctioning. Lothian NHS Board said that Mrs A was fit for an operation and there were no alternative treatments. Therefore, her case did not meet the criteria to require discussion at a multi-disciplinary team meeting.

23. Lothian NHS Board said that, as documented in Mrs A's medical records, Consultant 1 had reviewed Mrs A on 6 December 2012 in the presence of her daughter (Ms B) and the details of the surgical procedure and all potential complications were discussed with Mrs A. Lothian NHS Board also said that Consultant 1 agreed that in Mrs A's case consent was not documented according to General Medical Council guidelines. However, according to Lothian NHS Board, Consultant 1 had explained the risks and procedures to Mrs A and Ms B and in doing so had, therefore, essentially taken consent. In addition, they said that before a consent form is signed a speciality grade registrar always explains the risks and procedures to the patient. According to

Lothian NHS Board, Mrs A and her family had understood the procedure and the risks involved.

24. Lothian NHS Board said that on 7 December 2012, Mrs A was reviewed by the cardiac surgery nurse practitioner and by the cardiac surgery liaison nurse, both of whom had explained the pre-operative and post-operative pathways to Mrs A and had asked Mrs A and her family if they had any further questions; in particular, about the risks of surgery. According to Lothian NHS Board, Mrs A had 'clearly wished not to have very much information'.

25. Lothian NHS Board confirmed that Mrs A's death had been investigated by the procurator fiscal. A post-mortem examination was performed on 3 January 2013 by a pathologist acting on behalf of the procurator fiscal and the pathologist had issued Mrs A's death certificate. The procurator fiscal's investigation was closed on 25 January 2013. Mrs A's death had then been discussed at a monthly morbidity and mortality meeting once the procurator fiscal investigation had concluded.

Fife NHS Board's response to SPSO

26. Fife NHS Board said that the consultant cardiologist involved in Mrs A's case accepted that good communication between hospitals was important and for that reason Mrs A's medical records were sent with her when she was transferred from Hospital 1 to Hospital 2. The Board said that within Mrs A's records there was a very recent clinic letter outlining Mrs A's complex health issues and the consultant cardiologist considered this should have been appropriate.

Medical advice

27. The Adviser told my complaints reviewer that Mrs A was admitted to Hospital 1 as an emergency on 15 November 2012 following an out of hospital cardiac arrest, where she was successfully resuscitated and treated. The Adviser said that Mrs A had a previous history of cardiac surgery in 2009, when it was reported that she underwent mechanical aortic valve replacement and a coronary artery bypass grafting. In 2012, she had also undergone a stenting procedure. The Adviser also said that Mrs A had a previous history of chronic kidney disease, long standing type 2 diabetes, hypertension, previous stroke and atrial fibrillation.

28. The Adviser noted that on 22 November 2012 Mrs A was referred to Hospital 2 for urgent in-patient coronary angiography and she was subsequently transferred and admitted to Hospital 2 on 28 November 2012. The Adviser told my complaints reviewer he did not consider that there appeared to have been any significant delay in transferring Mrs A between Hospital 1 and Hospital 2. The Adviser said that he considered a reasonably detailed clinic letter concerning Mrs A's case was sent by the cardiology team at Hospital 1 to the cardiology receiving team at Hospital 2. However, in his view, this letter did not in any way deal with the background of Mrs A's presentation as an emergency to Hospital 1 with an out of hospital cardiac arrest in November 2012 and the subsequent management of her care and treatment within Hospital 1 prior to her transfer to Hospital 2 for urgent inpatient cardiological investigations and subsequently high risk urgent in-patient surgery. In the Adviser's view, he would have expected clearer specific documentation relating to the referral of Mrs A, a high risk heart patient, who also had considerable co-morbidity and associated medical conditions to have been sent by Hospital 1 to Hospital 2 at the time of her urgent transfer. The Adviser considered that the communication between Hospital 1 and Hospital 2 should have been better.

29. The Adviser said that various investigations and tests, including blood, renal and kidney function and a transthoracic echocardiography were carried out on Mrs A on 29 November 2012. A coronary and an aortic angiography were performed on 3 December 2012 and it was noted that consideration be given for re-do aortic valve replacement. In view of Mrs A's renal dysfunction, intravenous heparin was restarted and also intravenous fluids.

30. The Adviser said that Mrs A was originally listed for her cardiac surgery to be undertaken on 12 December 2012, which was subsequently cancelled due to an emergency involving another patient.

31. The Adviser noted that on 12 December 2012 Mrs A had some discharge from her umbilicus from which a microbiology swab was taken.

32. The Adviser considered it was likely that the risks and details of the surgery were explained to Mrs A and her family by Consultant 1 and the cardiac nurses. However, the Adviser was of the view that the explanation of the risks to Mrs A, in particular, the specific risks of mortality and potentially morbidity and the benefits of surgery, were not properly documented in the medical records and did not meet the standards of the General Medical Council

Guidance June 2008, *Consent: patients and doctors making decisions together* (GMC Guidance). The Adviser noted that Consultant 1 had agreed that, in Mrs A's case, consent was not documented according to GMC Guidance. The Adviser said that the GMC Guidance stresses the importance of making written documentation when explaining the risks of mortality and morbidity risks of surgery to patients. Also, although the Adviser considered that informed consent was obtained from Mrs A at the time, he was of the view the documentation used during the process of obtaining Mrs A's consent did not meet the appropriate standards. Furthermore, the Adviser said it was unclear who took the consent and there was no evidence of re-confirmation of the consent process following the original cancellation of Mrs A's surgery on 12 December 2012. The Adviser was of the view that Lothian NHS Board's response on these matters had been provided in retrospect.

33. The Adviser also noted that Mrs A's case was not discussed at a multi-disciplinary team meeting prior to her surgery. The Adviser told my complaints reviewer he regarded Mrs A as a high risk case and, as such, he considered that her case should have been discussed in a multi-disciplinary team meeting where more than one surgeon and one cardiologist were present, in order that high risk management decisions could be ratified and consultant surgeons supported in their decision making process.

34. The Adviser told my complaints reviewer that Mrs A's urgent re-do cardiac surgery for a partially obstructed mechanical aortic valve on 21 December 2012 was a relatively high risk procedure. However, he agreed with Lothian NHS Board that Mrs A had no alternative but to undergo this surgery in view of her significant previous medical history, her recent cardiac arrest and her previous cardiac surgery. The Adviser considered that it was reasonable that repeat coronary artery bypass grafting was not undertaken in view of the state of Mrs A's coronary arteries. The Adviser said he considered the technical aspects of Mrs A's surgery appeared to have been performed to a high standard.

35. The Adviser said that Mrs A's early recovery from the surgery was very good. The Adviser noted that Mrs A was returned to the intensive care ward after surgery and as she had made satisfactory progress she was then transferred to the high dependency ward on 22 December 2012. As Mrs A continued to make good progress, she was transferred to Ward 102 on the

morning of 23 December 2012. The Adviser considered these actions to be reasonable.

36. The Adviser said that Mrs A continued to be observed and while her blood sugars were stable, Consultant 1, on a ward round, had noted that Mrs A had a low haemoglobin of 7.7, a white cell count of 1.1 and her C-reactive protein, which is produced by the liver, was 124. In view of these results, a treatment plan was, therefore, put in place and her case was discussed with the haematology department and continuing antibiotic therapy was recommended. Consultant 1 also recommended Mrs A have a blood transfusion.

37. The Adviser told my complaints reviewer that it was recorded in Mrs A's medical records that at about 18:30 on 23 December 2012, after the start of the blood transfusion, Mrs A was noted to be shivering with an increasing heart rate, increasing temperature and reduced oxygen saturations. The Adviser said a transfusion reaction was suspected, the transfusion was discontinued and a series of blood tests were sent to the blood transfusion service.

38. The Adviser said that Mrs A continued to deteriorate, despite intravenous fluid to try and maintain an appropriate blood pressure, and she was complaining of abdominal pain. As she continued to deteriorate, she was transferred back to the intensive care ward at around midnight on 23 December 2012 for continuing treatment.

39. The Adviser told my complaints reviewer that at this time a provisional diagnosis was made of severe metabolic acidosis, on the background of a probable episode of bacteraemia (bacteria entering into Mrs A's blood stream). A transoesophageal echocardiography was undertaken to ascertain Mrs A's cardiac state. Her heart muscle function was noted to be satisfactory and there were no problems noted with the recently implanted aortic valve.

40. The Adviser agreed with Lothian NHS Board that the timing of Mrs A's deterioration at the time of the blood transfusion appeared to be coincidental with her developing a bacteraemia, in association with sudden acute liver failure due to decompensated cirrhosis of the liver (which had not been recognised prior to surgery). In the Adviser's view, it was most unlikely that Mrs A's blood was infected prior to her surgery, otherwise she would have not had such a good initial recovery from her surgery. The Adviser considered the procedures followed by the ward staff for a suspected transfusion reaction appeared

appropriate and in accordance with Lothian NHS Board's Blood Transfusion Clinical Policy and Procedures, copies of which had been supplied by Lothian NHS Board.

41. The Adviser said that, in view of Mrs A's mode of collapse and the finding of severe metabolic acidosis, she was referred for an emergency general surgical opinion to exclude a significant intra-abdominal problem. The Adviser considered there was a very timely review by general surgery, which included Mrs A going to theatre on the morning of 24 December 2012 for a diagnostic laparoscopy.

42. On 24 December 2012 a bacteria was noted in Mrs A's blood on microbiological testing (from a blood sample taken on 23 December 2012) and her antibiotics were changed at this time. On 25 December 2012 it was confirmed that this organism was enterobacter cloacae (a gastro-intestinal organism).

43. The Adviser said that Mrs A continued to deteriorate rapidly. On the morning of 25 December 2012 Mrs A developed atrial fibrillation. Also, Mrs A's blood glucose fell, consistent with deteriorating liver function, and her blood pressure continued to fall during the day. In addition, her lactic acidosis continued to rise and her liver function was abnormal, consistent with acute liver failure. During the early hours of the morning of 26 December 2012 there was continuing deterioration in Mrs A; she became unresponsive to therapy and died at 04:00. The Adviser noted that a DNACPR (do not attempt cardiopulmonary resuscitatation) consent had previously been agreed with Mrs A's family.

44. The Adviser told my complaints reviewer that, in their view, the actions taken by the nursing and medical staff when Mrs A clinically deteriorated from 18:30 on 23 December 2012 onwards appeared to be appropriate and timely. The Adviser also considered that appropriate timely intensive care intervention was undertaken following her readmission to the intensive care ward.

45. The Adviser considered it was reasonable that Mrs A's doctors did not recognise that she had liver cirrhosis prior to her surgery as the Adviser noted that, following Mrs A's transfer to Hospital 2, blood investigations from 29 November 2012 showed her liver function tests appeared to be within normal limits.

46. However, the Adviser told my complaints reviewer they had considered the results of the umbilical microbiology swab taken on 12 December 2012 due to Mrs A having some discharge from her umbilicus (see paragraph 31). The Adviser told my complaints reviewer this was found to be positive on 13 December 2012, when culture and sensitivity showed a small number of coliform organisms isolated. A note was made that this may have been a colonisation (the presence of bacteria in or on the body but which do not cause any medical problems) rather than an infection. The Adviser said that anaerobes (organisms) were isolated which were shown to be sensitive to metronidazole, an antibiotic used in the treatment of bacterial infections. The Adviser noted that the positive result from the umbilical swab was acted upon, as a seven day course of metronidazole was prescribed for Mrs A from 14 December 2012 until 20 December 2012. However, the Adviser considered the entries in Mrs A's nursing and medical records in relation to this were limited. The Adviser also told my complaints reviewer that it was not apparent from the medical records that the potential relevance of this positive finding for Mrs A, who was due to undergo high risk re-do cardiac surgery, was fully realised by the cardiac team treating her and whether consideration was given by Consultant 1 to potentially delaying Mrs A's surgery due to the risk of subsequent sepsis. In retrospect, the Adviser was of the view that this may have been the source of the subsequent bacteraemia and septicaemia responsible for Mrs A's death.

47. The Adviser also noted that there had been an early retraction of Mrs A's death certificate which had, according to the Adviser, been inappropriately completed by a non-consultant grade junior doctor.

(a) Decision

48. I accept the advice I have received that, given Mrs A's significant previous medical history, which had included previous cardiac surgery and a recent cardiac arrest, there was no alternative treatment to the urgent and high risk in-patient re-do cardiac surgery which Mrs A underwent. I acknowledge that the technical aspects of Mrs A's cardiac surgery appear to have been performed to a good standard and that Mrs A's early recovery from the surgery was good.

49. Unfortunately however, 48 hours after surgery, Mrs A's condition suddenly deteriorated around the same time as the start of her being given a blood transfusion. I understand the concerns raised by Mrs A's family about the sudden deterioration in Mrs A's condition at this time which happened in the

presence of members of the family and which must have been very distressing to witness. However, I am satisfied, based on the advice I have received, that the blood used in the transfusion was not contaminated; the action taken thereafter by the ward staff was appropriate; and Mrs A did not die because of a blood transfusion reaction. I also accept that Mrs A's deterioration at the time of the blood transfusion was coincidental with her developing a bacteria entering into her blood stream, in association with sudden acute liver failure due to decompensated cirrhosis of the liver.

50. I also accept the advice from the Adviser that, once Mrs A's condition deteriorated, full and appropriate intensive care resuscitative measures were undertaken by medical staff. I am also satisfied that there is no evidence that Mrs A was moved out of intensive care and high dependency wards too soon. Furthermore, I accept that it was reasonable that cirrhosis of the liver was not diagnosed in Mrs A before her surgery and that, in any event, if it had this would not have affected Mrs A's outcome.

51. However, my investigation identified several areas of concerns in Lothian NHS Board's care and treatment of Mrs A.

52. The advice I have received is that there appears to be a lack of clear cardiology referral documentation laying out Mrs A's complex high risk case from the cardiology team at Hospital 1 to the cardiology receiving team at Hospital 2 and this should have been better. Hospital 1 is the responsibility of Fife NHS Board. Taking account of the concerns raised by the Adviser that communication between Hospital 1 and Hospital 2 should have better and the importance of this matter, I provided Fife NHS Board with the opportunity to comment on a draft of this report.

53. The advice I have also received is that, as Mrs A's case was complex and high risk, her case should have been discussed at a pre-operative multi-disciplinary team meeting. I accept that the benefit of such a meeting is so that high risk management decisions, such as those involved in Mrs A's case, can be ratified and consultant surgeons supported in their decision making processes. Therefore, I consider Lothian NHS Board's criteria for multi-disciplinary team meetings should be reviewed.

54. It is of concern that the Adviser considered the written documentation relating to the consent process for Mrs A's surgery was poor and it was unclear

who took the consent. There was also no evidence of re-confirmation of the consent process following the cancellation of Mrs A's surgery on 12 December 2012. Also, while the Adviser considered it likely that Consultant 1 and the cardiac surgical team had explained the risks of and the details of the surgery to Mrs A and her family, the entries in Mrs A's medical notes did not meet the standards laid down in the GMC Guidance.

55. Furthermore, the advice I have received is that there is no evidence that a formal sign-off discharge summary fully describing Mrs A's case, her cause of death and a copy of the post-mortem report was sent to her general practitioner, as there should have been. I also acknowledge that there was an early retraction of Mrs A's death certificate which, according to the Adviser, had been inappropriately completed by a non-consultant grade junior doctor. I appreciate that this would have caused Mrs C and her family unnecessary distress.

56. Taking account of the advice I have received from the Adviser, I consider there were failings in the consent process and in record-keeping.

57. I note that, according to the advice I have received, a positive result from an umbilical swab taken from Mrs A on 12 December 2012 may have been the source of the subsequent bacteraemia and septicaemia responsible for Mrs A's death. Although Mrs A was prescribed appropriate antibiotics, metronidazole, the advice I have received is that the entries in Mrs A's medical records concerning this are limited and it is unclear from the records whether the potential relevance of this positive result for Mrs A, given that she was due to undergo high risk re-do cardiac surgery, was fully realised by the cardiac team treating her. It is also unclear whether consideration was given to potentially delaying Mrs A's surgery in view of the risk of subsequent sepsis.

58. Given the failings I have identified I, therefore, uphold this complaint.

(a) Recommendations

59. I recommend that Lothian NHS Board:	*Completion date*
(i) ensure that the comments of the Adviser, in relation to the issues of consent and proper and accurate record-keeping, are brought to the attention of the relevant staff and a review is carried out;	30 November 2015

(ii)	ensure the comments of the Adviser, in relation to the positive umbilical swab taken from Mrs A on 12 December 2012, are brought to the attention of relevant staff and they reflect on this; and	30 November 2015
(iii)	apologise to Mrs C and the other members of Mrs A's family for the failings identified in complaint (a).	30 October 2015

60. I recommend that Lothian NHS Board and Fife NHS Board: *Completion date*

(iv)	ensure the comments of the Adviser, in relation to the lack of clear cardiology referral documentation between Hospital 1 and Hospital 2, are brought to the attention of relevant staff.	30 November 2015

(b) Lothian NHS Board did not respond reasonably to Mrs C's complaint of 18 September 2013

61. Mrs C complained that Lothian NHS Board had taken four months to respond to her original letter of complaint and had failed to respond reasonably to the concerns she had raised.

62. Mrs C wrote to Lothian NHS Board on 18 September 2013 setting out her complaint.

63. On 4 October 2013 Lothian NHS Board wrote to Mrs C acknowledging her letter and said they were sorry to learn of her concerns and offered their condolences. The letter informed Mrs C that her correspondence had been forwarded to the appropriate service to review the issues she had raised. The letter enclosed a consent form to sign so that Lothian NHS Board could share confidential information with her. The letter also stated that Lothian NHS Board whenever possible tried to respond within 20 working days of receipt of the consent form.

64. Ms B, signed the consent form, which was date stamped as being received by Lothian NHS Board on 10 October 2013.

65. On 5 November 2013 Lothian NHS Board sent a letter of response to Ms B setting out Lothian NHS Board's response to the complaint. The letter concluded by stating that if she had any questions relating to the response she

should contact Lothian NHS Board's Customer Relations and Feedback Team. It also provided information about my office.

66. According to Lothian NHS Board's complaint file, the letter was sent to the incorrect address. I note that there was an error made by Lothian NHS Board with regard to the house number in their letter of 5 November 2013 to Ms B. There is an email on Lothian NHS Board's file dated 17 January 2014 stating the letter that had been returned 'not known at this address'. On 21 January 2014 Lothian NHS Board's Director of Communications and Public Affairs wrote to Ms B, at the correct address, offering his 'sincere apologies' for the delay which he stated was due to an administrative error in the formal letter of response to her complaint. A copy of Lothian NHS Board's response letter of 5 November 2013 was enclosed.

(b) Decision

67. I have carefully considered the complaints correspondence and also Lothian NHS Board's complaints procedure. I consider that Lothian NHS Board's letter of 5 November 2013 did appropriately respond to the concerns raised by Mrs C, even though she and Mrs A's family may not have agreed with Lothian NHS Board's response. However, unfortunately, due to an incorrect address in the letter, it was not received by Ms B and was returned as undelivered to Lothian NHS Board. It is unclear from Lothian NHS Board's file when the letter was returned. However, I am satisfied that when it was brought to the attention of the relevant persons in Lothian NHS Board, they acted timeously in sending a copy of the letter of 5 November 2013 to Ms B. Nevertheless, while I accept Lothian NHS Board apologised for the delay in providing a response to the complaint, I consider the apology letter was brief, lacked empathy and did not fully address the reasons for the delay. Accordingly, I uphold the complaint.

68. I note from Lothian NHS Board's complaint file that, in light of what occurred, their Customer Relations and Feedback Team have reviewed their processes and stated they would be more vigilant in checking addresses. Also, members of their administration team, supervisor and the complaints manager would all be made aware of what had occurred. Accordingly, I am satisfied Lothian NHS Board have taken appropriate action.

(b) Recommendation

69. I recommend that Lothian NHS Board:	*Completion date*
(i) apologise to Mrs C and Ms B for the failings identified in this complaint.	30 October 2015

70. Lothian NHS Board and Fife NHS Board have accepted the recommendations and will act on them accordingly. We will follow-up on these recommendations. Lothian NHS Board and Fife NHS 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.

Annex 1

Explanation of abbreviations used

Mrs C	the complainant
Mrs A	Mrs C's aunt and the subject of this report
Hospital 1	Royal Victoria Hospital, Kirkcaldy
Hospital 2	the Royal Infirmary of Edinburgh
the Adviser	a consultant cardiothoracic surgeon who provided independent advice on the clinical care and treatment provided to Mrs A
Consultant 1	a consultant cardiac surgeon
Ms B	the daughter of Mrs A
GMC Guidance	General Medical Council Guidance

Glossary of terms

aortic angiography	a procedure that uses a dye and radiography to see how blood flows through the aorta, the major artery leading out of the heart
atrial fibrillation	a heart condition that causes an irregular heartbeat
bacteraemia	presence of bacteria in the blood
cardiac	heart related
cardiothoracic	relating to the heart, chest or lungs
cardiac arrest	sudden stopping of heart function
coliform organisms	bacteria present in the intestinal tract
colonisation	the presence of bacteria in or on the body but which do not cause any medical problems
co-morbidity	the presence of two or more disorders or illnesses occurring in the same person
coronary angiography	a procedure that uses a dye and x-rays to see how blood flows through the arteries of the heart
coronary artery bypass grafting	a surgical procedure that improves blood flow to the heart
decompensated cirrhosis of the liver	where a damaged liver is not able to perform all its functions

echocardiogram	a monitor that records the electrical activity of the heart, allowing its function to be assessed
haematology	the branch of medicine involved in the treatment of the blood
haemoglobin	a protein in red blood cells that carries oxygen through the body
heparin	medication used to prevent blood clots from forming in the veins, arteries or lungs
hypertension	high blood pressure
intravenous	introduction of fluids directly into a patient's blood stream using a needle
ischaemic heart disease	a condition that affects the supply of blood to the heart
laparoscopy	a type of surgical procedure to look inside the body or perform a surgical procedure
metabolic acidosis	a condition that occurs when the body produces too much acid
prosthetic aortic valve replacement	the replacement of diseased heart valve with an artificial valve
septicaemia	a bacteria in the bloodstream
sepsis	a total body inflammatory response that occurs with severe infection
stenting	a procedure to open a narrowed coronary artery

transthoracic echocardiogram	a test that uses sound waves, ultrasound, to examine and take pictures of the heart
transoesophageal echocardiogram	a test that uses sound waves, ultrasound, to examine and take pictures of the heart
umbilicus	the depression in the centre of the surface of the abdomen

Annex 3

List of legislation and policies considered

General Medical Council Guidance June 2008, Consent: patients and doctors making decisions together

NHS Lothian Blood Transfusion Clinical Policy and Procedures 2011

NHS Lothian Blood Transfusion Clinical Policy and Procedures 2013