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: 201507563, Lothian NHS Board
Sector: Health
Subject: Hospitals / Clinical treatment / Diagnosis

Summary
Mr C, who suffered from a hereditary heart condition, had an operation at the Royal Infirmary of Edinburgh to remove a machine implanted in his chest to monitor his heart. The operation was carried out by a trainee doctor. When the trainee doctor encountered difficulties, he was assisted by a more senior trainee doctor. Mr C subsequently required a second operation to revise the scar the first procedure had left on his chest.

In investigating, I took independent medical advice from a consultant cardiologist, as well as considering the board's own investigation of the complaint.

Mr C complained the first operation had not been carried out to an appropriate standard. He said that the experience had been painful and distressing and believed the correct procedures had not been followed. Mr C believed the trainee doctor performing the surgery had not been competent to do so, noting that the time taken to perform the operation meant he required additional anaesthesia, as his initial dose had worn off.

The board said they had thoroughly reviewed Mr C's treatment. The board said the tools for cauterising the wound to stop bleeding post-surgery had not been available. Silk stitches had been used instead, but these may have contributed to the poor healing Mr C experienced. The board said the consultant responsible for supervising the operation was available, but had not been present throughout the operation. The board acknowledged Mr C's experience fell short of what he could have expected.

The adviser said the board had not adequately explored the conflict between the contemporaneous note of the operation and the conclusions reached by the complaint investigation. The operation note stated cauterisation had been used to stop Mr C's bleeding, but as the complaint investigation acknowledged, this could not have been performed as the equipment was not available at the time. The adviser said the operation note's inaccuracy had not been properly

explored, nor did the note record the difficulties encountered during the surgery. The adviser said it was unreasonable for a trainee doctor to be allowed to perform the surgery unsupervised, as it was not a straightforward procedure.

The adviser added the board did not address the issue of supervision. Their complaint response gave the impression a consultant had been present at points during the operation. The available evidence showed no consultant had been present at any point, nor had they been aware Mr C's procedure was being carried out by a trainee doctor. The adviser also noted Mr C's consent was not properly obtained and that there were inadequate records of the information provided to him prior to surgery.

I found the board failed to investigate Mr C's complaint thoroughly, although they had accepted the standard of treatment received was unacceptable. I also found they had failed to deal comprehensively with the service failures Mr C experienced. I am critical of these failings, which resulted in a misleading formal response being provided by the board and a lack of evidence that adequate steps had been taken to prevent a reoccurrence.

Mr C also complained that the effect of the first operation had not been recognised by the board. He had stated to the board that his business had suffered severely whilst he was unable to work and that he had been forced to cease trading. I was critical of the board for failing to address this issue, even though Mr C raised it twice during his complaint. I considered the board had to address the impact on him of the failure to carry out his surgery in a reasonable fashion.

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) provide evidence of the actions taken by Doctor 2 to improve their skills and their subsequent appraisals;	7 September 2016
(ii) provide evidence that Doctor 2 has continued to practice without significant subsequent complaints or concerns being raised;	7 September 2016
(iii) provide evidence that their policy for the supervision of trainees during surgical procedures has been reviewed;	7 September 2016

(iv)	review the consent forms used for this type of surgery to ensure they accurately reflect the potential complications;	21 September 2016
(v)	remind all staff of the importance of documenting consent fully and accurately; and	7 September 2016
(vi)	provide Mr C with a comprehensive and patient centred response to the issues he has raised concerning the impact of the surgeries on his ability to work and his finances.	21 September 2016

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 Mr C. The terms used to describe other people in the report are explained as they arise and in Annex 1.

Introduction

1. Mr C complained to the Ombudsman about the care and treatment he received during at the Edinburgh Royal Infirmary the surgical removal of his cardiac loop recorder from his chest. The complaint from Mr C I have investigated is that Lothian NHS Board (the Board) unreasonably failed to provide Mr C with appropriate treatment during a procedure in August 2014 (*upheld*).

Investigation

2. In order to investigate Mrs C's complaint, my complaints reviewer took medical advice from a consultant cardiologist (the Adviser). Although the Board upheld Mr C's complaint to them, we have decided to issue a public report on Mr C's complaint because the investigation identified issues which the Board's investigation had not addressed and inaccuracies in the Board's response to Mr C.

3. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. Mr C and the Board were given an opportunity to comment on a draft of this report.

Background

4. Mr C suffers from a familial (inherited) heart problem which can cause a disturbance to the rhythm of your heart beat. Three years previously (2011) Mr C had had a loop recorder implanted into his chest. This was a medical device which could monitor any such episodes of disturbed heartbeat.

5. On 3 July 2014 Mr C attended a clinic with his consultant (Doctor 1). At this appointment the decision was made to explant (surgically remove) the loop recorder. It was also noted Mr C had an unsightly chest scar and surgery could be carried out on this at the same time to improve its appearance.

6. Mr C was admitted on 14 August 2014 for the procedure. The listing for surgery stated 'Loop removal (excise old scar + remove loop)'. He was given an intravenous dose of Flucloxacillin (an antibiotic) beforehand at 11:25.

7. The procedure was undertaken in the cardiac catheter lab (CCL), rather than the operating theatre. It was performed by an ST4 (trainee) (Doctor 2) who was subsequently assisted by a more senior trainee (Doctor 3). Doctor 2's operation note stated 'Xyloid scar excised. Loop recorder removed. Skin

closed to layer with absorbable suture. Haemostasis achieved at end of procedure – diathermy also used. Steri strips to skin.'

8. The discharge documentation described the procedure as uncomplicated and noted there had been a 'wide scar revision' and that Mr C had been prescribed pain relieving medicine. The time taken to perform the operation was not recorded.

9. Mr C's wound required revision on 17 November 2014, which was carried out by Doctor 1. There was evidence of previous infection and the wound had failed to heal completely. Doctor 1 noted no signs of infection, but large amounts of silk suture.

December 2014 formal complaint

10. In December 2014 Mr C handed a letter of complaint to Doctor 1. The letter stated Mr C sought a full written explanation as to why the second operation was necessary. Mr C said that the consequences of the original operation had been serious for him as he was self-employed and had been unable to work. Mr C said he had an unhealed scar for twelve weeks which had been infected, but had not healed, despite repeated courses of antibiotics.

11. Doctor 1 passed this to the clinical nurse manager (CNM), to be registered as a complaint. This did not happen and in March 2015 Mr C telephoned the Board to find out why he had received no response to his complaint.

Email of 25 March 2015

12. Mr C then emailed the Board stating that he wished his letter to be considered as a formal complaint. He said Doctor 1 had told him the operation had not been carried out to an appropriate standard and the appropriate procedures had not been followed. Mr C complained that Doctor 2 should not have been left to perform the surgery unsupervised. Mr C said he had been told by Doctor 1 that the silk sutures left in the wound should not have been used under the skin. Mr C said that the protracted period off work caused by the failure of the first wound to heal and the need for a subsequent second unanticipated operation had ultimately forced him to close his business since he was unable to continue trading.

The Board's Investigation

13. On 30 March 2015, Doctor 1 provided the letter he had written to the CNM in December 2014. He said Mr C had a bad outcome from a minor operation. He noted diathermy was not available in the catheter laboratory, Mr C had bled extensively during the procedure and Doctor 2 and Doctor 3 had dealt with this by placing a large number of silk sutures under the skin. Neither doctor was familiar with the appropriate surgical procedures.

14. Doctor 1 said there had been a long delay after the operation before he was informed of any problems. Although Mr C had been treated for wound infection by his GP, Doctor 1 considered the problems were more likely chronic inflammation due to the presence of silk sutures in the superficial tissues of a patient prone to keloid scars (an overgrowth of dense tissue, beyond the borders of the original wound).

15. Doctor 1 said that he had spoken to Doctor 2, who had told him they had difficulties in achieving stopping the bleeding and had used large numbers of silk sutures to tie the blood vessels to achieve this. Doctor 1 said the problems had arisen because Doctor 2 had minimal experience of this procedure, and had been performing it unsupervised. When he had called for assistance Doctor 3 had attended, but was equally unfamiliar with the procedure. Doctor 1 said the correct equipment had not been used and they had not asked senior staff for help. Doctor 1 noted Mr C had found the experience frightening as he had the impression (correctly in Doctor 1's view) that Doctor 2 did not know what he was doing.

16. Doctor 1 said he had had several conversations with Doctor 2 about the incident. The Consultant Group had taken action to prevent Doctor 2 carrying out any unsupervised work in the catheter lab.

17. Doctor 1 said he had been unaware of Mr C's admission for the procedure, nor had he been aware of any issues that had arisen until long after the event. In his view the case underlined the importance of having procedures carried out by suitably trained and supervised individuals in the appropriate environment, with the correct equipment available.

18. Doctor 1 also included a copy of the note he had originally written following receipt of Mr C's complaint in December 2014 and a review of the case notes. This set out more briefly the details of the case. It noted that Mr C

felt he had been financially disadvantaged and that he might pursue financial compensation for loss of earnings.

19. Another consultant cardiologist (Doctor 4) investigated the complaint. On 30 March 2015 he wrote to the CNM, apologising for not having responded sooner. He said during the consent procedure the risks of wound healing and infection would have been discussed with Mr C. Doctor 4 said he thought a decision had been made to have the loop recorder removed in the catheter lab. He said that although he had no recollection of discussing the procedure he was sure he would have agreed this was a good idea.

20. Doctor 4 said he had spoken to 'a few people' about the procedure and he had been told a lot of silk sutures had been used to stop Mr C bleeding. This was unusual, although silk sutures were used to hold pacemaker leads in place beneath the skin; these were much fewer in number. Doctor 4 said he had had no contact with Mr C on the day of the operation and noted that he had not signed any of his paperwork, as this had been done by other members of staff.

21. Doctor 4 said he had been sorry to learn of Mr C's subsequent problems with wound healing. He noted from Doctor 1's letter that breakdown of the wound had been superficial and that it appeared the top layer of scar tissue had become separated from a very dense layer of scar tissue beneath the wound. Doctor 4 noted that a lot of silk sutures had been found beneath the skin and that Doctor 1 thought it likely these had contributed to the problems with healing.

22. Doctor 4 said he was sorry Mr C had experienced these problems from what should have been a benign procedure. Poor wound healing was a recognised feature or complication of having any device removed and Mr C noted that the original scar was also felt to be unsightly. Doctor 4 added he was sorry to learn that Mr C had been unable to work.

23. Doctor 4 subsequently sent an email to the CNM and to Doctor 1 on 30 March 2015. He noted that although he thought he was the consultant responsible for the patient, he had no recollection of the case, or of discussing it with either the consultant recommending the procedure, or the consultant whose list Mr C had originally been placed on. The healing problem he noted appeared to be superficial and there was no evidence of infection during the revision carried out in November 2014.

24. On 8 April 2015, Doctor 4 wrote an internal note regarding Mr C's treatment. He said he could not be sure, but it was likely that Mr C had undergone his treatment in the catheter laboratory he was supervising. He noted the procedure was carried out by Doctor 2 and Doctor 3, and that no one had mentioned any problems to him at the time, but that he had subsequently learnt that silk sutures had been used to achieve haemostasis.

25. Doctor 4 said they would in future discourage trainees from supervising other trainees and suggest they are supervised by consultants. Doctor 4 said he could only apologise to Mr C that he had suffered this complication of poor wound healing. Doctor 4 said this was a recognised but rare complication of any minor procedure.

The Board's Formal Response

26. The Board responded in writing on 28 April 2015. They said they appreciated Mr C's concern over the delay in his response, but they assured him that this was because the matter was being thoroughly investigated.

27. The Board responded that Doctor 4 had thoroughly reviewed Mr C's case notes. He noted that the removal of the cardiac loop recorder was carried out in the cardiac laboratory. It was not unusual for this type of procedure to be carried out there, but as there was no diathermy equipment there, silk sutures were used to tie off blood vessels. Sutures were commonly used in similar procedures, but the Board said the number used on this occasion may have contributed to the poor healing that subsequently occurred.

28. The Board noted that when Doctor 1 carried out his revision of the wound in November 2014, he found no evidence of infection, but he did find silk sutures and speculated this may have caused an inflammatory reaction, although it was unclear why this would have affected the superficial healing of the wound. The Board said scarring was not an infrequent complication of this sort of procedure, but they were sorry Mr C had experienced it.

29. The Board said Doctor 4 who was responsible for supervising the registrar carrying out the procedure was available, but was not present throughout the surgery. As a result of Mr C's experience the Board said the team had given assurances that arrangements were in place to ensure adequate supervision at all times.

30. The Board acknowledged Mr C's experience fell short of that which he could have expected and offered their apologies for this.

Complaint: The Board unreasonably failed to provide Mr C with appropriate treatment during a procedure in August 2014

Concerns raised by Mr C

31. Mr C said that he had found his experience painful and distressing. He had been alarmed by what he perceived as a lack of competence on the part of Doctor 2. The duration of the procedure meant that the initial anaesthesia had worn off, and he had experienced severe pain before more anaesthesia was provided. The experience had been distressing for him, since he had been conscious throughout and Mr C felt it had been apparent through the level of bleeding that Doctor 2 was struggling to carry the operation out.

32. Mr C said as a consequence of these failings, and the need to undergo a second surgical procedure, he had been unable to work for far longer than anticipated. Mr C had been self employed as a mechanic at the time and this extended period had resulted in the closure of his business. Mr C had also been unable to sustain his rental payments on his property and had been obliged to move back in with his parents.

33. Mr C supplied statements of his bank account and a printout generated by his former business' invoicing software. These showed a comparison between his earnings in 2013 and 2014. These showed Mr C's business was consistently performing better in 2014 than 2013, up until the surgery was carried out in August. Following that point, the business' earnings dropped every month, before Mr C was forced to close it in February 2015.

34. Mr C felt it was unreasonable that the failure to carry out his surgical procedure to an acceptable standard had resulted in a substantial loss of earnings, culminating in the closure of his business.

The Board's response

35. The Board's response to Mr C's complaint has been summarised in detail in the background section of the report. The Board have acknowledged Mr C's experience fell short of the service they aimed to provide and apologised for this. The Board noted they had fully upheld his complaint.

Medical advice

36. The Adviser noted that the only Scottish Intercollegiate Guidelines Network guidance that applied related to the pre-operative provision of antibiotics and that this had been adequately followed. The Adviser said the Board had not, however, adequately examined the conflict between the operation note by Doctor 2, which stated that diathermy had been used and the complaint investigation, which clearly recorded that diathermy, could not have been used as it was not available in the CCL. The Adviser said the presence of multiple silk sutures, found on the revision in November 2014 suggested strongly diathermy was not used.

37. The Adviser said it was unreasonable that a trainee had been allowed to carry out the procedure unsupervised. He said the operation note was inaccurate and difficulties had clearly been encountered but not recorded during the procedure. The Adviser added the requirement to excise a scar meant this could not be seen as a straightforward procedure, which increased the need for supervision for inexperienced doctors.

38. The Adviser said it was not unreasonable for the operation to have been performed under Doctor 4, rather than Doctor 1 who had planned the admission. This was not an unusual situation in large units incorporating a team of consultants and should not have caused any difficulties.

39. The Adviser's view was that the identity of the consultant responsible should have been clarified before the procedure was started by the completion of a World Health Organisation (WHO) checklist. This was a distinct document from a theatre care plan and itemised patient related factors, and essential aspects of the planned procedure, including the identity of the responsible consultant and how they could be contacted if not present. The Adviser noted this checklist had been introduced in Scotland in 2009 by the Scottish Patient Safety Programme. The Adviser noted that no checklist was present in the medical records.

40. The Adviser said it was not unreasonable for the procedure to have been carried out in the CCL.

41. The Adviser noted the Board had listed some of the actions they said they had taken in respect of Doctor 2 individually. Other issues remained unresolved, however, as the operation note was inaccurate and misleading as

to what had occurred in theatre. This did not appear to have been identified by the complaint investigation, or acted upon.

42. The Adviser said ultimately Mr C had undergone a surgical procedure, performed by a trainee who was not sufficiently competent to perform it. Neither Doctor 2 nor Doctor 3 had thought to seek advice or assistance from a more senior doctor. Consequently the standard of care he had received had fallen below a reasonable standard.

Decision

43. Mr C said he went for an operation to remove a loop recorder in August 2014. He said he was conscious the operation appeared to be taking longer than expected to complete. Mr C felt the surgeon performing the operation was having difficulties, as although he was working alone, he had to request assistance on several occasions. The procedure became very painful and Mr C had to request more anaesthetic on several occasions. This also made him think the operation was taking longer than it should have done.

44. The Board have accepted that Mr C did not receive a reasonable standard of care. I remain concerned about their investigation of this complaint, since the Board have not recognised the serious impact the failings in his care have had on Mr C. Additionally I am critical of the Board's formal response, which contains significant errors and omissions, which impact on the creditability of the Board's assurances that they have learnt from the case and taken action to prevent its reoccurrence.

45. The Advice I have received is that Doctor 2 was not competent to carry out the procedure on Mr C, which would appear to be borne out by the comments made by Doctor 1 as part of the Board's own investigation. The Board do not appear to have considered how, Doctor 2 came to perform surgery on Mr C without supervision. The advice also notes that the procedure was not entirely straightforward, as it involved scar excision, as well as the loop recorder's removal.

46. The Board's formal response to Mr C gives a misleading impression of the level of supervision Doctor 2 was receiving. The Board state that Doctor 4 was responsible for supervising Mr C's surgery and that 'whilst he was available, he was not present throughout'. As part of their investigation into the complaint, Doctor 4 stated explicitly that he had had no contact at all with Mr C on

14 August 2014 and that Mr C was discharged without Doctor 4 having seen him. The advice I have received notes that had the Board used the WHO checklist adopted in 2009 by the Scottish Patient Safety Programme, it would have been established prior to the operation commencing, which the responsible consultant was and how they were to be contacted if not present on the unit. I consider this significant as Doctor 4 has stated he was on call during the procedure and was unaware of Mr C's procedure and was not always present on the unit. It is unclear in these circumstances how Doctor 2 was to request assistance from Doctor 4 during the period the surgical procedure was being carried out.

47. The Advice has also stated the operation note for the procedure is inaccurate. The note, which has been signed by Doctor 2 records that absorbable sutures were used. This is untrue, as evidenced by Doctor 1's findings during his surgical revision of the wound on 17 November 2014, when he removed a large number of silk sutures. The operation note makes no reference to any difficulties experienced during the procedure and states that diathermy was used to achieve haemostasis. This cannot be accurate, as noted by Doctor 1 during the Board's investigation, since this equipment was not available in the CCL where the procedure was carried out. The Board's investigation does not address these inaccuracies and there is no record of Doctor 2 being asked to reflect or explain these inconsistencies.

48. Significantly, the Board's complaint investigation records no statement from Doctor 2. Its conclusions are based on reported but unrecorded conversations between Doctor 2 and Doctor 1. In other areas, such as obtaining Mr C's consent, the only evidence on file is a signed consent form. This contains minimal information other than the name of the procedure to be carried out and Mr C's signature. The Board has no evidence Mr C had the risks and possible complications of the procedure explained to him and we have no statement on record from Doctor 2 about the information he provided Mr C with prior to commencing surgery. I am critical of this, since the Board have subsequently stated that significant scarring was a recognised complication of the procedure. There is no evidence that this was discussed with Mr C, or explained to him.

49. Although the Board have stated Doctor 2 is now working with an increased level of supervision, no evidence has been provided to support this. The Board have also not provided evidence to support the statement in their letter to Mr C

that arrangements have been put in place to ensure supervision is provided during CCL procedures at all times. The internal correspondence provided by the Board is not as definite in the language it uses, stating only that trainees will be 'discouraged' from supervising other trainees and that it will be 'suggested' they are supervised by consultants.

50. The Board's formal response to Mr C is also misleading when apologising for the delay in responding to Mr C's complaint. The impression it gives is that the delay was due to the detailed nature of the investigation undertaken following Mr C's submission of his complaint in December 2014. There is no evidence that any investigation took place until Mr C followed the matter up with Doctor 1 in March 2015. As noted, although statements were sought from Doctor 1 and Doctor 4, the investigation that was carried out did not obtain statements from all the medical staff involved and did not identify or address all the failings Mr C experienced. It also failed to address the issue Mr C had raised about the impact that the procedure and subsequent complications had had on him personally and financially, although it was accepted in internal correspondence that the procedure's impact on Mr C had prevented him working.

51. The Board have already accepted that Mr C received an unacceptable standard of treatment. The evidence, however, shows the Board failed to investigate the matter thoroughly or deal comprehensively with the service failures Mr C experienced. I am critical of these failings, which resulted in a misleading formal response being provided by the Board and a lack of evidence that adequate steps have been taken to prevent a similar situation recurring again.

52. I uphold the complaint

53. In the circumstances, I consider that Mr C has been placed in a position where he has suffered a significant personal injustice, as his ability to work was compromised for an extended period causing him both personal anguish and almost certain financial loss. In my view, this is attributable in large part to the failings identified in this report. Mr C raised this in both his complaint letters to the Board and it is unacceptable for the Board to have ignored this issue. I consider the Board must provide Mr C with a comprehensive and patient centred response, which addresses the impact on him of the failure to carry out his surgery in a reasonable and appropriate fashion.

Recommendations

54. I recommend that the Board:	*Completion date*
(i) provide evidence of the actions taken by Doctor 2 to improve their skills and their subsequent appraisals;	7 September 2016
(ii) provide evidence that Doctor 2 has continued to practice without significant subsequent complaints or concerns being raised;	7 September 2016
(iii) provide evidence that their policy for the supervision of trainees during surgical procedures has been reviewed;	7 September 2016
(iv) review the consent forms used for this type of surgery to ensure they accurately reflect the potential complications;	21 September 2016
(v) remind all staff of the importance of documenting consent fully and accurately; and	7 September 2016
(vi) provide Mr C with a comprehensive and patient centred response to the issues he has raised concerning the impact of the surgeries on his ability to work and his finances.	21 September 2016

55. 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.

Annex 1

Explanation of abbreviations used

Mr C	the complainant
the Board	Lothian NHS Board
the Adviser	a consultant cardiologist who provided medical advice on the treatment provided to Mr C
Doctor 1	a consultant cardiologist
CCL	cardiac catheter lab
Doctor 2	a trainee doctor who performed the surgery on Mr C
Doctor 3	a more senior trainee doctor who assisted Doctor 2 perform surgery on Mr C
Doctor 4	the consultant cardiologist with responsibility for Doctor 2 and Doctor 3 on the day of Mr C's surgery
WHO	World Health Organisation

Annex 2

Glossary of terms

anaesthesia	a medical treatment to prevent pain whilst surgery is performed
cardiac catheter laboratory	a hospital facility used for minor surgery involving the heart and circulatory system
consultant group	consultants responsible for supervising the trainee doctors carrying surgical procedures
diathermy	medical technique, using heat from high frequency electric currents to cause bleeding vessels to clot
flucloxacillin	an antibiotic used to prevent infection during surgery
haemostatsis	a process to stop bleeding
keloid scar	an overgrowth of scar tissue that develops around a wound
loop recorder	a small device implanted under the skin to monitor the heart
silk suture	silk thread used to stitch the edges of a wound shut
steri-strip	narrow adhesive strips that help to close the edges of a small wound and encourage the skin to heal