Scottish Parliament Region: Lothian

Case 200502443: Lothian NHS Board

Summary of Investigation

Category
Health: Hospital

Overview
The complainant (Mr C) raised a number of concerns about the care his late wife, Mrs C, received in hospital where she received surgery and subsequently died.

Specific complaints and conclusions
The complaints which have been investigated are that:

(a) the full risks of surgery were never explained to Mrs C or Mr C (*upheld*);

(b) the Hospital failed to explain why Mrs C's drips were removed on 24 August 2004 (*upheld*);

(c) the Hospital failed to investigate adequately the cause of Mrs C's confusion and agitation displayed the week before her deterioration (*not upheld*); and

(d) the Hospital did not let Mr C know at the first opportunity that his wife was going into final decline and, as a result, he was denied the chance to spend valuable time with her before her death (*not upheld*).

Redress and recommendations
The Ombudsman recommends that the Board audit their practice in obtaining informed patient consent and implement any necessary change.

The Board have accepted the recommendations and have acted on them accordingly.

Main Investigation Report

Introduction

1. I shall refer to the complainant as Mr C and his late wife as Mrs C, Lothian NHS Board as the Board, and the Royal Infirmary of Edinburgh as the Hospital. A reminder of abbreviations used is at Annex 1. On 2 December 2005 the Ombudsman received a complaint from Mr C about his wife's care and treatment at the Hospital where she received surgery but later died on 26 August 2004.

2. The complaints from Mr C which I have investigated are that:

(a) the full risks of surgery were never explained to Mrs C or Mr C;

(b) the Hospital failed to explain why Mrs C's drips were removed on 24 August 2004;

(c) the Hospital failed to investigate adequately the cause of Mrs C's confusion and agitation displayed the week before her deterioration; and

(d) the Hospital did not let Mr C know at the first opportunity that his wife was going into final decline and, as a result, he was denied the chance to spend valuable time with her before her death.

Investigation

3. The investigation was assisted by two of the Ombudsman's clinical advisers, one a consultant surgeon and the other a nursing expert. I will refer to them as the Advisers. The Advisers' role was to explain, and give an opinion on, the events. We examined all papers provided by Mr C and the Board, all Mrs C's clinical records and a note of a meeting which Mr C and his family held with the Board on 15 September 2004 to discuss Mrs C's treatment. In line with the practice of the Ombudsman's office, the standards by which the complaint was judged was whether the events were reasonable, in the circumstances, at the time in question.

4. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. Mr C, his daughter and son-in-law have already met with one of the Ombudsman's Investigations Managers and an Adviser to discuss the investigation and the Advisers' detailed responses. Mr C and the Board have been given an opportunity to comment on a draft of this report which is largely a summary of the findings and decisions communicated to Mr C and his family at that meeting.

Background

5. Prior to her admission to the Hospital on 31 May 2004, Mrs C was significantly disabled by her claudication and she was more or less housebound. She also had significant arteriopathy and was known to have ischaemic heart disease, hypertension and severe aorto-iliac disease. Mrs C was referred to a Consultant Vascular Surgeon (Consultant 1), because of her claudication. At her review with Consultant 1 in September 2003, it was decided that she should be assessed for aortic surgery. She was reviewed by Consultant 1 on 5 April 2004 in the out-patient clinic. She was reviewed with her daughter and the clinic notes reveal that Consultant 1 had some doubts about Mrs C's fitness for this major surgery and, therefore, decided to admit her for assessment by a Consultant Anaesthetist before making a decision about the operation. The Consultant Anaesthetist, too, was of the opinion that the risk factors associated with Mrs C's medical condition and health were too great for direct aortic reconstruction. Consultant 1 agreed the risks were too great for direct aortic reconstruction, but felt that some intervention was necessary because of Mrs C's level of disability. As a result, a lesser operation with lower risk, but slightly reduced chances of success, was planned. This was an axillo bifemoral graft. He discussed this alternative procedure with her and she agreed to this.

6. Mrs C was admitted to the Hospital for surgery on 31 May 2004. A consent form was signed and is on record.

7. The procedure – axillo bifemoral graft - was performed on 1 June 2004. Three hours later, a second procedure was required when Mrs C's left foot became mottled with some calf tenderness while still in the recovery area. She was returned to theatre for a refashioning of the femora-femoral crossover graft.

8. On 7 July 2004 Mrs C was discharged home. Records show that her wound was dry and intact and that arrangements were made for a district nurse to remove her stitches.

9. On 12 July Mrs C's GP wrote to a surgeon at the Hospital (not Consultant 1) asking for a follow-up appointment as Mrs C's left groin wound was oozing fluid profusely which required two-hourly dressings.

10. On 19 July 2004, Mrs C was reviewed at the vascular clinic at the Hospital by a Senior House Officer (the SHO). The SHO confirmed that the discharge

was as described by Mrs C's GP, that the discharge was odourless and that there was no evidence of cellulitis or pus. A wound bag was put in place to enable carers to assess the amount of drainage. Records show that Mrs C was asked to return to the clinic in one week.

11. On 21 July 2004 Mrs C was referred to the Accident and Emergency Department of the Hospital in the early hours of the morning with a large, tense and pulsating swelling under the axillary wound. Mrs C was operated on as an emergency to remove the infected axillo bifemoral graft. Mrs C was admitted to the intensive care unit immediately after her operation, but was returned to the ward on 22 July 2004. However, her lower extremities became ischaemic and infracted and by noon that day, it was clear that she required bilateral above the knee amputation, that is amputation of both her legs above the knee. Records show Consultant 1 discussed this with Mrs C and her family at the time.

12. The bilateral above knee amputations were performed on 23 July 2004. Records show that Mrs C's progress after that was slow, but reasonable. She was able to be hoisted to sit in a chair, ate and drank fairly well and slept quite well.

13. However, this final operation was complicated by infections in the wound stumps.

14. Records for 16 August 2004 show confusion mentioned for the first time. Records indicate that nursing staff linked this to Mrs C's general condition, the presence of infection and the analgesia and sedation being given to her.

15. From 24 August 2004 Mrs C's condition deteriorated significantly. Mrs C was seen by a different consultant (Consultant 2) because Consultant 1 was away for a week. Consultant 2 considered that Mrs C's prognosis was poor and was unlikely to be reversed. He spoke with the family and it was agreed that she should be kept comfortable and was not for resuscitation. Records show that Mrs C was referred to and was seen by the Hospital's palliative care team who increased her sedation and suggested that all unnecessary medication should be discontinued. Sedation was being administered to Mrs C via a syringe driver. The last mention of communication with the family before Mrs C's death was on 24 August 2004.

16. Mrs C died on 26 August 2004.

17. Mr C had a number of concerns about Mrs C's care and treatment. In an effort to respond to Mr C's concerns the Hospital offered Mr C and his family a meeting and that meeting was held on 15 September 2004. The family did not pursue their complaints directly themselves after that meeting, but instead asked their MSP to write on their behalf, which he did, in May 2005. The Hospital's response dated 3 May 2005 summarised the steps the Board had taken up to that point to respond to Mr C's concerns and noted that the Patient Liaison Office had had no further approaches from Mr C since the meeting in September 2004. Mr C and his family returned to their MSP in September 2005 and reiterated their serious concerns that antibiotics and fluid nourishment were withheld from Mrs C during the last three days of her life. They believed that this lack of fluid and medicine made her inevitable death more painful and distressing than it should have been. In their further response, the Board explained that they could not offer any further or new insight in the case. Mr C then brought his complaint to the Ombudsman.

(a) The full risks of surgery were never explained to Mrs C or Mr C

18. I set out in this paragraph the Advisers' views, having considered all records.

19. Neither of the Ombudsman's two Advisers could find evidence of medical or nursing staff having discussed the risks and benefits of the axillo bifemoral graft. Clearly there had been some discussion about the possibility of an aorto bifemoral bypass graft in the out-patient clinic when Mrs C was first reviewed by Consultant 1. When Mrs C was reviewed by the anaesthetist on her admission to the Hospital, it was deemed that this operation carried too high a risk and, therefore, the lesser operation of axillo bifemoral graft was offered. Although Mrs C signed a consent form for this, there is no record about the potential risks involved and as such, any discussion about the surgery is implicit rather than explicit. Clearly as a decision had been made to perform a different operation and Mrs C had been reviewed and worked up by a consultant anaesthetist, both Mrs C and the family had an opportunity to be made aware that surgery carried significant risks of morbidity and mortality. However, without documented proof of this, it has not been possible to say that the full risks were explained to Mrs C and Mr C.

20. In the response to the draft report, the Board pointed out, and I agree, that it is documented and acknowledged that rigorous physical assessment was undertaken to determine Mrs C's fitness for the initial proposed procedure, that is, aorto bifemoral bypass graft. It is also documented that the reasons for pursuing surgical intervention at all were discussed with Mrs C at the out-patient clinic and that the less hazardous procedure – axillo bifemoral graft – was pursued, but was not the procedure of first choice.

21. The Board in their response felt that the documentation on file and the written evidence that Mrs C's physical condition excluded an aorto bifemoral bypass graft was explicit evidence of the significant risks of morbidity and mortality of surgical intervention. In the Board's view, the acceptance of the second procedure provided proof that there was an understanding of the poor results revealed by the assessment process.

22. The Board also pointed out that each of the procedures carried out as part of this assessment were explained to Mrs C, including a stress echo-cardiogram, ECG, chest x-ray, arterial pressure measurement in each leg to check the flow through the blood vessels and a full anaesthetic opinion. In the Board's view, the documentation regarding the tests and the assessment process provided evidence of Mrs C's understanding of both the risks and the benefits of both surgical procedures.

23. In addition, the Board pointed out that Consultant 1 had lengthy and detailed discussions with both Mrs C and her family about every aspect of her care, but the Board accept these detailed discussions were not documented. The Board told me that Consultant 1 was particularly rigorous in both his practice and his communication with patients and their families and the Board accepted it was unfortunate that this was not explicit within the documentation available during this investigation.

24. I note all the Board's comments and have considered them carefully. It is obvious that a good deal of careful thought went into Mrs C's care and treatment. That there was a detailed assessment of her suitability for the initially proposed procedure is evidenced in the fact that she was deemed unsuitable for that higher risk operation. I welcome the statements made by the Board about how rigorous Consultant 1 is in both his practice and his communication with patients and families. However, I remain of the view that although there is certainly some evidence, such evidence as there is does not

go far enough and it is still unclear from the documents available the degree to which the risks and benefits of the second, lesser operation were explained to Mrs C or Mr C. Given that it has not been possible, on the basis of the evidence, to say that the full risks were explained to Mrs C or Mr C, I uphold this complaint.

(a) Conclusion

25. The Advisers were concerned about the failure to document any discussion about the risks and benefits of the axillo bifemoral graft with Mrs C and her family. The Advisers both agreed that signature on a consent form is not considered sufficient evidence that such a discussion took place. I accept their view. Therefore, complaint (a) is upheld.

(a) Recommendation

26. The Ombudsman recommends that the Board audit their practice in obtaining informed patient consent and implement any necessary change. I am pleased to note that the Board have since changed the consent process in the vascular surgery department. Comprehensive information sheets are now given to each patient detailing the risks and benefits of the particular procedure. This information is discussed with the patient and a copy is placed in the medical record.

(b) The Hospital failed to explain why Mrs C's drips were removed on 24 August 2004

27. This point was not answered at the meeting Mr C and his family had with relevant hospital staff on 15 September 2004. However, given Mrs C's prognosis on 24 August 2004 and the involvement of the Hospital's palliative care team, the Advisers' view is that it was reasonable to conclude that the aim was to keep Mrs C as comfortable as possible with as little equipment in use as possible.

28. In their response to my draft report, the Board pointed to documentation which shows there was a discussion with Mrs C's family where they agreed that Mrs C's wishes were not to be resuscitated in the event of cardiac arrest. However, the Board accepted that there was no specific mention of withdrawal of intravenous fluids.

(b) Conclusion

29. I uphold this complaint. The Advisers' view, which I accept, is that the Hospital did not give Mr C sufficient notification of the fact that Mrs C was having active treatment removed and insufficient explanation as to why drugs were being removed from her arm. In my opinion, communication with the family on this point could have been better especially at the 15 September 2004 meeting. However, I also accept the Advisers' view that the timing of antibiotic and drip withdrawal was appropriate. I am pleased to note that the Board have informed staff that they must both fully inform the family when any aspect of care is changed and document this in the patient's notes.

(c) The Hospital failed to investigate adequately the cause of Mrs C's confusion and agitation displayed the week before her deterioration

30. Both Advisers are agreed that Mrs C's general condition was poor. She had been through major surgery, complicated by sepsis, revisional operation and bilateral amputations. So it was highly likely that she would have been confused and agitated. In addition, her general metabolic condition, the debilitating effects of surgery and the disorientating effects of this unusual environment in hospital all could have contributed to her general agitation and confusion.

(c) Conclusion

31. The Advisers are of the view that the management of Mrs C's state at this point in time was not unreasonable. I accept the Advisers' view and, therefore, I do not uphold this complaint.

(d) The Hospital did not let Mr C know at the first opportunity that his wife was going into final decline and, as a result, he was denied the chance to spend valuable time with her before her death

(d) Conclusion

32. I do not uphold this complaint. The final cause of Mrs C's death was the sudden occlusion of her distal aorta. This was due to a blood clot forming in a heavily diseased artery which supplied the lower half of her body with blood. Unfortunately this is a fatal occurrence and there is no surgery available to revive the patient with such a condition. In the Advisers' opinion once this catastrophic sudden event had been diagnosed, it was right and proper that Mrs C was treated with tender loving care but no active treatment. The Advisers' view is that it was entirely appropriate to withdraw antibiotics and all drugs other than painkillers, in order to ensure that Mrs C was made

comfortable and that her dignity was preserved as best as possible in the few hours before her death. The Advisers say that it seems that this was done in a compassionate way on reading the notes on the case file. The Advisers are satisfied that as soon as the diagnosis was made, Mrs C's family were made aware of the likely sequence of events and were asked to attend so that they could be with her in her last few hours. It was not until this moment that her active treatment had been withdrawn and, indeed, up until that time, all efforts were made to preserve Mrs C's life. As a consequence, in the Advisers' opinion, the medical team caring for Mrs C acted reasonably in events surrounding her final deterioration and death.

33. This is a very sad case and condolences go to Mr C and his family. Regrettably, Mrs C had severe arterial disease which was not amenable to surgical reconstruction. A palliative bypass operation was unsuccessful because of infection, a known complication, and once this bypass graft had been removed, Mrs C steadily declined with initially the need for bilateral amputations and subsequently with an acute aortic thrombosis. But I hope it is of some comfort to Mr C and his family to have the Advisers' reassurances, set out at paragraph 32, that they are satisfied Mrs C was made comfortable in her last few hours and was treated in a compassionate way.

34. The Board have accepted the recommendations and have acted on them accordingly.

20 June 2007

Annex 1

Explanation of abbreviations used

Mr C	The complainant
Mrs C	The complainant's late wife
The Board	Lothian NHS Board
The Hospital	Royal Infirmary of Edinburgh
The Advisers	Two of the Ombudsman's clinical advisers, one a consultant surgeon and the other a nursing expert
Consultant 1	The Consultant Vascular Surgeon who Mrs C was referred to because of her claudication
The SHO	The Senior House Officer who reviewed Mrs C on 19 July 2004
Consultant 2	The Consultant who saw Mrs C on 24 August 2004

Annex 2

Glossary of terms

Aorta	Main artery of the body
Cellulitis	Infection below the surface of the skin
Axillo bifemoral graft	Surgery performed to create a detour around a blocked section of an artery