Scottish Parliament Region: Lothian

Case 201300380: Lothian NHS Board

Summary of Investigation

Category

Health: Hospital; communication; staff attitude; dignity; confidentiality

Overview

The complainant (Mrs C) expressed concern that her late husband (Mr C) had not been given enough information prior to giving his consent to open heart surgery. Mr C died during the operation, and Mrs C had said that, if they had been fully aware of the risks involved, Mr C would not have chosen to go ahead with the operation.

Specific complaints and conclusions

The complaint which has been investigated is that the consent process for cardiac surgery was not properly carried out in that Lothian NHS Board unreasonably failed to provide sufficient information about the potential complication of Mr C's heart being attached to the back of the sternum (*upheld*).

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) ensure that staff refer to the General Medical Council Guidance, 'Consent: patients and doctors making decisions together' when agreeing and recording consent and risk for cardiac surgical procedures;	25 July 2014
(ii) ensure that unacceptable delays between patients' deaths and subsequent Audit Meetings do not occur in the future;	25 July 2014
(iii) ensure that Doctor 2 is reminded of the importance of record-keeping in all elements of care and treatment; and	25 July 2014
(iv) apologise to Mrs C for the failure to inform her and her husband adequately of the risks involved in his operation, and for the suffering that Mrs C has	9 July 2014

endured as a result of this failure.

The Board have accepted the recommendations and will act on them accordingly.

Main Investigation Report

Introduction

1. This complaint was brought to us by Mrs C, in relation to the care and treatment of her late husband (Mr C) who had open heart surgery in October 2012. Mr C had previously had cardiothoracic (open-heart) surgery in February 2010. When his symptoms returned, he agreed to have repeat surgery. Mr C died during the operation on 3 October 2012, due to complications resulting from his heart being attached to his sternum (breastbone).

2. Mrs C has complained that she and Mr C were not informed of the increased risks involved in repeat open-heart surgery, and specifically were not told of the risks relating to the adhesion of the heart and breastbone following Mr C's first operation. She has said that, if they had been informed of this before the operation, Mr C would not have had the operation. She has reported that they were told the risk of Mr C dying during surgery was three to four percent, which she felt was not really quantifiable.

3. Following Mr C's death, Mrs C complained to Lothian NHS Board on 13 January 2013. In their response to this complaint, it became evident that Mr C's heart had adhered to his breastbone following surgery in 2010. Mrs C was informed that this was a common situation and was part of the reason that repeat open heart surgery is more risky than the initial operation. Mrs C was unhappy with this response, as she said that Mr C should have been made aware of the potential for this complication. She, therefore, brought her complaint to my office.

4. The complaint from Mrs C which I have investigated is that the consent process for cardiac surgery was not properly carried out in that the Board unreasonably failed to provide sufficient information about the potential complication of Mr C's heart being attached to the back of the sternum.

Investigation

5. Investigation of the complaint involved reviewing the information provided by Mrs C and the Board's medical records for Mr C. My complaints reviewer also obtained independent advice from a medical adviser who is a consultant in adult cardiothoracic surgery. This advice was shared with the Board and with

Mrs C, and they were given the opportunity to comment. My complaints reviewer sought further advice on the comments that the Board provided.

6. 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 the Board have been given an opportunity to comment on a draft of this report.

Complaint: The consent process for cardiac surgery was not properly carried out in that the Board unreasonably failed to provide sufficient information about the potential complication of Mr C's heart being attached to the back of the sternum

7. In February 2010 Mr C had cardiothoracic (open heart) surgery which involved vein grafts to enhance the functioning of his heart. This was successful, and his cardiac symptoms improved significantly. However, after two years, he had a return of his angina symptoms (chest pain following low level exercise), and was referred back to the heart surgeon at the Royal Infirmary of Edinburgh by his local consultant cardiologist (Doctor 1) from a different health board.

8. Mr C was reviewed by the consultant cardiothoracic surgeon (Doctor 2) at a clinic on 30 August 2012. At this consultation they discussed the symptoms he was having, and the risks and benefits of surgery. A subsequent letter to Doctor 1 following this meeting indicated that Mr C was informed that there was a three to four percent risk of death during the operation (mortality), and a five to six percent risk of major complications following surgery (morbidity). The letter indicated that Mr C was willing to go ahead with repeat surgery, in view of the severe impairment of his quality of life at that time.

9. Mr C's clinical records do not mention the discussions between Mr and Mrs C and Doctor 2 in relation to the risks and benefits of the procedure. Mrs C has said that they were not told that Mr C's heart could have been attached to his sternum, and if they had been, Mr C would not have gone ahead with the surgery.

10. In subsequent correspondence with us, Doctor 2 has said that he uses a standard approach to discussing risks with patients. In his explanation of the risks of the operation, he said that he would have explained that what was proposed was a major operation, and there were associated risks. He would have provided the statistics set out above in relation to risk, and would have

provided a list of major complications, including bleeding, stroke, problems with the heart or lungs, and wound infection. He would have explained that various other complications could also arise, but the overall incidence was five to eight percent.

11. Doctor 2 has said that his standard approach would have included the following explanation of the risk:

> 'Sitting here today, we do not know whether you will be in the three to four percent who will not survive, or in the five to eight percent who will have a major complication, and we will all regret that you opted for the operation, or you will be in the about 90 percent of the people who will do well.'

12. Doctor 2 has said that he would have gone on to explain that repeat heart surgery held greater risks than the original operation, and that the benefits would be lower. He would explain that the heart and surrounding tissue are often stuck to the chest wall following the earlier operation. He explained that there is always a chance of injury to the heart and subsequent bleeding problems during the operation.

13. Mr C was admitted for surgery on 2 October 2012, and he signed the consent form for surgery on that day. This stated the nature of the surgery to be undertaken: 're-do coronary artery bypass grafts and repair of incisional hernia'. (The procedure was to involve diverting blood around narrowed or clogged parts of the heart arteries (blood vessels), to improve blood flow and oxygen supply to the heart, as well as a repair to a weakness in the wall of the abdomen, which was allowing the intestines to bulge under the skin. This included a 'median sternotomy', when the breast bone is cut open to allow access to the heart.)

14. Doctor 2 has subsequently reported that his standard procedure the day before surgery would have been to discuss the procedure briefly with Mr C and ask him if he had any questions. He would have reiterated that there were risks associated with the procedure, and would have asked if Mr C would have liked any further details about the risks. Mr C would also have met the anaesthetist at that point, and would have had further discussions about the risks involved with the operation. There is no reference to these discussions in Mr C's clinical records.

15. Surgery started at 14:15 on 3 October 2012, and it soon became apparent that the heart muscle was attached to the back of the sternum. This made it difficult for Doctor 2 to open up the chest. In doing this, a hole was created in the heart. As Doctor 2 worked to separate the heart from the sternum, the hole increased and Mr C's blood loss increased. Action was taken to reduce blood loss, and to progress with the surgery, but Mr C's heart stopped beating properly. Doctor 2 tried to shock it back into a normal rhythm, but this was ineffective. During this time, Doctor 2 was joined by three other surgeons, who came to assist him with the operation. After attempts to remedy the situation failed, with continued poor heart beat and substantial blood loss, the team took the decision that Mr C's condition had deteriorated so far that his life could not be saved. Mr C died at 16:54.

16. Guidance for doctors on gaining consent for cardiac surgery comes from two sources: the General Medical Council (GMC) and the Society of Cardiothoracic Surgeons of Great Britain and Ireland, in conjunction with the Parliamentary and Health Service Ombudsman.

17. The GMC addresses the issue of consent in their 'Guidance on Consent: patients and doctors making decisions together' (the Guidance). This sets out the principles on which good clinical decisions should be based and provides a framework for good practice. It also specifies what doctors must do to fulfil their duties.

18. The Guidance sets out the expectation that doctors will work in partnership with their patients, and this includes discussing with patients what their diagnosis, prognosis, treatment and care involve. They must also share with patients the information that the patient wants or needs to make decisions. The Guidance goes on to say that, in discussing what options are available to a patient, doctors must explain the benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor can recommend a particular option. However, it is for the patient to weigh up the potential benefits, risks and burdens of the various options, and make a decision from their own perspective.

19. The Guidance explains that the level of information that doctors should share with patients will vary, and should reflect, among other things, the nature and level of risk associated with the investigation or treatment.

20. It goes on to review how doctors should share information with patients. In particular, it says that patients should be given time to reflect, before and after they make a decision, especially if the information is complex or the treatment involves significant risks.

21. In relation to discussing risks, the Guidance says that clear, accurate information needs to be provided. The amount of information will depend on the patient and what they want or need to know. It says that discussions with the patient should focus on their individual situation and the risk to them. As well as discussing the possible outcomes of treatment (including side effects, complications and failures) and the impact of the patient's overall health on the likelihood for adverse outcomes, doctors should also try to understand the patient's views and preferences about any proposed treatment, and the adverse outcomes they are most concerned about.

22. The Guidance says that patients should be told if the treatment might result in a serious adverse outcome, even if the likelihood is very small. They should also be told about less serious complications if they occur frequently. The language used in these discussions needs to be clear, simple and consistent, and the doctor needs to be aware that patients may understand information about risk differently from them, and to check that the patient has understood any terms they are using, particularly in relation to the seriousness, frequency or likelihood of an adverse outcome. If patients need help to understand risks, then doctors should use written, visual or other aids to assist their explanation.

23. In relation to recording consent, the Guidance states that, for treatments that are complex or involve significant risk, the patient's consent must be written. This is so that it is clear what has been explained and agreed to. The patient's medical records must include a record of the key elements of the discussion with the patient. This should include the information provided, any specific requests by the patient, and details of any decision that were made.

24. Before the treatment begins, the Guidance states that the decision to give consent for treatment should be reviewed with the patient, to give the opportunity for them to raise any further questions or concerns, and to ensure that they are still happy to go ahead.

25. The Society of Cardiothoracic Surgeons has set out its preferred approach in 'A Good Practice Guide to Agreeing and Recording Consent' (the Good Practice Guide). This sets out expectations in relation to the provision of consent. It states that during the initial consultation 'the surgeon should specifically discuss the most frequent and high impact risks to the patient, including the risk of operative mortality'. Following this consultation, the Good Practice Guide says that patients need to be given access to further information in a form that they can take home, so they have a chance to consider it in detail.

26. The Good Practice Guide also states that patients undergoing repeat procedures need to have information repeated, as the risks of repeat surgery are generally higher than the original operation. It should not be assumed that the patient 'already knows all about it'. In addition, it recommends ensuring that records are kept of what was discussed, the patient's responses, and the doctor's perception of the patient's understanding of the information. The record should also include any additional information sources that have been given to the patient and should highlight where specific mention has been made to particular issues.

27. The NHS Lothian Consent Form includes a Note to Patients. This explains that the health professional will provide information about the procedure, but that they can also ask questions, and can refuse treatment. It states that the patient should be provided with enough information to be able to make a decision, and that the following information should be provided:

- Nature of the condition and the proposed procedure;
- Benefits of the procedure;
- Nature and probability of significant risks, including consideration of the ratio of risks and benefits;
- Inability of the practitioner to predict results;
- Potential irreversibility of the procedure;
- Likely result of not having the proposed procedure;
- Alternatives available, including risks and benefits.

28. In response to this complaint, the Board went into some detail in relation to the discussions that Doctor 2 had with Mr and Mrs C. They explained his standard approach to discussions around risk and consent, as described above. They also provided information about the 'Audit Meetings' that take place after the death of a patient. They reported that these are normally held once a

month. However, Mr C's case was not discussed until 6 December 2013, over a year after his death. The Board explained that this was because his notes were believed to be missing.

29. Notes from the meeting provided greater detail of what happened during Mr C's surgery, including the fact that Doctor 2 requested assistance from other surgeons when the operation was proving difficult. The Board provided an account by another consultant cardiothoracic surgeon, Doctor 3, who came to assist in the operation. His report on the incident (prepared in response to our enquiries, in December 2013) indicated that he joined the operating team when Mr C was already in a critical condition. The hole in his heart was evidently quite extensive, and his heart was not beating well. Attempts to re-circulate the blood were also proving problematic. Doctor 2 and Doctor 3 were in agreement that Mr C's condition was irretrievable, and that no further attempts should be made to keep him alive.

30. During our investigation into this complaint my complaints reviewer sought clinical advice, particularly relating to the consenting process. The Adviser (an expert in adult cardiothoracic surgery) highlighted a number of issues with the way this process had been undertaken.

31. The Adviser noted that it was common for the sternum to become attached to the heart following open heart surgery. He explained that this is particularly severe shortly after surgery, so it is a particular risk when repeat surgery is carried out relatively soon after the original surgery. Normally a period of two to three years is considered 'recent' in relation to repeat open heart surgery. Mr C's second operation was two years and eight months after his original operation.

32. The Adviser reviewed the mortality and morbidity statistics provided to Mr C, and agreed that these were appropriate, given Mr C's age and health. These rates were slightly higher than the risks he had been told for his first heart operation. This reflected changes in the statistics available to Doctor 2, and the impact of changes in Mr C's condition.

33. The Adviser went on to review the information that was given to Mr C in relation to the risks associated with surgery. He said that, while Mr C was informed of the statistic risks associated with the proposed operation, he should have been clearly informed that repeat cardiac surgery carries an increased risk

(of double to triple the risk of the first time procedure), and this should have been referred to and documented at Mr C's out-patient review and in subsequent documents.

34. The Adviser also considered that he was not told specifically enough about the risk of catastrophic bleeding due to the heart being adhered to the sternum. Doctor 2 has provided my complaints reviewer with details of what was explained to Mr C in his out-patient review on 30 August 2012. However, the Adviser was critical that this was not recorded in Mr C's clinical records at the time, and Mr C was not provided with any written information about the risks involved in the operation. He also noted that, while details of the proposed procedure were noted on the consent form, signed by Mr C on 2 October 2012, this did not include any reference to the risks involved in the operation.

35. The Adviser went on to say that a detailed record of the content of the consultation on 30 August 2012 should have been made, including specific reference to the risk of bleeding and damage to the heart due to its potential adherence to the sternum. He said that these risks should also have been documented in Mr C's notes when he was admitted for repeat surgery, and should have been specifically referred to on the consent form.

36. In particular, the Adviser said that the specific risks of early repeat surgery (including the risk of damage to the front of the heart and catastrophic bleeding) should have been clearly indicated to Mr C and on the informed consent form.

37. In addition to concerns relating to the recording of consent, the Adviser also noted that Doctor 2 should have included reference to the assistance provided by colleagues in his notes on the operation. This information was only provided following our enquiries to the Board.

38. The Adviser went on to say that it was common practice to get a Computerised Tomography (CT) scan of the thorax (the chest and ribs) prior to a second operation. He explained that this can assist in locating the site of previous surgical interventions and in identifying how closely adhered the heart is to the sternum, and particularly, how near the various structures of the heart are to the sternum. It may also have provided additional information in relation to the condition of the blood vessels in Mr C's heart, which would have aided decision making.

39. Doctor 2 has since confirmed that he will now be taking CT scans of all his patients prior to repeat open heart surgery.

40. The Adviser also commented on some of the procedures undertaken during surgery, and the order in which these had been done. He said that, while practice varies between units, the use of a CT scan would have assisted with decision making prior to the operation. He also commented that it was very unusual for a patient to have the same surgery carried out by the same surgeon within such a short period.

41. Finally, the Adviser noted the significant delay in the Audit Meeting relating to Mr C's death. He said that the delay of over a year was 'unacceptable from many perspectives'.

42. In his conclusion, the Adviser said that the risk of life-threatening bleeding during repeat open heart surgery should have been explained to Mr and Mrs C and that a pre-operative CT scan would have been potentially helpful and should have been performed.

43. During my investigation, the Board were given the opportunity to comment on the advice that we received. In response, the Board's cardiothoracic surgery team commented on elements of the Good Practice Guide, and they agreed that it would be appropriate for the patient to be sent a copy of any relevant correspondence.

44. In response to the draft report, the Board noted the Adviser's opinion that it was unusual for a patient to have repeat surgery carried out by the same surgeon within such a short period. However, the Board favour using the same surgeon for repeat surgery, in order to provide continuity of care for patients.

Conclusion

45. Mr C had undergone open heart surgery in 2010 and had not experienced any significant complications. When he attended Doctor 2's clinic on 30 August 2012, it was Doctor 2's responsibility to ensure that Mr C understood that a repeat operation held greater risks than the first operation, and to explain to him what these risks might include. Given Mr C's previous experience, it would have been important for Doctor 2 to judge that Mr and Mrs C accepted that this was a new situation, with new risks.

46. Doctor 2 was also responsible for ensuring that appropriate records were kept of these discussions, and also to provide Mr and Mrs C with enough written information that they could consider the situation, and the risks involved, in consenting to surgery, following the clinic appointment on 30 August 2012. I am particularly critical of the limited recording of any discussions in relation to the consenting process.

47. Doctor 2 has told us what his standard approach to discussions with patients is, and what he tells patients prior to repeat open heart surgery. However, there is no evidence that these full discussions took place on 30 August 2012. I also note that his standard explanation does not attempt to provide an alternative explanation of risk than the percentage risk of death or serious complication. Indeed, the fact that he has a standard way of explaining risk indicates that he does not tailor his explanation to the needs and understanding of individual patients, as described in the Guidance.

48. The evidence indicates that the way in which Mr C gave consent for his operation on 3 October 2012 fell far short of the Guidance set out by the GMC, as well as the Good Practice Guide which focuses on cardiothoracic surgery in particular. There is no contemporaneous written evidence that Mr and Mrs C were given sufficient information to provide informed consent, that the discussions responded to any questions raised by Mr and Mrs C, or that they were offered any written information.

49. In addition, I note the advice that we have received, which clearly states that CT scans should be used to aid decision making in relation to repeat open heart surgery. This could also have assisted Doctor 2 in identifying and explaining the specific risk involved in dissecting the heart from the sternum. I recognise that Doctor 2 has since said that he will be carrying out CT scans for all subsequent patients undergoing repeat open heart surgery, as an aid to decision making.

50. I note that Mr C was not given as much information as he needed, to provide informed consent. I also note that Doctor 2's set approach to providing information on such a critical issue indicates a lack of appreciation for the patient's perspective. I note that there is no evidence whether Doctor 2 highlighted the specific difficulties related to repeat open heart surgery, or any discussion around the new circumstances of this operation as compared to his previous operation. Finally, the lack of a CT scan prior to these discussions

meant that Doctor 2 could not provide as much information about the potential risks associated with dissecting the heart from the sternum as he otherwise could have.

51. It is clear that the Board failed to ensure that Mr C gave appropriate, informed consent for his operation. This led Mr C to have an operation which Mrs C has said he would not have had, if he had fully understood the risks involved. I accept that it would never have been possible to know what would happen during surgery, and the level of adhesion could not have been determined prior to surgery, not even with a CT scan. I also appreciate that Doctor 2 anticipated some level of adhesion in the way he undertook the surgery. However, Mr and Mrs C would have been better placed to make a fully informed decision, and to accept the risks involved (should they have chosen to), if they had been given more information prior to the operation. With these failings in mind, I uphold this complaint.

52. In this case, my concern extends beyond the consenting process. I note the substantial delay in the Board's Audit Meeting following Mr C's death. This meeting appears to only have been held in response to our investigations. The team have said that Mr C's notes were missing (and this may have been due to their use in responding to Mrs C's complaint). The fact that Mrs C was expressing concern and formally complaining should have made it all the more important for this meeting to have been held as early as possible, to provide Mrs C with as much information as possible, both about what happened and about what action the Board was proposing to take to ensure this situation did not happen again. The Board's practice is to hold these meetings once a month, with the expectation that cases are discussed as close to the event as possible. Clearly this did not happen, and the evidence would suggest that this case would not have been discussed at all if Mrs C had not brought her complaint to us.

53. I am also very critical of Doctor 2's approach to record-keeping. His clinic notes from 30 August 2012 did not provide any information about the discussion he had with Mr and Mrs C. In addition to this, his operation notes also failed to include reference to the fact that his colleague joined him towards the end of the procedure. I will address these concerns in one of the recommendations below.

Recommendations

54. I recommend that the Board:	*Completion date*
(i) ensure that staff refer to the General Medical Council Guidance, 'Consent: patients and doctors making decisions together' when agreeing and recording consent and risk for cardiac surgical procedures;	25 July 2014
(ii) ensure that unacceptable delays between patients' deaths and subsequent Audit Meetings do not occur in the future;	25 July 2014
(iii) ensure that Doctor 2 is reminded of the importance of record-keeping in all elements of care and treatment; and	25 July 2014
(iv) apologise to Mrs C for the failure to inform her and her husband adequately of the risks involved in his operation, and for the suffering that Mrs C has endured as a result of this failure.	9 July 2014

55. The Board have accepted the recommendations and will act on them accordingly. The Ombudsman asks that the Board notify him when the recommendations has been implemented.

Annex 1

Explanation of abbreviations used

Mrs C	the complainant
Mr C	the complainant's late husband
the Board	Lothian NHS Board
the Adviser	cardiothoracic surgery adviser
Doctor 1	Mr C's local consultant cardiologist
Doctor 2	the consultant cardiothoracic surgeon
GMC	General Medical Council
the Guidance	'Guidance on Consent: patients and doctors making decisions together'
the Good Practice Guide	'A Good Practice Guide to Agreeing and Recording Consent'
Doctor 3	the second consultant cardiothoracic surgeon
CT scan	computerised tomography scan

Annex 2

Glossary of terms

Cardiothoracic surgery	surgery to the organs inside the thorax or chest
Morbidity risk	the risk of poor health, disability or disease
Mortality risk	the risk of death

Annex 3

List of legislation and policies considered

The Society of Cardiothoracic Surgeons; 'A Good Practice Guide to Agreeing and Recording Consent' (2005)

General Medical Council; 'Guidance on Consent: patients and doctors making decisions together' (2008)

NHS Lothian Consent Form, Note to Patients (in use in 2010 and 2012).