Scottish Parliament Region: South of Scotland

Case 200600373: Ayrshire and Arran NHS Board

Summary of Investigation

Category

Health: Hospital; Clinical Treatment; Opthalmic Surgery

Overview

The complainant (Mrs C) raised concerns that she had an eye operation at Ayr Hospital (the Hospital) which was performed by a consultant surgeon (the Consultant) on the wrong eye (her right eye) and she has been left blind because of this. Mrs C also complained that correct procedures were not followed by the senior house doctor who obtained her consent for the operation.

Specific complaints and conclusions

The complaints which have been investigated are that:

(a) Mrs C was subjected to an eye operation, performed by the Consultant, on the wrong eye (her right eye) (*not upheld*); and

(b) Mrs C was asked to sign a consent form for the operation which she could not see and the contents of the form were not read out to her (*no finding*).

Redress and recommendations

The Ombudsman recommends that Ayrshire and Arran NHS Board (the Board):

(i) ensure that discussions with patients about treatment is recorded, particularly where a change to the planned operation is made. She also recommends that the Board ensure that the recognised complications arising from surgery are discussed with the patient and a record of the discussion made; and

(ii) ensure that the Consultant makes certain that his procedure in obtaining consent from patients who are visually impaired is properly recorded in the clinical notes whenever it is followed.

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

Main Investigation Report

Introduction

1. Mrs C suffers form a macular degeneration eye condition (ARMD). Following a request for a second opinion, Mrs C's eyes were assessed during 2002 by a consultant surgeon (the Consultant). Thereafter, decisions were subsequently taken about the treatment she would require. Mrs C was seen by the Consultant up to 23 April 2004 and an eye operation was planned. This operation was performed at Ayr Hospital (the Hospital) on 25 May 2004. In Mrs C's view, the eye operation was performed on the wrong eye - her right eye. Furthermore, Mrs C stated that the Consultant was 'doing major experimental surgery without my consent. My right eye was my stronger eye and I am now totally blind in that eye.'

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

(a) Mrs C was subjected to an eye operation, performed by the Consultant, on the wrong eye (her right eye); and

(b) Mrs C was asked to sign a consent form for the operation which she could not see and the contents of the form were not read out to her.

Investigation

3. The investigation of this complaint involved obtaining and reading all the relevant documentation, including correspondence between Mrs C and Ayrshire and Arran NHS Board (the Board). I have had sight of the Board's complaint file and Mrs C's medical records. I have also read correspondence relating to Mrs C's GP and her attendances at other hospitals. The investigation was aided by an ophthalmic clinical adviser (the Adviser) who, following her review of all relevant documentation and medical records, provided a detailed report on the complaint.

4. 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 were given an opportunity to comment on a draft of this report.

(a) Mrs C was subjected to an eye operation, performed by the Consultant, on the wrong eye (her right eye)

5. Mrs C checked in to the Hospital around 14:30 on 24 May 2004 and her husband (Mr C) stayed with her until the evening visiting time. According to Mrs C, on that same day, she understood that her eye operation, scheduled to

take place on 25 May 2004, was for a left vitrectomy and lens implant which she had previously arranged with the Consultant on 23 April 2004 (see paragraph 1). When making her complaint to the Ombudsman, Mrs C stated 'He told me that I had haemorrhaged in both eyes. In his letter to my GP dated 23 April 2004, he wrote as well as telling me that he would do a vitrectomy and lens implant on my left eye. There are no doubts in my mind that that was the operation I was going to have done'.

6. Mrs C stated that after Mr C left the Hospital, she was asked by a senior house doctor (the Doctor) to sign the consent form for the operation.

7. Mrs C advised that she did not meet the Consultant from 23 April 2004 'until I was on the operating table in the theatre, about 14.30 hours. When I was on the operating table, the Consultant informed me that he had changed his mind and that he would operate on my right eye rather than on my left one'.

8. According to Mrs C when she came out of the anaesthetic, she noticed something flapping at the top corner of her right eye: 'This flapping sensation continues to this day.'

9. Mrs C stated that the Consultant did not see her either before or after the operation (see paragraph 7) and, although Mr C had requested to meet with him before Mrs C's operation, the Consultant was not available. The Consultant met with Mr C after the operation and, according to Mrs C, told Mr C that the operation went well but that he had had to cut into the retina.

10. Mrs C was discharged on 26 May 2004. Thereafter, Mrs C attended routine check-ups with the Consultant at the Hospital on 17 June 2004 (a follow-up report was sent to Mrs C's GP) and 2 September 2004 (no report was sent to either Mrs C or her GP), while simultaneously attending private ophthalmic consultations.

11. Mrs C advised that some four weeks later, the retina in her right eye became detached and she was seen by two ophthalmic surgeons at another hospital. According to Mrs C, the ophthalmic surgeon who saw her on 14 October 2004 told her 'someone has experimented with your right eye'.

12. According to Mrs C she also had a consultation at a hospital in England on 15 March 2005 and was told 'that my right eye was badly damaged'.

13. In her letter to the Board dated 26 May 2006, Mrs C stated 'In his determination to find an excuse to operate on my right eye, [the Consultant] decided that the right eye stood to benefit more from surgery, but it has left me blind in that eye and he neglected to operate on my left eye'.

14. As part of my enquiries I wrote to the Board on 20 February 2007 and I received their reply on 14 March 2007.

15. The Board described Mrs C's original eye problem as 'a bilateral extensive exudative age related macular degeneration (ARMD), a condition which eventually leads to loss of vision. However, it was stated that 'the surgery did return some useful vision and thereby delayed the eventual blindness'.

16. The Board referred me to their complaint reply to Mrs C dated 13 April 2006, where they stated:

> 'it was found that your left eye had haemorrhaged under the retina from the age related membrane and the vision was worse in that eye. Even though surgery was considered by [the Consultant] and discussed with you, it was considered very high risk and therefore it was decided to observe rather that intervene. Subsequently the haemorrhage in your left eye cleared leaving just a scar behind, which cannot be helped by surgery. [The Consultant] then decided, after discussion with you, that the right eye stood to benefit more from surgery. He has documented this fact in the notes. You were therefore added to the waiting list for surgery on the right eye and consented for surgery on the right eye.'

17. The Board went on to comment that, following written consent given by Mrs C on 24 May 2004 for 'Right Phaco + IOL + Vitrectomy + Endolaser under general anaesthetic' (see paragraph 6), this operation was carried out on 25 May 2004 (see paragraph 7).

18. In a further letter to Mrs C dated 17 August 2006, the Board stated 'it is documented in the notes that it was decided to operate on your left eye for a vitrectomy. [The Consultant] has, however advised that both you and your husband were told that should the situation change between then and the day of surgery, this decision would be revised. As part of the explanation, [the Consultant] said that if there is a membrane under the retina and if it is removable, it may be necessary to cut into the retina to remove the membrane.

In your case the submacular membrane had already scarred and [the Consultant] did not cut into the retina'.

19. As part of my investigation, I asked the Adviser for her assessment of this aspect of the complaint.

20. The Adviser outlined that Mrs C was seen privately and also in the NHS and that the records she reviewed in this case were all NHS records.

21. In the Adviser's view, 'the records for [Mrs C]'s attendance at the Hospital are clear and are accompanied by letters that are detailed and clear with treatment and follow-up plans. A letter dated 23 April 2004 from the Consultant to Mrs C's GP, lists Mrs C for left vitrectomy and cataract surgery'.

22. The Adviser stated that the Consultant had arranged, prior to admission to perform a left vitrectomy, phakeomulsification with insertion of intraocular lens. Mrs C was admitted one day prior to the surgery (see paragraphs 1 and 5).

23. According to the Adviser, the Hospital in-patient notes were also clear, with a concise record of Mrs C's surgery. The case notes entry for 24 May 2004 recorded that Mrs C was to undergo right-sided surgery. The consent was for the right eye. Right-sided surgery was performed. The Adviser also stated that following Mrs C's complaint to the Board, the Consultant explained that he decided, on admission, that the right eye was worse than the left eye and, therefore, elected to perform right-sided surgery. He stated that he discussed this himself with Mrs C. There is an entry in Mrs C's case notes that recorded 'she is to undergo right vitrectomy, phaco and IOL and endolaser under GA', this is undated and unsigned (see paragraph 16).

24. In the Adviser's view, the confusion surrounding this case 'is in part due to the difficulty of treating a blinding disease with treatments that have inherent complications and for which benefits are slight'.

25. The Adviser considered the Consultant's explanation, following Mrs C's complaint to the Board, for the reasons he changed his decision from left to right-sided surgery (see paragraph 23). The Adviser noted, 'The Consultant in a statement explains that on admission, he discussed the position with [Mrs C] and that the right eye was now the worse eye, he would operate on the right eye'.

26. The Adviser went on to conclude that, on Mrs C's admission, as the Consultant diagnosed that the left vitreous haemorrhage had absorbed significantly, the Consultant elected to perform right-sided surgery (see paragraph 25). The Adviser considered that, clinically, she had no issue with this scenario and it was perfectly reasonable. Furthermore, 'I understand why the Consultant did this and it is a very reasonable clinical decision. The decision seems to have been made after admission'. The Adviser noted, however, that there was little in the notes to explain this decision.

27. In addition, the Adviser stated that Mrs C reported to the Consultant that she was 'very very pleased. Her vision did improve. [Mrs C] did not report any problems until she developed a retinal detachment. When [Mrs C] developed further problems, she only then complained about her treatment'. In this context, the Adviser stated that the retinal detachment may or may not have been due to the previous vitrectomy. 'The temporal association suggests a link, but this cannot be proved. [Mrs C] may have developed a similar problem had she undergone left-sided surgery'. In the Adviser's opinion, Mrs C is blind in the operated eye and this may or may not have followed the vitrectomy. It may have happened anyway or it may have been precipitated by the vitrectomy.

28. The Adviser considered the Board's response to Mrs C's complaint dated 13 April 2006 and noted that, within this letter, the Board had stated that Mrs C was listed for surgery on her right eye (see paragraph 16). This was not correct. The Consultant's letter dated 23 April 2004 to Mrs C's GP advised 'she is listed for left surgery'. This letter was copied to Mrs C (see paragraphs 5, 21 and 22).

29. Within the Board's further response to Mrs C's complaint dated 17 August 2006, the Adviser opined that while the Board had accurately addressed each of the points that Mrs C raised, it still did not address 'the fundamental question as to why it was planned to operate on the left eye and then this was changed to the right eye'.

30. To clarify all the aspects of this complaint, the Adviser presented a clinical overview as follows:

> '[Mrs C] had developed age-related macular degeneration and was not suitable for conventional treatment. [Mrs C] had sought [the Consultant]'s advice for possible submacular surgery, but initially surgery was not

recommended. Thereafter [Mrs C] developed vitreous haemorrhages and severe visual loss. Left vitrectomy was recommended, however, right vitrectomy was performed.'

The Adviser explained that the Consultant had elected to proceed with 'right cataract extraction with insertion of intraocular lens and vitrectomy' and in her view, Mrs C 'derived a significant benefit from the procedure for five months and thereafter developed an inoperable retinal detachment in the right eye - [Mrs C] is now blind in her right eye'.

31. In the Adviser's view, 'The retinal detachment may or may not have been due to the previous vitrectomy' and 'she may have developed a similar problem had she undergone left-sided surgery'. She stated, 'in my opinion, [Mrs C] is blind in the operated eye and this may or may not have followed the vitrectomy. It may have happened anyway or it may have been precipitated by the vitrectomy'. Although the Adviser considered there was confusion surrounding this case (see paragraphs 22, 25, 26 and 27), partly due to the difficulty in treating such a blinding disease, in her view Mrs C was not subjected to an operation on the wrong eye and added that, although she is blind in the right eye, this is because Mrs C developed an inoperable retinal detachment, complicated by neovascular glaucoma.

(a) Conclusion

32. Mrs C's distress is understandable, given that some five months after her operation she lost her sight in the operated eye (see paragraphs 11, 12 and 13). However, it is recorded that Mrs C was pleased with the initial outcome of the procedure and did not report any problems to the Board until she developed a retinal detachment (see paragraphs 11, 12 and 27).

33. Furthermore, it has been established that there was a change of plan with Mrs C's care and the advice I have received is that clinical situations do change and, on some occasions, it is necessary to alter surgical plans (see paragraph 25). However, although I agree with the Adviser that it was right and proper for the Consultant to change his original decision and to opt for surgery to the right eye, based on clinical presentation at the time, he has made no record of this reversal in the medical notes for 24 May 2004 (see paragraph 26). Nor have I been able to establish from the clinical records what Mrs C was told. She is clear that the reason for the change of decision to operate on her right eye rather than her left eye was not explained to her prior to obtaining her

consent. There is nothing in the clinical records to indicate that this was explained to Mrs C or Mr C.

34. Given the evidence outlined above and having reviewed all the relevant documentation, I agree with the Adviser that there was confusion surrounding this case but that did not mean the Consultant had operated on the wrong eye; it meant that the Consultant had changed his pre-operative plan. Accordingly, I do not uphold this complaint. However, I have serious concerns about the failure to record the reasons for the change in procedure as stated above. I am also concerned that there is no record that the recognised complications arising from this type of surgery were discussed with Mrs C. In view of this, the Ombudsman makes the following recommendations.

(a) Recommendation

35. The Ombudsman recommends the Board ensure that discussions with patients about treatment is recorded, particularly where a change to the planned operation is made. She also recommends that the Board ensure that the recognised complications arising from surgery are discussed with the patient and a record of the discussion made.

(b) Mrs C was asked to sign a consent form for the operation which she could not see and the contents of the form were not read out to her

36. Mrs C told me that when Mr C left her in the ward after evening visiting time on 24 May 2004, the Doctor came to her and asked her to sign a consent form. According to Mrs C, she told him that she could not see the form and 'he put his pen in my hand and guided it to where I was to sign. At that time I believed I was there for an operation on my left eye and that is what I was signing for. He did not read the contents of the form to me'.

37. Mrs C stated that Mr C could have been asked to read the form to her. Mrs C advised 'none of the rules for the signing of any document by a blind person were adhered to'.

38. In their reply to me dated 14 March 2007, the Board stated that the Consultant had met with Mr C in the Hospital to tell him Mrs C had been admitted. The Consultant told Mr C that he would go to the ward and speak with Mrs C about the operation. The Consultant went to the ward and 'discussed in great detail what the operation would involve, the possible complications and what benefits [Mrs C] may gain from the surgical procedure.

After discussion I [the Board] am informed [the Consultant] assured [Mrs C] that [the Doctor] would consent her as part of her pre-operative assessment'.

39. Thereafter the Doctor, acting on the Consultant's implicit instructions 'once again read out to her what the operation was going to be' and referred to earlier discussion the Consultant had with Mrs C.

40. According to the Board, 'The following morning, when Mrs C was brought to the operating theatre, the Consultant once again visited her in the pre-operative area, as is his practice with all patients and again explained to Mrs C what the procedure was going to be, what the risks were and what the benefits would be'.

41. The Board added that 'a substantial number of patients that [the Consultant] operates on as a vitreo-retinal surgeon are severely visually impaired. I am informed that [the Consultant] always explains to patients in great detail as to what the operation will involve and what the consent form says. In most cases the explanations are far more detailed than those listed on the consent form, however the consent form is still read out to the patient'.

42. Within her report about this complaint, the Adviser noted that on Mrs C's admission, she was consented by the Doctor and that this fully completed consent was performed one day prior to the surgery. The Adviser outlined that the consent form was signed and dated by the Doctor and signed by Mrs C (see paragraph 6). I have seen the consent form and confirm that it was signed and dated by the Doctor and Mrs C on 24 May 2004.

43. The Adviser also considered that the Consultant had explained he had a protocol for obtaining consent from patients with poor vision (see paragraph 39) and stated he had advised that he himself discussed with Mrs C that the procedure was to be performed on the right eye. The Consultant also stated that the Doctor had read the consent form to Mrs C and her signature was also signed and dated by the Doctor.

44. The Adviser noted that Mrs C had stated that she did not meet with the Consultant until the day of the surgery (see paragraph 9).

45. Thereafter, the Adviser considered the following differing views: that 'the consent process had, according to [the Consultant] been followed' (see

paragraphs 39, 41, 42 and 43) but according to Mrs C, the consent was not read out to her by the Doctor (see paragraph 36).

46. In the Adviser's view it was good practice that the consent form was signed on the day prior to surgery and that, according to the Consultant, he had also discussed the procedure with Mrs C on the day prior to surgery (see paragraph 38 and 42).

47. The Adviser concluded 'I cannot choose one version of events over the other. I can say that the correct documentation for consent is present, signed and dated and filled in the notes. I don't find any procedural irregularities in the consent'.

48. The Doctor had made a note on 24 May 2004, including ticking that consent had been obtained but he did not indicate that the original plan had changed.

(b) Conclusion

49. As stated at (a) paragraph 32, I understand the distress Mrs C has undergone since the loss of sight in her right eye. However, I acknowledge that we do not know and have no way of knowing what was said between the Consultant, the Doctor and Mrs C prior to her operation on 25 May 2004, other than what is recorded and entered on the consent form that is present, signed, dated and filed in the documentation reviewed.

50. I have taken into account the clinical advice I have received, that the consent was obtained in accordance with normal procedures, however, given that I have received two differing accounts on how the consent was obtained and there is no documentation to support either view, I have concluded, on balance, that I cannot make a finding. However, as at (a) I have serious concerns about the failure to document the procedure followed to obtain consent and I am critical of this aspect.

(b) Recommendation

51. The Ombudsman recommends that the Board ensure that the Consultant makes certain that his procedure in obtaining consent from patients who are visually impaired is properly recorded in the clinical notes whenever it is followed.

52. The Board have accepted the recommendations and will act on them accordingly. The Ombudsman asks the Board to notify her when the recommendations have been implemented.

Annex 1

Explanation of abbreviations used

Mrs C	The complainant
The Consultant	The Consultant Surgeon who operated on Mrs C
The Hospital	Ayr Hospital
The Board	Ayrshire and Arran NHS Board
The Adviser	An ophthalmic clinical adviser
Mr C	Mrs C's husband
The Doctor	The Senior House Doctor who consented Mrs C for her operation

Annex 2

Glossary of terms

ARMD	The commonest cause of visual loss in those over 65 in the Western world. The condition leads to loss of vision, principally affecting the centre of the vision. The wet form of ARMD consists of leakage under the centre of vision. The dry form, less severe consists of thinning of the retina, or light sensitive portion of the eye
Cataract Surgery	Surgery to remove the lens combined with insertion of intraocular lens. If this is performed using Phacoemulsification and hence cataract extraction = phaco
Macula	Central portion of the retina that allows fine vision
Neovascular Glaucoma	A condition where abnormal blood vessels cause gross elevation of the pressure in the eye, with destruction of the light sensitive tissues
Phacoemulsification and IOL	Phacoemulsification is the removal of the natural lens using ultrasound power with insertion of a prosthetic lens = IOL
Ophthalmic Surgeons	Eye surgeons
Retina	Light sensitive portion of the back of the eye

Submacular surgery	Surgery which involves going beneath the macula, usually to remove choroidal neovascularisatio, lying beneath the macula. It is combined with vitrectomy
Vitrectomy	Operation to remove the vitreous jelly in the eye. The vitreous jelly is in the middle of the eye. Vitrectomy is performed as part of the operation called submacular surgery. To allow access to the macula, it is necessary to remove the vitreous jelly. Vitrectomy is also performed for removal of vitreous haemorrhage and for repair of retinal detachment
Vitreoretinal Surgeon	Skilled ophthalmic surgeon who specialises in surgery of the retina and vitreous