Scottish Parliament Region: South of Scotland

Case 201101334: Borders NHS Board

Summary of Investigation

Category

Health: Hospital; Ophthalmology

Overview

The complainant (Mrs C) raised a number of concerns about the treatment she received at Borders General Hospital (the Hospital) following cataract surgery. Mrs C had concerns that she had received insufficient information about the proposed surgery and choice of anaesthetic; that an inappropriate method of anaesthetic was used; and when problems occurred following the surgery there was a delay in her being referred for specialist assessment.

Specific complaints and conclusions

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

(a) the information and advice provided to Mrs C before surgery was insufficient to allow her to make a fully informed decision or to give valid consent for surgery (*not upheld*);

(b) the pre-operative assessment was inadequate in that Mrs C was not assessed by her surgeon prior to surgery and the assessment did not take full cognisance of the particular risks involved (*not upheld*);

(c) the choice of sharp needle anaesthesia was inappropriate and unreasonable (*upheld*);

(d) the post-operative care and treatment was inadequate. In particular, that there was an unreasonable and unexplained delay in referring Mrs C for a specialist opinion (*upheld*); and

(e) the complaints handling by Borders NHS Board (the Board) was inadequate (*upheld*).

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) remind staff of the risks of carrying out sharp needle anaesthesia in patients with high myopia;	29 February 2012
(ii) apologise to Mrs C for perforating her eye during	29 February 2012

surgery;

(iii)	remind staff of the need to refer patients for specialist opinion as soon as the clinical situation has been identified;	29 February 2012
(iv)	apologise to Mrs C for the delay in making a specialist referral; and	29 February 2012
(v)	remind staff of the need to conduct a Critical Incident Review where an adverse incident has occurred in order to establish whether practices require to be amended.	29 February 2012

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

Main Investigation Report

Introduction

1. The complainant (Mrs C) raised a number of concerns about the treatment she received at Borders General Hospital (the Hospital) following cataract surgery. Mrs C had concerns that she had received insufficient information about the proposed surgery and choice of anaesthetic; that an inappropriate method of anaesthetic was used; and when problems occurred following the surgery there was a delay in her being referred for specialist assessment. Mrs C complained to Borders NHS Board (the Board) but remained dissatisfied with their response and contacted my office.

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

(a) the information and advice provided to Mrs C before surgery was insufficient to allow her to make a fully informed decision or to give valid consent for surgery;

(b) the pre-operative assessment was inadequate in that Mrs C was not assessed by her surgeon prior to surgery and the assessment did not take full cognisance of the particular risks involved;

(c) the choice of sharp needle anaesthesia was inappropriate and unreasonable;

(d) the post-operative care and treatment was inadequate. In particular, that there was an unreasonable and unexplained delay in referring Mrs C for a specialist opinion; and

(e) the complaints handling by the Board was inadequate.

Investigation

3. In order to investigate this complaint my complaints reviewer reviewed all of the correspondence between Mrs C and the Board as well as documentation and statements relating to the Board's investigation of the complaint. My complaints reviewer also reviewed Mrs C's clinical records and sought advice from one of my professional medical advisers (the Adviser) who is a consultant ophthalmic surgeon.

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. An explanation of the abbreviations used in this report is contained in Annex 1. A glossary of the medical terms used in this report is at Annex 2.

Background

5. Mrs C had a cataract operation as a day case on her left eye on 28 January 2010 and on removing the patch the following morning she could not see. She attended the Hospital and saw a consultant ophthalmologist (the Consultant) who said that he thought he had nicked Mrs C's sclera with the needle containing anaesthetic during the operation and this had caused a haemorrhage. Mrs C attended further reviews by the Consultant on 3 February 2010, 10 February 2010, 16 February 2010 and 19 February 2010. On 23 February 2010 the Consultant contacted the Eye Pavilion in Edinburgh for a specialist opinion and Mrs C attended there the following day. The clinician in Edinburgh then carried out a series of three operations on Mrs C's left eye having diagnosed a vitreous haemorrhage and retinal detachment. Mrs C now has limited vision of shade and outline only from the left eye. In August 2010 the clinician performed a cataract operation on Mrs C's right eye with the use of a topical anaesthetic which was 100 percent successful.

(a) The information and advice provided to Mrs C before surgery was insufficient to allow her to make a fully informed decision or to give valid consent for surgery; and (b) The pre-operative assessment was inadequate in that Mrs C was not assessed by her surgeon prior to surgery and the assessment did not take full cognisance of the particular risks involved

6. Mrs C complained to the Board about the treatment which she received at the Hospital for the cataract surgery to her left eye. Her concerns included why no assessment was carried out at the Pre-Assessment Clinic on 14 January 2010 in view of her high myopia and that there would be an increased risk of complications as she was of a young age for having cataracts. Mrs C had also not been told that the original surgeon was to be changed to the Consultant and when she saw him by chance on 19 January 2010 he deemed there was not a requirement to speak to her prior to surgery. Mrs C said she felt she should have had a discussion about the types of anaesthesia available and the risks. Mrs C also said there were difficulties in obtaining biometric measurements of her eyes because she was not told to attend the Pre-Assessment Clinic without wearing her contact lenses. As a result Mrs C had to re-attend the Clinic on 19 January 2010 for her eyes to be measured.

7. The Board responded to the complaint and said that Mrs C had attended a pre-assessment appointment on 14 January 2010 where a full medical history

was taken except for biometric measurements because Mrs C had attended wearing her contact lenses so a further appointment was made for 19 January 2010. The Board continued that there was no problem with obtaining Mrs C's biometric measurements. An apology was made that staff had not made it clear to Mrs C that she should not wear her lenses to the pre-assessment appointment and that the written instructions which are sent to patients prior to the appointment have been revised to highlight this issue. It was explained that in order for patients to be seen as soon as possible there is a pooled waiting list therefore surgery might not be carried out by the original consultant. However, the new consultant would have the clinical notes and the Consultant did discuss the high myopia with Mrs C on 19 January 2010. The Board explained that Mrs C was not offered topical anaesthesia at that time as they did not have a consultant ophthalmologist with adequate experience in that technique. The situation has now altered and topical anaesthesia is now offered to patients.

Clinical advice

8. The Adviser said that he would expect the risks and types of anaesthesia to be explained to a patient prior to surgery. Consent must be obtained in the full knowledge of both general and special risks relevant to the operation and anaesthesia. It is the responsibility of the individual administering the anaesthetic to discuss possible complications of the anaesthetic. The Adviser looked at the consent form which Mrs C had signed and it appeared to be a generic form with no sections dealing with the benefit or risks of the procedure. In the case of cataract surgery the denoted risks should certainly include bleeding and retinal detachment as occurred in this case. The General Medical Council (GMC) guidance is explicit in regard to serious adverse outcomes, even if the likelihood is very small. The Adviser was aware that health authorities increasingly used specific cataract surgery consent forms. The Adviser noted that in Mrs C's case that the Board had said that an explanation of the surgery was provided as well as a yellow booklet which he assumed was an explanatory leaflet. He felt that the consent form which was used was inadequate. It provided no evidence to the patient or the clinician that due process was followed however thorough the oral information might have been at the time the form was completed. My complaints reviewer obtained copies of booklets (Pre-assessment appointment for cataract surgery; Cataract surgery under local anaesthetic; and Cataract surgery) which are issued to patients who undergo cataract surgery and these do provide examples of the risks associated with cataract surgery. The booklet explains that a local anaesthetic will be used and

can be given in drop form or by injection. This decision on the type of anaesthetic would depend on the individual consultant.

9. The Adviser said that it would be standard NHS practice not to give an assurance that a particular practitioner would perform an operation but that the person would have appropriate experience. The Adviser considered the pre-operative assessment and felt that it appeared to follow conventional practice although ideally the biometry measurements should have allowed a gap of a week between Mrs C leaving out her contact lenses and the readings being taken. The Adviser was satisfied that Mrs C's high myopia was taken into account before surgery since it was recorded, and the pre-operative biometry (eye measurements) confirmed the increased length of the left eye, greater than 30 millimeters, compared to a typical length of 22-24 millimeters in most adults. The choice of low power replacement lens inserted into Mrs C's left eye also reflected awareness by staff of the high myopia.

(a) Conclusion

10. The issue which I have considered is whether Mrs C received appropriate information and advice prior to surgery. This includes the risks relating to the actual surgery and the anaesthetic which was administered. I have taken into account the Adviser's comments in which he felt that the consent form was inadequate and that consideration should be given to a more specific form for cataract surgery. Mrs C believes that she did not receive adequate information. The consent form which has been used in this case is a generic form and would apply to all operations carried out in the Board area. It states that the patient consents to the particular operation and for the administration of general, local, or other anaesthetics for any of these purposes.

11. While there is no record of what exactly was explained by staff to Mrs C the information booklets state that a local anaesthetic (eye drops or injection) will be used and also the benefits and risks of cataract surgery. Although there is no way of establishing exactly what Mrs C was told by staff about the risks and benefits of surgery and types of anaesthesia I am satisfied that the information booklets provide adequate explanation in this regard and as a result I do not uphold this complaint.

(b) Conclusion

12. Mrs C believed that the pre-assessment was inadequate and that insufficient notice was taken of her high myopia. The advice which I have

received is that the assessment which was carried out was appropriate and staff were aware of Mrs C's high myopia and that it was appropriate to proceed to cataract surgery. There can be no guarantee that a particular practitioner will carry out an operation and there are reasons why it may be appropriate for another practitioner to carry out a procedure. The Board have explained that in this instance, the Consultant's operating list was shorter and, therefore, Mrs C had her surgery sooner than would have been the case. The consent form also highlights that no assurance can be given that a particular practitioner will carry out a procedure. In this case the Consultant had access to Mrs C's medical records and it was appropriate for him to perform the surgery. I do not uphold this complaint.

(c) The choice of sharp needle analgesia was inappropriate and unreasonable; and (d) The post-operative care and treatment was inadequate. In particular, that there was an unreasonable and unexplained delay in referring Mrs C for a specialist opinion

13. Mrs C questioned why she had received a needle anaesthetic during surgery as she had high myopia and whether the staff had considered an alternative method of anaesthesia such as topical anaesthesia in order to reduce the risk of problems. She also wondered whether the needle anaesthetic should have been administered by an anaesthetist rather than a consultant ophthalmologist. She also felt that there had been a delay in treatment in that following surgery when it was established she had suffered a vitreous haemorrhage it took 26 days for her to be referred to specialists in Edinburgh. Mrs C felt that staff should have assessed her as being an emergency and made an immediate referral to Edinburgh. Mrs C subsequently requested the Board to provide copies of protocols and required to know if staff had followed relevant Royal College of Ophthalmologist (RCOP) cataract guidelines.

14. The Board responded that normal treatment was carried out on Mrs C's left eye and sharp needle anaesthesia was standard practice in the Board area at that time unless the patient had a mental health illness, learning disabilities or could not tolerate local anaesthesia. There was no delay in referring Mrs C to Edinburgh as vitreous bleeding is not considered to be an emergency and ultrasonography did not indicate the eye had been punctured or that there was retinal detachment. Normal management was to observe and to allow the blood to absorb and clear and when this did not happen a referral was made to Edinburgh for vitrectomy surgery.

15. The Adviser did not think the use of sharp needle anaesthesia was appropriate in Mrs C's case. The RCOP Cataract Surgery Guidelines 2004 are explicit on this point due to the risks of ocular perforation. The reasons for the increased risk are due to the significantly larger size of eyeball in a high myopia and also sometimes the presence of an outpouching of the back surface of the eye known as a posterior staphyloma, which both increase the chance of a needle perforation occurring. The Adviser continued that apart from this risk, high myopia patients are more prone to spontaneous retinal detachment than the rest of the population but evidence for increased risk of retinal detachment following uncomplicated surgery in high myopia patients is controversial.

16. The Adviser explained that vitreous haemorrhage and retinal detachment are extremely rare after cataract surgery. The frequency of these events is increased by operative complications such as rupture of the posterior lens capsule and that did not occur in Mrs C's case. The Adviser noted that Mrs C's eye was soft at the time of surgery and also the comment was made that the Consultant thought that he had nicked the sclera. This led the Adviser to conclude that Mrs C's eye was perforated by the needle during administration of the local anaesthesia. This was the cause of the problems which have led to the loss of sight in Mrs C's left eye. The Adviser noted that the Board's response that ultrasonography did not indicate that Mrs C's eye had been perforated appeared to be disingenuous, since ultrasonography would not have revealed a needle puncture in the sclera.

17. The Adviser noted that Mrs C was not referred for management of her vitreous haemorrhage and detached retina until nearly four weeks had elapsed from her cataract operation. He said it was clear that a haemorrhage was present in Mrs C’s left eye the day after surgery. He said the static ultrasound images of 3 February 2010 appeared to show a retinal detachment and Mrs C should have been referred to a specialist in retinal surgery immediately. The Adviser went on to say that the consequences of delayed treatment of retinal detachment include proliferative vitreoretinopathy which makes repair much more difficult and results in a worse visual outcome. The Adviser could not say whether the outcome would have been any better had an earlier referral been made but he believed the delay was unacceptable.

(c) Conclusion

18. Mrs C believes that the use of sharp needle anaesthesia was inappropriate and that staff should have considered an alternative method of anaesthesia. The Board have explained that at the time of Mrs C's surgery there were no ophthalmologists who had adequate experience of topical anaesthesia in post and that sharp needle anaesthesia was standard practice unless the patient met a certain criteria. The advice which I have received is that in a patient with high myopia they are at increased risk of ocular perforation due to a significantly larger eyeball and that there could be the possibility of outpouching of the back surface of the eye which would increase the possibility of needle perforation. I uphold this complaint.

(c) Recommendations

19. I recommend that the Board:	*Completion date*
(i) remind staff of the risks of carrying out sharp needle anaesthesia in patients with high myopia; and	29 February 2012
(ii) apologise to Mrs C for perforating her eye during surgery.	29 February 2012

(d) Conclusion

20. I have now considered whether the care and treatment which was provided post-operatively was adequate or appropriate. Again, the advice which I have received is that Mrs C's eye was perforated by the anaesthetic needle and that the haemorrhage was evident the day following the surgery. Ultrasound imagery on 3 February 2010 appeared to show that Mrs C had suffered a detached retina and it was at that stage that she should have been referred to a specialist in retina surgery. It took nearly four weeks for the referral to be made and by that time proliferative vitreoretinopathy had occurred which made repair more difficult. Although my Adviser was unable to say whether the delayed referral had adversely affected the outcome I too have deemed that the delay in seeking a specialist opinion was unacceptable and I uphold this complaint.

(d) Recommendations

21. I recommend that the Board:	*Completion date*
(i) remind staff of the need to refer patients for specialist opinion as soon as the clinical situation	29 February 2012

has been identified; and

(ii) apologise to Mrs C for the delay in making a specialist referral. — 29 February 2012

(e) The complaints handling by the Board was inadequate

22. Mrs C was dissatisfied with the Board's responses to her complaint. She felt her questions had not been answered fully and she wished the Board to provide her with copies of their policies and procedures which showed that they had acted in accordance with the RCOP guidelines. She also requested that the Board provide her with a copy of any root cause analysis or adverse incident report which took place to investigate the errors which occurred during her treatment.

23. The Board said that the difficulties Mrs C experienced arose following a complication of her surgery and was not reported through the clinical incident procedure. The details of the case have been discussed with the clinicians working within the unit and while they were sympathetic to the difficulties which were experienced due to complications of surgery, they did not feel that any changes were necessary to current guidelines and practices within the unit.

24. The Adviser did not believe that the Board had acted in the spirit of the RCOP guidelines. He also noted that they had mentioned that they did not feel that any changes were necessary to their current guidelines and practices within the unit. The Adviser thought that Mrs C's circumstances fell into the category of a critical incident that should have been reported and acted upon. The Adviser concluded that Mrs C has suffered permanent sight loss through the inappropriate method of administration of local anaesthesia and that there had been a failure to recognise and deal with the complications promptly. He also felt the Board's responses to Mrs C's complaints were ill-informed, inadequate and disingenuous.

(e) Conclusion

25. I am concerned about the manner in which the Board responded to Mrs C's complaint. Mrs C's problems were caused by the inappropriate method of anaesthetic which was used and this perforated her eye which would not have been the case if an alternative method of local anaesthesia had been used. The mentioning of ultrasonography in the response letter was meaningless as it would not have identified a puncture of the sclera. I am also concerned that the Board did not feel there was a need to change their

procedures and policies or conduct a critical incident review. At the very least, I would have expected a critical incident review to have been carried out in order to establish what occurred during and following Mrs C's surgery and findings would be reached and recommendations made which could reduce the likelihood of similar errors happening again. I uphold this complaint.

(e) Recommendation

26. I recommend that the Board:	*Completion date*
(i) remind staff of the need to conduct a Critical Incident Review where an adverse incident has occurred in order to establish whether practices require to be amended.	29 February 2012

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

Annex 1

Explanation of abbreviations used

Mrs C	The complainant
The Hospital	Borders General Hospital
The Board	Borders NHS Board
The Adviser	Ombudsman's professional medical adviser
The Consultant	Consultant Ophthalmologist who treated Mrs C
GMC	General Medical Council
RCOP	Royal College of Ophthalmologists

Annex 2

Glossary of terms

Biometric measurements	Eye measurements
Myopia	Nearsightedness
Ocular perforation	Penetrating eye injury
Posterior lens capsule	Back part of membrane surrounding cataract
Proliferative vitreoretinopathy	Progressive scar tissue formation in the retina and adjacent gel at the back of the eye
Retinal detachment	Retina pulled from normal position in the eye
Sclera	Tough white outer coating of the eye
Sharp needle anaesthesia	Anaesthesia delivered through a needle
Topical anaesthetic	Local anaesthetic drops applied to numb the surface of the eye prior to cataract surgery
Vitreous haemorrhage	Bleeding into the gel occupying the space between the back of the eye lens and the retina