Scottish Parliament Region: North East Scotland

Case 200701066: Tayside NHS Board

Summary of Investigation

Category

Health: Hospital; Informed Consent

Overview

The complainant (Mrs C) raised a number of concerns that she had not consented to the operation as performed and had not consented to a spinal anaesthetic. Mrs C also complained that there was a lack of follow-up.

Specific complaints and conclusions

The complaints which have been investigated are that Tayside NHS Board (the Board):

(a) failed to obtain informed consent for spinal anaesthesia *(upheld*);

(b) performed an operation which was different to the planned haemorrhoidectomy without appropriate explanation of the new procedure (*upheld*); and

(c) failed to provide the necessary follow-up care and treatment (*upheld*).

Redress and recommendations

The Ombudsman recommends that the Board:

(i) apologise to Mrs C for the failure to ensure she adequately understood and consented to the anaesthetic options; and

(ii) use the events of this case and in particular Mrs C's experience, as part of induction and training programmes about the consent process.

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

Main Investigation Report

Introduction

1. On 25 July 2007, the Ombudsman's office received a complaint from the complainant (Mrs C) that on 21 May 2007 she had had an operation which was not the one she had agreed to and that she had not consented to a spinal anaesthetic. She also complained that she had not received adequate advice or follow-up after the operation. Mrs C complained to Tayside NHS Board (the Board) on 31 May 2007 and a response was sent on 9 July 2007.

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

(a) failed to obtain informed consent for spinal anaesthesia;

(b) performed an operation which was different to the planned haemorrhoidectomy without appropriate explanation of the new procedure; and

(c) failed to provide the necessary follow-up care and treatment.

Investigation

3. Investigation of this complaint involved obtaining and reviewing Mrs C's relevant clinical records and the Board's complaint file. I have also obtained the views of a medical adviser to the Ombudsman (the Adviser) and sought further comments from the Board on the procedures for obtaining consent.

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) The Board failed to obtain informed consent for spinal anaesthesia

5. Mrs C complained that she had been assured by the doctor who had performed her rectal examination in April 2007 that she needed an operation to remove haemorrhoids and that this would be performed under anaesthetic without her ever needing to be aware of what was going on. Mrs C told me she was anxious about surgery and had specifically asked that she be unconscious. Mrs C attended for this operation on 21 May 2007 and was distressed to be given a spinal anaesthetic by the anaesthetist (the Anaesthetist), topped up with 2mg Midazolam, and by the fact that a mucosal banding operation was performed rather than a haemorrhoidectomy (see complaint (b)).

6. In response to my enquiries the Board told me that the consent form which was completed for Mrs C's operation is part of the standard operation document which records pre-operative, operative and post-operative information. Mrs C had signed the documents which states 'I agree to the administration of a general, local or other anaesthetic as deemed necessary by the anaesthetist'. The document as used in May 2007 has been subsequently altered and now has a section which allows for comment on the pre-operative discussions with the patient although the Board noted that such a discussion would still have taken place in Mrs C's case even if it was not recorded as such. The Board also noted that the decision as to choice of anaesthetic is made by the anaesthetist and no other member of staff would be able to promise a particular type of anaesthetic to Mrs C. Staff would be expected to note Mrs C's concerns in the pre-operative assessment notes to ensure the anaesthetist was aware of this.

7. The Board noted that the Anaesthetist would have considered spinal anaesthesia to be the best approach from both a safety and post-operative comfort perspective but that she would not have insisted on a spinal anaesthetic if she knew the patient did not want this. The Board also noted that had a general anaesthetic been necessary Mrs C would have required to be operated on in a larger hospital because of the additional risks of this procedure.

8. The Adviser told me that the consent process operated by the Board (for anaesthesia and the actual operation) involved pre-operative as well as 'on the day' discussions between the patient and the anaesthetist. He told me that this is in-line with good practice. The Adviser noted that spinal anaesthesia was the appropriate first choice of anaesthetic in this case and as such he had no clinical concerns about this decision by the Anaesthetist. However, he noted that there is nothing in the clinical records to suggest that Mrs C had anaesthetic choices explained to her and the consent form covered all options so could not assist in clarifying this point. He noted that the final element of the consent form was countersigned by a first year doctor. He expressed concern that a more junior doctor may have the knowledge of the procedures and anaesthetics but would not necessarily have developed the necessary communication skills to ensure that the patient understood the information being given. He considered that in this instance it is clear that Mrs C was not aware of what was going to happen to her or the possible alternatives and that it is simply not credible that the discussion with the junior doctor covered these points. Even if some explanation had been attempted, there were no checks in

the system to ensure Mrs C's understanding of the anaesthetic or surgical options.

9. In response to the draft of this report the Board noted that the junior doctor who obtains consent would have been under the supervision of a senior colleague who would be available for support and guidance when required.

(a) Conclusion

10. The anaesthetic provided to Mrs C was entirely appropriate and the practice of the Anaesthetist providing the anaesthetic is not in question. However the process for obtaining consent as explained to me by the Board lacked any clear opportunity to confirm the patient's understanding. Arguably such confirmation cannot be written into processes but requires skilled communicators to obtain informed consent. In as much as Mrs C is clear that she did not want spinal anaesthesia and this was not identified anywhere in the pre-operative process it is simply not possible that informed consent for spinal anaesthesia was obtained in her case. I consider the failure in this case was of to ensure that the communication was appropriate and effective for the recipient. I uphold this aspect of the complaint.

(a) Recommendation

11. The Ombudsman recommends that the Board

(i) use the events of this case and in particular Mrs C's experience, as part of induction and training programmes about the consent process as the Ombudsman recognises that obtaining informed consent requires skills generally acquired through practice rather than processes; and

(ii) apologise to Mrs C for the failure to ensure she adequately understood and consented to the anaesthetic options.

(b) The Board performed an operation which was different to the planned haemorrhoidectomy without appropriate explanation of the new procedure

12. Mrs C complained that she had been told she required a haemorrhoidectomy but that this had not been done. She told me that during the operation the surgeon (the Consultant) had tried to talk to her through a mask but she had not been able to understand what he was saying. It was only when she came home from hospital the next day and read the discharge letter that she realised that she had had a different procedure called mucosal banding. Mrs C told me that when she complained that she had not had the

procedure she had expected and wanted, she was told by the Board she had consented to this. Mrs C complained to me that she had not consented to this other procedure.

13. In response to my enquiries the Board told me about the overall process for obtaining consent (see paragraph 6). They noted that the Consultant had only been able to discover the true nature of Mrs C's problem once he had completed his examination of Mrs C under anaesthetic. As the operation had begun he explained to Mrs C at that point that she would require a different procedure and carried out that procedure with her agreement. The Board noted that even the small amount of sedation may have impacted on Mrs C's recall of the discussion.

14. The Adviser noted that the procedure actually carried out on Mrs C was clinically appropriate in light of the Consultant's examination findings and that it would not have been possible to predict this before hand. The Adviser told me that if Mrs C had been under a general anaesthetic it would have been appropriate for the Consultant to continue to operate as he did without asking for Mrs C's specific consent as this was what was clinically appropriate. He noted, however, that Mrs C had a spinal anaesthesia with additional anaesthetic and that the level of amnesia even in a lightly sedated patient will be significant even where she appeared to understand at the time. In this case he concluded the Consultant was lulled into a false sense of security by believing he had imparted that information during the operation when he had not.

(b) Conclusion

15. The operation undertaken was entirely appropriate and the practice of the surgeon is again not in question. I accept that the Consultant did discuss the procedures and changes with Mrs C. I am however critical of the fact that her understanding of the changes and the consequent effect on follow-up (see complaint (c)) were not discussed prior to her discharge to ensure Mrs C understood the changes. Accordingly I uphold this aspect of the complaint.

(b) Recommendation

16. The recommendation at (a)(i) is also relevant here.

(c) The Board failed to provide the necessary follow-up care and treatment

17. Mrs C complained to the Board very shortly after the operation that she had been discharged from hospital without any follow-up. Mrs C told me she had heavy bleeding for several days afterwards and was in pain all the time. Mrs C's complaint was sent to this office on 23 July 2007 and she was seen by the out-patient clinic for follow-up on 30 July 2007.

18. In response to my enquiries the Board told me that the usual follow-up after mucosal banding varies from surgeon to surgeon but that not all patients require follow-up. In this instance an appointment was made for six to eight weeks post-operation. The Board also advised me that the information provided pre-operatively to mucosal banding patients differs from that given to haemorrhoidectomy patients. The Board told me that mucosal banding patients are advised that there may be some bleeding for a week to ten days after the banding.

19. The Adviser noted that the appointment on 30 July 2007 appeared to be a satisfactory consultation and that this level of follow-up was appropriate. He considered, however, that Mrs C's concern was a lack of immediate aftercare and explanation at discharge. The Adviser concluded that it is best to treat sedated patients as completely unaware with regards to any verbal explanations given during the operation and that it would be useful for written explanatory notes to be given to a patient after the operation.

(c) Conclusion

20. The Adviser noted in paragraph 13 that Mrs C had not been given an understanding of the revised procedure by the Consultant. There is nothing in the clinical record to suggest that Mrs C received an explanation of the revised course of action or the likely post-operative effects of mucosal banding. The medical advice I have received is that while the actual follow-up action was appropriate, insufficient information or advice was given to Mrs C who was distressed by the unexpected post-operative side-effects. An adequate explanation is an integral part of care and treatment and I uphold this aspect of the complaint.

(c) Recommendation

21. The recommendation at (a)(i) is also relevant here.

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

Annex 1

Explanation of abbreviations used

Mrs C	The complainant
The Board	Tayside NHS Board
The Adviser	A medical adviser to the ombudsman
The Anaesthetist	The anaesthetist who gave Mrs C her anaesthetic
The Consultant	The surgeon who performed Mrs C's operation

Annex 2

Glossary of terms

Haemorrhoidectomy	The surgical removal of haemorrhoids
Mucosal banding	Application of rubber bands to ease a rectal prolapse back into place