Scottish Parliament Region: Lothian

Case 200901758: Lothian NHS Board

Summary of Investigation

Category

Health: Hospital; Gynaecological and Obstetric; clinical treatment; complaint handling

Overview

A Member of Parliament (Mr D) raised a complaint on behalf of a constituent (Ms C). It was first raised within Lothian NHS Board (the Board) on 25 July 2007. The complaint focused on the lack of consent on 2 March 2007 for additional clinical procedures to be undertaken during a pre-arranged surgical procedure. In her view, Ms C had not been given adequate time to fully consider the options and the attendant risks before consenting fully to the potential, additional surgery. It subsequently took 17 months to resolve her complaint at the local resolution stage of the NHS complaints procedure before the matter was referred to the Ombudsman's office on 27 July 2009.

Specific complaints and conclusions

The complaints which have been investigated are that:

(a) the Board's actions in relation to obtaining consent from Ms C for the removal of her left fallopian tube during a laparoscopic adhesiolysis and left salpingostomy were unsatisfactory (*upheld*); and

(b) the Board delayed in responding to Ms C's complaints (*upheld*).

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) apologise to Ms C for the decisions taken to carry out additional surgery without her clear understanding of the potential outcomes;	30 July 2010
(ii) ensure elective surgical consent forms are clearly set out and appropriately understood and signed by the patient or their representative;	30 July 2010

(iii)	apologise to Ms C and her representative for the delays experienced in the handling of their complaint; and	30 July 2010
(iv)	ensure the revised internal complaints procedure provides all the necessary components set out in the NHS complaints procedure to guarantee a consistent approach to complaint handling within the Board.	30 July 2010

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

Main Investigation Report

Introduction

1. On 25 July 2007 Ms C raised a complaint to Lothian NHS Board (the Board) about the surgical procedures she had undergone and her concerns that she had not fully consented to all the procedures that were carried out whilst she was under general anaesthetic. The complaint was taken up by a Member of Parliament (Mr D). Mr D wrote to the Board on 1 February 2008 asking for the resolution of this complaint. A final letter in response to the complaint was received by Mr D on 12 December 2008. Following this, comments were made by Ms C to Mr D about the response letter received and these were passed to the Board to respond to on 4 February 2009. The matter was referred to the Ombudsman's office on 27 July 2009.

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

(a) the Board's actions in relation to obtaining consent from Ms C for the removal of her left fallopian tube during a laparoscopic adhesiolysis and left salpingostomy were unsatisfactory; and

(b) the Board delayed in responding to Ms C's complaints.

3. It is the case that the care and treatment for the condition identified was appropriate and correct. The care and treatment, at the time of the surgical procedure carried out on 2 March 2007, is not being challenged within the body of this report.

Investigation

4. Ms C described suffering symptoms of abdominal pains at the beginning of March 2006 which she saw her GP about. Further to her experience of increased pain at this time she contacted NHS 24 and was advised to go the Royal Infirmary Edinburgh (the Hospital) to be seen. Examinations resulted in an invitation to return to the Hospital the following day for a scan. At this time, a clinical view was taken to wait to see if the pains continued which they did, and Ms C was subsequently referred for a laparoscopy. This surgical procedure was carried out on 6 December 2006, which confirmed her clinical condition as being a 'stuck left ovary' and that a 'fallopian tube was blocked'. A further clinical appointment was made for 19 December 2006 to discuss the treatment options with a consultant.

5. On 25 July 2007 Ms C complained to the Board about the care and treatment that she received. She asked for explanations and answers to be provided to her. The response to Ms C's complaint was received on 12 December 2008 and subsequently referred to the Ombudsman on 27 July 2009.

6. In order to investigate these matters the complaint file and the clinical records have been provided by the Board. Clinical advice has been sought in relation to the handling of the clinical issues in respect of the complaint raised and full consideration has been given to the delays in the handling of the complaint.

7. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. Ms C, Mr D and the Board were given an opportunity to comment on a draft of this report.

(a) The Board's actions in relation to obtaining consent from Ms C for the removal of her left fallopian tube during a laparoscopic adhesiolysis and left salpingostomy were unsatisfactory

8. Ms C had surgery on 2 March 2007 following earlier clinical discussions about the potential surgery. On 19 December 2006 she had an out-patient appointment and agreed to surgery and a consent form was signed in anticipation of the clinical procedure being carried out as agreed.

9. On 2 March 2007 Ms C recalls she was seen by her consultant (Doctor 1) after the surgical procedure had been carried out that day.

10. Following the surgery, Ms C was told her left ovary and fallopian tube had been removed. Ms C considers she understood this was going to be a procedure to unblock the tube rather than remove it. Ms C was transferred to a ward for post-operative care and discharged home on 4 March 2007. She does not consider she received an explanation regarding the surgery and what had taken place, and the staff on the ward had not been able to answer her questions as they did not have her medical notes on the ward with the information about the surgery that had been undertaken. Ms C explained, in her initial letter of complaint dated 25 July 2007 to the Board, that she had 'felt very groggy' and did not believe what had been said to her as the additional procedures had never been discussed with her as options. She has said it took five weeks for any information to be sent to her GP to enable them to talk about

what had taken place. It transpired the information within the report to the GP was too little to answer all her questions. Ms C said the report indicated 'There was a mass and it could have been caused by endometriosis', which Ms C says she thought had been ruled out at the end of 2006.

11. The Board's response to the complaint which was sent to Mr D on 12 December 2008 gave an overview of the clinical care since early 2006 up to and including the care and surgical treatment that became a matter of concern for Ms C. In relation to the matter of consent Doctor 1 has said that he did discuss the issues of any additional procedures with Ms C. Following the surgery, Doctor 1 has recorded he visited the patient and told her what had been carried out and that he would arrange an opportunity to talk to her about this.

12. Doctor 1 saw Ms C on 25 May 2007 with her husband and explained what had taken place and the measures he had taken to ensure her right fallopian tube was patent and he did not anticipate this would add any burden to her fertility. He agreed to support a referral to a fertility clinic to support the couple's options to conceive.

13. As part of the investigation into the complaint, Doctor 1 explained that the procedure had been difficult and the option to undertake the additional surgery was in the knowledge that it would not affect the patient's ability to conceive in the longer term and leaving the site in the condition he observed would bring added complication and a risk of ectopic pregnancy.

14. The gynaecological adviser to the Ombudsman (the Adviser) noted a decision was made on 31 October 2006 for Ms C to undergo a laparoscopy. The Adviser has reviewed the medical records and has said:

> 'At the time of the consultation with [attending doctor on 3 December 2006, Doctor 2] the decision to proceed with laparoscopy was entirely appropriate.
>
> The consent for the diagnostic laparoscopy was obtained by [Doctor 2] at the time of the consultation on 31/10/06. This was countersigned by the patient on the same day and details the procedure as a diagnostic laparoscopy. The diagnostic laparoscopy was undertaken on 6/12/06.'

15. A consent form for further treatment was initiated on 19 December 2006. The original form reads:

> 'Laparoscopic adhesiolysis and left salpingostomy, risks of bleeding, infection and injury to blood vessels, bowel and bladder discussed.'

The Adviser notes:

> 'This is in [registrar to Doctor 1, Doctor 3]'s writing and is countersigned by [Doctor 3] dated 19/12/06. She records her grade as registrar. [Ms C] has countersigned this consent on the reverse and again this is dated 19/12/06.
>
> There is a subsequent addition to the form that reads:
>
> > '+/- laparotomy' and this is initialled by [Doctor 2]'. And initialled by the complainant.
>
> There is a further addition on the consent form:
>
> > 'pre-op laparascopic reassessment +/- adhesions = and salpingectomy'.
>
> There is a signature which corresponds to [Doctor 1] … and is followed with the numbers 2307.
>
> '2307' appears to refer to the date of surgery, that being 2 March 2007. In his report [Doctor 1] states he met [Ms C] in the pre-admission area to re-consent. This re-consent has not been countersigned by the patient.'

16. The Adviser has considered the consent form to be unsatisfactory as there are a number of additions with no counter signatures from the patient. In this respect the Adviser has said:

> 'It is unclear as to the level of understanding that the patient had prior to proceeding with surgery on 2/3/07.'

17. The Adviser notes that a follow-up appointment was held between Ms C and Doctor 1 11 weeks after the surgery had taken place. He considers this should have been done within one or two weeks of surgery as other procedures had been carried out during the surgery.

(a) Conclusion

18. There was a consent form available and used in part. This, however, has not demonstrated that adequate discussion took place regarding the options that Doctor 1 subsequently chose from during the surgical procedure undertaken on 2 March 2007. Doctor 1 had spoke to Ms C about the procedure after the surgery, but this was not an appropriate form of communication when she was unable to fully grasp the nature of what had been discussed with her. I uphold this complaint.

(a) Recommendations

19. I recommend the Board:	*Completion date*
(i) apologise to Ms C for the decisions taken to carry out additional surgery without her clear understanding of the potential outcomes; and	30 July 2010
(ii) ensure elective surgical consent forms are clearly set out and appropriately understood and signed by the patient or their representative.	30 July 2010

(b) The Board delayed in responding to Ms C's complaints

20. Ms C raised the complaint within the Board about her concerns regarding the lack of consent given for additional procedures to be undertaken whilst she was in surgery on 2 March 2007. It subsequently took 17 months from 25 July 2007 to 12 December 2008 to resolve her complaint at the local resolution stage.

21. The NHS complaints procedure is guidance for services provided within the NHS to refer patients and service users to a complaints procedure. It indicates there is a 20 day investigation period for NHS boards to resolve a complaint at local resolution stage, allowing an opportunity to address the issues raised.

22. The complaint was initially raised with the Board on 25 July 2007 by Ms C. It was then referred to Mr D to act as her representative on 22 January 2008. On 1 February 2008, complaint details were forwarded by Mr D to the Board. On 18 June 2008 the Board wrote to Mr D and let them know there had been a delay as a result of the complexity of the case. They apologised for the delay in the handling of the complaint. On 26 September 2008, Mr D wrote to the Board once again seeking a response. A response letter was sent to Mr D on 12 December 2008 which was sent to Ms C for her consideration. Ms C

provided some comments on 29 January 2009 regarding the response and Mr D forwarded those to the Board on 4 February 2009. The Board acknowledged Mr D's letter on 15 April 2009 and provided a further response to Mr D on 12 May 2009 in which the Board offered a meeting for Ms C to meet a Clinical Nurse Manager to try to resolve the concerns. This offer was declined as Ms C considered too much time had passed. The complaint was referred to me on 27 July 2009, two years after the original complaint was raised with the Board.

23. The complaint focused on the clinical issues described in paragraph 8 to paragraph 19 in this report and drew attention to Mr D's concern about the length of time the Board took to address Ms C's concerns. It would be usual for me to refer a matter, not investigated by the Board at that point, for their consideration, however, on this occasion the delays are clearly set out in the documentation provided and it is clearly evidence of a lack of response to the issues raised by Ms C and her representative. The correspondence demonstrates the original complaint was not addressed appropriately and in line with the NHS complaints procedure.

24. There were a series of considerable delays within the procedure (see paragraph 22) and a failure on the part of the Board to let Ms C know that where she remained unhappy after the delay in resolving her complaint exceeded 40 days, she could refer the matter to this office. There is very little evidence of the complainant being kept up to date and advised of the delays and their reasons. Additionally, Ms C's representative, Mr D, took on the case and did not have regular contact with and feedback from the Board. Mr D was not advised of the reasons for the delays unless contact was initiated by him.

(b) Conclusion

25. There is no clear accountable reason for the lengthy delay in the handling of this complaint. The Board has informed my office, as part of other enquiries and investigations undertaken that there is an extensive review of the complaints process underway within the Board and there have been some internal problems experienced which are now being addressed. The Board anticipated a new internal procedure to be effective in early 2010. In view of the length of time the Board took to resolve the complaint and their lack of explanation and contact with the complainant throughout the period, I uphold this complaint.

(b) Recommendations

26. I recommend the Board:	*Completion date*
(i) apologise to Ms C and her representative for the delays experienced in the handling of their complaint; and	30 July 2010
(ii) ensure the revised internal complaints procedure provides all the necessary components set out in the NHS complaints procedure to guarantee a consistent approach to complaint handling within the Board.	30 July 2010

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

Ms C	The complainant
The Board	Lothian NHS Board
Mr D	Ms C's representative, constituency Member of Parliament
The Hospital	Royal Infirmary Edinburgh
Doctor 1	Consultant
The Adviser	Gynaecological adviser to the Ombudsman
Doctor 2	Attending doctor on 3 December 2006
Doctor 3	Registrar to Doctor 1

Annex 2

Glossary of terms

Ectopic pregnancy	Pregnancy outside the uterus
Laparoscopic adhesiolysis	Freeing of scar tissue
Left salpingectomy	Removal of left fallopian tube
Left salpingostomy	Opening of left fallopian tube

Annex 3

List of legislation and policies considered

NHS complaints procedure 'Can I help You?' Issued October 2005