Scottish Parliament Region: Glasgow

Case 200500732: Greater Glasgow and Clyde NHS Board

Summary of Investigation

Category

Health: Hospitals; Oncology; Diagnosis and treatment

Overview

The complainant (Ms C) raised a number of concerns about surgery she underwent for removal of a breast tumour at the Western Infirmary, Glasgow, (the Hospital) and about the subsequent radiotherapy treatment at the Beatson Oncology Centre (the Centre). She believed that both had been more extensive than she had been advised and that, as a result, she was at a greater risk of developing lymphoedema.

Specific complaints and conclusions

The complaints which have been investigated are that:

(a) on 24 March 2004 at the Hospital, during surgery to remove the tumour, all lymph nodes in Ms C's armpit were removed against her express wishes (*partially upheld to the extent that consent was not correctly taken*)[1]; and

(b) during subsequent radiotherapy treatment at the Centre, the total armpit area was irradiated (*not upheld*).

Redress and recommendations

The Ombudsman recommends that:

(i) when launching the new policy on consent, the Board arrange appropriate training for staff to ensure it is fully implemented and audit its implementation to confirm that it is being followed consistently; and

(ii) the Board ensure that all staff are aware of the need to provide full explanations when responding to complaints and that staff dealing with complaints contact all appropriate staff for comment when doing so.[2]

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[1] It should be noted that I conclude that Ms C did not receive a full auxiliary clearance but only a sample clearance which was in line with her wishes (see paragraph 25).

[2] On this point the Ombudsman would draw the Board's attention to the recommendation for a general review of complaints handling in report number 200500103 published in March 2007.

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

Main Investigation Report

Introduction

1. On 5 October 2005 the Ombudsman received a complaint from a woman referred to in this report as Ms C about the care and treatment she received at the Western Infirmary, Glasgow (the Hospital), on 24 March 2004 and subsequent treatment at the Beatson Oncology Centre (the Centre). On 24 March 2004 Ms C underwent surgery at the Hospital to remove a breast tumour and she then had radiotherapy at the Centre.

2. On 3 September 2004 Ms C took up a number of concerns she had about her surgery; the radiotherapy treatment and other matters with Greater Glasgow (now Greater Glasgow and Clyde) NHS Board (the Board). After exchanges of correspondence and meetings concluding in September 2005, Ms C remained dissatisfied.

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

(a) on 24 March 2004 at the Hospital, during surgery to remove the tumour, all lymph nodes in her armpit were removed against her express wishes; and

(b) during subsequent radiotherapy treatment at the Centre, the total armpit area was irradiated.

Investigation

4. The investigation of this complaint involved obtaining all the background documentation relating to the complaint and Ms C's medical records. Advice was also obtained from a clinical adviser to the Ombudsman (the Adviser). I also considered a number of extracts from medical textbooks submitted by Ms C. The abbreviations used in the report are explained in Annex 1 and the medical terms used in the report are explained in Annex 2.

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

(a) On 24 March 2004 at the Hospital, during surgery to remove the tumour, all lymph nodes in her armpit were removed against her express wishes

6. A consultant surgeon at the Hospital (Consultant 1) wrote to Ms C's General Practitioner on 2 March 2004 to say that, following a diagnosis of

invasive breast cancer, a lesion would require 'localisation' and that this had been explained to Ms C. (Localisation is required when a tumour is small: see paragraph 13 for a fuller explanation of this procedure.) The letter went on to say that Ms C had concerns about having an axillary clearance (a removal of all the lymph nodes in the axilla or armpit) and that it was agreed she would only have an axillary sample as part of her procedure. Ms C has said she was concerned about this because her great aunt had suffered lymphoedema and skin cancer following treatment for breast cancer. Lymphoedema is a condition in which excess fluid called lymph collects in tissues and causes swelling (oedema). This can occur after lymph vessels or lymph nodes in the axilla are removed by surgery or damaged by radiation, impairing the normal drainage of lymphatic fluid.

7. Ms C was admitted for the surgery to the Hospital on 23 March 2004. She was surprised she was not admitted on the theatre list of Consultant 1 but another consultant (Consultant 2). It was explained to her that Consultant 2 was part of the team and that this was normal procedure. The surgery took place on 24 March 2004. After she had received the initial medication (pre-med) and was in the ante-theatre but before she had received the anaesthetic, Ms C was asked to sign a consent form. She has said she was unable to read this as she was not wearing her glasses. On entering the theatre she was greeted by the Professor of Surgery (the Professor). She then underwent surgery which took one hour and ten minutes. After the operation a Senior House Officer (the SHO) examined Ms C. Ms C said that prior to the examination the SHO was asked by Consultant 2 to 'check out his handiwork'.

8. Following completion of her radiotherapy at the Centre, Ms C was concerned about her treatment and asked to see her notes. The consent form contained the figure 15.1 in the corner and states that she had consented to 'Proposed procedure – Wide local excision of Lt Breast with Axillary Clearance'.

9. Ms C said this led her to firmly believe that 15 nodes and the sentinel were removed. She also felt that the length of her scar indicated 'clearance'; that the length of time taken was unusual for a smaller operation; and that it was most likely the surgery had been carried out by the SHO as part of a tutorial by the Professor. Ms C had also seen a discharge form and a letter from the consultant responsible for her treatment at the Centre (Consultant 3) to Consultant 1, which both indicated she had undergone an axillary node clearance.

10. In a letter dated 21 July 2005[3] the Board said that the operation was carried out by Consultant 1 with the SHO in attendance. The Professor had been in the theatre at the start because Ms C had to be on his theatre list because of the equipment needed to undergo localisation. It was likely that the SHO undertook the final stage of closing the wounds.

11. They accepted that the consent form had been wrongly completed and explained that it had been completed by a locum House Officer who appeared to have wrongly included the normal wording which referred to a full clearance. It was, however, stressed that Consultant 1 was aware that Ms C required a sample and that this was the surgery that was carried out.

12. The Board also accepted that the consent form should have been dealt with beforehand, ie, prior to the time it was obtained (see paragraph 7). They said that when staff were unable to find a consent form in Ms C records they did not wish to delay the transfer to theatre. It was also confirmed that the pre-medication drugs were not sedatives.

13. With reference to the procedure itself, the Board described the process of 'localisation'. As Ms C's tumour was small it had to be located using a 'localising' needle while she was under anaesthetic and before the main operation began. Tissue was then removed from around the tip of the needle to be certain all the cancer had been removed. Following the removal of the tumour the specimen that was removed was x-rayed to confirm that it contained all of the tumour. They concluded: 'This additional time to carry-out the x-rays inevitably means that the length of anaesthesia is greater in patients who have impalpable cancers that have to be localised when compared to palpable cancers where no x-rays of the specimen are required'.

14. They also said that there was 'no such thing as a normal scar length' and that the length of 8 cm was not inappropriate and did not indicate axillary clearance. The operating note and the pathology report clearly stated only three nodes were sampled. The letter from Consultant 3 to Consultant 1 (see paragraph 9) was incorrect and subsequent letters from him of 15 July and 9 August 2004 made it clear that only three nodes had been removed. I have

[3] This was not the only response Ms C received and was part of a larger correspondence between Ms C and the Board concerning her complaint.

seen the letters and all three letters refer to three nodes under the heading 'diagnosis' and wide local clearance under the heading 'treatment'.

15. I have seen the operation note and the pathology report. The note was typed on 25 March 2004 and said that Consultant 1 was assisted by the SHO. It indicates the procedure was an 'axillary sample'. The pathology report refers to an 'axillary sample' and three nodes.

16. The Adviser who reviewed Ms C's complaint said that:

> 'I couldn't find any operation notes in [Consultant 1]'s handwriting and it would seem that the typewritten note was not written by her either but I think there is no doubt whatsoever that [Consultant 1] carried out the operation with the assistance of [SHO].'

17. The Adviser was concerned that the notes were inconsistent and recorded at a number of points that an axillary clearance had occurred and at others that there had been an axillary sample. However, the pathology report was thorough and clear and the Adviser concluded:

> 'There have been all sorts of written mix ups … but I am clear in my own mind from the pathology report that only three nodes were removed from the axilla.'

18. The Adviser was also very critical of the way consent was obtained (see paragraph 7). The consent form was dated 23 March 2004 but it is not disputed it was obtained prior to the operation on 24 March 2004 (see paragraph 12). The Adviser has said that the fact it referred to clearance and not sampling showed 'the importance of consent for surgical procedures to be obtained by the surgeon carrying out the procedure or at second best someone who can perform the procedure and understand its ramifications'.

19. In response to my questions, the Hospital provided copies of their policy on consent to treatment then in force and of a draft policy that was undergoing consultation at the time of this report. The policy in force at the time of Ms C's treatment makes it clear that it was the responsibility of the professional providing the treatment to ensure consent had been obtained correctly. This could be delegated if that was not practicable but only if the member of staff was sufficiently trained and had sufficient knowledge of the proposed investigation or treatment. On the timing of consent, the policy states there should be 'sufficient time for the patient to reflect' and that it was 'good practice

to confirm with the patient immediately prior to the procedure that he/she hasn't had a 'change of mind'. The draft policy largely repeats this advice on responsibility and timing.

20. In response to a previous draft of this report, the Board also provided more detail about the events surrounding Ms C's operation including a full explanation for the presence of the Professor in the theatre when Ms C arrived. The Board said that it had been intended that the Professor would carry out the operation but that he noted that the consent as signed did not match what he had been told by Consultant 1. They said he called Consultant 1 who came to the theatre and carried out the operation. Ms C had said she believed it would have been impossible for Consultant 1 to perform the operation as she had a clinic that day. The Board confirmed that on Wednesdays, Consultant 1 routinely had meetings or teaching duties and it would have been possible for her to leave these at short notice.

21. The Board were asked why Ms C had not been told this in the letter of 21 July 2005. They said the response had been based on comments by the Professor but he was on long term sick leave and could not comment further. They also said that they assumed that staff felt the letter of 21 July 2005 was a full response to the questions asked.

22. The Board confirmed that, as operating surgeon, it was the responsibility of the Professor to arrange for consent to be taken. He was able to delegate this and had likely done so here. They said he did act appropriately when he recognised that the consent as signed did not match the information given by Consultant 1.

(a) Conclusion

23. As the Adviser has concluded, and in line with what was recorded in the pathology report, I consider that Ms C underwent axillary sampling as agreed and not axillary clearance. However, the fact that this was not correctly documented in the consent form, in some of her notes, her discharge form and in the letters to Consultant 1 (see paragraph 9) did lead to Ms C's concerns that axillary clearance had occurred and to her subsequent complaint. The Board have apologised for the error in the letter and also for the method in which consent was taken. This was not in line with either their current or new draft policy on consent.

24. It is also unfortunate that the detail about why the Professor was in the theatre but Consultant 1 carried out the operation was not made available to either Ms C or this office prior to the first draft report being issued. I have noted that Consultant 1, who carried out the operation, did not appear to have been asked to comment in July 2005.

25. Despite the additional detail provided, no explanation has been given as to why the Professor did not ensure accurate, written consent had been obtained prior to surgery. While I remain concerned that a full explanation of events was not given to Ms C and the additional stress this has caused her, I would, though, like to commend the Professor for his actions when he realised that the consent given was in conflict with his conversation with Consultant 1. I would also like to commend Consultant 1 for deciding that, as she had been given verbal consent, she should carry out the operation herself. However, it remains the case that, prior to the operation, Ms C's express wishes (that she wanted to undergo axillary sampling) had not been correctly noted in line with their own policy on consent. Although my investigation has established that the operation itself was in line with her wishes; I partially uphold this complaint to the extent that the consent was not taken in line with policy prior to the operation and did not correctly document her wishes.

(a) Recommendation

26. The Ombudsman recommends that:

(i) when launching the new policy on consent, the Board arrange appropriate training for staff to ensure it is fully implemented and audit its implementation to confirm that it is being followed consistently; and

(ii) the Board ensure that all staff are aware of the need to provide full explanations when responding to complaints and that staff dealing with complaints contact all appropriate staff for comment when doing so[4].

(b) During subsequent radiotherapy treatment at the Centre, the total armpit area was irradiated

27. Consultant 1 referred Ms C to the Centre for radiotherapy. Her letter of 2 April 2004 to the Centre said Ms C had only had an axillary sample but did not note Ms C's concerns about lymphoedema. Ms C attended the Centre between April and August 2004 and on 1 September 2004 wrote saying she had grave

[4] On this point the Ombudsman would draw the Board's attention to the recommendation for a general review of complaints handling in report number 200500103 published in March 2007.

concerns that she had been irradiated unnecessarily. She said that during the third or fourth week of radiotherapy the total area of her axilla and left breast broke down leaving the skin looking like 'raw beef'. Ms C said she had believed only the breast would be irradiated and repeated her concerns about lymphoedema.

28. On 19 October 2004 the Medical Director of the Centre (the Director) replied that the consultant who had been responsible for her treatment at the Centre (Consultant 3) advised that he had explained to Ms C the benefits of radiation treatment to the breast and the possible side effects. Consultant 3 had also said that he had told Ms C the axilla would not be treated and the Director could confirm that this was the case.

29. A meeting was then arranged for 14 December 2004. The Director gave a detailed explanation of the treatment Ms C had undergone. He said that part of the armpit skin (not the axilla) was radiated to ensure all breast tissue (including the axillary tail of the breast) was included in the treatment. He said when radiation was aimed directly at the skin there is no radiation effect for the first few millimetres but that blistering can occur in skin folds. Staff try to keep the skin as flat as possible. Sometimes the skin reaction is more severe because of individual sensitivity. The Director said he did not believe the rash on her right breast could be related to the radiotherapy on her left or to her use of Tamoxifen. He agreed to review the treatment plans and on 13 January 2005 Ms C received further information based on information from an x-ray film. She was informed that the Director had said that nodes at levels 2 and 3 of the axilla could not have been treated with the fields used but that 'Any residual nodes (after the sentinel node excision) in the lower most part of the axilla (lower level 1) will have been included, but [the Director] believes that is always the case in radiotherapy to the whole breast'.

30. Ms C complained to the Ombudsman that she felt the only reason she was advised to have radiotherapy was because Consultant 1 knew there had been a clearance and that she understood, because her tumour was small, oestrogen positive, nodes negative, and she was prescribed Tamoxifen, there was no need for radiotherapy. In any event, she had agreed to only have the breast irradiated and said she still did not know whether the axilla was irradiated or not. She said she suffered from post irradiation morphoea (skin discomfort and redness).

31. The Adviser has confirmed that it is normal practice to give radiotherapy to the breast even where the lymph node is negative. 'Data from several prospective trials show that no radiotherapy doubles the risk of local recurrence.' The Adviser also said that 'Lymphoedema tends to arise as a result of a combination of axillary surgery and [radiotherapy]' and there would have been no need to mention this as a possible side effect.

32. The Adviser said further:

'Morphoea was diagnosed on a skin biopsy taken from [Ms C's] right thigh. [The Professor] had obtained advice from a dermatological colleague who said that it was highly unlikely that this had been as a result of her radiotherapy or Tamoxifen. Radiotherapy causes skin changes but only in the area irradiated.'

33. In conclusion the Adviser said that:

'I have no doubt in my own mind that she did not receive [radiotherapy] to her axilla other than to the axillary tail. I believe her to have had correct treatment and caring treatment for her breast cancer.'

(b) Conclusion

34. On the basis of the advice given, I consider Ms C received appropriate care and treatment from the Centre and her axilla was not fully irradiated. I do not uphold this complaint.

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

22 August 2007

Annex 1

Explanation of abbreviations used

Ms C	The complainant
The Hospital	The Western Infirmary, Glasgow
The Centre	The Beatson Oncology Centre, Glasgow
The Board	Greater Glasgow (now Greater Glasgow and Clyde) NHS Board
The Adviser	Clinical adviser to the Ombudsman
Consultant 1	The consultant surgeon who performed the surgery on 24 March 2004
Consultant 2	The consultant surgeon who was named on Ms C's admission letter and discharge form to her General Practitioner
The Professor	The Professor of Surgery at the Hospital
SHO	The Senior House Officer who assisted Consultant 1 during Ms C's surgery
Consultant 3	The consultant at the Centre who treated Ms C
The Director	The Medical Director of the Centre

Annex 2

Glossary of terms

Axilla	The armpit
Axillary clearance	Removal of all lymph nodes in the axilla
Axillary tail	Part of the breast tissue which extends in to the axilla
Lesion	A broad term that can be used to describe almost any abnormality involving any tissue or organ due to any disease or any injury. In this report it should be taken as referring to the small, cancerous tumour in Ms C's left breast.
Localisation	The process by which a small tumour or lesion is located using a 'localising' needle while the patient is under anaesthetic
Lymph nodes	Small rounded or bean-shaped masses of lymphatic tissue surrounded by a capsule of connective tissue: they are located in many places in the lymphatic system throughout the body and filter the lymphatic fluid
Lymphoedema	A condition in which excess fluid called lymph collects in tissues and causes swelling
Morphoea	Skin changes that are localised to one or more patchy areas of skin that become hardened, dry, smooth and slightly pigmented
Oedema	Refers to conditions where too much fluid has accumulated in the body

Oestrogen positive	A positive result for oestrogen indicates that the cancer's growth is affected by the homone oestrogen and that it is likely to respond to hormonal therapy which deprives the cancer cells of oestrogen
Sentinal node	The first lymph node that receives lymphatic drainage from a tumor
Tamoxifen	An anti-oestrogen drug often prescribed to patients who have been diagnosed with breast cancer
Tumour	An abnormal mass or tissue – it may be benign or cancerous