Scottish Parliament Region: Lothian

Case 200500468: Lothian NHS Board

Summary of Investigation

Category

Health: Cancer; Clinical treatment/diagnosis

Overview

The complainant (Ms C) was concerned that her cancer could have been diagnosed earlier had the appropriate referral been made, and felt that Lothian NHS Board (the Board) failed to deal with her complaint in a satisfactory manner. During my investigation, concern was also raised over the content of a letter from a Consultant Surgeon regarding the investigation of Ms C's mammograms.

Specific complaints and conclusions

The complaints which have been investigated are:

(a) failure to make appropriate referrals despite agreed practice *(upheld)* the consequences of which had a devastating impact on Ms C's life *(not upheld)*;

(b) that the NHS complaints process took too long (*upheld*) and that the NHS Independent Review Panel's report did not reflect many of the issues raised and made no recommendations *(not upheld)*; and

(c) whether a question raised by a Consultant Surgeon regarding the appropriateness of the investigation of Ms C's mammograms was justified *(no finding)*.

Redress and Recommendations

The Ombudsman recognises that the Board have already taken steps to address the issues raised and, therefore, has no recommendations to make. She has, however, asked that the Board let her have further information about the monitoring of their referrals process.

Main Investigation Report

Introduction

1. On 13 May 2005 the Ombudsman received a complaint from Ms C that Lothian NHS Board (the Board) failed to refer her correctly following her diagnosis of lobular carcinoma in situ (LCIS). Ms C complained that as a result her breast cancer was not diagnosed as quickly as it should have been. She believed that she, therefore, required more extensive treatment than would have been the case if an earlier diagnosis had been made and also that her life expectancy had been adversely affected. Ms C complained through the NHS complaints procedure but remained dissatisfied at the conclusion.

2. Ms C's complaints to the Ombudsman which I have investigated are:

(a) failure to make appropriate referrals despite agreed practice, the consequences of which had a devastating impact on Ms C's life; and

(b) that the NHS complaints process took too long and that the NHS Independent Review Panel's report did not reflect many of the issues raised and made no recommendations.

During the investigation Ms C raised a further matter, on which I asked the Board to comment. Therefore, the investigation additionally considered:

(c) whether a question raised by a Consultant Surgeon regarding the appropriateness of the investigation of Ms C's mammograms was justified.

3. Ms C raised further points about the possibility that she might have been included in drug trials, which Ms C understood had already started at the Western General Hospital (the Hospital) at the time. She was particularly unhappy that she believed she had lost the opportunity to participate in the trials. In her letter of 22 August 2005, however, Ms C noted that she might not have been chosen for the trial even if she had been a patient at the Hospital, that she might not have been in the group that received the drug and that it might not have worked for her. The range of variables meant that any conclusion could only amount to speculation and, therefore, I did not investigate this complaint.

4. During this investigation I have had access to the letters and documents sent by Ms C to the Ombudsman, Ms C's clinical records for the relevant period and the

complaint correspondence. I corresponded with the Board and I had access to SIGN Guideline 29: Breast Cancer in Women (published October 1998). I also obtained clinical advice from a clinical adviser to the Ombudsman (the Adviser), and my conclusions are based on that advice.

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

Investigation

6. On 30 September 1999 Ms C attended a breast screening at which an abnormality was identified. She was recalled on 3 November 1999 for further mammograms to be taken and for clinical examination which showed microcalcification in her right breast. Core biopsies were carried out on 10 November 1999 and Ms C was reviewed a week later by a multi-disciplinary assessment team which consisted of a Consultant Breast Surgeon (Consultant 1), a Consultant Radiologist and the Clinical Director for the South East Scotland Breast Screening Programme. Consultant 1 told Ms C that she had been diagnosed as having LCIS which is not a cancer but refers to changes found in the cells in the lining of the milk-producing lobes of the breast. LCIS is a significant risk factor for bilateral breast carcinoma.

7. Consultant 1 wrote to Ms C's GP on 17 November 1999. He confirmed the finding of LCIS and said that this normally indicated an increased cancer risk factor that required more regular observation. Consultant 1 did not quantify the level of increased risk but said that he would see Ms C again at his clinic at the Hospital in three months. On 29 November 1999, however, Ms C's GP asked Consultant 1 to see Ms C again to clarify the diagnosis.

8. Consultant 1 wrote to Ms C's GP on 10 January 2000, saying that he had seen Ms C again on 7 January 2000. He said he had again explained to her that a diagnosis of LCIS simply reflected that there was an increased risk of Ms C developing breast cancer. Because of that, all that was advised was to have an annual examination and mammography. He said that further follow-up would be at the Breast Screening Unit (the Unit). On 11 January 2000 the Director of the Unit

told Ms C she would have a three month appointment with Consultant 1 and a one year appointment for screening at the Unit.

9. Ms C attended the Unit on 27 September 2000 for further mammograms. She was told by letter that there was no sign of breast cancer and her next screening would be in about two years time. Her doctor was sent details of the outcome of the examination and told that Ms C had been 'returned to the routine screening programme'.

10. Ms C attended a further appointment at the Unit on 24 April 2002 following which she was told by letter that the examination was satisfactory, there was no evidence of breast cancer and she would be invited again for her next screening in three years.

11. On 4 September 2003 Ms C's GP asked that she be seen urgently as she had a lump in her right breast. On ultrasound scan this was seen to be a cyst but the ultrasound scan also detected suspicious areas in both breasts which on core biopsy proved to be malignant. Ms C had breast cancer in both breasts and in November 2003 underwent a bilateral mastectomy with clearance of the lymph nodes, followed by chemotherapy.

(a) Failure to make appropriate referrals despite agreed practice, the consequences of which had a devastating impact on Ms C's life; and
(b) That the NHS complaints process took too long and that the NHS Independent Review Panel's report did not reflect many of the issues raised and made no recommendations

12. I normally report on the investigation of each element of the complaint separately, but as the explanations provided to Ms C about the referrals are an integral part of the history of the handling of her complaint, I have reported these facts under one heading in this report. The conclusions I have reached are, however, reported separately (at paragraphs 23-28).

13. Ms C first raised her concerns in a letter to the Clinical Director of the Scottish Breast Screening Programme dated 13 December 2003. In that letter she said that she considered that she should have had annual mammograms and that although

that would not have prevented cancer developing, her condition could have been picked up and treated earlier and possibly less invasively if she had.

14. The Chief Executive of the Board wrote to Ms C on 17 February 2004. He said that following diagnosis of LCIS there is a need for more regular observation and it is normal procedure for this to be done annually at the Hospital. In Ms C's case, however, she was advised that her follow-up would be undertaken at the Unit. The follow-up appointment took place there on 27 September 2000 and the mammography did not identify any concerns. It was at that point that an error had been made regarding her recall. The Unit did not recognise that it had the specific responsibility to carry out Ms C's annual screenings. Ms C was thereafter returned to routine screening (i.e. the normal three-yearly screening programme).

15. The question of annual follow-ups was raised with Consultant 1 when Ms C complained. In his response to the Clinical Director he said that he had been new to the Department when he saw Ms C. He was not fully aware then that protocols stated that with a diagnosis of LCIS Ms C should have been followed-up at the Hospital, and not the Unit. The decision to send her to the Unit had been taken at the time of the multi-disciplinary meeting and his recollection was that the suggestion had come from the Unit. In his letter to Ms C the Chief Executive said that this decision was not correct. He said that there was no doubt that Ms C should have received annual screenings as a risk factor had been identified. He apologised for the failure to screen her annually. He said that the Unit followed protocols whereby only one recall appointment was made and then women were returned to routine (three-yearly) screening. The reason for this is that the Unit follows only 'well-women' whereas women (such as Ms C) with an increased risk who needed more frequent follow-up are seen at the Hospital.

16. Ms C responded on 7 March 2004. She said that she accepted that mistakes can happen and procedures could break down and that is what had happened when she was referred to the Unit instead of the Hospital. Ms C disputed, however, that the significance of the original diagnosis or that the need for annual checks was explained to her. She also thought that her treatment should have been the same wherever it took place.

17. The Chief Executive responded with further explanation but Ms C remained dissatisfied and wrote again on 9 May 2004. She noted that Consultant 1 said that he had told her of the increased risk and the need for annual mammograms but that was not her recollection. She would have to agree to differ over the content of those discussions. Ms C also questioned the practice of informing women by letter if there was no problem but giving the results orally at a meeting if there was. Ms C suggested that given the charged atmosphere at such meetings they should be followed up with a letter to the patient confirming the diagnosis, implications and possible treatment plans.

18. On 2 June 2004 the Chief Executive wrote to Ms C again. He said that the Director had written to everyone concerned to remind them that those requiring annual review should be seen at the Hospital. He also said that Ms C's suggestion on the benefit of written information had been accepted and information leaflets were being developed.

19. In Ms C's response on 19 June 2004 she said she was surprised that no steps had been taken until then to ensure that women requiring follow-up were referred to the Hospital. On 8 July 2004 the Chief Executive confirmed that had always been the policy but it was reiterated because of her case.

20. Despite further correspondence Ms C was dissatisfied. On 25 October 2004, in line with the NHS complaints procedure operating at the time, she requested an Independent Review of her complaint. An Independent Review Panel (IRP) was convened, terms of reference were agreed and two Clinical Assessors were appointed who each provided a report for the Convenor of the IRP. A draft report was issued on 4 April 2005 and Ms C was invited to comment, which she did. The final report was issued on 20 April 2005. It identified communication failures between the two departments involved. It also recognised that Ms C had been followed-up at a clinic for 'well-women' when she was in reality at risk with a relatively rare condition and should have been provided with specific regular follow-up. The Panel made no recommendations, however, saying that measures were now in place to refer women appropriately and support them. Ms C remained dissatisfied and on 13 May 2005 she complained to the Ombudsman.

21. Ms C pointed out to the Ombudsman that the reasons for referral to the Unit were not documented in her clinical notes. One of the terms of reference of the IRP was to review current arrangements to give reassurance that the system had been changed to avoid similar situations arising. At the IRP meeting evidence was taken from the new Clinical Director of the Screening Service (who had taken up her post in April 2002). On 25 February 2004 the Clinical Director had issued a Memorandum to all surgeons, radiologists and pathologists confirming the policy of referring women to the Hospital. When the complaint was investigated, the Clinical Director explained that clear protocols are now in place for the management of patients with LCIS. All such cases are discussed at a multi-disciplinary meeting and the outcome of the meeting is recorded. She also said that on appointment to the Unit all new consultants are now given an induction pack with all of the department protocols together with the appropriate leaflets.

22. There is no adequate note of the multi-disciplinary team meeting at which it was decided that Ms C should be referred to the Unit rather than the Hospital for follow-up. Consultant 1 has explained that he did not know what the policy was as he was new, and said that his recollection is that Ms C was referred there so that she would have 'benefit from continuity of staff'. He also said that this suggestion came from the then Clinical Director of the Unit, at the multi-disciplinary meeting. Information from the Unit also suggests that the then Clinical Director had accepted responsibility for undertaking ongoing annual reviews of Ms C (and that this was most unusual) but acknowledges that there is no clear record of the reason for this and that protocols were not clearly understood. Given, however, the time that has passed and the changes that have been made since these events I did not deem it appropriate or necessary to further investigate the specifics of this. I simply note that there is no clear evidence available to enable me to understand why the decision was taken.

(a) Conclusion

23. LCIS is not a common condition and it is, therefore, important that protocols associated with it are clearly laid out and understood. It is clear from the papers I have seen that the protocol for women with the condition is that a yearly mammogram should be carried out for 10-15 years at the Hospital (not at the Unit). The Adviser has confirmed that this is the advice that is usually given. This, however, clearly did not happen in Ms C's case.

24. Although protocols existed about follow-up there is evidence that they were not clearly known to all staff (paragraph 22), and I have seen no evidence that they were formally recorded in an accessible way. Consultant 1 said that he had been new to the Department at the time and so he was not fully aware of the protocols. This was clearly relevant to the failure to arrange annual appointments for Ms C at the Hospital. However, the evidence I have seen suggests that this decision was taken by the team involved in Ms C's care, not by Consultant 1 alone. The fact that Consultant 1 was new to the position and that Ms C's condition was uncommon does not excuse the fact that the multi-disciplinary team failed to follow the relevant protocol. I, therefore, uphold Ms C's complaint that she was incorrectly referred.

25. I agree with Ms C that there is no recorded explanation of why the multi-disciplinary team did not follow the protocol in her case. It is clear from the information I have seen (paragraph 22) that it was exceptional that she was referred to the Unit for annual screening, so I would expect the reasons for the decision to have been recorded. The fact that they were not is in itself unsatisfactory and had this remained unaddressed the Ombudsman would have made recommendations accordingly. Prior to the involvement of our office, however, the Board had reviewed procedures in the light of Ms C's experience and had put in place significant measures (paragraph 21) to avoid this situation happening again. I am satisfied that these were appropriate. The Ombudsman, therefore, has no further recommendations in respect of this element of the complaint. She does, however, ask that the Board notifies her of the measures they have put in place to monitor that practice is being correctly followed and to let her know the results.

26. Ms C said that she considered that the failure to screen her annually had a devastating effect on her health. She suggested that the abnormality in her left breast, which was detected in September 2003 and which led to further investigations, might have been detected in April 2003 had she been recalled at that time. The Adviser pointed out, however, that the cancer itself was not detected by mammography in September 2003. The cancer would not, therefore, have been seen even if mammograms had been done in April 2003 (one year after the previous mammogram of April 2002). The Adviser also said that even if the abnormality had been seen in April 2003 the short time difference involved (five months – April to September) would have meant that the treatment was likely to

have been exactly the same. I am, therefore, not persuaded that there is evidence that the failure to screen Ms C annually specifically affected her treatment or her health. I do not uphold this part of the complaint, although I fully recognise that Ms C has indeed had a devastating experience and has had to have long and difficult treatment as a result of developing breast cancer.

(b) Conclusion

27. Ms C first raised her concerns with the Board in a letter dated 13 December 2003. Paragraphs 13-21 reflect that then, over a long period of time, considerable correspondence passed between Ms C and the Board as she sought information about her complaints. The IRP Report was issued on 20 April 2005 (some 16 months after Ms C's initial letter) and I agree that this process took too long. The length of time that the old NHS complaints process took was a matter of general criticism throughout the country. I uphold this part of Ms C's complaint. I recognise, however, that the NHS complaints procedure has now been changed with all but the initial resolution stage being abolished. The Ombudsman, therefore, has no recommendations in respect of this aspect of the complaint.

28. Ms C does not accept that the IRP Report is fair and accurate. It is, however, my view and that of the Adviser that the Report, taken in conjunction with the two clinical assessments provided, is appropriate and fairly summarises the core of the problem, which was a lack of communication and understanding. It also noted that the Board had made improvements that addressed the reasons for the problem. That is why the Report itself contained no recommendations. I am satisfied that this was appropriate as the issues had already been addressed. I, therefore, do not uphold this part of Ms C's complaint.

(c) Whether a question raised by a Consultant Surgeon regarding the appropriateness of the investigation of Ms C's mammograms was justified

29. On 9 July 2005, Ms C drew my attention to a copy of a letter from another Consultant Surgeon (Consultant 2) dated 23 December 2003. In the letter, addressed to the Clinical Director of the Screening Service, Consultant 2 said:

> 'The mammogram report in 2003 suggested the calcifications present on the films were unchanged from those of 2001. It is interesting, however, that further views of this calcification suggested they were suspicious. The issue this raises is were the 2001 calcifications appropriately investigated?'

Ms C raised this with me because she was concerned that earlier mammograms might not have been reviewed properly.

30. I asked the Board to comment on this and received a reply from the Chief Operating Officer. Before replying he referred back to the Consultant Surgeon who wrote the original letter that had raised Ms C's concerns. The Chief Operating Officer said that in fact there was no mammography done in 2001. Mammogram films were held for 1999, 2000, 2002 and 2003. The mammogram report on films taken on 16 September 2003 makes comparison with the films of 24 April 2002. In the report, a new opacity on the right breast was considered benign. On the left breast an area of possible distortion was noted. Benign type microcalcification was also noted, showing no change from 24 April 2002. He confirmed that on further review this statement was felt to be appropriate.

31. Because of the possible area of distortion in the left breast a further view was requested and performed on 22 September 2003. That extra film showed that the calcification around the area of distortion was more extensive than could be seen on the standard film and as such was slightly suspicious. Core biopsies of these calcifications were recommended. At the same time, however, Ms C had bilateral ultrasound and carcinomas were detected in both breasts. The calcifications were, therefore, not biopsied separately.

32. The Chief Operating Officer also pointed out that the core biopsies from 2003 show that calcification in the right breast was benign and that in the left breast was a mixture of benign and malignant pathology. He said that it is, therefore, not possible to say whether the calcification seen on the mammogram in 2002 was malignant, it may in fact have been benign. As a consequence, it is possible that even if a biopsy had been performed in 2002 the result might have yielded benign pathology.

33. As a result of my request four radiologists have reviewed Ms C's mammograms of 1999, 2000, 24 April 2002 and 16 and 22 September 2003. On reviewing the screening films of 24 April 2002 they have agreed with the initial judgement made on the oblique films that the calcification had not changed since 2000 or 1999. In view of this and taking into account both the knowledge available about calcification and the radiological practice at the time they considered this

was an appropriate decision. They noted that similar calcification was biopsied in the right breast in 1999 and was found to be benign with LCIS being an incidental finding. This was confirmed by a Consultant Pathologist at a recent review.

34. I note that in the letter described in paragraph 29, Consultant 2 went on to comment that he had explained to Ms C that he also felt it unlikely that the cancers would have been diagnosed on earlier mammograms as there had been little change in what could be seen. He said:

> 'I informed [Ms C] that even if she had had mammograms earlier, then given the lack of change - I showed her the 2003 report, which in essence said that apart from a bit of distortion, there had not been a major change in mammograms since 2001 - it is unlikely the cancers would have been diagnosed on earlier (2002) mammograms.'

(c) Conclusion

35. Firstly, there were no mammograms taken in 2001. The mammograms to which the 2003 mammograms were compared were those from 2002. The opinion of radiologists who have since reviewed the mammograms was that the calcification detected in 2002 was appropriately investigated as judged by the knowledge and practice at that time. I note that the Board took this matter seriously and have reviewed the relevant films. This action was appropriate. I am satisfied on the evidence provided that Ms C's mammograms have been thoroughly reviewed and that no specific cause for concern has been found.

36. The Consultant Surgeon's letter understandably caused Ms C to question whether her mammograms had been appropriately reviewed. My reading of his letter, however, is that he merely raised a question about the calcifications rather than giving a firm opinion that they were not appropriately checked. He said quite clearly in the same letter that he considered there was little change in the mammograms taken and examined over time. I am, therefore, not able to reach a finding on this as a specific complaint, but I note that the Consultant Surgeon was entitled to raise the question.

30 January 2007

Annex 1

List of abbreviations used

Ms C	The complainant
The Board	Lothian NHS
LCIS	Lobular carcinoma in situ
The Hospital	Western General Hospital, Edinburgh
The Adviser	Clinical adviser to the Ombudsman
The Unit	Breast Screening Unit
SIGN	Scottish Intercollegiate Guideline Network
Consultant 1	A Consultant Breast Surgeon, one of the multi-disciplinary team working with Ms C following her initial diagnosis with LCIS
IRP	Independent Review Panel
Consultant 2	A second Consultant Breast Surgeon who later took over Ms C's care

Annex 2

Medical terms used

Biopsy	Removal of tissue from the body for microscopic examination and diagnosis
Carcinoma	A cancer that develops from tissues covering or lining organs or glands of the body
Lobular carcinoma in situ (LCIS)	Changes found in the cells in the lining of the milk-producing lobes of the breast. May result in increased risk of breast cancer
Microcalcification	Particles observed on a mammogram that are found in the breast tissue, appearing as small spots on the picture. These usually occur from calcium deposits caused by the death of breast cells which may be benign or malignant. When clustered in one area they may indicate the presence of cancerous cells