Scottish Parliament Region: Glasgow

Case 200700709: Greater Glasgow and Clyde NHS Board

Summary of Investigation

Category

Health: Clinical treatment/Diagnosis

Overview

The complainant (Mr C) complained on behalf of his wife (Mrs C), concerning the care and treatment she received prior to being diagnosed as having ovarian cancer.

Specific complaints and conclusions

The complaints which have been investigated are that:

(a) Mrs C's care and treatment were inadequate and, despite her history of breast cancer and an ovarian cyst, no follow-up appointment was made for her in November 2003 *(upheld);*

(b) in Mrs C's circumstances, a hysterectomy should have been considered much earlier (*not upheld*); and

(c) Mrs C's treatment was dictated by financial concerns *(not upheld*).

Redress and recommendations

The Ombudsman recommends that Greater Glasgow and Clyde NHS Board (the Board) proffer a sincere apology to Mrs C for the failure to treat her properly. Further, in view of the Consultant's comments about not doing anything differently, and given the Board's comments at paragraph 15, the Ombudsman requests that the Board provide her with a copy of the 2008 audit of Guideline 34.

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

Main Investigation Report

Introduction

1. On 25 June 2007, the Ombudsman received a complaint from Mr C on behalf of his wife (Mrs C), concerning the care and treatment she received prior to being diagnosed as having ovarian cancer. Mr C said that, in 1999, Mrs C was diagnosed with, and treated for, breast cancer. Later, in November 2003, Mrs C was admitted to the Southern General Hospital (the Hospital) in Glasgow bleeding heavily from a polyp in her uterus. Prior to the polyp being removed, she was scanned and an ovarian cyst was revealed, however, after the operation for the removal of the polyp Mrs C was released from hospital without any follow-up being required.

2. In 2004 Mrs C had her gall bladder removed but her general health did not improve and, in January 2006, she was sent for a colonoscopy. While the colonoscopy was apparently clear, blood tests taken at the time revealed that his wife had ovarian cancer. Mr C said there were also indications that her liver was affected. Mrs C has since had a hysterectomy and undergone six months of chemotherapy.

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

(a) Mrs C's care and treatment were inadequate and, despite her history of breast cancer and an ovarian cyst, no follow-up appointment was made for her in November 2003;

(b) in Mrs C's circumstances, a hysterectomy should have been considered much earlier; and

(c) Mrs C's treatment was dictated by financial concerns.

Investigation

4. The investigation of this complaint involved obtaining and reading all the relevant documentation, including correspondence between Mr C and Greater Glasgow and Clyde NHS Board (the Board). I have had sight of Mrs C's medical records and the Board's complaints file and I have also sought advice from an independent medical adviser (the Adviser). On 2 November 2007 I made a formal enquiry to the Board advising them of my intention to investigate and their response to me was dated 13 November 2007.

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

(a) Mrs C's care and treatment were inadequate and, despite her history of breast cancer and an ovarian cyst, no follow-up appointment was made for her in November 2003

6. In September 1999 Mrs C was diagnosed with a carcinoma of the left breast. At that time she was 39 years old. Mrs C was treated with chemotherapy followed, on 3 March 2000, by surgery with subsequent follow up radiotherapy. It is noted in a letter of 15 March 2000 that the chemotherapy initiated amenorrhea (cessation of periods) right from when it commenced.

7. Mrs C subsequently remained well concerning follow-up with her breast cancer but on 19 August 2003 she was referred by her GP to the Gynaecology Department at the Victoria Infirmary, Glasgow, with a history of vaginal bleeding over the preceding few months. However, before she could be seen in the Gynaecology Clinic, Mrs C was admitted through the Accident and Emergency (A&E) Department on 29 August 2003 with an episode of heavy vaginal bleeding. Mrs C was admitted to Ward 50 and was subsequently discharged, with a diagnosis of a large fibroid polyp protruding from her cervix. Mrs C was given medication to reduce the bleeding. An ultrasound scan and a gynaecology out-patient appointment were organised.

8. Mrs C was seen in the gynaecology out-patients department on 8 September 2003 by a registrar (the Registrar), when it was recorded that Mrs C's last menstrual period had been in 2000 but that she had been experiencing vaginal bleeding on a daily basis since April 2003. Examination at the time confirmed the presence of a 5 x 3 centimetre fibroid-like polyp. An ultrasound scan (both transvaginal and transabdominal) revealed an endometrium (lining of the womb) thickened to 1.28 centimetres and a right ovary that contained a 2.1 centimetre cyst or follicle. This was referred to in the Registrar's subsequent letter (of 16 September 2003) to the GP and a decision was made for admission for removal of the fibroid polyp and hysteroscopy (a procedure using a small telescope to visualise the inside of the uterine cavity) to be performed under general anaesthesia.

9. Mrs C underwent surgery on 25 November 2003 to remove the large fibroid polyp and, additionally, hysteroscopy was undertaken. This revealed a

normal endometrium with a small fibroid at the top of the uterus. A sample of the endometrium was obtained and sent for histology and the doctor who carried out the operation wrote to Mrs C's GP on 27 November 2003 describing her operation and treatment and mentioned that if she continued to bleed heavily, sufficient to make her anaemic, then she may well require a hysterectomy because of her fibroid uterus. This doctor wrote again to Mrs C's GP, enclosing a copy of the histopathology report received, but in neither of the letters was any mention made of the small ovarian cyst/follicle seen on the ultrasound scan (see paragraph 8).

10. In June 2004 Mrs C was referred for the removal of her gall bladder and surgery was undertaken on 4 July 2005. No follow-up was arranged following on from this procedure but on 30 December 2005 Mrs C was urgently re-referred by her GP to hospital with a number of symptoms which concerned him. He asked for an urgent appointment. A CT scan was taken on 13 January 2006 and this showed the presence of tumour deposits within the liver, extensive ascites, peritoneal thickening and bilateral complex cystic masses in the ovaries. The question was raised as to whether these findings were due to recurrent breast cancer or a primary ovarian malignancy. Fluid was tapped from the abdomen but this did not give a firm diagnosis and subsequent diagnostic laparoscopy with biopsy was undertaken on 1 March 2006. The tumour markers CA125 and CEA were both significantly elevated, at 1159 and 373.6 respectively. (A tumour marker is a chemical produced by cancer cells that can be picked up in a blood test. The level of the marker goes up as the cancer grows. CA125 is a tumour marker for ovarian cancer and CEA is a marker for the presence of colon, lung and liver cancers.) In the light of the then presumed diagnosis of ovarian cancer, surgery was undertaken on 11 April 2006, removing uterus tubes, ovaries and omentum (an area of fatty tissue within the abdomen affected by the tumour. Additionally, a liver biopsy was undertaken. A letter to Mrs C's GP of 2 May 2006 confirmed her diagnosis as an ovarian papillary serious cystadenocarcinoma, although the liver biopsy was more in keeping with recurrent breast cancer. Chemotherapy was then commenced.

11. Mr C's concerns related to the quality of care and treatment his wife received. It was his belief that medical staff missed an opportunity to deal at an earlier date with what became his wife's ovarian cancer. He believed she should have been followed up after she had undergone surgery in November 2003 (see paragraph 9). However, the Board's view was that, at the

time of her admission and treatment in 2003, medical staff were concerned about two things: to identify and stop the source of Mrs C's bleeding; and to establish whether she was at risk of cancer of the endometrium (the lining of the uterus), as women with a history of breast cancer have a slightly greater risk of this. The histology of the polyp showed this to be the source of the bleeding and tests showed that the rest of the lining of Mrs C's womb was normal. This being so, there was no evidence to support carrying out a hysterectomy at that time. The Board also sought comment from the consultant obstetrician and gynaecologist concerned (the Consultant) who commented that 'a 2cm cyst would not be regarded as an abnormal finding, even with [Mrs C]'s prior history of cancer'. The Consultant said that it had been decided not to follow up Mrs C in 2003 after he had made reference to guidelines and an appropriate scoring system. In relation to these, the Consultant said that, while there were recommendations about four month follow-up on cysts of 2 centimetres to 5 centimetres, there was still debate about what to do with 2 centimetre cysts. A hysterectomy was not thought to be required, as the lining of Mrs C's womb showed nothing abnormal. He commented in a letter that was sent to Mr C on 5 June 2007 that 'if he were presented with a similar case then he would not change anything'. Essentially, in the Board's view, Mrs C was given appropriate treatment and Royal College guidelines (the Guidelines) had been followed.

12. I specifically sought independent advice about this. The Adviser told me that only one reference had been made to the cyst identified in September 2003 (see paragraph 8) and that was in the Registrar's letter to the GP on 16 September 2003 (see paragraph 8). The cyst was referred to in the scan report as either a cyst or a follicle. This latter was the small cyst which developed during a menstrual cycle and contained an egg. These follicles can reach between 1.8 centimetres and 2.2 centimetres in size before ovulation occurs and can sometimes persist after ovulation as a corpus luteum cyst (these can grow to 2 centimetres to 5 centimetres in size) thus, the Adviser said, the findings of a cyst or follicle measuring some 2.1 centimetres in a pre-menopausal woman would normally be taken as a reflection of the stage of the cycle in which the scan was undertaken. At the time of the ultrasound scan in 2003 (see paragraph 8) Mrs C was 43 years old and, the Adviser said, under normal circumstances would be considered to be pre-menopausal. He indicated, however, that Mrs C's situation was complicated in the light of her previous chemotherapy. While he said that there appeared to be some confusion in the notes as to whether Mrs C was truly menopausal or not - as the admitting notes to A&E (see paragraph 7) suggested that her last period was in

April 2003 – nonetheless, he said that it was clearly recorded in earlier correspondence that Mrs C's periods stopped after the commencement of chemotherapy (see paragraph 6) and the Registrar who conducted the out-patient consultation on 8 September 2003 recorded that Mrs C had been menopausal from 2000. In the Adviser's opinion, the admitting doctor in A&E was confusing the situation with the onset of Mrs C's presenting symptom of vaginal bleeding. The focus of investigation and treatment at that time (August 2003) was, he said, clearly related to Mrs C's vaginal bleeding, which was secondary to the large fibroid polyp, and the decision to proceed with the removal of the polyp and the hysteroscopy was entirely appropriate management for this condition. Nonetheless, no further reference was made to the ovarian cyst/follicle and, in the Adviser's view, it appeared that this was subsequently overlooked by members of the team who were responsible for Mrs C's care and treatment. In particular, it was not mentioned in the correspondence to the GP in late 2003 (see paragraph 9). The Adviser also commented that, from the records available, it was unclear whether staff managing Mrs C at the time of the hysteroscopy were aware of the 2.1 centimetre cyst or not, as no further reference was made to it but that it was clearly recorded on the ultrasound scan report. He said he would have expected any surgeon undertaking surgery to review the notes fully before commencing. Its presence should have been noted and a plan of management recorded.

13. The Adviser commented that the management of small ovarian cysts, that is, those ranging in size of between 2 centimetres and 5 centimetres, which have been found in post-menopausal women have been a difficult diagnostic problem and have led to the publication of a Royal College of Obstetricians and Gynaecologists guideline number 34. This is entitled 'Ovarian Cysts in Post Menopausal Women' and was published in October 2003, thus falling between the date of Mrs C's initial consultation on 8 September 2003 and her subsequent surgery on 25 November 2003. Amongst the recommendations made is that ovarian cysts in post-menopausal women should be assessed both with ultrasound and with the tumour marker CA125. It is then possible, by using features of ultrasound scan appearance of the cyst, menopausal status and from information obtained from CA125, to calculate a 'Risk of Malignancy Index' (RMI). The Adviser said that, although in Mrs C's case no CA125 appears to have been undertaken, it was still possible to calculate the RMI as the cyst/follicle had none of the alerting factors indicated in the Guidelines and thus the ultrasound score was zero. Given this finding, the RMI must have been

zero. This would, therefore, have put Mrs C into a low risk group. However, the Adviser went on to emphasise that the Royal College recommended that all simple unilateral cysts of less than 5 centimetres were managed conservatively provided that the CA125 level was normal. Although Mrs C's cyst/follicle measured 2.1 centimetres, no CA125 had been undertaken but, even in the low risk category (that is, when the CA 125 level is normal), it was recommended that a follow-up ultrasound scan was undertaken after an interval of four months. The Adviser said that the recommendation continued with the statement, 'This of course depends upon the views and symptoms of the women and on the gynaecologist's clinical assessment'. In Mrs C's case, no further comment is made with regard to the cyst/follicle following on from the consultation on 8 September 2003 (see paragraph 8). The Adviser said that no further consideration appears to have been made concerning the cyst although, at 2.1 centimetres in a post-menopausal woman, it clearly fell within the Guidelines. He added that, additionally, Mrs C was in a higher risk category as she had a previous history of breast cancer and he expressed surprise at the Consultant's comments that he would not change anything about Mrs C's treatment (see paragraph 11) because, he said, at the very least a plan of management should have been drawn up and discussed with the patient. The Adviser made the point that the Guidelines were available from October 2003 and at the time of the Consultant's comment about not changing anything (see paragraph 11).

14. Given the opinion of the Adviser, in my formal letter of enquiry (see paragraph 4) to the Board, I asked the reasons why Mrs C had not been assessed in accordance with Guideline number 34. The response I received was that the Consultant 'does not wish to speculate about the division's application of a Royal College of Obstetricians and Gynaecologists' guidelines which was first published between the dates of [Mrs C]'s initial assessment and her day surgery for a uterine polyp'. With regard to a follow-up ultrasound, the Consultant reiterated the view that ultrasound scans are 'well known to be an imperfect test from experience of their use in studies of screening for ovarian malignancy. It is not known if small cysts like the one identified in September 2003 are the precursors of advanced ovarian cancer'. He also said that while Mrs C's periods had stopped 'she was still only 43'. Although he accepted that Mrs C was at a higher risk of ovarian cancer because of her previous breast cancer, he said that he was unaware of any guidelines regarding ultrasound or RMI score adjustments in women in this category and that it was not covered by the Guidelines.

15. In commenting on the draft of this report, the Board said that it would not have been possible for them to have implemented a guideline within a month of its publication as it is normal practice to initiate a local review process to assess the guideline's applicability and, thereafter, where appropriate, develop an implementation plan. The Board said that between April and June 2005 they undertook an audit of Guideline 34, the outcome being to recommend a change of practice to reflect it. They said that a follow-up audit was due to be repeated this year and they have confirmed to me that their practice (and that of the Consultant) is now in line with Guideline 34.

(a) Conclusion

16. Mrs C had a history of breast cancer and it was noted in the clinical records that from March 2000 she had not had a period. In September 2003 she was then identified as having a polyp and a small cyst and, while the medical team dealing with Mrs C correctly prioritised dealing with the polyp which was the source of her bleeding first (see paragraph 11), they made no further reference to the cyst either in correspondence or in treatment. This was despite the fact that the Royal College recommends that all simple unilateral cysts of less than 5 centimetres are managed conservatively, where CA125 levels are normal (see paragraph 13). Mrs C had not had a CA125 marker undertaken so her CA125 level could not be presumed to be normal - as it had not been undertaken, the result was unknown. Conservative management recommended a follow-up ultrasound scan after four months. This did not happen and, despite the Consultant's opinion about ultrasound being an imperfect test for the screening for ovarian cancer, I have to conclude that Mrs C's treatment was not as it should have been. Although we will never know whether follow-up and a scan in Mrs C's case would have identified early onset ovarian cancer, this was an opportunity missed and possible options for treatment (including taking no action, as it may have been considered that the cyst would resolve spontaneously) were not considered. Notwithstanding the Boards comments about the implementation of the Guideline (see paragraph 15), upon which I have sought further advice, I have been told that the fact remains that the information contained in the Guideline was available to practitioners after publication and had the cyst/follicle not been overlooked then possibly it could have applied in this case. I am also concerned that the Consultant reported in the Board's correspondence with Mr C that 'he would not change anything' (see paragraph 11). I uphold this complaint.

(a) Recommendation

17. In the circumstances, the Ombudsman recommends that the Board proffer a sincere apology to Mrs C for the failure to treat her properly. Further, in view of the Consultant's comments about not doing anything differently, and given the Board's comments at paragraph 15, the Ombudsman requests that the Board provide her with a copy of the 2008 audit of Guideline 34.

(b) In Mrs C's circumstances, a hysterectomy should have been considered much earlier and (c) Mrs C's treatment was dictated by financial concerns

18. Mrs C has since had a hysterectomy but Mr C believed that this procedure should have been considered in 2003. He said that to have done so may have reduced Mrs C's subsequent problems. However, the Board's view was that the hysteroscopy in 2003 showed that the lining of Mrs C's womb showed nothing abnormal (see paragraphs 8, 9 and 11) and that histology revealed that the scrapings from the lining of her womb were also normal. In the circumstances, the Consultant did not consider this procedure to be necessary. The Adviser's view was also that, at the time of Mrs C's presentation in 2003, a hysterectomy was not indicated.

(b) Conclusion

19. I have to be guided by the Adviser in so far as care and treatment are concerned and, accordingly, I do not uphold this part of the complaint.

(c) Conclusion

20. Finally, throughout, Mr C has had a concern that his wife's treatment was dictated by finance and, while I note this, I have seen no evidence at all to support his suspicion. I do not uphold this aspect of the complaint.

21. The Board have accepted the recommendations in this report 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

Mr C	The complainant
Mrs C	The complainant's wife
The Hospital	The Southern General Hospital
The Board	Greater Glasgow and Clyde NHS Board
The Adviser	The independent medical adviser
A&E	Accident and Emergency
The Registrar	The registrar in the gynaecology out-patients department
The Consultant	The consultant obstetrician and gynaecologist
The Guidelines	The Royal College of Obstetricians and Gynaecologists Guidelines
RMI	Risk of Malignancy Index