Scottish Parliament Region: Mid Scotland and Fife

Case 200502186: A GP Practice in the Forth Valley NHS Board area

Introduction

1. On 14 November 2005 the Ombudsman received a complaint from a woman (referred to in this report as Ms C) about the care and treatment which she received from her local medical practice (the Practice) prior to her diagnosis with breast cancer.

2. Ms C said that she had raised her concerns about her breasts with the Practice since 2001 but the Practice had failed to diagnose breast cancer or refer her to a specialist. Ms C said she had also been refused a mammogram because she was not yet 50. Shortly after her 50th birthday Ms C went for a mammogram. As a result she was diagnosed with breast cancer. Ms C considered that the Practice should have diagnosed her breast cancer earlier, and/or that she should have been referred to a specialist or for a mammogram earlier in which case her breast cancer would have been diagnosed sooner and she would not have required such intensive treatment and her chances of long term survival would have been greater.

3. The complaint from Ms C which I have investigated was that the Practice should have diagnosed Ms C's breast cancer or should have referred Ms C to a specialist or for a mammogram.

4. Following the investigation of all aspects of this complaint did not uphold it.

5. A draft of this report was issued to both Ms C and to the Practice and both made comments. As a result, changes have been made in the report but the conclusion remains unchanged.

6. In the light of the issues raised in this investigation, the Ombudsman is of the view that it may be timely for the relevant SIGN guideline on breast cancer in women to be reviewed. She will draw this to the attention of Quality Improvement Scotland (QIS).

Investigation and findings of fact

7. The investigation of this complaint involved examining documents supplied by Ms C, Ms C's clinical records (including letters from the consultant who treated Ms C (Consultant 1) and Ms C's surgeon (Surgeon 1)) and the correspondence in connection with the complaint. I have also received clinical advice from the Ombudsman's independent adviser (the Adviser) and my conclusions have taken account of that advice.

8. Ms C wrote to the Practice on 8 March 2005. She said that on her own initiative, in December 2004, soon after reaching her 50th birthday she had attended for a mammogram check. She had been recalled for a biopsy which showed that she had a tumour in her right breast and in the lymph glands under her right armpit. The tumour and lymph glands had subsequently been removed. Scans of her liver and bones had proved normal and she was about to begin chemotherapy. Ms C described these events as having occasioned the most traumatic feelings of her life.

9. In her letter to the Practice Ms C said that she had always made a point of checking her breasts regularly and had regular checks at the Practice. In 2001 she had asked GP 1 (a doctor at the Practice at that time who has since left) to check her breasts as she was aware of thickening under her right armpit. At that time she had asked if she could be sent for a mammogram. GP 1 said that the NHS did not offer breast screening for women under 50, that it was quite in order to have breast tissue under the armpit and that Ms C did not have anything sinister. In 2004 Ms C asked GP 2 (another doctor at the Practice) to check her breasts. She told GP 2 that she was concerned about the thickening and lumpiness under her right armpit. GP 2 had also assured her that there was nothing unusual about that and when asked why it was not the same as Ms C's left armpit had replied that it might be because Ms C was right-handed. Ms C said that she again asked about getting a mammogram and was told that she would have to wait until she was 50. Ms C said that she was bitterly disappointed that a correct diagnosis was not made earlier[9].

10. On 10 March 2005 the Practice offered the option of an informal meeting or a written response.

11. Ms C replied that she would like the meeting followed by the formal

[9] Ms C did not mention in her letter that she had also raised her concerns with GP2 in 2003.

complaints process. Ms C also sent the Practice a copy of page 21 of a book *'Cancer Help*' by Marion Stroud. Ms C highlighted the paragraph which she considered to be relevant and which I quote here:

> 'Some women have naturally lumpy breasts which makes it difficult for them to sort out what is normal and what is not. Other women are considered to be at higher than normal risk because of family history of cancer of the breast. Both of these groups can be referred to a specialist breast clinic by their doctor.'

12. Ms C said that she considered that as she had lumpy breasts this meant that she should automatically have been sent for a specialist check. She said that when she saw GP 2 she had a lump in her breast or armpit and enlarged glands under her armpit. Ms C considered that she should, therefore, have been referred to a specialist at that time. Ms C asked why she had not been referred to a specialist on either occasion.

13. GP 2 wrote to Ms C on 8 April 2005. GP 2 said that when she had examined Ms C in April 2004 she did not detect any abnormality in her breasts or armpits which made her concerned about a possible malignancy in Ms C's breasts. GP 2 referred to her conversation with Ms C the previous week during which Ms C had told her that she had said to GP 2 in April 2004 that she wanted to have further examinations done. GP 2 said that she had not detected that from their conversation at the time otherwise she would have referred Ms C to the Breast Clinic at Stirling Royal Infirmary. Ms C had also told GP 2 during the conversation that she had so much trust in GP 2's reassurance at that time that she had not sought further investigation before she went for mammography straight after her 50th birthday.

14. In response to Ms C's complaint the Practice wrote to Consultant 1 on 8 April 2005 at the hospital where Ms C was being treated. They explained the circumstances and the advice which they had given to Ms C. They said that Ms C had said that when Consultant 1 saw her at his clinic he said that her tumour should have been picked up before and probably that GP 2 should have diagnosed it the previous April. They said that Ms C's case had caused a great deal of heart searching in the Practice as to whether they should be dealing with such cases differently and they hoped Consultant 1 would be able to give them some guidance. They asked:

1. How likely was it that the tumour was present in 2001?

2. Did Consultant 1, from his experience, feel that the tumour should have been palpable clinically in April 2004?

3. Was there an age above which they should refer anyone with lumpy breasts for mammography or should they continue their current practice of clinical examination and referral if there was a suspicious lesion?

They said that they would use the answers to discuss the matter within the Practice with a view to improving their care of women with breast problems.

15. Consultant 1 replied that he had not said that the tumour should have been picked up earlier. He had said that there was no way of knowing whether it could have been picked up earlier. He may have said that if screening mammography had been available to Ms C a year earlier it might have been picked up. With regard to the specific questions he responded as follows:

1. It was possible that the tumour could have been present in 2001 but if it was it would have been very small indeed and unlikely to be detectable clinically. Equally it was entirely possible that it had developed since then.

2. It is possible that the lesion may have been palpable in April 2004 but it would have been smaller at that time and the detection of small cancers in patients with lumpy breasts was never easy. Equally it might not have been palpable at that time. There was no way of knowing for sure.

3. The Practice's current policy was perfectly reasonable and they didn't need to change it. Most breasts are lumpy to a greater or lesser extent but providing the lumpiness does not feel suspicious and providing it is symmetrical when comparing one side with the other it is perfectly reasonable for the Practice to carry on as it was doing.

16. In a letter dated 10 June 2005 Ms C said that she accepted entirely what Consultant 1 had written. She accepted that he had not said that her tumour should have been picked up earlier. Ms C had said that she had made that comment and it was still her opinion. Ms C said that she had discussed the question of a mammogram with Consultant 1 and he told her they were available from age 35. Ms C asked the Practice to find out from Surgeon 1,

who had carried out her surgery, how long she had had the cancer.

17. The Practice wrote to Surgeon 1 on 27 May 2005. They said that Ms C thought that it might have been Surgeon 1 who commented about whether the tumour should have been diagnosed earlier. They asked whether he thought the tumour would have been palpable in April 2004 and if he knew how long Ms C had had the tumour.

18. Surgeon 1 replied on 7 July 2005. He said that he would not have thought the tumour could have been picked up earlier – quite the opposite in fact. At the time of Ms C's surgery he didn't think the tumour was palpable and if he had been asked to examine her breast without the presence of a mammogram he would not have been able to detect a clinical abnormality. Surgeon 1 said that Ms C's breast cancer would have been present for some time prior to diagnosis but that was the case with all breast cancers. As guidelines exist at the moment Ms C had no indication or suitability for mammography prior to the Breast Screening Service sending for her after the age of 50. Surgeon 1 said that he thought that the Practice's care of Ms C could not have been criticised in any way.

19. The Practice sent Consultant 1 a further list of questions on 8 July 2005 to which Ms C wished to have answers. The questions were:

1. What had he found on examination at the Breast Clinic in February 2005?

2. If GP 2 had made the referral to the Breast Clinic in April 2004 would the treatment have been different?

3. What was found during and after surgery?

4. Can the pathologist give the age of the cancer?

They explained that Ms C said that she was trying to establish whether the treatment or prognosis would have been different if she had been referred in April 2004.

20. Consultant 1 replied on 5 August 2005 in the following terms:

1. When he saw Ms C at the Breast Clinic he could palpate a small lump in the lower quadrant of her right breast. He said, however, that his examination had taken place after he had seen the mammograms and it is always easier to find something if one knew from the mammograms exactly where to look. At the time of the examination there were no obviously enlarged lymph nodes in the axilla (the area under the arm) but axillary examination is notoriously unreliable and trying to determine whether or not lymph nodes are involved pre-operatively is in reality no better than tossing a coin. That is why axillary staging is carried out in all patients.

2. He thought the question was hypothetical and difficult to answer accurately. If Ms C had undergone mammography in April 2004 and that had demonstrated the presence of a tumour the surgical treatment would have been exactly the same as she underwent in 2005. In terms of prognosis it was conjecture but the three most important prognostic indicators were the grade of the tumour, its size and the presence or absence of lymph node deposits and the number of nodes affected. Of those indicators, size was the weakest predictor. At the time of surgery the tumour was Grade 11 and he could say with a reasonable degree of certainty it would have been Grade 11 ten months earlier. It may have been that fewer lymph nodes would have been affected but it was impossible to know in the same way as the tumour may have been a little smaller. However, as size is the least powerful predictor he doubted if it would have had any significant impact on the prognosis.

3. The procedure Ms C underwent would have been exactly the same if it had been carried out in April 2004. Lumpectomy involves wide excision of the tumour because it is essential that the resection edge should be clear of disease. For that reason the tumour itself is not seen during surgery. In the same way axillary clearance is a defined anatomical dissection and even during surgery it is difficult to know whether or not the lymph nodes are affected. The other treatment which Ms C received would have been the same as well.

4. It is not possible to tell pathologically the age of any tumour. It is only possible to describe it as presented to the pathologist.

21. Ms C wrote a formal letter of complaint to the Practice on 16 September 2005. She said that her complaint was both clinical and procedural. The

clinical aspect of her complaint concerned the Practice's failure to diagnose breast cancer from 2001. Ms C said that by 2004 her symptoms should have been picked up by any competent GP. Her symptoms in 2004 were difference in breast size (right breast was pulling towards tumour), lump in right breast, thickening and lumpiness in right armpit. The procedural aspect concerned the information that she would have to wait until she was 50 to have a mammogram. Ms C said that a woman in her position should not have been denied a proper, full examination simply because she was not 50.

22. After Ms C read her clinical notes she wrote again on 9 October 2005. In that letter she referred again to her meeting with GP 1 in July 2001. She said that GP 1 had examined her breasts and told her that she had an extension of breast tissue under her right armpit but nothing sinister was going on. She had asked GP 1 because the nurse had advised her at a clinic in April 2001 that if she was concerned about that she should see her GP. Ms C repeated her complaint about the GP not sending her for screening. Ms C said that the absence of any reference to GP 1's examination in her notes meant that when she attended GP 2 later there was no previous record of her concern[10]. Ms C said that no competent doctor should have allowed her to leave the surgery without referring her to a specialist.

23. On 27 October 2005 the Practice sent their formal response to Ms C. They said that with regard to the clinical aspect of her complaint Ms C considered that her breast cancer was diagnosable when she was seen by the doctors at the surgery. Unfortunately a breast cancer had to be of a certain size before it could be detected by examination. They were unable to find any evidence of a breast cancer in Ms C's case. They had consulted with the experts involved in Ms C's care and it was not possible to say whether it would have been present in a state which was diagnosable when Ms C attended the surgery. The advice they had been given would appear to suggest that it may not have been diagnosable at that time. With regard to the procedural question it was a matter of fact that breast screening for asymptomatic women showing no sign of breast cancer begins at 50 in the UK. However, the screening services will see any woman whose doctor feels they have signs of breast cancer at any age. The doctors who saw Ms C did not think that there were signs of breast cancer and, therefore, did not refer her for early screening. In response to Ms C's further questions they replied that:

[10] It was only after she had accessed her clinical notes that Ms C made reference to her visit to GP 2 in 2003.

1. The conversation in 2001 was a matter of recollection which could only be resolved in face to face discussions with GP 1.

2. The clinical entry from the nurse was straightforward.

3. This appeared to be a reiteration of Ms C's complaint that her breast cancer should have been diagnosed earlier. In an ideal world all breast cancers would be detected in their very early stages but that is not always possible despite the best level of care. All doctors are required to keep their patients' best interests at heart providing investigation, diagnosis and treatment as appropriate. It would not normally be appropriate to use the breast screening service purely on the grounds of patient anxiety with no clinical evidence of any problem. Both GP 1 and GP 2 do refer patients to the breast services prior to the age of 50 when they feel it is necessary but in Ms C's case they did not feel it was clinically indicated. Part of only using services when clinically indicated is the knowledge that it is in the best interests of each patient for those services to be available as soon as possible when required.

4. The Practice suggested that Ms C could discuss with GP 2 whether an earlier note in her records indicating her concerns would have led to her taking a different course of action. They offered Ms C a meeting with GP 1 and GP 2 to try to resolve any outstanding issues.

24. Ms C did not take up the offer of a meeting and she then complained to the Ombudsman.

Conclusion

25. In investigating this complaint, and assessing the evidence provided by the complainant and the Practice, I have taken into account the policy in place for screening patients, and the guidelines for referral of women with symptoms of breast cancer. I have also considered the feedback received by the Practice from Consultant 1 (see paragraphs 15 and 20), the views of Surgeon 1 (see paragraph 18) and the advice received from the Ombudsman's Adviser.

26. In 1986 the Forrest Report recommended that breast screening should be introduced for all women between the ages of 50 and 64 in the UK. As a result the Scottish Breast Cancer Screening Programme was established in the late

1980s. If a GP suspects that a woman outwith that age range has breast cancer s/he can refer her to the specialist breast clinic where the appropriate examination, mammography, biopsy or scan can be done.

27. The relevant Guideline at the time Ms C attended the Practice was the Scottish Intercollegiate Guidelines Network (SIGN) Publication No. 29, *Breast Cancer in Women*, which was published in October 1998. Section 4.2 (see Annex 2) gives guidance to GPs regarding the management and referral of patients with breast cancer symptoms. It aims to encourage women to report any concerns they have to their GP and provides a list of conditions which would then require referral to hospital for assessment.

28. Ms C said she reported her concerns about her breasts on three separate visits to the Practice: on 18 April 2001 when she saw a nurse at the Practice followed by a consultation with GP 1; on 24 March 2003 when she had a consultation with GP 2; and on 30 April 2004 when she saw GP 2 for a second time. On the first occasion she reported puffiness under her right armpit, on the second she was concerned that the fatty area was enlarging and on the third she noted her continuing concerns about her breasts. Ms C said she requested a mammogram on the first and third visits and was told that the NHS did not perform screening for women under the age of 50 when no symptoms of breast cancer had been detected on examination.

29. The notes in Ms C's medical records state that:

> First visit - It is recorded that Ms C was concerned that she felt her right axilla had 'more fat' under it than the left. Ms C was advised by the nurse to see the GP should she continue to be anxious. Ms C saw GP 1 who examined her breasts on the same day. There is no note of this in Ms C's medical records which the GP attributes to that fact that the file remained with the Practice Nurse. GP 1's recollection is that Ms C was concerned about fullness in the right axillary area compared to the left but that on examination that related to the axillary tail of breast. It was normal breast tissue with no worrying features or axillary mass. She reassured Ms C that this was due to breast asymmetry. Ms C asked about breast screening and GP 1 told her that the service was available to women once they are aged 50 years.
>
> Second visit – It is recorded that Ms C's breasts were lumpy but nothing

abnormal was detected. GP 2 then wrote to Ms C on 8 April 2003. She said that during the examination she had not detected any abnormality in Ms C's breasts or armpits which made her concerned about a possible malignancy in Ms C's breasts.

Third visit - GP 2 recorded in the medical notes that Ms C's breasts were normal – a bit lumpy but benign. There is no comment in the records concerning a request for a mammogram.

30. Ms C said in her complaint to this office that when she attended the Practice she had a lump and enlarged glands. I note, however, that neither of these were recorded in the medical notes, nor did Consultant 1 find any obviously enlarged axillary lumph nodes when he examined Ms C (see paragraph 20).

31. The Adviser is of the view that the clinical findings at examination in 2001 did not provide any reason to refer Ms C for further examination. In her letter to the Practice of 17 March 2005 Ms C quoted from a book which said that women with lumpy breasts can be referred to the breast clinic by their doctor. However, the Adviser said that lumpy breasts are a variant of normal and that would not provide justification to refer Ms C for further examination. With regard to Ms C's continuing concerns about the difference between her breasts, he further advised that the two sides of a person are often not the same and that asymmetry would not be a reason to refer a patient for further investigation. GP 2 had stated that during her examination she had not detected any abnormality in Ms C's breasts or armpits which made her concerned about a possible malignancy. The Adviser was of the view that in the absence of any such finding there would be no justification in terms of the guidelines for sending Ms C for further investigation. The Adviser said Ms C was examined appropriately on 24 March 2003 and 30 April 2004 and that the results are recorded as lumpy but benign.

32. Ms C is clearly of the view that her reported symptoms warranted a referral for a mammogram. She has sent further literature to me which makes reference to features that women should be aware of in reporting concerns about their breasts to their GPs. However, even in the presence of these features it is for the GP to examine a patient and to reach a clinical judgement on whether the symptoms raise cause for concern, taking into account the Forrest Report and the SIGN guidelines. In Ms C's case, the GPs were of the

view that her symptoms did not require a referral.

33. I have to consider whether, taking all the relevant information into account, this was a reasonable decision for the GPs to make. The advice I have received is that there was no justification for a referral in Ms C's case and that the clinical decisions of the GPs were in line with the relevant policy and guidelines. It may be that another GP in another Practice may have come to a different view, but that does not mean that GP 1 and GP 2 acted unreasonably.

34. Unfortunately when Ms C went for a mammogram herself shortly after her 50th birthday, she was diagnosed with breast cancer.

35. I can, therefore, understand why she is aggrieved that she was not referred for a mammogram at an earlier date. However, as well as the opinion of the Adviser I have also borne in mind the evidence from Consultant 1 and Surgeon 1 who said that he could not have detected any abnormality on examination.

36. In all the circumstances, I do not uphold the complaint.

Further Action

37. This complaint has not been upheld. Nevertheless, the literature available to patients does aim to raise awareness about the symptoms of breast cancer and quite rightly encourages women to seek the opinion of their GP. As stated above, it is for the GP to make the clinical judgement in line with the appropriate policies and guidelines and on the basis of their experience. The relevant SIGN guideline on breast cancer in women was published in 1998. The Ombudsman is of the view that it may be timely for this guideline to be reviewed. A copy of this report will be sent to QIS and their attention drawn to this specific aspect arising from this complaint.

30 May 2006

Annex 1

Explanation of abbreviations used

Ms C	The complainant
GP 1	The GP who treated Ms C in 2001
GP 2	The GP who treated Ms C in 2003 and 2004
Consultant 1	The consultant who treated Ms C
Surgeon 1	The surgeon who operated on Ms C
QIS	Quality Improvement Scotland
SIGN	Scottish Intercollegiate Guidelines Network

Annex 2

Extract from SIGN Publication No 29
Breast Cancer in Women (Section 4.2)

'LUMP

- any new discrete lump
- new lump in pre-existing nodularity
- asymmetrical nodularity that persist at review after menstruation
- abscess or breast inflammation which does not settle after one course of antibiotics
- cyst persistently refilling or recurrent cyst (if the patient has recurrent multiple cysts and the GP has the necessary skills, then aspiration is acceptable)

PAIN

- if associated with a lump
- intractable pain that interferes with a patient's lifestyle or sleep and which has failed to respond to reassurance, simple measures such as wearing a well supporting bra, and common drugs
- unilateral persistent pain in post-menopausal women

NIPPLE DISCHARGE

- all women aged 50 and over

- women under 50 with:
  - bloodstained discharge; or
  - bilateral discharge sufficient to stain clothes; or
  - persistent single duct discharge

NIPPLE RETRACTION OR DISTORTION, NIPPLE ECZEMA
CHANGE IN SKIN CONTOUR'