Scottish Parliament Region: Highlands and Islands

Case 201200733: Western Isles NHS Board

Summary of Investigation

Category

Health: Hospital; general medical; clinical treatment; diagnosis

Overview

The complainant (Ms C), an advocate, raised a number of concerns on behalf of Mr A. Mr A's late wife (Mrs A) was referred urgently by her GP for the investigation of symptoms suggestive of breast cancer on three occasions within a period of seven months. Mrs A was referred urgently to the Breast Clinic at the Western Isles Hospital (the Clinic) in Stornoway three times between May and November 2008 but she was not referred on to the Highland Breast Centre in Inverness (the Breast Centre) until December 2008. Cancer was diagnosed in January 2009.

Mrs A was a young woman whose first child was under two years old when she first reported her symptoms to her GP. By the time the cancer was diagnosed, she was some 12 weeks pregnant with her second child. Although the child was delivered safely and Mrs A was treated for her cancer, the cancer later returned and she died aged 33 years in June 2011.

Specific complaint and conclusion

The complaint which has been investigated is that the Board unreasonably delayed diagnosing Mrs A's breast cancer *(upheld)*.

Redress and recommendation

The Ombudsman recommends that the Board:	*Completion date*
(i) issues a written apology for the failings identified.	27 April 2013

The Board have accepted the recommendation and will act on it accordingly.

Main Investigation Report

Introduction

1. Ms C, an advocate, brought this complaint on behalf of Mr A, the husband of the late Mrs A. Mrs A was 30 years old when she reported to her GP on 12 May 2008 that she was suffering from discomfort and nodularity (small lumps) in her right breast. She also reported 'tiny' amounts of discharge from both breasts since the birth of her child just over a year previously. The GP referred her urgently to the Western Isles Hospital (the Clinic) on 20 May 2008.

2. Mrs A was seen by a consultant general surgeon (the Surgeon) and following an ultrasound scan the Surgeon wrote to Mrs A's GP on 25 July 2008 that he was 'reassured' that there was 'no abnormality' in the right breast. Mrs A then returned to her GP on 28 August 2008 complaining of a lump in her right breast. The GP again made an urgent referral describing the lump as being 'the size of a small golf ball'. Mrs A was seen in the Clinic on 2 September 2008 by a locum consultant surgeon (the Locum) who then wrote to her GP on 8 September 2008. The Locum wrote that he had detected 'thickening' of the breast tissue rather than a distinct lump and that he was going to repeat the ultrasound scan. Mrs A was reviewed in the Clinic again on 30 September 2008 by the Surgeon and advised to take Evening Primrose Oil (EPO – a natural remedy thought to be beneficial to women with painful breasts). A review was arranged for four months' time.

3. Mrs A, however, went to her GP again in November 2008 complaining of an enlarged right breast with an inverted (inward turning) nipple and puckering of the skin. She was at this time some six weeks pregnant. The GP again made an urgent referral stating that he could also detect a 'golf-ball sized lump which is mobile'. The Surgeon again saw Mrs A on 25 November 2008 when he detected a 'large palpable mass' in her right breast. He requested a further ultrasound scan and reviewed Mrs A on 16 December 2008. At this time, mainly at Mrs A's insistence, the Surgeon referred her to the Highland Breast Centre in Inverness (the Breast Centre), which has a multi-disciplinary team that can provide triple assessment, as recommended by national guidance. Further testing was carried out there and breast cancer diagnosed in January 2009.

4. The complaint from Ms C which I have investigated is that the Western Isles NHS Board (the Board) unreasonably delayed diagnosing Mrs A's breast cancer.

Investigation

5. My complaints reviewer gathered evidence from Ms C and the Board and took clinical advice from a consultant general surgeon with experience in the management of carcinoma of the breast. My complaints reviewer also took advice from a consultant radiologist with a special interest in breast imaging.

6. 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.

Complaint: The Board unreasonably delayed diagnosing Mrs A's breast cancer

7. Mrs A was 30 years old and had given birth to her first child just over a year previously when she attended her GP on 12 May 2008 complaining of 'discomfort and nodularity in her right breast'. The urgent referral from the GP stated that Mrs A had had the symptoms for about two weeks and that she had also noticed 'skin puckering on the right hand side'. The referral letter also noted that Mrs A had experienced discharge from both nipples since the birth of her child.

8. The GP continued that on examination there was no:

> 'redness or increase in temperature … [but] … clear puckering of the skin of the right breast on the lateral [outer] aspect. There was no axillary lymph nodes on both sides. Breasts exhibited generalised nodularity.'

9. Mrs A was reviewed in the Clinic on 20 May 2008 and an ultrasound scan was ordered. On 25 May 2008 the Surgeon wrote to Mrs A's GP informing him of this. The ultrasound scan took place on 5 June 2008 at a hospital in another NHS Board area. The report stated: 'Particular attention paid to the upper outer quadrant. No underlying abnormality seen.'

10. The Surgeon wrote to the GP again on 25 July 2008 stating that Mrs A had not attended the Clinic for review on 22 July 2008 but that he was reassured that the report of the ultrasound scan had shown no abnormality and he would not be sending Mrs A an appointment for any further follow-up.

11. Mrs A returned to her GP on 28 August 2008 complaining of an increasing lump in her right breast, this time in the 'inner lower quadrant'. The GP made another urgent referral to the Surgeon.

12. Mrs A was seen in the Clinic on 2 September 2008 by the Locum who, in a letter to the GP dated 8 September 2008, stated that he had noted 'breast thickening' but 'no definite lump'. The Locum wrote to the GP to tell him that he had ordered a repeat ultrasound scan, again at a hospital in another NHS Board. The second scan took place on 18 September 2008 and the report stated: 'Particular attention is paid to the area of clinical question medially [central]. No masses seen.'

13. On 3 October 2008 the Surgeon wrote to the GP stating that he had reviewed Mrs A in the clinic on 30 September 2008 and was 'pleased that her right breast ultrasound shows no abnormality'. He continued that he had recommended that Mrs A should try taking EPO and that he would review her again in four months' time.

14. However, before this review could take place Mrs A reported to her GP on 17 November 2008 that she was experiencing a unilateral increase in size in her right breast. She was at this time six weeks pregnant and the GP's third urgent referral stated:

> '…On examination the right breast is definitely larger … with inversion of the right nipple whilst the left looks normal. There is some puckering in the right lower quadrant … there is definitely a lump the size of a golf ball in the lower quadrant … with puckering of the skin while the lump is being moved. …'

15. Mrs A was seen by the Surgeon in the Clinic on 25 November 2008 and in his letter to the GP dated 27 November 2008 he noted: '… She presented with a large mass in the right breast … Interestingly this lady has been followed up in the breast clinic for some time. …' The letter continued that a repeat ultrasound had been requested with 'possible tissue sampling' and that the Surgeon would review Mrs A in the clinic when the results were received.

16. The Surgeon reviewed Mrs A on 16 December 2008 and in the letter of referral to the specialist Breast Centre he stated: '… [Mrs A] presented in [his] clinic on 25/11/08 with a large mass in the right breast. This lady conceived some 10 or 11 weeks ago. …'

The letter went on to describe the two previous referrals and the results of the ultrasound scans. It continued:

> '…I requested to repeat the ultrasound scan and possible tissue sampling. The ultrasound scan of her right breast was carried out and demonstrated diffuse subcutaneous oedema [accumulation of fluid] involving most of the breast. No other breast abnormality seen.'

17. The Surgeon's letter ended that: '… [Mrs A] herself would appreciate your help.'

18. Mrs A was seen in the Breast Centre on 31 December 2008 where examination and repeat ultrasound scanning produced suspicious results. Biopsies (tissue samples) were taken from the right breast and Mrs A and her husband, who had attended with her, were made aware of the possible diagnosis of breast cancer. Mrs A was reviewed again in the Breast Centre on 7 January 2009 when 'Locally advanced/inflammatory carcinoma [cancer] – RIGHT breast.' was confirmed.

19. The letter sent to the Surgeon from the Breast Centre stated that the treatment plan was for chemotherapy to start once Mrs A was 16 weeks pregnant with surgery to follow. However, by the end of the chemotherapy Mrs A would be nearly due to deliver her baby so the Breast Centre was going to liaise with the Obstetric team on when best to perform the surgery. This would also be followed by radiotherapy which again would only be safe to do once Mrs A had had her child.

Advice received

20. My complaints reviewer took advice from an independent adviser who is a consultant general surgeon with experience in the management of carcinoma of the breast (the Surgical Adviser). The Surgical Adviser first addressed the issue of the two-month follow up appointment after Mrs A's first referral to the Clinic. The Surgical Adviser was of the opinion that in view of the fact that Mrs A had been referred urgently by her GP, with all the anxieties that would have surrounded her symptoms and the referral, a wait of two months for the results of her ultrasound scan and follow-up was not appropriate.

21. The Surgical Adviser also commented that had the ultrasound scan shown the cancer at this first scan, a period of two months would not have been a suitable time to wait to commence treatment.

22. My complaints reviewer asked the Surgical Adviser if ultrasound scanning was the appropriate investigative tool to use in Mrs A's case. The Surgical Adviser was of the view that it was. Mrs A was a 30-year-old woman and ultrasound scanning is the preferred investigation in the under-35 age group as mammography is less sensitive and accurate in this age group. This is in line with the advice provided by the Scottish Intercollegiate Guidance Network (SIGN) in SIGN 84 paragraph 2.3.1 which states:

> 'Mammography – Must be performed as part of triple assessment … Mammography is not recommended under the age of 35 unless there is a strong clinical suspicion of carcinoma. Ultrasound – May provide additional information to mammography. Can be useful for focal breast disease in women under 35 years.'

23. The Surgical Adviser was also asked whether the Surgeon was right to be 'reassured' by the negative result of the first ultrasound scan. The Surgical Adviser thought that it was reasonable for the Surgeon to have been reassured at this stage. In the absence of any other signs of malignancy, which there were not at this time, there was no reason for the Surgeon to disbelieve the negative result of the scan.

24. Similarly, the Surgical Adviser was of the opinion that ultrasound scanning was still the appropriate investigation to undertake when Mrs A was referred for the second time in August 2008. The Locum requested a scan with a fine needle aspiration cytology (FNAC) (removal of fluid for laboratory testing) if the scan revealed a lesion (tumour). The Surgical Adviser considered this was appropriate and that as no lesion was reported from the scan, no FNAC was undertaken. Again, in the absence of any other clinical suspicion the Surgical Adviser was of the view that there was no reason to doubt the results of the ultrasound scan.

25. The Surgical Adviser was also of the view that it was appropriate to recommend that Mrs A took EPO and be followed up in four months' time. The Surgical Adviser commented that EPO can be beneficial to patients with benign breast disease and this was, therefore, an appropriate suggestion at this stage in the absence of clinical signs of malignant disease.

26. On the matter of the third urgent referral from the GP in November 2008, the Surgical Adviser was of the view that there were at this time clear features that were highly suggestive of breast cancer. However, the Surgeon did not appear to consider this as a possible diagnosis as it is not recorded in his record of the assessment of 25 November 2008 which was sent to the GP on 27 November 2008. The Surgeon then waited some three weeks for the results of the scan and to review Mrs A on 16 December 2008.

27. In his letter of referral to the Breast Centre of the same date, the Surgeon does not express a suspicion of cancer but does refer to cellulitis and flattening of the nipple which the surgical adviser stated are both indicators of cancer. The Surgical Adviser was of the view that by the third urgent referral from the GP there were clear signs of potential cancer and an urgent ultrasound scan should have been ordered.

28. The Surgical Adviser was also of the opinion that the facilities for the management of the diagnosis of breast cancer in the Western Isles at the time of these events were not to the standard required by the 'Healthcare Improvement Plan for Scotland' (a plan to improve standards within the NHS in Scotland including setting specific standards for certain services, including breast cancer). SIGN produce guidelines for the investigation, diagnosis and management of various health conditions. SIGN 84 deals with the 'Management of breast cancer in women', and was first published in 2005.

29. The Surgical Adviser stated that the requirement in 2008 was for a patient with suspected breast cancer to be seen within 28 days. She also stated that there was a requirement for rural teams to link with multi-disciplinary team (MDT)s and for rapid access and one-stop facilities to be introduced. Although Mrs A was seen within 28 days for each of her three referrals to the Clinic, it was not until her third referral, and mainly at her own request, that she was referred to the one-stop facilities at the Breast Centre.

30. Overall, the Surgical Adviser is of the view that the management of Mrs A's condition for the first two referrals was reasonable but that by the third referral more urgent and proactive management should have taken place.

31. In a letter to Ms C dated 26 April 2012 the Chief Executive of the Board told her that the Board had reviewed the referral procedures for breast cancer

and they were changed in 2009 to reflect the changing standards within the NHS in Scotland. The Chief Executive stated that this change was prompted by the evolving nature of the national guidance and not in response to any particular complaint.

32. The Chief Executive stated that since 2009 any woman requiring to be seen by a breast specialist should be referred directly to the Breast Centre.

33. In a letter to SPSO dated 11 March 2013 the Chief Executive of the Board provided further information on this matter. The Chief Executive stated that SIGN 84 was circulated to relevant clinicians within the Board in January 2006. However, he stated that the guidance issued by SIGN is a guideline, and he confirmed that the Board had no record of any governance or surgical management team meetings explaining why SIGN 84 was not implemented.

34. The Chief Executive stated that the Board's practice at the time remained that patients would be referred in the first instance to the Surgeon, until he left the employment of the Board in May 2009. The Chief Executive stated that providing specialist care in peripheral centres is a challenge and the only way for the Board to arrange this for patients with breast symptoms was to refer all patients directly to the Breast Centre. The Chief Executive confirmed that this was implemented from September 2009.

35. My complaints reviewer also took advice from a consultant radiologist with a special interest in breast imaging (the Sonography Adviser). The Board were unable to provide images for the Sonography Adviser to view for the ultrasound scan done on 5 June 2008 but the report of the images was reviewed. The Sonography Adviser considered that in view of the presenting symptoms and the lack of abnormality as reported on the image it would have been reasonable to have discharged Mrs A at this time.

36. The Sonography Adviser said that this would be the usual procedure in a woman of under 35 with the symptoms reported.

37. The Sonography Adviser was able to review the images for the other two ultrasound scans taken on 18 September 2008 and 9 December 2008. On the matter of the first scan, the Sonography Adviser could detect no distinct masses but could detect skin thickening (about 2 millimetres instead of the normal

1 millimetre). The Sonography Adviser was of the view that this was a subtle and non-specific finding.

38. The Sonography Adviser said that although a subtle finding, skin thickening is not normal and could be linked to several conditions including infection, inflammation or inflammatory cancer. The Sonography Adviser was of the view that this should have triggered further investigation at this stage. This would have included follow-up within one or two weeks.

39. On the matter of the scan taken on 9 December 2008 the Sonography Adviser noted that the skin thickening was considerably worse at approximately 8 millimetres and there was clear evidence of fluid within the breast. Although there was still no evidence of a distinct mass or lesion, the Sonography Adviser said that the clinical findings were 'highly suggestive' of inflammatory breast cancer and an urgent biopsy should have been undertaken. The Sonography Adviser would also have expected examination of the axillary lymph nodes to have been done at this time.

40. Overall, the Sonography Adviser was of the view that the care provided to Mrs A fell below that expected in the setting of a MDT which, as per SIGN 84 as referred to above, should have been the norm within the NHS in Scotland since 2005.

Conclusion

41. Although unusual in a woman of under 35, breast cancer does occur in this age group and the symptoms that Mrs A was reporting were suspicious of this condition, as evidenced by the three urgent referrals from her GP within seven months.

42. Both advisers have said that the findings from the first referral were inconclusive. I also note that the main problem reported at that time was located in the upper outer quadrant of the right breast but the cancer was eventually discovered in the lower inner quadrant of the right breast.

43. I am, therefore, satisfied that in the case of the first referral the care provided was reasonable.

44. On the matter of the second and third referrals I am not satisfied. The Sonography Adviser stated that there were subtle indications that all was not

well by the time of the second ultrasound scan. These should have prompted further investigation and follow-up. By the third referral and ultrasound scan there were clear signs of cancer and these should have been followed up urgently. Instead there was a delay of a week before she was seen in the Clinic and referred routinely to the Breast Centre.

45. Mrs A was not seen in the Breast Centre until 31 December 2008 which was in total a delay of some six weeks from the urgent referral from her GP on 17 November 2008.

46. I note, and have seen evidence, that the Board have since these events introduced a system where any woman being referred by a GP for symptoms suggestive of breast cancer are now referred directly to the Breast Centre. This means that they have the advantage of referral to the MDT at an early stage as per the SIGN 84 guidance.

47. I note the Chief Executive's comment, as referred to in paragraph 31 above that the changes in the referral system were not a response to any particular complaint. However, I also note that the changes took place in 2009, after Mrs A's cancer was diagnosed. I am also concerned to note that there did not appear to have been a system in place to ensure that clinicians were taking SIGN 84 guidance into account in respect of their clinical practice. I take the view that it is incumbent on health boards to ensure that national guidance is not only disseminated but is also taken cognisance of by their clinicians.

48. Mrs A did not have the advantage of early referral to the MDT and I find that some three years on from the introduction of SIGN 84 this was not acceptable. It is not possible to say now what the outcome may have been for this young mother had she been referred to the MDT at an earlier stage. However, the guidance in place at the time was clear and she should have had the opportunity to have been referred to the MDT, at least from the second referral from her GP.

Recommendation

49. I note that the Surgeon is no longer employed by the Board and that, as referred to in paragraph 34, the Board now refer women directly to the Breast Centre. I, therefore, have no practical recommendations to make.

50. I recommend that the Board:	*Completion date*
(i) issues a written apology to Mr A for the failings identified in this report.	27 April 2013

51. The Board have accepted the recommendation and will act on it accordingly. The Ombudsman asks that the Board notify him when the recommendation has been implemented.

Annex 1

Explanation of abbreviations used

Ms C	The complainant
Mr A	The widower of the aggrieved (the injured party)
Mrs A	The aggrieved
GP	General Practitioner
The Clinic	The general surgery clinic at the Western Isles Hospital
The Surgeon	The consultant general surgeon
The Locum	The locum consultant surgeon
EPO	Evening Primrose Oil
The Breast Centre	The Highland Breast Centre at Raigmore Hospital in Inverness
The Board	Western Isles NHS Board
The Surgical Adviser	The Ombudsman's general surgical adviser
SIGN	Scottish Intercollegiate Guidelines Network
FNAC	Fine Needle Aspiration Cytology
MDT	Multi-Disciplinary Team – a team of various health professionals who aim to effectively investigate, diagnose and

	treat specific illnesses
The Sonography Adviser	The Ombudsman’s radiology adviser

Annex 2

Glossary of terms

Axillary lymph nodes	part of a system of glands which move fluid and hormones around the body. Located in the underarm
Biopsy	removal of a small tissue sample for testing in the laboratory
Cellulitis	cell damage caused by infection or inflammation
Chemotherapy	treatment of cancerous cells using chemicals which destroy the cancer cells but can have serious and uncomfortable side effects
Evening Primrose Oil (EPO)	a natural remedy thought to be beneficial in women with benign breast problems
Inverted nipple	inward turning nipple
Mammography	special x-ray of the breast tissue
Nodularity	with the appearance or feel of small lumps or nodules
Palpable mass	a lump or area of tissue that can be felt under the skin
Skin puckering	where the skin drags or wrinkles
Ultrasound scan	a specialist, non-harmful, scanning technique using sound waves to produce images of the body that can be observed on a screen or transferred to photographic film