

Diagnostic Radiologists, Drs B, C and D
A Private Radiology Practice

A Report by the
Health and Disability Commissioner

(Case 02HDC10479)



Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

| | |
|-------|-----------------------------------|
| Mrs A | Consumer |
| Dr B | Provider / Diagnostic Radiologist |
| Dr C | Provider / Diagnostic Radiologist |
| Dr D | Provider / Diagnostic Radiologist |

Complaint

On 31 July 2002 the Commissioner received a complaint from Mrs A about the standard of services provided to her by three registered medical practitioners, Dr B, Dr C and Dr D, diagnostic radiologists at a private radiology practice, in a city. The complaint was summarised as follows:

Dr B

Dr B, diagnostic radiologist, failed to provide Mrs A with services of reasonable care and skill in 1997. In particular he did not:

- *adequately report a mammogram Mrs A had on 10 September 1997. In 2001 or 2002 Mrs A was diagnosed with breast cancer and required a mastectomy*
- *arrange appropriate investigation of a spiculated area in her left breast*
- *provide Mrs A with sufficient information. In particular, he did not inform her that there was a spiculated area in her left breast and the significance of this finding*
- *properly take into account Mrs A's family history of breast cancer when reporting her mammogram.*

Dr C

Dr C, diagnostic radiologist, failed to provide Mrs A with services of reasonable care and skill in 1999. In particular he did not:

- *adequately report a mammogram Mrs A had on 14 July 1999. In 2001 or 2002 Mrs A was diagnosed with breast cancer and required a mastectomy*
- *arrange appropriate investigation of a spiculated area in her left breast*
- *provide Mrs A with sufficient information. In particular, he did not inform her that there was a spiculated area in her left breast and the significance of this finding*
- *properly take into account Mrs A's family history of breast cancer when reporting her mammogram.*

Dr D

Dr D, diagnostic radiologist, failed to provide Mrs A with services of reasonable care and skill in 1999. In particular he did not:

- *adequately report a mammogram Mrs A had on 14 July 1999. In 2001 or 2002 Mrs A was diagnosed with breast cancer and required a mastectomy*
- *arrange appropriate investigation of a spiculated area in her left breast*
- *provide Mrs A with sufficient information. In particular, he did not inform her that there was a spiculated area in her left breast and the significance of this finding*
- *properly take into account Mrs A's family history of breast cancer when reporting her mammogram.*

An investigation was commenced on 7 November 2002.

Information reviewed

- Mrs A's medical notes from her general practitioner
- Mrs A's medical notes from a Breast Clinic
- Responses from Dr C, Dr D and Dr B
- Original screening mammograms of Mrs A's left breast taken in 1995 (2), 1997 (2), 1999 (2) and 2001 (4) (including bilateral mammogram with ultrasound taken on 3 December 2001) and Reports
- Original screening mammograms of Mrs A's right breast taken in 1995 (2), 1997 (2), 1999 (2), 2001 (2) and Reports
- Postoperative mammograms of Mrs A's right breast taken in 2002 (3) and 2003 (2)

Independent expert advice was obtained from Dr Wendy Hadden, radiologist (Member of the Breast Imaging Reference Group of the Royal Australian and New Zealand College of Radiologists (RANZCR) and the Mammography Accreditation Programme (RANZCR)).

Information gathered during investigation

Overview

Mrs A (date of birth 1935) had a family history of breast cancer. Her sister and a niece had both had the disease. Mrs A was accordingly aware of the need for regular mammograms and as a precautionary measure she had "routine" screening mammograms every two years from 1995 to 2001. The mammograms taken in 1995 and 1997 were reported by radiologists at a private radiology practice in a city. Those taken in 1999 and 2001 were reported at another private radiology practice, also in the same city. On 3 December 2001, a

lesion that was subsequently confirmed to be breast cancer was identified in Mrs A's left breast. On 17 January 2002 she underwent a mastectomy of her left breast.

[...] was a private radiology practice. In early 1998, it was purchased by [...], also a private practice. Radiologists at the private radiology practice perform mammography at the request of referring doctors, both for asymptomatic patients and for patients with abnormalities and symptoms. In 1998 the practice commenced the process of obtaining accreditation with International Accreditation New Zealand ("IANZ"), which was subsequently achieved. The practice has in place a quality assurance programme recognised by the National Radiation Laboratory.

Dr D is the managing partner at the private radiology practice. He is a Fellow of a College of Radiologists overseas, and educational affiliate of RANZCR.

Dr B was employed part-time by a Public Hospital, and part-time by the private radiology practice, from 20 April 1998 to 14 December 2001. In 1994 he obtained the RANZCR Diploma. He has been a Fellow of the College since 1995. He has specialist registration with the New Zealand Medical Council as a diagnostic radiologist. He is currently employed full-time by the Public Hospital and Breast Screen Aotearoa as a diagnostic radiologist. He holds a senior position in the radiology department at the Public Hospital.

Dr C completed a fellowship in Musculoskeletal Radiology at an overseas university and worked in private practice overseas from 1991-1998. He has been a Fellow of the RANZCR since 1991 and is a corresponding member of an overseas Radiology Society. He is enrolled in the RANZCR Continuing Medical Education programme.

Background

Mrs A first had a screening mammogram on 10 April 1995. She had been referred to the private radiology practice for this routine procedure by her GP. The mammogram was reported by another radiologist in the same practice:

“BILATERAL MAMMOGRAM: No abnormality seen in both breasts.”

On 10 September 1997 Mrs A had a standard two-view screening mammogram of both breasts, again at the private radiology practice. The two views were:

- a) the cranio-caudal view (“the CC view”)
- b) the medial-lateral oblique view (“the MLO view”)

The mammogram was reported by Dr B as follows:

“MAMMOGRAM: Comparisons are made with the previous mammogram of April 1995. There has been no significant change. No mass lesion or suspicious micro calcification. No evidence of malignancy.”

On 14 July 1999 Mrs A had a bilateral mammogram at the private radiology practice. It was reported by Dr C, and double reported by Dr D, as follows:

“BILATERAL MAMMOGRAPHY: 14 JUL 1999

Both breasts are of similar shape and size with no evidence of skin thickening or nipple retraction. There is a spiculated area in the outer aspect of the left breast which is unchanged since previous examination of September 1997 and is consistent with some radial scarring. Otherwise the appearance of each breast is unremarkable. No abnormality of the axillae.

IMPRESSION: No evidence of malignancy or other significant pathology. There has been little change in appearance since examination of 10/9/97.

The reporting of a “spiculated area” showing on a breast screening mammogram refers to an area of the breast that may contain a lesion with a stellate, star-like or spiky appearance. In the course of their responses, Drs D, C and B have referred variously to the “spiculated area” or the “lesion” seen on Mrs A’s mammograms. To avoid confusion I have used the former term in my report.

Mrs A advised me that every time she had a mammogram she “reminded the radiologist that there was a family history of breast cancer”. She says she was “always told to wait in the room until they came back. They would say ‘you can go, everything is alright (sic)’. Naturally I was always very happy about this.”

However, Mrs A said that when she had another mammogram at the private radiology practice on 3 December 2001, “Dr B came in and told me he would like to scan my left breast. He said that there was an area in my breast that had changed and that it would probably have to come out.”

This mammogram was reported by Dr B, and double reported by Dr D as follows:

“BILATERAL MAMMOGRAPHY WITH ULTRASOUND: 3 Dec 2001

INDICATION: Screening mammogram. Positive family history.

Findings: Comparisons are made with the previous mammograms of July 1999, September 1997 and April 1995.

A small amount of residual glandular tissue in both breasts. In the LEFT lateral breast there is the impression of a small area of increased density and distortion. This is mentioned on the previous mammogram report. The appearances on the CC view show little change from mammograms right back to April 1995 but the appearances on the MLO view suggest there may be some increased density in this region compared with previous mammograms. Magnification compression views were obtained and confirm a small spiculated density. The remainder of both breasts are unchanged and unremarkable with no focal densities or suspicious microcalcifications seen elsewhere in either breast.

Ultrasound was performed of the LEFT breast. In the 3 o'clock position there is a small hypoechoic area measuring just over 6mm in diameter. This has irregular margins and posterior shadowing. This measures about 7mm in diameter.

Comment: The appearances are of a small spiculated density on mammography and a hypoechoic irregular density on ultrasound in the 3 o'clock position of the left breast. Today's films are suspicious of a small malignancy. However against this is the fact that there has been very little change in the mammographic appearance over 6 years. This raises the possibility that there may be a benign aetiology such as a radial scar.

Imaging features are sufficiently suspicious that I feel this requires further work-up. Surgical referral is advised.

This will probably require surgical removal for definitive histological examination but either a stereotactic guided or ultrasound guided biopsy could be performed to see if malignancy can be confirmed prior to any surgery."

Mrs A immediately spoke to her GP who arranged an appointment for her with a breast and general surgeon, at a Specialist Medical Centre.

The breast and general surgeon saw Mrs A at his Breast Clinic in a region on 14 December 2001. I have been provided with the breast and general surgeon's notes, and relevant correspondence. In a letter from the breast and general surgeon to Ms A's GP, he states:

"[Mrs A] herself has noticed nothing untoward in either breast. She does have a family history of breast cancer with a sister who underwent mastectomy at age 68 and a niece (daughter of another sister) who underwent mastectomy at age 32. Her mammogram clearly shows a spiculated lesion in the left breast. This has been gradually developing since 1997 and I think it is most likely to be breast carcinoma but one of the slow growing, very well differentiated types such as a tubular carcinoma. I will endeavour to get confirmation of this. [A radiologist in private practice] has very kindly agreed to carry out an ultrasound guided core biopsy [in a region] here today ..."

The radiologist in private practice performed an ultrasound guided core biopsy on Mrs A's left breast at the region's radiology practice on 17 December 2001. He reported to the breast and general surgeon and Mrs A's GP:

"A total of 4 cores were obtained from the rather poorly defined nodule laterally in the left breast without complication."

On 20 December 2001, the breast and general surgeon advised Mrs A and her GP that the core biopsies had confirmed "infiltrating ductal carcinoma". Mrs A elected to have a left breast mastectomy and axillary clearance and underwent this procedure at a Private Hospital, in a city, on 17 January 2002. The histopathology report following this procedure stated:

“MACROSCOPIC

The specimen consists of a left mastectomy and axillary clearance ... Situated in the inferior breast approximately 40mm from nipple there is a stellate lesion which measures 14mm in maximum dimension. The tumour is 20mm from the inferior margin and approximately 12mm from the deep margin. No abnormality is seen in the remainder of the breast apart from focal fibrosis.

MICROSCOPIC

Sections through the tumour show infiltrating duct carcinoma, NST. ... No tumour necrosis is seen and there is no neural or vascular invasion identified ... Tumour measures 14mm in maximum dimension microscopically and clears excision margins by greater than 10mm.

The remainder of the breast shows mild fibrosis and a small calcified fibroadenoma.”

In response to my provisional opinion, Dr D clarified the matter of the different descriptions of the size of the lesion detected by ultrasound and on excision. He noted:

“The measurement on an ultrasound was 7mm. The lesion was poorly defined on mammogram, it probably had similar dimensions. The histological measurement on microscopy was 14mm. [The assumption] that this indicates that the tumour had increased in size between December 2001 and January 2002 ... is a false assumption. The microscopic extent of invasion can be considerably more than what is visible on ultrasound or mammography and the tumour is unlikely to have increased in size in one month when it did not change significantly in four years.”

A subsequent mammogram in June 2002 was reported as “clear”, with the breast and general surgeon noting that there was “no sign of any local regional recurrence of her breast cancer”.

Mammogram of 10 September 1997

Dr B advised me that on 10 September 1997, he did not meet Mrs A. This was his usual practice for screening mammography at the time, unless further views or ultrasound scans were required. He confirmed that in reporting Mrs A’s mammogram on this date, he made comparisons with the previous mammogram of 10 April 1995 and noted that there had been no significant change. He noted that “the crux of [Mrs A’s] complaint rests on the presence of a subtle area of spiculation in the lateral left breast on the CC view. This area was not visualised on the MLO view [on 10 September 1997] and showed no change from the mammogram of 10 April 1995.”

Dr B also explained:

“The area in question is only visualised on one view. It is not an obvious spiculated area of mass. Areas of possible spiculation may be caused by carcinomas but may also be

caused by other processes ... These areas are frequently caused by overlap of normal tissues or by previous surgery, infection or inflammation.

Had the area of subtle spiculation been malignant, features that could have indicated this would have been:

- a) prominence of the abnormality
- b) there could have been the presence of a mass or density associated with this area
- c) the lesion could have been visible on the second view of the breast
- d) there could have been change over the two-year period since the previous mammogram.

These features were **not** present on the mammogram of 10 September 1997.

The appearance in question, on the CC view, is not a prominent abnormality.

There is no identifiable mass on the mammogram of 10 September 1997.

No abnormality was evident on the second view of the breast. A true lesion will usually be seen on both views of a breast whilst a summation shadow, from overlapping normal tissues, is only visible on a single view.

A characteristic of a benign abnormality is a stable appearance over time. It is very unusual for a carcinoma to remain in appearance for a prolonged period. An unchanged appearance over a period of two years is usually taken as strong evidence of a benign cause when dealing with a mammographic abnormality.

The fact that the area in the left breast remained stable for four years, 1995 to 1999, before changes were observed at six years is extremely unusual. Mrs A states in her letter [of complaint] that the breast and general surgeon was also 'surprised the lesion had not grown earlier'. Therefore it is unlikely that the spiculated area could have been unfaillingly diagnosed as significant on 10 September 1997."

The mammogram reported by Dr B on 10 September 1997 was not "double read" (verified by two radiologists). I have been informed that throughout the 1990s there was a gradual shift in practice from single to double reporting of mammogram films, in recognition of the difficult nature of mammographic reporting. The private radiology practice moved to the practice of double reporting in late 1998 or early 1999. I understand that this was in line with practices adopted at Breastsreen Aotearoa (the New Zealand National Breast Screening Programme) and as a result of recommendations from the New Zealand branch of the RANZCR.

Mammogram of 14 July 1999

Dr C provided me with background information on the process of having a mammogram at the private radiology practice in 1999. When a patient arrived she would be met by a radiographer, who would ask a series of questions, including family history, the history of any breast problems or surgery, the presence or absence of symptoms, and the presence of

any discomfort or palpable lumps. The mammogram would then be performed with two standard MLO and CC views of each breast taken. The films would be taken into the radiologist on duty and the films would be hung by the radiographer and any relevant history given to the radiologist.

Dr C advised:

“During [the] examination [by the radiologist], old films were also reviewed, and if the radiologist was happy with the findings, the radiographer would then tell the patient that the examination appeared unremarkable, and the patient was told that once the films had been reviewed by another radiologist, the report would be sent to her doctor/s and the films would be sent out to her.

If there were any areas of concern on the mammogram or the patient complained of symptoms such as pain or a palpable lump, further views and/or an ultrasound would be performed. Approximately 30-50% of patients had further examination for which the threshold was very low. If there was a finding of concern, [the] patient’s doctor would be contacted and the wishes of the referring doctor followed in discussing the findings with the patient.

... After the initial report the films would be reviewed by a second radiologist and at that stage the films would be sent to the patient.”

Dr B explained that in 1999, the private radiology practice did not have a written radiologists’ protocol. However, they followed guidelines published by the RANZCR and local hospitals. He noted that “as we only had 3 radiologists we were able to discuss issues easily and ensured our practice of mammography was at the required level”.

On 14 July 1999 Mrs A’s mammogram was “double read” by Dr C and Dr D. In response to Mrs A’s complaint, Dr C explained that “the stability of the lesion [or spiculated area in the left breast] was critical in coming to the judgement that the lesion was benign. A total of 4 radiologists had viewed the lesion since 1995 and had come to the same conclusion ...”

Dr C noted that “after viewing the mammograms and taking careful note that there had been little change in the lesion since 1997 and the earlier examination of 1995, I made the judgement that the lesion was stable and of benign aetiology. I would have expected some change in the appearance of this lesion during that time. My initial judgement was then agreed with by the second reader, Dr D.”

Dr D informed me that when he reviewed the mammogram screens on 14 July 1999:

“the opacity ... [was] visible on the cranio-caudal views in the lateral part of the left breast and a mass of just under 2cm diameter with some distortion of the surrounding breast. The opacity is virtually identical with that seen in 1997 and 1995.

On the medio-lateral oblique views the lesion [was] very diffuse and difficult to distinguish in the surrounding breast tissue. It contains some strands of fat density within

the lesion. There is no associated calcification, no lymphadenopathy and no abnormality elsewhere in the breast.

... The absence of any change in abnormality on mammogram is usually a reliable sign that it is not evidence of a cancer. The lack of change in this lesion over a period of 4 years between 1995 and 1999 and the presence of a fatty density within the lesion on the oblique view led me to believe that this was a benign lesion. I did mention it in my report to the general practitioner, [...] but indicated that it was unchanged. Had I felt that it was significant then further investigation would have taken place at the time of this mammogram.

... I stress that it was my opinion along with Dr C in 1999 that this lesion was unchanged for 4 years and therefore we were of the opinion that it did not require further investigation at that time. I believe that this opinion conformed with internationally accepted standards of practice at that time.”

Mrs A's family history

Mrs A is particularly concerned that Dr B, Dr C and Dr D did not take into account her family history of breast cancer when reviewing her mammograms in 1997 and 1999. She informed me that every time she had a mammogram she told the private radiology practice staff of her family history. Drs B, C and D have not specifically confirmed, in their responses, whether this information was actually conveyed or known to them.

However, Dr B did inform me that “family history is communicated to the radiologist via a questionnaire that is filled out by the patient. This questionnaire is read at the time the mammograms are interpreted. I would have been aware of the history via the questionnaire and I would have taken this into account when I examined the screening mammogram in 1997.”

Mrs A provided me with an original private radiology practice questionnaire, apparently completed on her behalf, which includes, under the heading “*family history of breast cancer (please state relationship and age at diagnosis)*” the response “*sister 69 years plus niece 35 years*”. Unfortunately, this questionnaire is not dated. Aside from the entry on the mammogram report dated 3 December 2001, it is the only written record I have seen that attests to Mrs A's family history of breast cancer being known to the radiologists at the practice. However, because it is undated, I cannot be certain of when it would have been considered by them.

Dr B also advised:

“A positive family history does increase the relative risk of developing breast cancer. The increase in risk is in the order of 1.5 to 2 times increased risk if there is a 1st degree relative who develops a post-menopausal breast cancer. This still means that the large majority of women with a positive family history will not develop a breast cancer over their lifetime. The majority of breast cancers detected with screening mammography were developed in women who do not have a family history. All mammograms, with or

without a family history, must be carefully scrutinised for evidence of breast cancer but there is always a tendency to be particularly vigilant in women who have a positive family history.”

Dr D advised me that “with regard to Mrs A’s family history of breast cancer, this would have been taken into account. It is recorded in the information available to us at the time of reporting. Although a family history of breast cancer does increase the incidence of cancer, the lack of change in [the spiculated area in Mrs A’s left breast] was the overriding finding.”

Information given to Mrs A

Mrs A feels “let down” by the private radiology practice, particularly by the lack of information provided to her by the radiologists in 1997 and 1999. She has complained that “their procedures, particularly of patients’ rights to be informed – no matter how small the problem is – need to be looked at”. The key information that Mrs A felt was denied her was the radiologists’ identification of a spiculated area in her left breast.

Dr B advised:

“It would not be usual to inform a client of all benign findings. As an example of the current level of information provided to patients, the National Breast Screening service does not provide a report to patients detailing benign findings. Films are reported as either (a) no evidence of malignancy or (b) requiring further investigation. On 10 September 1997 I did not consider the area in question to be an indicator of malignancy and therefore did not consider it of sufficient significance to inform Mrs [A].”

Dr C commented:

“In cases where apparently benign lesions such as scarring, architectural asymmetry or calcification are seen, the findings are not necessarily conveyed to the patient. The aim is to avoid unnecessary confusion and stress in patients. This is particularly important as many of our patients drive long distances, issues of patient safety are involved as we do not want them distracted by undue stress. This issue has been raised by some of our referring doctors. The findings would usually be conveyed to the referring doctor in the report with the appropriate explanation as occurred in the case of Mrs [A]. We are always willing to discuss findings with patients if requested. In this case no such request was made.”

Dr D stated:

“I would like to stress that it is our practice to review the x-rays with another Radiologist before issuing a report as is international standard practice. While Mrs [A] was at [the private radiology practice] she would have been informed that the examination was adequate and that a report would be sent to her general practitioner. We do not give our patients a final report until this has been performed and I feel it is appropriate that the report once defined by 2 radiologists is sent to the GP. It is then the GP who is responsible for correlating the findings with the clinical situation, and relating the findings to the patient.”

Retrospective reviews of Mrs A's mammograms

It is clear that from 1997 onwards, Mrs A's mammograms were interpreted with reference to screens taken in previous years. The critical factor for each subsequent radiologist reporting the mammograms was the stability, ie, unchanging nature, of the spiculated area in Mrs A's left breast.

However, Mrs A explained in her letter of complaint that during a consultation with her surgeon in December 2001, he put all of her mammograms on a screen, and "pointed to a mark [the spiculated area] in my left breast in 1995, then said 'there it is in 1997, definitely there in 1999 and also in 2001'". Mrs A says she was shocked to be told this, particularly because at no time in 1995, 1997 or 1999 had anything been mentioned to her about a lesion or spiculated area showing on the mammograms. In response to my provisional opinion, Mrs A clarified that when this discussion occurred, she had not yet had a biopsy and her breast cancer had not been confirmed. I have not contacted the breast and general surgeon to confirm his recollection of this consultation and the nature of his discussion with Mrs A. However, as Mrs A describes it, the breast and general surgeon was able to show her the spiculated area of her left breast in each year's mammogram, upon reviewing them all together in the context of a suspicion of a small malignancy recently identified by Dr B. It is important to note that Drs C, D and B had themselves also been able to see the spiculated area in each mammogram. The crucial point, however – as I have noted above – is that until 2001 they had not been able to see any change in it, and therefore did not consider it to be cancer.

Dr B commented:

"A characteristic of a benign abnormality is a stable appearance over time. It is very unusual for a carcinoma to remain stable in appearance for a prolonged period. An unchanged appearance over a period of two years is usually taken as strong evidence of a benign cause when dealing with a mammographic abnormality. The fact that the area in the left breast remained stable for four years, 1995 to 1999, before changes were observed at six years, is extremely unusual ...

The mammographic abnormality present on the mammograms of April 1995, September 1997 and July 1999 is not of an obvious cancer or of a notably suspicious area. If it was, one or more of the four radiologists who examined the films over this time would have requested further investigation. Whilst in retrospect this interpretation may have been an incorrect one, it was the opinion of four individual radiologists over this period ...

With the benefit of hindsight it is apparent that the spiculated area is that in which a small carcinoma was subsequently diagnosed by me in December 2001 but, when discovered by me in December 2001, this was still a radiographically subtle lesion. This is evidenced by the language I used in [the first substantive paragraph of] that report.

At the time the cancer was discovered in 2001 an ultrasound scan was performed which showed a mass 7mm in diameter. This is very small and well below average for detection of a breast carcinoma. ... The fact that the mass was only 7mm at detection suggests it

was still very small and makes the fact there was subtle spiculation in this area six and a half years earlier, extraordinarily unusual.”

Finally, Dr B stated:

“Mammographic interpretation is a difficult area of radiology and it is acknowledged that abnormalities on mammograms are much easier to interpret with the benefit of hindsight. Studies have suggested that, even with high quality screening mammography services, an abnormality is detectable in retrospect on previous mammograms, in about 11-25% of patients diagnosed with a carcinoma. This does not necessarily indicate that they were sufficiently abnormal at the time to detect or report.”

Dr B’s comments on this issue are important, in light of events that followed his reporting of Mrs A’s mammogram in December 2001, and given the views expressed by my expert, Dr Hadden (discussed below).

I note that Mrs A requested a review of her mammograms from the radiologist in private practice and his radiologist colleagues at the Breast Cancer Screening Unit for the region. I have been provided with a copy of the private practice radiologist’s letter to Mrs A, dated 7 June 2002, in which he writes:

“I showed and discussed your x-rays with each Radiologist at [the Breast Cancer Screening Unit] as well as all of us together as a group. There was a unanimous reluctance from all the Radiologists to provide an opinion on these in an informal setting. There was also a unanimous suggestion that you really need to discuss all your concerns with the Radiologists directly involved in [the city].

You provided all your x-rays and reports for us to review. You attended for screening mammography at each examination which means you never had any symptoms or breast lumps. The examination dated 3.12.01 demonstrated a small stellate lesion in the left breast ...

Retrospective analysis in radiology especially mammography is usually easy. Just because a lesion is visible in retrospect doesn’t mean it was sufficiently abnormal at the time to detect or report. There are many factors which make an x-ray abnormality suspicious enough to investigate further and conversely many features which make an abnormality less worrisome. One of the most reassuring features is stability over time.”

Mrs A disputes the private practice radiologist’s comment that she “never had any symptoms” and says that after the 1999 mammogram she often had pain in her left breast but “kept telling myself all the mammograms have been clear”.

Independent advice to Commissioner

The following expert advice was obtained from Dr Wendy Hadden, an independent radiologist:

“In reply to your request for expert advice on the ability of several radiologists to detect the cancer in the left breast of the complainant, Mrs [A] I will discuss the appearance of the cancer on the mammograms that I have available for review, attempt to answer the questions you have posed and add a comment.

First let me say that the radiological community in New Zealand is small and that the radiologists Drs [B], [C], and [D] are known to me but we are not personal friends, that we do not work together, nor do we have any relationships through our extended private practices.

Screening mammograms from 10-4-1995, 10-9-1997, 14-7-1999 and 3-12-2001 have been reviewed. Two post operative mammograms from 14-6-2002 and 12-2-2003 of the right breast were also made available. The cancer was detected on the screening mammogram of 3-12-2001.

Knowing that a cancer has been detected in the left breast always makes it easier for a reviewing radiologist to see the cancer. It is much harder to visualise the cancer in the normal screening situation where there are very few women (3–10 per 1000 women screened) with a cancer.

Now that a cancer has been detected in the left breast it can be seen on the mammograms of 1997 and 1999 as well as on the mammogram when it was detected in 2001. There is also an asymmetric density on the first mammogram in 1995 in the same area as the cancer. While not a cancer in 1995 the change in this area may have contributed to later difficulties in visualisation of the cancer. If subsequent mammograms were compared with the 1995 mammogram and it was used as a baseline to look for change, it may have been felt that there was little change and that in the later mammograms this was normal asymmetry. In 1997 the asymmetry in the left breast is a little more obvious than in 1995 and in one view there is the suggestion of spiculation but not sufficient spiculation to call a cancer. In 1999 the spiculation is seen in one view, the MLO view, but is not seen in the other view, the CC view, where there is very little density, interspersed fat, and no spiculation. It would be easy to justify this as being normal asymmetric breast tissue as Dr [C] did in 1999. See report 14th July 1999. Presumably he has seen the lesion but has come to the conclusion that it does not have enough features to call it a cancer. By 2001 the lesion has increased in density is spiculated in both views and should be detected for what it is, a cancer.

This is the process of screening for disease in healthy women. Many breasts will have a density that looks like the spiculated density of a cancer. It is not easy for the radiologist to tell the difference between the spiculation of a cancer from spiculation in normal breast tissue. The radiologist does not always make the correct call. A cancer may be

missed but equally cancer may be called when there is no cancer. To call a cancer in the screening situation is a major event and is not to be done lightly. Both the false negatives and the false positive calls by the reading radiologist are part of the screening process just as is the true positive call that a cancer is present is part of screening. It was this screening process with the attendant risks that Mrs [A] consented to undergo when she had the first screening examination.

Whether another radiologist would have seen this lesion on the 1999 mammogram and been more suspicious of it being a cancer is uncertain. Ideally these lesions should be detected as early as possible but equally these lesions are being 'missed' until they become more obvious as in 2001. In 1999 if this lesion had been considered to be a cancer it would have needed to be proved to be a cancer with further mammography, ultrasound and biopsy. It was 'a small spiculated density on magnification compression views' when these were obtained in 2001 and it was 6 or 7mm on ultrasound at that time. Thus when detected it was a small cancer at about the lower limit that can be detected on ultrasound. In 1999 it would have been less than 6mm and perhaps not visible on ultrasound. Even if it had been called by the radiologist or the primary care provider in 1999 had picked up on the word spiculated and investigated this lesion further by sending the woman back to the radiologist for ultrasound it may or may not have been found to be a cancer at that time.

I would like to think that a skilled radiologist would be able to detect this cancer in 1999 but I cannot be sure of this. The lesion is in the borderline region for detection.

As to the radiologists who looked at the mammograms there is no reason to disagree with the reports of [another radiologist in the same practice] in 1995, or Dr [B] in 1997. They gave normal reports on what were 'normal' screening mammograms. Dr [C] and Dr [D] in 1999 commented on the lesion but concluded it was still a 'normal' examination. They were wrong but a difficult call for the reasons suggested above. Would it have been found if they had called Mrs [A] back in 1999 for further mammograms and ultrasound? I am not sure. Has the delay from 1999 to 2001 altered the prognosis for Mrs [A]? I suspect not.

The slow change over a number of years is in keeping with a slow growing, low grade tumour as this tumour subsequently turned out to be. The axillary nodes were clear of tumour giving an excellent prognosis for this 14mm Grade 11 lesion. **Even in 2001 this is still a screen detected lesion and this point seems to have been lost on the people looking after and advising Mrs [A].** The surgeon who saw her in December 2001 makes no comment but the tumour was presumably not palpable. Particularly it was biopsied under ultrasound guidance rather than by palpation. With a size of less than 2cm, a position deep in the breast and not palpable when detected on mammography, it is unlikely that this tumour would have been detected by Mrs [A] for some time. She is fortunate that it was detected when it was. Further delay and with increase in size there is the potential for a change in grade to a more malignant tumour and for spread to the axillary nodes.

This was a screening procedure and the family history of breast cancer should not influence the call. This information in the screening situation can be misleading with the potential for false positive diagnosis. I do not have a reference but knowledge of family history of breast cancer was looked at as to whether it was an aid to diagnosis in the screening situation of the Australian Screening Programme. The knowledge of breast cancer in the family did not help to detect cancers. It is more significant in the young woman outside the screening age range where cancer may be an issue based on a family history of breast cancer, and in those who present with lumps.

Is there fault on the part of the radiologists involved? They missed a cancer but ‘missed cancers’ are a fact of screening. Missing a cancer is part of the screening process. Not all cancers will be found and for the women who have their cancer missed this will be devastating. In this case the delay has probably not been significant and has not altered the outcome.

The radiologists involved should learn from this case and improve for the future but censure in this situation would make radiologists unwilling to perform screening mammography and would have the potential to harm the screening programme in New Zealand.

The last question asked is about professional standards. I do not see any references to standards nor is it stated whether [the private radiology practice] is accredited to the RANZCR programme for performing mammography. Similarly there is no mention of ISO accreditation or adherence to NZ standards for radiology practices. I assume the practice is not accredited. Nevertheless these are measures of the quality of the mammography not of the ability to read the mammograms. The quality of the mammograms changes for the better between 1997 and 1999 with perhaps major changes in film and processing in the interval. The mammograms in 1999 and 2001 are of diagnostic quality with sharp mammograms with good contrast such that small lesions should be detected. It was not because of poor quality mammography that the lesion was not detected.

Finally may I comment? This is one of several similar cases I have reviewed for the Commissioner where the surgeon, oncologist or other health care provider has indicated to the woman ‘they can see the cancer in the breast long before the radiologist detected it’. It may make them feel good but it does nothing for the woman involved. It is easy to detect the cancer with hind sight and once the diagnosis has been made. Perhaps better to reinforce the positive features of the situation that this is a screen detected cancer with a good prognosis.”

I asked Dr Hadden for further information about spiculation. She explained that nearly every woman’s mammogram will show spiculation and, in her view, a lot of unnecessary anxiety would be caused by informing all women about the presence of spiculation. The information to give to women is whether cancer is present.

My advisor also commented that in Mrs A's case, the spiculation showed only in one view, which raises doubt about the possibility of cancer, as it is more likely to be caused by an overlapping shadow.

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4

Right to Services of an Appropriate Standard

- 1) *Every consumer has the right to have services provided with reasonable care and skill.*

RIGHT 6

Right to be Fully Informed

- 1) *Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including –*
 - a) *An explanation of his or her condition; ...*
-

Opinion: No breach – Drs C and D

Mammogram of 14 July 1999

Right 4(1) of the Code affirms the right of every patient to have services provided with reasonable care and skill. A key question in this case is whether Dr C and Dr D exercised reasonable care and skill on 14 July 1999 in reporting Mrs A's mammogram. I have also considered whether they acted with reasonable care and skill when they concluded that, although on the mammogram there was "a spiculated area in the outer aspect of the left breast", no further investigation was required. In my opinion, Dr C and Dr D did act with reasonable care and skill, for the following reasons.

The mammogram taken on 10 April 1995, in respect of which another radiologist in the same practice reported "no abnormality seen in both breasts", formed a baseline to look for change in subsequent mammograms reported by Dr B in 1997, Dr C and Dr D in 1999, and on 3 December 2001 by Dr B when he detected Mrs A's breast cancer.

My expert, Dr Hadden, advised that there is no reason to disagree with the reports of the other radiologist in the same practice in 1995 or Dr B in 1997. She stated that they were "normal reports" on "normal" screening mammograms. I accept that advice. I acknowledge

that in 2001 Mrs A would have found it particularly distressing to be told by the breast and general surgeon that he could see a spiculated area on her 1997 and 1999 mammograms. Indeed, Dr Hadden remarked that there is actually an asymmetric density on the 1995 mammogram in the same area of the breast where the cancer was ultimately identified. However, in my opinion, this does not mean that Dr C and Dr D failed to adequately read and report the 1999 mammogram or that they should have arranged for further mammograms or ultrasound to be carried out to further examine the spiculated area.

The dominant factor that appears to have influenced Dr C's and Dr D's decisions on 14 July 1999 was that the spiculated area had not changed since the previous examination of September 1997. Dr C noted "the stability of the lesion was critical in coming to the judgement that the lesion was benign. A total of 4 radiologists had viewed the lesion since 1995 and had come to the same conclusion ..." Both Dr C and Dr D stated that they would have expected some change in the appearance of the spiculated area over time, were it to be indicative of the presence of a malignant lesion. In my view that is a reasonable expectation for a radiologist reporting on mammograms.

In addition, the spiculated area showed on one view of the mammogram only. As noted by Dr Hadden, in such circumstances "it would be easy to justify this as being normal asymmetric breast tissue as Dr [C] did". My advisor commented that nearly every woman's mammogram will show some spiculation. If it shows on only one view it would be reasonable for the radiologist to have a lower index of suspicion of the presence of cancer. In that situation a radiologist may instead conclude that the spiculation is caused by an overlapping shadow. However, if spiculation shows on both views, and has changed in the interval since the previous mammogram, the radiologist's index of suspicion should be raised and further investigation is necessary and appropriate.

I am guided by Dr Hadden's comment that "whether another radiologist would have seen this lesion on the 1999 mammogram and been more suspicious of it being a cancer is uncertain. Ideally these lesions should be detected as early as possible but equally these lesions are being 'missed' until they become more obvious as in 2001." The lesion was "borderline for detection" in 1999. Had Dr C and Dr D requested further investigation at that time, it is possible that the lesion would not have been detected, or even that a biopsy would have confirmed it as being benign at that time. In this regard it is also important to note that in 2001, when Dr B arranged for further mammography and ultrasound, and suggested in his report that a biopsy be performed – because by that time the lesion in Mrs A's left breast had increased in density and *was* spiculated in both views – he still reported it as "a small spiculated density" on magnification compression views and found it to be 6 or 7mm in size on ultrasound. Dr Hadden noted that "it was a small cancer at about the lower limit that can be detected on ultrasound. In 1999 it would have been less than 6mm and perhaps not visible on ultrasound."

In my opinion, Dr C and Dr D adequately reported Mrs A's mammogram in 1999 and, accordingly, did not breach the Code.

Family history

Providing services with reasonable care and skill also involves listening to the information given by the patient and others. Mrs A states that she always made staff at the first and second private radiology practices aware that both her sister and a niece had had breast cancer. I have seen only one questionnaire completed in respect of Mrs A which notes that this was the case. Unfortunately, it is not dated. There is no reference to Mrs A's family history on the 1995, 1997 or 1999 mammogram reports, although Dr B does record on the report for 3 December 2001 that there is "positive family history". Dr C described the "standard process" for a woman having a mammogram at the private radiology practice in 1999, but cannot specifically state that information about Mrs A's family history was actually conveyed to him either by his patient or his staff.

In these circumstances, I cannot be certain that Dr C and Dr D were aware of Mrs A's family history or that they took it into account when reporting on the 1999 mammogram. However, in deciding whether Dr C and Dr D acted with reasonable care and skill, I am further guided by my expert advice that "family history of breast cancer should not influence the call [as to the presence of cancer]. This information in the screening situation can be misleading with the potential for false positive diagnosis." Dr B also commented on this issue when he responded to Mrs A's complaint, stating that "all mammograms, with or without a family history, must be carefully scrutinised for evidence of breast cancer but there is always a tendency to be particularly vigilant in women who have a positive family history".

I consider that irrespective of whether Dr C and Dr D actually knew of Mrs A's family history and took it into account, they were obliged to carefully consider the mammogram and exercise reasonable care and skill when reporting on it. I accept that it is not easy for a radiologist to tell the difference between spiculation that is cancer and spiculation that is shadowing in normal breast tissue. With the benefit of hindsight, Dr C's and Dr D's reporting may have been incorrect. However, I am satisfied that on 14 July 1999 Dr C and Dr D acted appropriately and made a reasonable assessment of the mammogram when they concluded that because the spiculated area was evident on the MLO view only and had not changed since 1997, it was benign and did not require further investigation. Accordingly, in my opinion they did not breach Right 4(1) of the Code.

Opinion: No breach – Dr B

Mammogram of 10 September 1997

In my opinion, Dr B's reporting of Mrs A's mammogram on 10 September 1997 also did not breach Right 4(1) of the Code. In reaching this conclusion I have applied much of the same reasoning set out above in relation to Dr C and Dr D.

Key factors in determining that Dr B acted with reasonable care and skill include Dr Hadden's advice that "there is no reason to disagree" with Dr B's report in 1997 and that it

was a “normal report” on a “normal” screening mammogram. Dr Hadden also noted that the 1997 asymmetry reported by Dr B was “a little more obvious than in 1995 ... but not sufficient spiculation to call a cancer”. I accept that advice.

It is important to note that in 1997, Dr B did not have the benefit of “double reporting” on the mammogram. Acting alone, he nevertheless compared the 1997 mammogram with that reported by the other radiologist in the same practice in 1995, which was appropriate. Because the spiculation was visible on one view only, and had showed no changed since 1995, he concluded that no further investigation was required. I consider that this was a reasonable decision to make and I am satisfied that Dr B exercised reasonable care and skill when reaching it.

In response to my provisional opinion, Mrs A challenged Dr B’s comments about the lesion being “very small” and of a size “well below average for detection”. She referred me to information contained in a BreastScreen Aotearoa advertisement, a copy of which is attached to this report as Appendix 1. The headline asks, “Can you find the breast cancer on this page?” The text advises, “It’s that tiny 4mm dot on the question mark at the end of the headline. That’s the size of the smallest change found by regular mammograms. The average size found by women during self examination is 20mm.”

BreastScreen Aotearoa is the free national breast X-ray service offered (during the time period covered by this case) to all women in New Zealand aged 50 to 64 years, who have no breast cancer symptoms. I have considered additional information published on the service’s website and contacted BreastScreen Aotearoa’s National Screening Unit. An important statistic held by the Unit, which is not contained in the advertisement referred to by Mrs A, is that the average size of a breast lump detected by a first mammogram is 12mm.

The lesion in Mrs A’s left breast was approximately 7mm in size, and unchanged over four years, when confirmed by ultrasound on 3 December 2001. As pointed out by Dr D, although the histological measurement of the lesion on 17 January 2002 was 14mm, the difference is explained by the fact that “the microscopic extent of invasion can be considerably more than what is visible on ultrasound or mammography”.

I accept that for Dr B to have described the size of Mrs A’s breast lump as “well below average” for detection on a screening mammogram was a fair comment. I also note Dr Hadden’s comment that “with a size of less than 2cm, a position deep in the breast and not palpable when detected on mammography, it is unlikely that this tumour would have been detected by Mrs [A] for some time. She is fortunate that it was detected when it was.”

Family history

There is no evidence that Dr B was aware of Mrs A’s family history when reporting on her mammogram. He did not meet Mrs A in 1997. He may have seen a questionnaire completed by her, or spoken to his staff, but this cannot be confirmed. Nevertheless, I am reassured by Dr B’s comment that “all mammograms, with or without a family history, must be carefully scrutinised for evidence of breast cancer but there is always a tendency to be particularly vigilant in women who have a positive family history”. I commend this approach to all

radiologists. In the absence of evidence that he failed to take into account family history, I am satisfied that Dr B provided appropriate services to Mrs A when he read her mammogram, and did not breach the Code.

Opinion: No breach – Drs C, D and B

Adequacy of information disclosure

Right 6(1)(a) of the Code affirms every patient's right to receive information that a reasonable patient, in that patient's circumstances, would expect to receive, including an explanation of her condition. Mrs A has complained that she should have been informed that there was an area of spiculation showing on her mammograms in 1997 and 1999.

There is some debate as to whether it would have been the responsibility of the diagnostic radiologists or Mrs A's GP to inform her of the presence of spiculation on her mammograms. Irrespective of whose role it might be, I am guided by the comment of my expert that "to call a cancer in a screening situation is a major event and is not to be done lightly".

Dr Hadden explained that most mammograms will show some spiculation and that it is the responsibility of the radiologist to interpret the screen and decide whether cancer is present. If every woman were told when there was spiculation on her mammogram, many women would be worried unnecessarily. Dr C also expressed concern about this issue when he said that "the aim is to avoid unnecessary confusion and stress in patients". Clearly, the most significant information that a woman requires following a mammogram is whether or not cancer is present; ie, either there is "no evidence of malignancy" or the screen "requires further investigation". Any additional information provided to a patient will reinforce one of these two conclusions. Accordingly, in terms of Right 6(1)(a), the most important information that had to be conveyed to Mrs A in 1997 and 1999 was that there was, in the radiologists' opinion, no evidence of malignancy shown on her mammograms. It is clear that this information was provided to her.

Mrs A was not provided with any additional information as to why a "no evidence of malignancy" report was given. I can appreciate that, in retrospect, she feels that there was in fact evidence of a malignant or pre-cancerous lesion, which she should have been informed about. In response to my provisional opinion on this issue, Mrs A told me she still feels that she should have been informed there was a spiculated area in her left breast that was evident but unchanged between 1997 and 1999. She said:

"If [the private radiology practice] had suggested a scan in 1997 or 1999 and everything was okay, I would have been reassured, not upset. Surely the patient should be part of the decision to wait and see ...

Dr [B] said the lesion remained stable for a long time. I should have been told it was there. The choice whether to leave it or have it investigated should have been mine ...

I feel distressed that this lesion had been left in my breast without my knowledge ... I disagree that anxiety would be caused by informing women about the presence of [a] lesion or spiculation. My experience is they say 'they would prefer to be told'."

I have therefore considered whether a reasonable patient, in Mrs A's circumstances, would expect to receive information as to the presence of unchanged spiculation on one view of her left breast. This is particularly significant given that Mrs A's circumstances included a family history of breast cancer.

Dr B advised me that it would not be usual to inform a client of all benign findings. I accept that this is reasonable in most cases. However, if Dr C, Dr D or Dr B was aware of Mrs A's family history of breast cancer and her anxiety about it, it may have been reasonable to provide additional information. As Mrs A has said, they could have informed her that whilst there was "no evidence of malignancy", there was an area of spiculation that had remained unchanged since 1995, which accordingly gave them no cause for concern. This information would have been no different to that recorded in Dr C's and Dr D's 14 July 1999 report.

It is, however, easy to say this with the benefit of hindsight. It is also clear that Drs C, D and B were acting in what they considered to be Mrs A's best interests, and trying to avoid causing her "unnecessary confusion and stress" when they told her only that her mammogram was normal. In their view, and that of my expert, there was "no evidence of malignancy" and there was no need to report in more detail on a benign report. (In this regard, I have noted a statement on the BreastScreen Aotearoa website that "possible over-diagnosis" and earlier detection of slow-growing cancers that could be successfully treated later when a lump is felt "may cause additional months or years of cancer-related anxiety".) I am sure that, had any more information been provided to Mrs A in 1997 or 1999, she would have sought a second opinion. However, even if she had done so, it is not certain that cancer would have been detected or confirmed.

I acknowledge that Drs C, D and B could have given more information to Mrs A than they actually did. However, I am satisfied that the radiologists acted in what they believed to be their patient's best interests, in accordance with accepted standards of reporting practice, and that the information provided to Mrs A was reasonable in the circumstances. Accordingly, the radiologists did not breach Right 6(1)(a) of the Code.

Other comments

Co-operation among providers

In response to my provisional opinion, Mrs A confirmed that she always told the person taking her mammograms that she had a family history of breast cancer and “if this fact was not conveyed to [the radiologists] it is a serious lack of communication”. She also commented that for a mammogram questionnaire not to be dated is “very careless in an x-ray clinic”.

Right 4(5) of the Code gives every patient the right to co-operation among providers to ensure quality and continuity of services. In the context of a radiology practice, it is clear that there must be co-operation between all staff involved in screening mammograms, including repeat screening mammograms, in order to ensure that quality services are provided. There must be an appropriate level of communication between the radiographers who speak to the patients and take the X-rays, and the radiologists, who may not meet the patient but are required to read and interpret the X-rays. Patients need to be reassured that the information they give to front-line staff (such as radiographers) will be passed on in an appropriate manner. One way to ensure this would be for a mammogram questionnaire to be completed and dated, signed by the patient, and then countersigned by the radiographer and radiologist. A copy of the questionnaire should be retained by the practice and copies sent to the patient and her GP.

Clearly, all mammograms must be carefully scrutinised for evidence of breast cancer, irrespective of the patient’s family history. There is a risk that a radiologist’s knowledge of a positive family history may influence the interpretation of a mammogram, resulting in a false positive report. Nevertheless, providers need to have systems in place to obtain and share relevant patient information, including family history. I encourage staff at the private radiology practice to take note of Mrs A’s comments about this issue, and observe the requirements of Right 4(5) in their practice.

Co-operation and effective co-ordination is also important between providers from different specialities in different clinics. Radiologists, GPs and surgeons should work together to avoid causing any further distress to patients in situations that are already upsetting and difficult. Mrs A became distressed and concerned when the breast and general surgeon allegedly said that a spiculated area in her left breast was evident in her mammograms from 1995 onwards. Mrs A has since confirmed to me that at the time of that consultation, the breast and general surgeon did not know for certain that the spiculated area contained a malignant tumour. She states that the breast and general surgeon was always positive and that she has drawn great strength from his honesty and care. While I therefore do not propose to comment further on this issue, I endorse the comment of Dr Hadden, that it is preferable for subsequent providers to reinforce to patients the positive features of the process of breast cancer screening, particularly in cases where cancer has been identified by a mammogram when palpation, self breast examination, or ultrasound may not have been able to do so. I also note the advice of the private practice radiologist to Mrs A that “just because a lesion is visible in retrospect doesn’t mean it was sufficiently abnormal at the time [of the previous mammogram] to detect or report”.

Limitations in the screening process

In her report, Dr Hadden said, “[The radiologists] missed a cancer but ‘missed cancers’ are a fact of screening. Missing a cancer is part of the screening process. Not all cancers will be found and for the women who have their cancer missed this will be devastating.” Mrs A told me, “I cannot take this lightly, surely this is a matter of public safety.”

I acknowledge Mrs A’s concerns. However, it is also important to understand the limitations of the screening process. Dr Hadden referred to these in her report, when she said: “It is not easy for the radiologist to tell the difference between the spiculation of a cancer from spiculation in normal breast tissue. The radiologist does not always make the correct call. A cancer may be missed but equally cancer may be called when there is no cancer. To call a cancer in the screening situation is a major event and is not to be done lightly. Both the false negatives and the false positive calls by the reading radiologist are part of the screening process just as is the true positive call that a cancer is present ...”

I note that information published by BreastScreen Aotearoa also highlights these issues.

Education

Mrs A told me that she hoped the private radiology practice would follow my recommendations for improving their practice. She also emphasised her view that women “put their trust in ... mammograms” and that the screening process is “a matter of public safety”. I acknowledge her concerns. It is for these reasons that this report is intended to have a wider audience than simply Dr C, Dr D and Dr B, as evident from the recommended “follow-up actions” below.

I also wish to highlight the comments of Dr Hadden that “the radiologists involved should learn from this case and improve for the future but censure in this situation would make radiologists unwilling to perform screening mammography and would have the potential to harm the screening programme in New Zealand”.

Providers’ responses to Provisional Opinion

In a written response to my provisional opinion, Dr C commented:

“This case reinforces the difficulties [in] interpreting certain mammographic examinations particularly when lesions are apparently stable.

[The] comments of Dr Hadden have given us renewed confidence in the complaints system and encouraged us to strive to improve our service. We have taken note of the comments in the opinion that may help us improve our performance.”

Dr D also responded to my provisional opinion and advised, “I also will take note of your suggestions for follow up actions.”

Recommendations

I recommend that Dr C, Dr D and Dr B take the following actions:

- Continue to review their practice in light of this case and my report. I note that the practice at the private radiology practice has changed since 1997, and mammograms are now reported by two doctors. In some circumstances it would be appropriate for the reporting radiologists to explain this to patients, who may be reassured that a second opinion is being given on a mammogram at the time of first reporting. In addition, the private radiology practice may wish to consider the need for further investigation where an area of spiculation recurs in a series of mammograms even where no significant change is apparent. I note Dr D's comment that "in light of this case and further knowledge which has become available more recently at international conferences, I feel that should a similar lesion present in the future, even if it had not changed significantly, I would recommend further investigation".
- Review their information disclosure practice and consider whether in certain circumstances it may be appropriate for the radiologist to give the patient additional information beyond the standard reporting conclusions. Information about the presence of spiculation and its significance may need to be disclosed in circumstances where it is known that the patient is concerned about a family history of breast cancer.

Follow-up actions

- A copy of this report will be sent to the Medical Council of New Zealand and the Australian and New Zealand College of Radiologists.
- A copy of this report, with details identifying the parties removed, will be sent to BreastScreen Aotearoa, Women's Health Action, and the Federation of Women's Health Councils Aotearoa, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix 1

Can you find the breast cancer on this page?

Mammograms (breast x-rays) can find really small cancers long before you feel, or notice anything unusual.

That's why it's so important to have a mammogram every two years. The earlier a cancer is found and treated, the better your chance of surviving.

Nearly 10% of women in New Zealand develop breast cancer and most have no relatives with the disease.

The risk increases as you get older. Three-quarters of breast cancer cases are diagnosed in women aged 50 and over.

That's why BreastScreen Aotearoa, New Zealand's national breast screening programme is offering **free mammograms for women aged 50 to 64**. If you're in this age group and you haven't enrolled yet, call our 0800 number and make an appointment.

Have you found the breast cancer yet? It's that tiny 4mm dot on the question mark at the end of the headline. That's the size of the smallest change found by regular mammograms. The average size found by women during self examination is 20mm – about the size of a 5 cent piece.

Call 0800 270 200

Or visit our website: www.breastscreen.org.nz

