

**Radiologist, Dr B**  
**Radiologist, Dr C**  
**Radiologist, Dr D**  
**The Private Radiology Facility**

**A Report by the**  
**Health and Disability Commissioner**

**(Case05HDC11656)**



Health and Disability Commissioner  
*Te Toihau Hauora, Hauātanga*



## Parties involved

Mrs A	Consumer
Dr B	Provider/Radiologist
Dr C	Provider/Radiologist
Dr D	Provider/Radiologist
A Private radiology facility	Provider/Private radiology facility
Dr E	Breast, endocrine and general surgeon
Ms F	Director, Private radiology facility
Dr G	General Practitioner
Mrs H	Radiation Technologist
Mrs I	Radiation Technologist

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## Complaint

On 11 April 2005 the Commissioner received a complaint from Mrs A about the services provided by a private radiology facility and radiologists Drs B, C, and D. The following issues were identified for investigation:

- *Whether Dr B appropriately read Mrs A's mammograms and ultrasound scans of 25, 26 June 2003 and 13 January 2004*
- *Whether Dr C appropriately read Mrs A's mammograms and ultrasound scans of 25, 26 June 2003 and 13 January 2004*
- *Whether Dr D appropriately read Mrs A's mammograms and ultrasound scans of 25 and 26 June 2003*

An investigation was commenced on 11 October 2005.

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## Information reviewed

Information received from:

- Mrs A
  - Dr B
  - Dr C
  - Dr D
  - A private radiology facility
  - Dr E
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Mrs A's clinical records were obtained from the private radiology facility. Independent expert advice was obtained from Dr Wendy Hadden, radiologist.

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## **Information gathered during investigation**

### **Summary**

Mrs A, aged 42 years, went to a private radiology facility in June 2003 for a routine mammogram as part of a Well Woman check. Dr B identified "simple cysts" in Mrs A's right breast on the mammogram and asked her to return the following day for an ultrasound scan. The scan and mammogram images were read by Drs C and D, who supported Dr B's initial diagnosis and asked Mrs A to return for follow-up six months later. The follow-up mammogram performed by Dr C in January 2004 was also double read by Dr D. They concluded that although the cyst had increased in size it was still a simple cyst. In July 2004 Mrs A had a further mammogram, which showed a mass lesion in the central right breast. Dr C performed an ultrasound guided biopsy, the results of which confirmed that Mrs A had invasive carcinoma of the breast. She was referred to a breast surgeon and had a radical mastectomy in July 2004.

### **The private radiology facility**

The private radiology facility is a private company owned by radiologists Dr D, Dr B and Dr C. The private radiology facility specialises in the provision of imaging services to women, specifically mammography, bone density, pregnancy and pelvic ultrasounds. Dr C was the designated leader of the breast imaging and assessment component of the private radiology facility. Drs B, C and D are all Fellows of the Royal Australian and New Zealand College of Radiology.

### **Chronology**

During the 1990s Mrs A had a series of ultrasound examinations performed in relation to breast cysts. In 2003, during a visit to her general practitioner, Dr G, she was advised to have a mammogram as part of a Well Woman health check, recommended for women over the age of 40 years.

#### *June 2003*

On 25 June 2003 Mrs A attended the private radiology facility for a screening mammogram. Mrs A had a referral form from Dr G. The assessing medical radiation technologist, Mrs H, noted on the form: "(No details from Dr — no definite lumps felt then by pt — general lumpiness.) Lump felt in the last 2 months Rt side, previous ductogram Lt breast 1998."

Mrs A completed a "Mammographic Questionnaire" prior to the mammogram. She indicated that the purpose of the examination was screening rather than diagnosis.

Mrs A recorded that a grandmother was diagnosed with breast cancer when she was in her seventies. The questionnaire included a representational diagram of a breast. Mrs A drew (in pencil) a dot on the diagram above the nipple on the right breast and she annotated, "large lump". Different handwriting (presumed to be Mrs H's) below Mrs A's note records, "last 2 months", and under the diagram, "generalised lumpiness".

When a mammogram is taken at the private radiology facility, the usual practice is for the films to be read immediately by a radiologist. However, when Mrs A had her examination there was no radiologist on duty. Mrs H recorded that she had performed the standard four views and, because she was concerned about the results, arranged for Mrs A to return for an ultrasound scan the following day.

Before Mrs A returned to the private radiology facility on 26 June, Dr B read the four films taken by Mrs H. She compared the films with the mammogram images Mrs A had taken on 16 November 1999, and reported on her findings. She also noted on the radiologist's Desk List (which records the examinations performed that day and the provisional results) that Mrs A needed to have an ultrasound scan and/or biopsy to identify the true nature of the changes in the breast tissue identified in the mammogram. Dr B's report concluded:

"Appearances consistent with simple cysts in the right upper breast. The marker indicating the thickening in the right upper breast is not definitely a circumscribed opacity on mammogram. Very low density microcalcifications appear to be associated with this. [Mrs A] will return on 26.06.03 for additional magnification lateral views of the right upper breast and ultrasound. An additional report will then be issued.

NB. This report is pending a double reading. If there is any change at the second read, a further report will be issued.

The false negative rate of mammography is 10%. Management of a lump must be based on the clinical criteria."

Dr B performed a detailed clinical examination and comprehensive ultrasound on Mrs A on 26 June. There was no evidence of a spiculate (splintered) mass or distortion. A magnified view showed a cluster of about five microcalcifications of very low density. The ultrasound confirmed the presence of a number of small cysts in both breasts. The right upper breast had a palpable, 10mm cyst with a slightly thick wall, with a cyst of similar nature lying immediately adjacent. The largest cyst (14mm) in the right breast was not palpable. A Doppler ultrasound examination of the cysts was normal. Dr B found no solid masses or tissue distortion in either breast. She concluded that the lumpiness was due to benign cystic changes. Dr B considered that the cysts were "simple" cysts and benign in nature.

Mrs A subsequently stated that she knew Dr B as a child. She recalled that they "had a good chat" while Dr B was performing the examination. Dr B told Mrs A about her interest in breast cancer detection and the work she had done in the area in New

Zealand and overseas. Dr B informed Mrs A that there was some calcification and she would discuss this with the other doctors, but felt it would be fine. Mrs A recalled that the calcification seemed to be a different issue to the cyst, which she was told was fine. Mrs A said, “When [Dr B] assured me that my cyst was a ‘simple’ one, I believed her and did not question it.”

Dr B noted that consensus would be reached on a double reading of Mrs A’s films the following week when an additional report would be made. Dr B recommended that Mrs A be followed up in one year.

Dr C was the duty radiologist on 30 June and 1 July 2003. She double read Mrs A’s mammography and ultrasound images. She recorded on the Desk List that she had double read the images and her preference was for Mrs A to have follow-up in six months for stereotactic biopsy.

On 4 July 2003 Dr D reviewed the mammography and ultrasound images and the reports. Dr D concurred with Dr C’s management plan.

Dr B, Dr C and Dr D met to discuss Mrs A’s case and agreed that Mrs A should be seen again in six months for review of the calcifications. Dr B added this plan as an addendum to her 26 June report, and a copy was sent to Dr G. Dr B also telephoned Mrs A to inform her of the results and advise her to have a further examination in six months.

#### *13 January 2004*

On 13 January 2004 Mrs A returned to the private radiology facility. She again completed a “Mammographic Questionnaire”. This time she did not allude to a breast lump, thickening or any other breast symptoms. Mrs H was again Mrs A’s radiographer. There is no record on the questionnaire that Mrs A reported any complaints or symptoms even after the mammogram was completed.

Mrs A does not recall what she entered on the form. She was under the impression that she was at the private radiology facility to have a normal mammogram. She said:

“The fact that the ‘simple’ cyst had increased in size didn’t phase me whatsoever. ‘Simple’ cysts don’t turn nasty! They didn’t mention anything about it and I was told the calcification had dissipated. Not for one moment did I realise the film that had been taken wasn’t a normal ‘plain’ mammogram and so far as I was concerned everything was great.”

Dr C was the duty radiologist on 13 January 2004. Dr C reviewed the films and reported that the cluster of microcalcifications in the right upper breast, seen in June 2003, had resolved. She described scattered calcifications throughout the breast, which appeared benign, and persisting rounded densities in keeping with the previously identified breast cysts. Dr C was of the opinion that there were “no features suspicious of neoplasia” (cancer) and advised Mrs A to return for routine bilateral mammography in six months when the ultrasound scan would be repeated.

Dr D double read these films with Dr C's report, and concurred with Dr C's advice to Mrs A.

Mrs A stated that she was told that the calcification had dispersed and "everything was fine". However, she recalled that the cyst was still present in January 2004, and had increased in size. Mrs A stated:

"Despite the existence of the 'cyst' on both this occasion and on the previous occasion, and the fact that the 'cyst' had increased in size, no invasive investigation, such as a biopsy or any attempt to drain the 'cyst' was undertaken."

*5 July 2004*

On 5 July 2004 Mrs A had a further mammogram, a routine recall six-month bilateral mammogram. She again completed a mammography questionnaire and made reference to her grandmother having had breast cancer. Mrs A indicated on the form that her attendance was for routine screening. The technologist that day was Mrs I. Mrs I recorded on the form, "increased size ? cyst R breast", and indicated that the lump identified by Mrs A was in the supra-areola region (above the nipple).

Mrs I performed a standard four-view mammogram. The mammogram showed a new cluster of calcifications associated with a mass lesion in the central right breast. Mrs I immediately arranged for Mrs A to have an ultrasound. The ultrasound showed that the mass was 6 x 4cm, partially solid and partially cystic in nature.

Dr C read the images and considered that further examination, using an ultrasound-guided biopsy of the lesion, was needed. A second radiologist double read the films. The findings were reported to Dr G by telephone and in writing.

The histology report from the breast biopsy showed cores of breast tissue infiltrated by carcinoma together with some ductal carcinoma in situ.

On 9 July Mrs A contacted her medical centre and was given an immediate appointment to see Dr G. Dr G informed Mrs A of the results of the biopsy and referred her to a breast surgeon, Dr E. Mrs A uplifted the mammography films from the private radiology facility and took them to her appointment with Dr E.

Mrs A recalls that when Dr E viewed the films he "immediately noticed" the area of the breast where there had been a change in breast tissue. Dr E recalls: "From memory the main invasive cancer did not show up at all well on mammography. The only clue was some calcification in the breast." Dr E examined Mrs A and informed her that she would require a mastectomy. He made arrangements for her to have detailed radiological examinations of her abdomen, chest and body.

Dr E subsequently advised:

"Calcification in the breast is more commonly due to precancerous change (ductal carcinoma in situ, rather than invasive cancer) or entirely benign. Calcifications in

the breast are also one of the more difficult types of abnormality to call. It is always easy in retrospect when a cancer has been diagnosed to read things appropriately, but not so simple when these things are done blind. ...

We frequently do nothing with breast cysts. If a cyst is simple on ultrasound then it is not something that has to be drained or something that carries a serious risk of malignancy with it. We drain cysts usually only when they are causing problems or getting larger.

Appropriate diagnostic work up of a breast lump is the so called 'triple assessment', this entails:

1. History and examination
2. Appropriate imaging
3. If a significant lump or asymmetrical thickening is present, a sample for microscopic examination; usually a fine needle aspirate or core needle biopsy.

... If an area of the breast was changing clinically or getting bigger then once again a specialist breast service would normally repeat needle tests or remove the abnormal area. In [Mrs A's] case, attention has been focussed on the imaging abnormality rather than any clinical abnormality."

Mrs A had a mastectomy on 27 July 2004. The results of the histological examination of the lymph node specimens removed during surgery revealed that 10 of 15 lymph nodes were involved. Mrs A subsequently had chemotherapy and radiotherapy.

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## **Independent advice to Commissioner**

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

"Thank you for the opportunity to provide expert medical advice on this case. First let me say that I have read and will follow the guidelines to expert advisors in commenting upon this case. I will also add in the beginning that I see no conflict of interest in reviewing this case. As the radiological community in New Zealand is a small one I know or know of the three radiologists involved. One I taught when they were a registrar. One I worked with on the College of Radiologists. These associations were at least 10 to 15 years ago and we have had little or no contact recently. The third radiologist I have heard of but do not know. None of the three radiologists are personal friends nor are we associated through the Public Hospital system, BreastScreen, or our private practices.

I have read the material provided about [Mrs A], about the lead up to, and the final diagnosis of breast cancer. I have reviewed the mammograms, the film record of



the ultrasound examinations, and the reports of those examinations from 16.11.1999 to 5.7.2004.

In answer to your questions:

**1. Is the mammogram report dated 25.6.2003 appropriate?**

The report and decisions made are entirely appropriate. The findings on the mammogram are accurate and the correct decision was made by the radiologist to get [Mrs A] to return for further mammographic views to magnify the calcifications that were seen on the mammogram and to assess the densities further. The additional mammograms would show the calcifications better and allow the radiologist to decide whether they were benign or malignant calcifications. An ultrasound examination was also suggested to see whether the benign appearing opacities and the increased density associated with the calcifications was due to cysts and a benign process, fibrocystic change, in a normal breast, or the changes were indicators of a cancer in the breast. The return visit was organised by the practice promptly without delay for the next day.

**2. Is the ultrasound report dated 26<sup>th</sup> June appropriate?**

It describes the findings of benign cysts and says the palpable abnormality was a slightly thick walled cyst. A second adjacent cyst and an impalpable third cyst are noted. No attenuating lesion or other focal abnormality that looks like a cancer is recorded as being seen nor is any seen now on review of the record of the examination. Thus it would be appropriate to think that this was benign fibrocystic change. The report also suggests that the radiologist palpated the breast and did not feel anything more suspicious than fibrocystic change. However the wall of the palpable cyst is quite thick and as such is not a simple cyst. The radiologist cannot be sure on imaging grounds alone that this is a simple cyst. The cyst would need to be aspirated to be certain it was a benign cyst. At the same time as the ultrasound examination further special magnification views of the calcifications in the breast were made and the calcifications were thought to be benign. With hindsight these are not benign calcifications but it was a reasonable assumption at the time as was the final diagnosis of benign breast disease.

**3. Are the recommendations made in the report dated 26.6.2003 appropriate?**

On the consensus reading of the case the calcifications were called benign calcifications. There must have been doubt at this consensus meeting. If the three radiologists had been totally happy with the conclusion that this was benign disease they would have recommended return to screening with follow up mammography in one year. Instead they chose to watch the calcifications thinking that if there was a slim chance the calcifications were malignant rather than benign

they should become more numerous and look more like malignant calcifications within this space of time. If they did not change in appearance this would confirm that anything happening in the breast was a benign process. A six month follow up is not unreasonable but it was not the correct recommendation for [Mrs A]. More emphasis in the decision making process on the thick walled nature of one of the cysts, the area of mammographic density that was not a cyst, and the presence of calcifications with all three together in one area of the breast may have slanted the decision more towards intervention and biopsy and altered the final outcome. Even if the ultrasound findings were not what one would have expected if a cancer was present in the breast a more aggressive approach to cancer detection with aspiration of the cyst or biopsy of the calcifications may have given a diagnosis.

The final pathology report suggests that the cancer was widespread clumps of malignant cells spread through a large area of the breast. Not one lesion and not an easy cancer to find. The thick wall to the cyst may have been the cancer involving the cyst but one cannot be sure. Aspiration of the cyst fluid may or may not have given a diagnosis. If a biopsy of the calcifications had been undertaken the diagnosis may have been made but these suggestions are suppositions. One or both additional tests may or may not have produced an earlier diagnosis of cancer for [Mrs A].

#### **4. Is the mammographic report dated 13.1.2004 appropriate?**

The report of this date says that the calcifications have dissipated. I assume meaning they are no longer visible. This is largely true. They are much more difficult to see if one can see them at all. The fact that they had gone away was taken to mean these were benign calcifications. It was overlooked or forgotten that very rarely malignant calcifications can do this. Mammographic quality is technically good and should have allowed calcifications if present as they had been on the previous mammogram to be seen. The radiologists saw the cysts that were present on the mammogram but they overlooked several unfavourable signs on these two views of the breast. The breast is smaller than six months previously, a strand of tissue extends posteriorly to the chest wall, the chest wall appears to be pulled forward, and the area of density has increased in size. These signs suggest but are not absolutely diagnostic for a malignant process infiltrating the breast. A non magnified mammogram of the breast may have shown these changes so that they could be more readily detected for what they were. It may have been possible to detect the cancer at this stage if plain mammography had been performed and compared with earlier examinations, if a further ultrasound examination had been performed, or if a clinician familiar with palpating breast cancer had examined the breasts. However the radiologist reading the mammograms was lulled into a false sense of security by the disappearance of the calcifications and did not do or request further tests. Now, looking at the various examinations that were done and knowing that a cancer was present it is easy to see the subtle changes and

appreciate them for what they indicate, probably easier than it was at the time they were done.

**5. Are the recommendations made in the report dated 13.1.2004 appropriate?**

In view of the fact that the radiologist thought the disappearance of the calcifications indicated a benign process it was perfectly reasonable to return [Mrs A] to routine screening meaning mammography of both breasts in six months time. It was reasonable to suggest further ultrasound at that time.

**6. Should an ultrasound examination or any other tests have been completed or recommended on 13.1.2004?**

There are no guidelines that I am aware of to say that when magnification views of calcifications are performed an ultrasound should be performed. The radiologist doing the diagnostic workup decides what to do. Magnification views alone of calcifications are perfectly appropriate. It was unfortunate for [Mrs A] that the calcifications were not visible on these views. The whole situation would have changed if malignant calcifications had been found on 13.1.2004. The radiologist concerned has considerable experience in breast work and would have recognised them for what they were. The subtle signs overlooked can easily be discounted as normal but with malignant calcifications present they would have been recognised for what they were.

**7. What standards apply in this case?**

The case was not performed as part of BreastScreen Aotearoa where there are standards and guidelines to be met in all cases. This was a private clinic providing an imaging service. The curricula vitae of all three radiologists confirm that they have been trained in breast imaging and all three have considerable experience of diagnosing breast cancer on mammograms and ultrasound. The assessment standard as set out by BreastScreen Aotearoa was adhered to in working up the case. [Dr D] states that the practice follows the quality guidelines of the RANZCR but does not say whether the practice has been accredited or not.<sup>1</sup> If they are accredited then there has been an independent check that the quality of the mammography component of the practice is satisfactory. Whatever the situation the quality of the mammograms and ultrasound and the documentation of the findings cannot be faulted. The quality of the imaging was not at fault and poor mammography can not be used as an explanation for why the cancer was not detected sooner.

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<sup>1</sup> The private radiology facility was not accredited at the time of these events; the clinic is currently working towards accreditation.

It is difficult to know whether other radiologists would have detected this cancer. It is equally difficult to know whether a more aggressive approach with early resort to intervention would have found this cancer or not.

There is no standard that will tell a radiologist what to do in an individual case. It is knowledge and experience that guides how a radiologist works up a case to find or exclude cancer. This was a difficult case to work up. Looking back it is easy to say that early biopsy may have detected the cancer. But why when there was a second chance at the six month follow up to find the cancer had the calcifications disappeared. This removed the one reliable clue that would have led to a biopsy six months sooner than the diagnosis was made. I do not know the answer to this question. When the diagnosis of cancer was made in July 2004 the calcifications were again seen on the mammogram. They had increased in type and were obviously malignant calcifications. At that time the radiologist [Dr C] had no hesitation calling them malignant and going straight to biopsy to make a diagnosis.

**8. Were there any aspects of the care provided by [Drs B, C and D] that you consider warrant additional comment?**

This is a difficult case. There were missed opportunities for early biopsy and diagnosis and there were subtle clues that may have led to an earlier diagnosis but I cannot honestly say that the radiologist was at fault or that anything the radiologists did wrong delayed the diagnosis. Imaging is not a perfect test and cancers do not always declare their presence in a readily detectable fashion. [Mrs A] has my sympathy and I can only say how sorry I am that the care and attention that she received from [the private radiology facility] did not allow an early diagnosis of breast cancer to be made.”

*Further advice*

Dr Hadden provided the following additional advice:

“ ...

1. Re the nature of the cysts reported on 25 and 26 June 2003. It was incorrect to call the cyst simple when it was described as having a ‘slightly thick wall’. A number of the cysts were simple, and one or more of the simple cysts may have contributed to the palpable lump, but in truth, they can not then all be labelled together as simple.
2. The radiologists came to a reasonable conclusion that they were dealing with a benign process such as fibrocystic change. In another case very similar appearances may be benign and fibrocystic change. They came to the wrong conclusion. These eventually turned out to be malignant calcifications. In the very first report [Dr B] correctly raised the suspicion of a problem in the breast but the subsequent workup did not find the breast cancer and the conclusion

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was a benign process. It did not show up as a spiculated density on workup as so many cancers do.

3. Just how difficult it was to find this cancer is uncertain but it was experienced radiologists that came to the wrong conclusion. Given the same appearances different radiologists may have reached the same conclusion as these radiologists that this is benign disease. I have the advantage of knowing there is a cancer in the breast and thus it is easier for me to see subtle changes as malignant.
4. If there was any deviation from normal practice then it was the fact that they failed to aspirate the thick walled cyst and make sure that the palpable lesion resolved.
5. In answer to your third question about the report of 13 Jan 2004. Again with knowledge and hindsight it is easier for me to see subtle changes and call them malignant than it was for the radiologists at the time. The decrease in breast size and the stranding are subtle. They could have been thought to have been produced by poor radiographic technique. It is unfortunate for [Mrs A] that the calcifications seemed to disappear. The false reassurance from this was not appreciated by the radiologists. In similar circumstances other radiologists may have had the same thought that this was benign disease just as these radiologists thought or they may have agreed with me that they are signs of malignant disease. The knowledge there is a cancer makes it easier to recognise these changes for what they are.
6. One might say that if only those calcifications had persisted on the mammogram in January 2004 one or two of them may have looked malignant like they did on the mammogram when the diagnosis was made, and this cancer may have been found sooner.”

## **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.*
  - 2) *Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.*
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## **Other relevant standards**

The Medical Council of New Zealand's publication *Good Medical Practice: A Guide for Doctors* (2004) states:

"1. Patients are entitled to good standards of medical care. The domains of competence that follow are medical care, communication, collaboration, management, scholarship and professionalism.

### **Medical care**

#### **Good clinical care**

2. Good clinical care must include:

- an adequate assessment of the patient's condition, based on the history and clinical signs and, an appropriate examination
- providing or arranging investigations or treatment when necessary
- taking suitable and prompt action when necessary."

## **Opinion: No Breach — Dr B, Dr C and Dr D**

### *June/July 2003 mammogram/ultrasound assessment and reporting*

Rights 4(1) and 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code) give every patient the right to have services provided with reasonable care and skill, and in compliance with professional standards. The Medical Council of New Zealand expects that doctors provide their patients with good clinical care, which includes appropriate examinations and investigations.

Mrs A had a ten-year history of breast cysts. In June 2003, when she was aged 42 years, Mrs A's general practitioner referred her to the private radiology facility for a routine mammography screen. Mrs A attended the private radiology facility on 25 June 2003. The assessing medical radiation technologist noted that although Mrs A's doctor had not specified any problems, Mrs A reported that there had been a lump in her right breast for the past two months. The technologist detected abnormalities on the mammogram films, but because there was no radiologist working at the private radiology facility at the time, she asked Mrs A to return the following day for an ultrasound scan.

On 26 June, Dr B read the films taken by the technologist and compared these films, prior to Mrs A's appointment, with those taken in November 1999. Dr B reported her findings, concluding that the appearance of Mrs A's right breast was "consistent with simple cysts". Thickening in the right upper breast appeared to have associated low density microcalcifications. Dr B footnoted the report that a double reading was pending and that mammography has a false negative rate of 10%.

I am advised by my independent radiology expert, Dr Wendy Hadden, that the report and decisions on Mrs A's mammogram taken on 25 June 2003 were entirely appropriate. The findings were accurate and the decision to have Mrs A return for further examinations was correct and organised promptly for the next day.

Mrs A had the ultrasound scan at the private radiology facility as planned on 26 June. Dr B also performed a detailed clinical examination of Mrs A's breasts, finding a number of small cysts in both breasts. In the right breast, there was a 10mm palpable cyst with a "slightly thick wall" and a further 14mm non-palpable cyst, of similar nature. Dr B found no solid masses or tissue distortion in either breast and concluded that the lumpiness in Mrs A's right breast was due to benign cystic changes. Dr B reported her findings and noted that the films would be double read the following week. Mrs A was advised to attend for follow-up in one year.

Dr Hadden advised that it was incorrect for Dr B to call the cyst "simple" when it was described as having a "slightly thick wall". Dr Hadden stated that a number of the cysts in Mrs A's right breast were simple, and one or more of the simple cysts may have contributed to the palpable lump, but they could not all be labelled together as "simple". A radiologist cannot be sure of the true nature of a cyst on the grounds of imaging alone. The cyst would need to be aspirated to be certain that it was benign.



Dr B correctly raised the suspicion that there was a problem in Mrs A's breast, but the subsequent workup did not find breast cancer. It did not show up as a spiculated density as many cancers do, and the conclusion was of a benign process.

Dr B performed further special magnification views of the calcification in Mrs A's breast when conducting the ultrasound scan, and concluded that the calcification was benign. Dr Hadden stated, "With hindsight these are not benign, but calcifications, but it was a reasonable assumption at the time as was the final diagnosis of benign breast disease."

Dr C was the duty radiologist at the private radiology facility on 30 June and 1 July 2003. She recorded that she double read Mrs A's mammography and ultrasound images, and recommended that Mrs A be followed up in six months rather than in one year as Dr B had suggested.

On 4 July, Dr D reviewed Mrs A's mammography and ultrasound images and recorded that she agreed with Dr C's assessment.

Dr Hadden advised that the three doctors must have had some doubts about Mrs A's results at their consensus meeting. If they had been totally happy with the conclusion they would have recommended that Mrs A return for follow-up in one year. Instead, they chose to look at the calcifications again in six months, reasoning that if the changes were malignant rather than benign they would, over that time, become more numerous and take on more of the appearance of malignant calcification. Dr Hadden stated that the six-month follow-up was not unreasonable, but was not the correct decision for Mrs A. If more emphasis had been placed on the thick-walled nature of one of the cysts, this may have slanted the decision more towards intervention and biopsy and altered the final outcome.

Dr Hadden stated:

"The final pathology report suggests that the cancer was widespread clumps of malignant cells spread through a large area of the breast. Not one lesion, and not an easy cancer to find. The thick wall to the cyst may have been a cancer involving the cyst, but one cannot be sure. Aspiration of the cyst fluid may or may not have given a diagnosis. If a biopsy of the calcifications had been undertaken, the diagnosis may have been made but these suggestions are suppositions. One or both additional tests may or may not have produced the earlier diagnosis of cancer for [Mrs A]. ...

Just how difficult it was to find this cancer is uncertain, but it was experienced radiologists that came to the wrong conclusion. Given the same appearances different radiologists may have reached the same conclusion as these radiologists that this is benign disease. ... If there was any deviation from normal practice then it was the fact that they failed to aspirate the thick walled cyst and make sure that the palpable lesion resolved."



I accept Dr Hadden's advice that the cancerous changes later found on Mrs A's June 2003 mammogram were not easy to find and that it was not unreasonable for Drs B, C and D to come to the conclusions they did. With the benefit of hindsight, it would have been prudent for the doctors to have aspirated the palpable cyst. However, it is not clear that this would have conclusively diagnosed the presence of cancer. Where doctors act reasonably and, in so doing, miss a diagnosis, their actions are not legally culpable. In these circumstances, in relation to the June 2003 mammogram and ultrasound examination, Dr B, Dr C and Dr D did not breach the Code.

#### *January 2004 mammogram*

On 13 January 2004 Mrs A returned to the private radiology facility as recommended. Mrs A recalls that she still had the breast lump at this visit and that it had increased in size. However, when Mrs A completed the mammography questionnaire there is no record that she mentioned the presence of any breast lumps. The medical radiation technologist took two magnification views of Mrs A's breasts.

Dr C reviewed the films and reported that the cluster of microcalcifications seen in the June 2003 mammogram had "dissipated". There were calcifications scattered throughout the breast and persisting rounded densities, but Dr C considered that these features were benign.

Dr D double read the films with Dr C's report. Mrs A was reassured that there was no evidence of carcinoma.

Dr Hadden advised that when Dr C reported that the calcifications had dissipated, it was assumed that they were no longer visible. Dr Hadden, after reviewing the films taken on 13 January, stated: "This is largely true. They are much more difficult to see if one can see them at all." Dr C concluded that since they had dissipated, they had been benign. Dr Hadden said that in coming to this decision, Dr C had "overlooked or forgotten that very rarely malignant calcifications can do this".

Dr Hadden commented that Dr C and Dr D saw the cysts that were present on the mammogram, but overlooked several unfavourable signs. The breast was smaller than six months previously, a strand of tissue extended to the chest wall, the chest wall appears to have been pulled forward and the area of density had increased in size. Dr Hadden stated that these signs suggest a malignant process infiltrating the breast, but are not absolutely diagnostic. She said Dr C was "lulled into a false sense of security" by the disappearance of the calcifications and did not perform or request further tests. A non-magnified, plain mammogram of Mrs A's breast may have shown these changes and could have been compared with the earlier examinations. A further ultrasound examination or physical examination performed by a clinician experienced in palpating breast cancer may have detected the cancer at this stage.

Dr Hadden stated that there are no guidelines (as far as she is aware) which state that an ultrasound should be performed when magnified views of calcifications are done. The private radiology facility radiologists adhered to the practice standards and guidelines set by Breastscreen Aotearoa when working up a case. Dr Hadden noted

that the quality of their mammograms and ultrasound, and documentation of the findings, “cannot be faulted”.

Dr Hadden concluded:

“There is no standard that will tell a radiologist what to do in an individual case. It is knowledge and experience that guides how a radiologist works up a case to find or exclude cancer. This was a difficult case. ... There were missed opportunities for early biopsy and diagnosis and there were subtle clues that may have led to an earlier diagnosis, but I cannot honestly say that the radiologist was at fault or that anything the radiologists did wrong delayed the diagnosis. Imaging is not a perfect test and cancers do not always declare their presence in a readily detectable fashion.”

I am guided by my expert’s advice on this difficult case. It is clear, with the benefit of hindsight, that in January 2004 there were signs of malignant disease in Mrs A’s breast which were missed by the private radiology facility radiologists. However, my expert was unable to equivocally state whether other radiologists would have detected this cancer, and if a more aggressive approach and earlier intervention would have resulted in the correct diagnosis. In these circumstances, there is no proper basis to conclude that Dr D and Dr C provided substandard radiology services to Mrs A in January 2004.

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### **Follow-up actions**

- A copy of my final report will be sent to the Medical Council of New Zealand, Breastscreen Aotearoa and the National Screening Unit.
- A copy of my final report, with details identifying the parties removed, will be sent to the Royal Australian and New Zealand College of Radiologists, and the Federation of Women’s Health Councils Aotearoa, and placed on the Health and Disability Commissioner website, [www.hdc.org.nz](http://www.hdc.org.nz), for educational purposes.