# Sonographer, Mr B Radiologist, Dr C Pacific Radiology Limited

# A Report by the Health and Disability Commissioner

(Case 14HDC00558)



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# **Executive summary**

- 1. On 23 September 2011, Ms A presented to general practitioner (GP) Dr E, having noticed a lump at the anterior (front) base of her neck on the right-hand side. Dr E considered that there was a tender lump, around 2cm in diameter, in her right thyroid gland. Blood tests were normal. A referral for an ultrasound of the thyroid gland was arranged by Dr E.
- 2. The same day, a thyroid gland ultrasound scan was performed at Pacific Radiology, by sonographer Mr B.
- 3. No specific mention is made in Pacific Radiology Limited (Pacific Radiology) procedure documents of a need to assess lymph nodes within the neck. However, Pacific Radiology advised that adjacent lymph nodes should be scanned if any thyroid abnormality is demonstrated. The local lymph nodes adjacent to the thyroid gland were not scanned by Mr B. No comments were recorded by Mr B in the designated sonographer worksheet space headed "lymph nodes". Mr B did not make contact with the reporting radiologist regarding the ultrasound.
- 4. On 27 September 2011, Dr C, radiologist, reviewed the ultrasound images together with the referral form and sonographer worksheet. Dr C reported the right thyroid to be slightly bulkier than the left, the presence of nodules, and a finding suggestive of a multinodular goitre. No biopsy/fine needle aspiration (FNA) was recommended. Dr C stated that on (recent) review of the thyroid images, he now feels that the right lower lobe nodule shows findings that are suspicious, and he should have recommended a biopsy at the time.
- 5. Over the next two years, Ms A attended a number of primary care consultations, some of which related to her concerns about the lump in her neck. No apparent changes were noted during this time. However, in January 2014, owing to her on-going concerns, Ms A requested a referral to a consultant.
- 6. On 29 January 2014, general and endocrine surgeon Dr D performed targeted preliminary survey sonography, which demonstrated that the nodule of the right lobe of the thyroid, as well as a smaller one on the left lobe, were very slightly larger than when studied in 2011. Dr D referred Ms A for a formal ultrasound and a guided FNA of the right and left thyroid nodules.
- 7. On 11 February 2014, radiologist Dr G performed an evaluative scan and noted an adjacent mass (which was separate from the nodule of the right lobe of the thyroid). Dr F was suspicious of this and performed FNA on both masses. The FNA biopsies of both areas confirmed papillary thyroid carcinoma in both masses. A CT scan on 14 February 2014 confirmed the presence of the carcinoma in the thyroid nodule, as well as a right-sided cervical lymphadenopathy. On 17 February 2014, Dr D referred Ms A to a head and neck surgeon. Ms A subsequently required extensive surgery and radiotherapy.

# **Findings**

- 8. Dr C failed to query the absence of imaging of the local lymph nodes, to ensure that he had all the relevant information to make his assessment. Furthermore, he failed to interpret the 27 September 2011 scan as showing suspicious findings and, accordingly, he failed to recommend FNA. Dr C did not provide services to Ms A with reasonable care and skill and, accordingly, he breached Right 4(1) of the Code.<sup>1</sup>
- 9. In relation to the ultrasound Mr B performed on 27 September 2011, he did not follow accepted professional practice and scan the lymph nodes adjacent to the thyroid gland. Mr B's care was suboptimal. He failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.
- 10. Pacific Radiology Limited's protocol did not explicitly refer to the need to assess and/or scan lymph nodes adjacent to the thyroid. Pacific Radiology Limited was aware of Mr B's practice to adequately fulfil the minimum requirements of an examination, but did not take action to ensure that he extended his examinations, in order to be consistent with accepted practice. Pacific Radiology failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

#### Recommendations

- 11. The Commissioner recommended that:
  - a) Dr C provide a formal written apology to Ms A. In response to my provisional report, Dr C provided an apology letter for forwarding to Ms A.
  - b) Dr C have an independent radiology peer perform a quality review of a random selection of thyroid ultrasound review reports he has completed in the last 12 months.
  - c) Mr B have an independent sonographer peer perform a quality review of a random selection of thyroid ultrasound scans and accompanying sonography worksheets he has completed in the last 12 months.
  - d) The Medical Radiation Technologists Board consider whether a review of Mr B's competence is warranted.
  - e) The Medical Radiation Technologists Board consider taking steps to ensure that all New Zealand sonographers adopt a consistent approach to ultrasound scanning of the thyroid, including the adjacent lymph nodes, and clear documentation thereof.
  - f) Pacific Radiology audit compliance with the changes it has made to its ultrasound protocols to include a requirement for sonographers to assess and/or scan adjacent lymph nodes when scanning the thyroid gland.
  - g) The sub-regional clinical leadership group consider the clarity of local DHB guidelines surrounding indications for FNA in a patient presenting with a neck

<sup>&</sup>lt;sup>1</sup> Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

- lump, and report back to HDC regarding any amendments, within three months of the date of this report.
- h) The Ministry of Health consider the wording of the national guidelines for primary care, surrounding indications for FNA in a patient presenting with a neck lump.

# **Complaint and investigation**

- 12. The Commissioner received a complaint from Ms A, and an investigation was commenced on 21 October 2014. The following issues were identified for investigation:
  - Whether Dr C provided Ms A with care of an appropriate standard from September 2011 to March 2014.
  - Whether Pacific Radiology Limited provided Ms A with care of an appropriate standard from September 2011 to March 2014.
- 13. The investigation was extended to include:
  - Whether sonographer Mr B provided Ms A with care of an appropriate standard in September 2011.
- 14. The key parties referred to in the report are:

Ms A Consumer, complainant

Mr B Sonographer
Dr C Radiologist
Pacific Radiology Limited Provider

15. Information was also reviewed from:

Dr D General and endocrine surgeon

Dr E General practitioner

Dr F Radiologist

Two district health boards

Also mentioned in this report:

Dr G Radiologist

- 16. Independent expert advice was obtained from a consultant radiologist, Dr Hament Pandya (**Appendix A**).
- 17. Independent expert advice was obtained from a sonographer, Ms Naomi Rasmussen (**Appendix B**).

# Information gathered during investigation

#### Introduction

18. On 23 September 2011, Ms A presented to her general practitioner (GP), owing to a lump at the base of her neck. From that point on, her care and assessment involved a number of different providers in different disciplines (sonography, radiology, further primary care, general and endocrine surgery, and head and neck surgery).

# **Initial presentation to GP**

- 19. On 23 September 2011, Ms A presented to Dr E<sup>2</sup> having noticed a lump at the anterior (front) base of her neck on the right-hand side.
- 20. Dr E reviewed Ms A. On examination he considered that there was a tender lump, around 2cm in diameter, in her right thyroid gland.<sup>3</sup>
- 21. Dr E recorded:

"Found a lump at Rt side of base of neck. [On examination] Rt thyroid lobe lump, 2cm, tender, to do [blood tests] now + [ultrasound]."

- 22. Blood tests showed Ms A to have normal biochemical function. She had a TSH level of 1.5 mlU/L,4 normal thyroid antibodies, and her CRP<sup>5</sup> level was normal (less than 3).
- 23. Dr E arranged a referral to Pacific Radiology Limited for an ultrasound of the thyroid gland.
- 24. Under "Services Required", Dr E noted "Ultrasound Thyroid". He also included the information as recorded in the clinical notes (above).
- 25. In his response to HDC, Dr E reiterated: "Clinically I believed that the lump was presented in the right lobe of her thyroid gland."

# **Pacific Radiology Limited**

26. At Pacific Radiology Limited (Pacific Radiology) and elsewhere in New Zealand, ultrasound examinations are performed routinely by sonographers.

#### Pacific Radiology policy

27. A sonographer's responsibilities are outlined in section 3.2 of the Pacific Radiology Ultrasound Manual<sup>6</sup> — "Sonographer Responsibilities". These are deemed to be threefold: to the patient, to the reporting radiologist, and to the referring clinician.

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<sup>&</sup>lt;sup>2</sup> Vocationally registered in general practice.

<sup>&</sup>lt;sup>3</sup> The thyroid is a highly vascular, brownish-red gland located anteriorly in the lower neck.

<sup>&</sup>lt;sup>4</sup> TSH (thyroid stimulating hormone) is a pituitary hormone that stimulates the thyroid gland to produce thyroid hormones. Normal range is 0.3–5.0 mlU/L.

<sup>&</sup>lt;sup>5</sup> CRP (C-reactive protein) is produced by the liver. Levels rise in response to inflammation in the body.

28. Section 3.2.1 "Responsibility to Patient" includes:

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• Extend the examination to other areas as may be indicated by findings during the examination.

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29. Section 3.2.2 "Responsibility to the Reporting Radiologist" includes:

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- The Sonographer will discuss with the reporting radiologist the results and/or prepare a worksheet as appropriate.
- The Sonographer will provide to the reporting radiologist additional clinical information provided as ascertained from the patient."
- 30. The sonographer worksheet is a contemporaneous record of the scan. The sonographer worksheet used by Pacific Radiology headed "Thyroid/Parathyroid Report Sheet" makes provision for the documentation of lymph node status in a designated space on the sheet specifically marked "lymph nodes".
- 31. Section 3.2.3 "Responsibility to the Referring Clinician" includes:

"The Sonographer should perform the examination requested by the referrer and [original emphasis] use initiative where appropriate. Thorough reading of clinical details and other information on the request form, supplemented by asking appropriate questions of the patient, is important in the process to provide a comprehensive and tailored study and should liaise with the radiologist if concerned as to the appropriateness of the scan with regards to the clinical details."

Thyroid ultrasound procedure

- 32. The Pacific Radiology thyroid ultrasound procedure for a sonographer includes:
  - "12.1.4 Procedure
  - note any neck lumps, get a clinical history e.g. Difficulty swallowing

. . .

• Images are obtained of both thyroid glands in sagittal and transverse planes to include isthmus<sup>7</sup>.

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<sup>&</sup>lt;sup>6</sup> Issue date 8 October 2009.

<sup>&</sup>lt;sup>7</sup> The thyroid has two lobes that lie on either side of the windpipe, and is usually connected by a strip of tissue known as an isthmus.

- Any pathology is examined and measured. Colour Doppler is used, if necessary, on any mass to help determine its nature."
- 33. Furthermore, Pacific Radiology advised HDC that adjacent lymph nodes should be scanned if any thyroid abnormality is demonstrated. It advised HDC that in 2011 this was encouraged but not adhered to by all sonographers on all occasions.
- 34. Pacific Radiology also stated that it was recommended practice for a sonographer to ensure that the area of concern to the patient had been scanned.

#### Peer review system

35. Pacific Radiology told HDC that at the time of these events it had a sonographer peer review system in place, and it also received feedback from radiologists regarding scan quality. At the time of these events, a charge sonographer would review cases with each sonographer at an annual review, and more frequently if feedback from radiologists dictated it. Sonographers work alongside other sonographers in multiroom ultrasound branches, and radiologists are on site for case review.

# Sonography care provided

- 36. On 27 September 2011, sonographer Mr B<sup>8</sup> performed a scan of Ms A's thyroid at Pacific Radiology.
- 37. Mr B told HDC that he has no recollection of this particular ultrasound examination. Mr B took 44 images of the thyroid gland, of both greyscale and colour Doppler type.
- 38. There are no images of Ms A's lymph nodes.<sup>9</sup>
- 39. Mr B recorded his findings (including the dimensions of the right and left thyroid) on the worksheet and archived this into the reporting system.
- 40. No comments were recorded by Mr B in the designated space in the worksheet headed "lymph nodes". Mr B did not make contact with the reporting radiologist regarding the ultrasound.
- 41. With regard to the ultrasound he performed on 27 September 2011, Mr B told HDC:

"The protocol in place at the time of the scan did not require the routine imaging of the lymph nodes of the neck, consequently, I made no attempt to image them during the scan in question, nor did I image them on any of my thyroid scans at that time."

## 42. Furthermore, Mr B stated:

"Some referrers are more specific in their requests regarding scanning of the thyroid, and specify the lymph nodes of the neck in their requests.

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<sup>&</sup>lt;sup>8</sup> At the time of these events, Mr B was employed by Pacific Radiology.

<sup>&</sup>lt;sup>9</sup> One of the images taken of Ms A's thyroid shows a partial nodule at the left edge of the thyroid.

I can only assume that the worksheet was designed to accommodate such requests, allowing the sonographer to fill-in the appropriate spaces.

I have reviewed my images of 27/9/11, and note that one of the images does show a partial node at its left edge. The image was taken to show the thyroid lobe, my focus being entirely on the pathology identified within that lobe, and I did not notice the node at all at that time.

If my attention had been drawn to it, then I would, of course, have not only imaged it, together with all the other neck nodes, but I would have entered comments on the worksheet. The fact is ... I did not see it.

The company protocol has been amended to include imaging of the neck nodes as required imaging.

In conclusion, I affirm that the scan which I performed on [Ms A] on 27/9/11 was done to the best of my ability, and entirely within the relevant protocol in place at that time."

# 43. Pacific Radiology stated in its response:

"Imaging of, and comment on the normality or otherwise of the lymph nodes should have been part of this examination, as the thyroid itself was abnormal. Sometimes patients are referred with more vague symptoms, found to have a normal thyroid gland and a full examination of the cervical nodes may not be undertaken. Pacific Radiology sonographers are expected to adhere to examination protocols and fill in their worksheets in a comprehensive fashion."

# 44. Pacific Radiology added:

"Pacific Radiology always encourages sonographers to answer the clinical question that has been put to them as well as they can. They are health professionals in their own right, and the reporting radiologist is critically dependent on the way they scan the patient so that we have as much information as we can to inform our final opinion. Sometimes referral forms are non-specific, omit important clinical information and contain poorly framed questions. However, by the hands-on nature of the interaction between patient and sonographer further clinical details usually emerge and sonographers should use this information to extend the examination as they are trained and encouraged to do."

45. Pacific Radiology also stated that Mr B was regarded as a sonographer who would adequately fulfil the minimum requirements of an examination, rather than extend the examination. He is a very experienced sonographer. On occasions radiologists had to seek clarification from Mr B about his findings, as his worksheets were often brief and lacking in detail. However, these matters were viewed as more about style of practice, rather than raising any major competence issues.

# 46. Pacific Radiology added:

"Nodular and/or enlarged thyroid glands in New Zealand patients are extremely common. Ultrasound is a very insensitive and non-specific test for thyroid cancer.

Documentation of neck lymph node examination was more variable in 2011 than it is now. The variability in documentation of cervical nodes in 2011 has been verified by an internal review of worksheets from that period.

Some sonographers would have a general look around the anterior neck, and document this with saved images, others would have a look but not necessarily document this ..."

# Radiology report, Dr C

- 47. Dr C, a radiologist, <sup>10</sup> reviewed the ultrasound images on 27 September 2011 together with the referral form and sonographer worksheet. His care of Ms A was limited to this one ultrasound report.
- 48. Dr C told HDC that he had close relationships with the Pacific Radiology sonographers and that they all knew that he wished to be consulted in any difficult case and, if possible, to examine the patient himself. Dr C was not contacted by Mr B.
- 49. Dr C said that he was not made aware that the scan was anything other than straightforward. He interpreted the referral information he had received as meaning there was a thyroid mass, and he assumed that all relevant anatomy had been scanned. Dr C told HDC that he had no indication from the referral information he received or from the sonographer of any other issue. He stated that, if he had suspected any problem with the examination, his normal practice would be to speak directly with the sonographer.
- 50. Dr C reported the right thyroid (52 x 19 x 15mm) to be slightly bulkier than the left (53 x 15 x 11mm) and recorded:

"[A] predominantly solid nodule is seen at the lower pole of the right lobe (19mm). A smaller nodule of mixed solid and cystic echogenicity is seen at the lower pole of the left lobe (16mm). Several other tiny nodules are seen bilaterally. Intervening thyroid tissue appears normal ... Findings suggest a multinodular goitre 11."

- 51. The report was sent electronically to the referrer, Dr E.
- 52. Dr C, in his response to HDC, stated:

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<sup>&</sup>lt;sup>10</sup> An independent contractor for Pacific Radiology. Dr C is a Fellow of the Royal Australian and New Zealand College of Radiologists (with vocational scope registration).

<sup>&</sup>lt;sup>11</sup> A swelling of the neck resulting from enlargement of the thyroid gland.

"On review of the thyroid images, I now feel that the right lower lobe nodule shows findings which are suspicious and I should have recommended a biopsy at that time."

#### 53. Dr C also stated:

"With hindsight, on attending for ultrasound in 2011, the patient had ...

- 1. The enlarged thyroid, consisting of multiple nodules commented on in my report.
- 2. The 9mm node (normal size but abnormal echogenicity) which was presumably impalpable — not commented on in my report.
- 3. A larger palpable mass more inferiorly which was the patient's concern and the reason for presentation to her GP — not scanned in 2011."

# Further primary care, 12 September 2011

- 54. On 28 September 2011 Ms A telephoned Dr E for her results. Dr E recorded that he told Ms A that the ultrasound had shown more nodules besides the one she had noticed, and advised her that her blood test results were normal and that she "[needed] to keep an eye on the lump". He told HDC that he explained to Ms A that she should re-present if she noticed changes.
- 55. Dr E told HDC that he believed the ultrasound had been performed on the lump that Ms A detected and which he had examined at the appointment on 23 September 2011, and that the ultrasound had confirmed the presence of a lump of similar location and size to that which he had detected clinically (ie, within the right lobe of the thyroid).
- 56. In relation to further investigations, Dr E responded to HDC:<sup>13</sup>

"Neither the bloods nor the ultrasound report raised any concerns that the lump was sinister and required further investigations. The reporting radiologist will usually suggest a FNA<sup>14</sup> if there are concerns about the appearance of the lump on ultrasound. No such recommendation was made in this case."

# National primary care guidelines

57. The relevant national primary care guidelines<sup>15</sup> make no specific recommendation regarding FNA in the primary care management of suspected thyroid cancer. However, there is a recommendation that:

<sup>&</sup>lt;sup>12</sup> A consumer's main source of regular healthcare in the community.

<sup>&</sup>lt;sup>13</sup> In his 2014 response to HDC, Dr E made reference to a local DHB referral guideline which was not in place at the time of the events in question.

The use of a thin needle to withdraw material from the body (a biopsy) for analysis. For example, when a nodule is felt in the thyroid, fine needle aspiration may be done to remove a tissue sample that can be examined to determine whether the nodule is benign or malignant.

<sup>&</sup>lt;sup>15</sup> Ministry of Health/NZ Guidelines Group. Suspected Cancer in Primary Care. 2009.

"A person should be referred urgently to a specialist if they have a thyroid swelling AND one or more of the following ... a solitary nodule increasing in size."

#### **Further care**

- 58. Over the next two years, Ms A attended a number of primary care consultations, some of which related to her concerns about the lump in her neck. No apparent changes were noted by primary care providers during this time. However, on 29 January 2014, owing to her own on-going concerns, Ms A saw general and endocrine surgeon Dr D, for another opinion.
- 59. Dr D performed targeted preliminary survey sonography, which demonstrated that the nodule of the right lobe of the thyroid, as well as a smaller one on the left lobe, were very slightly larger than when studied in 2011. Dr D referred Ms A for a formal ultrasound and a guided FNA of the right and left thyroid nodules.
- 60. On 11 February 2014, radiologist Dr G performed an evaluative scan and noted an adjacent mass (which was separate from the nodule on the right lobe of the thyroid). Dr F was suspicious of this and performed FNA on both masses. The FNA biopsies of both areas confirmed papillary thyroid carcinoma in both masses. Dr F informed Dr D. A CT scan on 14 February 2014 confirmed the presence of the carcinoma in the thyroid nodule as well as a right-sided cervical lymphadenopathy. 16
- 61. On 17 February 2014, Dr D referred Ms A to a head and neck surgeon. Ms A subsequently required extensive surgery and radiotherapy.

# Subsequent changes and improvements to practice

Mr B

62. In response to this investigation, Mr B stated to HDC:

"I scanned [Ms A] almost 4 years ago, and have no memory of the scan specifically, but ... I am truly mortified at this sequence of events, and I deeply regret that images of the lymph nodes in the neck were not included in my examination, as this would have dramatically changed the outcome.

I have taken this complaint very personally, and, as soon as I was made aware of the case, immediately changed my scanning technique to always include images of the neck nodes in all thyroid scans, whether the thyroid is ultrasonically normal or abnormal.

At the time of the scan I was unaware that best practice was to image the neck lymph nodes, in the presence of an abnormal thyroid gland, so I performed a scan of the thyroid gland, and, when abnormalities were evident, I concentrated all my efforts on producing the best images that I could.

<sup>&</sup>lt;sup>16</sup> A generic term for lymph node enlargement of any aetiology, benign or malignant.

To the best of my knowledge at the time, I performed a thorough examination of the thyroid gland, as requested by the patient's GP. In all of my 35 years as a sonographer, I have always endeavoured to maintain the highest professional standards. I sincerely hope that [Ms A] makes a full recovery, and, if you feel it appropriate, please convey to her my deepest apologies for my part in this tragic series of events that have unfolded around her."

#### Dr C

- 63. Dr C advised HDC that he accepts the radiology expert advice obtained by HDC and stated that, as a result of this case, he:
  - reviewed 50 thyroid ultrasound cases reported on at Pacific Radiology in late 2011 by his colleagues, and found that his reports did not differ significantly from those of his colleagues in content or recommendations;
  - presented the case at a Pacific Radiology clinical audit meeting with colleagues;
  - arranged for all his thyroid ultrasound reports to be audited (as a second read) by colleagues before being issued; and
  - is more frequently recommending biopsy for thyroid nodules.
- 64. Furthermore, Dr C offered his sincere apologies to Ms A for any role he may have played in the delay in diagnosis of her thyroid disease.

Pacific Radiology

65. Pacific Radiology advised HDC:

"[A]s a result of this case we have reiterated to our sonographers the importance of looking at the lymph nodes in a general way for all parties who come for a 'thyroid ultrasound scan', especially if they have nodules seen in the gland ..."

- 66. Pacific Radiology reiterated that there has always been an unwritten expectation that all scans that indicate an abnormality within an organ or structure would include scanning the adjacent lymph nodes. The worksheets have always included an area for this to be recorded. Specific mention of "lymphadenopathy" was formally added to the "Evaluate" section of the ultrasound manual in 2015, 17 although Pacific Radiology noted that this had been widely discussed previously as a requirement for all abnormal scans.
- 67. Pacific Radiology also told HDC that, subsequent to this matter, a charge sonographer also performs monthly random audits of all sonographers' work. Any feedback from the radiologists on any scan/sonographer is dealt with immediately and more dedicated follow-up and auditing performed until all parties are confident that the sonographer has adapted his or her technique to a satisfactory level.

# Responses to provisional report

68. Ms A's comments have been incorporated into the "information gathered" section of the report where appropriate.

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<sup>&</sup>lt;sup>17</sup> Copy provided to HDC.

- 69. Dr C responded that he accepted that he had failed to interpret the scan accurately as showing a suspicious finding, and subsequently did not recommend FNA, and he deeply regretted it. He said: "I take a pride in my work and I am disappointed in myself for having failed to recognise the indication for FNA."
- 70. Dr C provided an apology letter for forwarding on to Ms A.
- 71. Dr C also stated:

"I would also point out that, as [with] most other radiologists, I report over 10,000 cases per year (many do considerably more). Each case may contain multiple images; an ultrasound may contain 50–100 images; a CT may contain 1000–2000. It is not possible to be correct all the time."

72. Dr C stated in relation to querying the absence of imaging of the local lymph nodes:

"In this matter I was following accepted practice at Pacific Radiology at the time ... In 2011 sonographer worksheets were routinely accepted with or without evidence that regional nodes had been examined, and irrespective of the findings in the thyroid. The practice has changed since I have made my colleagues aware of this current case, but in 2011 I was following the accepted norm."

#### 73. Dr C also stated:

"I would have expected the sonographer to have had a conversation with the patient and so been alerted to extend the examination, but this clearly did not happen. When I came to report the case later in the day, I had no indication from the sonographer worksheet that this was anything more than routine. I did not arrange for the patient to be recalled to image the lymph nodes. That was not what I or my colleagues did in those circumstances in 2011."

- 74. Dr C said that in his many years of practice in New Zealand this is the first time he has been the subject of a formal complaint, and that he took it most seriously and has done all in his power to ensure that it should not happen again.
- 75. Mr B responded:

"[T]he Commissioner has recommended that the [Medical Radiation Technologists Board] review my license to practice. I submit that at no time has my ability to perform a competent scan of the neck been questioned. This case is concerned with an omission of scan images, and not an inability to obtain those images. I am, consequently, at a loss to understand this recommendation, and submit that there is no evidence to support it. The fact that I was unaware at that time that best practice was to image the adjacent lymph nodes does not reflect on my practical scanning ability."

76. Pacific Radiology responded:

- It has had no cause to doubt the standards of care Dr C has provided to patients either before or since this case. It agreed that the policy of documenting and reporting all neck nodes was incompletely adhered to in 2011.
- It has made it clear to all sonographers that it is expected that a survey and documentation of neck lymph nodes is the standard of care for all thyroid scans, or cases of non-specific neck lumps. Radiologists have also had it emphasised to them that their reports must include mention of lymph node findings.
- Radiologists have been reminded of international guidelines with respect to criteria that should be applied to recommending biopsy of thyroid nodules.
- Subsequent to 2011, Mr B was the subject of multiple audits, peer review, and mentoring sessions.

# **Opinion: Preliminary comment**

- 77. Ms A presented to Dr E on 23 September 2011, owing to a lump at the base of her neck. From that point on, her care and assessment involved a number of different providers in different disciplines (sonography, radiology, further primary care, general and endocrine surgery, and head and neck surgery). In February 2014 Ms A was diagnosed with carcinoma in a thyroid nodule and a lymph node in the right side of her neck.
- 78. I am concerned about deficiencies that occurred at the beginning of Ms A's care pathway, which influenced her subsequent management and contributed to a delay in her diagnosis. These are discussed below.
- 79. During this investigation, I reviewed the care provided by the general practitioners and Dr D, and the sonography and radiology care provided in 2014, and sought expert advice. I do not have concerns about the care provided in 2014. Accordingly, this report relates only to the sonography and radiology care provided to Ms A in 2011.

# Opinion: Dr C — Breach

- 80. Dr C, radiologist, reviewed the 27 September 2011 ultrasound images, the original referral form, and Mr B's worksheet. Dr C said that he was not made aware that the scan was anything other than straightforward. He interpreted the referral information he received as meaning there was a thyroid mass, and he assumed that all relevant anatomy had been scanned. Dr C and Mr B did not discuss Ms A's case.
- 81. Dr C reported the right thyroid to be slightly bulkier than the left and recorded:

"[A] predominantly solid nodule is seen at the lower pole of the right lobe (19mm). A smaller nodule of mixed solid and cystic echogenicity is seen at the lower pole of the left lobe (16mm). Several other tiny nodules are seen bilaterally. Intervening thyroid tissue appears normal ... Findings suggest a multinodular goitre."

82. Dr C, in his response to HDC, acknowledged:

"On review of the thyroid images, I now feel that the right lower lobe nodule shows findings which are suspicious and I should have recommended a biopsy at that time."

83. I am mindful of a comment made by my expert, consultant radiologist Dr Hament Pandya:

"[I]t is important to take into account that accurate distinction between benign and malignant thyroid nodules using ultrasound, can be very difficult. Based on my experience, it is unquestionably one of the areas of imaging that many non-specialist radiologists approach with some trepidation ... the practical difficulty lies in the fact that most of the features suggestive of malignancy are also often seen (to varying degrees) in benign nodules. The judgement of whether a nodule may be malignant therefore has to be based on the cumulative probability of a number of imaging features being present within that nodule."

84. In relation to Dr C's reading and reporting of the 2011 ultrasound scan, Dr Pandya advised me:

"[T]he ultrasound scan performed in September 2011, demonstrated 5 out of 6 criteria for designating a thyroid nodule as being suspicious.

The main criteria being:

- Presence of microcalcification
- Poorly defined margins
- Prominent internal vascularity
- Absent halo around the nodule
- Nodule being 'taller than wide'
- Presence of abnormal cervical nodes

On this basis, (as [Dr C] has also previously asserted), [Fine Needle Aspiration] of the right sided thyroid nodule should have been suggested ...

I would therefore suggest that there has been a moderate departure from generally accepted practice."

85. I accept Dr Pandya's expert advice that FNA should have been recommended by Dr C because the 27 September 2011 ultrasound scan findings demonstrated sufficient criteria for designating the thyroid nodule as suspicious.

- 86. Furthermore, Dr Pandya notes that based on the history described and the ultrasound findings in September 2011, the ultrasound should have been extended to involve the local lymph node groups. He states:
  - "Adequate sonographic assessment of thyroid nodules should always include imaging of the local lymph node groups, which is widely accepted as standard procedure."
- 87. I am critical of Dr C in this respect, for failing to query the absence of imaging of the local lymph nodes to ensure that he had all relevant information to make his assessment.

#### Conclusion — standard of care

88. Dr C failed to query the absence of imaging of the local lymph nodes, to ensure that he had all the relevant information to make his assessment. Furthermore, he failed, at the time, to interpret the scan accurately as showing suspicious findings and, subsequently, he did not recommend FNA. Accordingly, in my view, Dr C did not provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

# Opinion: Mr B — Breach

### Standard of care

- 89. Mr B, an experienced sonographer, performed the thyroid gland ultrasound that took place at Pacific Radiology on 27 September 2011. The referral information from Dr E clearly indicated potential pathology ie, there were concerns about a lump in Ms A's thyroid. This should have prompted Mr B to take more action than he did in this case.
- 90. I am concerned about the standard of care Mr B provided, including some of his stated rationale for his decision-making. This case has highlighted that there appears to have been a degree of variability in professional sonography practice in New Zealand in 2011.
- 91. Mr B's relevant responsibilities are outlined in section 3.2 of the Pacific Radiology Ultrasound Manual "Sonographer Responsibilities", as well as section 12.1.4 of the Pacific Radiology thyroid ultrasound procedure for a sonographer.
- 92. Explicitly stated responsibilities included:
  - Extending the examination to other areas as may be indicated by findings during the examination.
  - Discussing with the reporting radiologist the results and/or preparing a worksheet as appropriate.

- Providing to the reporting radiologist additional clinical information provided as ascertained from the patient.
- Performing the examination requested by the referrer and using initiative where appropriate.
- Thorough reading of clinical details and other information on the request form, supplemented by asking appropriate questions of the patient.
- Noting any neck lumps and obtaining a clinical history.
- 93. In addition, while the following is not explicitly referred to in the Pacific Radiology procedure documents, Pacific Radiology also advised HDC that:
  - adjacent lymph nodes should be scanned if any thyroid abnormality is demonstrated, and in 2011 this was encouraged but not adhered to by all sonographers on all occasions; and
  - it was recommended practice for a sonographer to ensure the area of concern to the patient had been scanned.

# Scanning adjacent lymph nodes

94. The referral information provided by Dr E clearly indicated potential concerns about the thyroid gland. He recorded:

"Found a lump at Rt side of base of neck. [On examination] Rt thyroid lobe lump, 2cm, tender, to do [blood tests] now + [ultrasound]."

- 95. Under "Services Required" Dr E noted "Ultrasound Thyroid". He also included the information as recorded in the clinical notes.
- 96. This should have prompted Mr B to scan the adjacent lymph nodes as well as the thyroid gland.
- 97. Mr B scanned Ms A's thyroid. He has acknowledged that he did not at that time routinely survey or scan the local lymph nodes adjacent to the thyroid. No images of the lymph nodes were taken.

# 98. Mr B told HDC:

"The protocol in place at the time of the scan did not require the routine imaging of the lymph nodes of the neck, consequently, I made no attempt to image them during the scan in question, nor did I image them on any of my thyroid scans at that time."

- 99. I accept Mr B's statement and find that he did not scan the adjacent lymph nodes in this case, as it was not his usual practice to do so.
- 100. I am mindful that while it was not explicitly outlined in its 2011 protocol, Pacific Radiology stated that "adjacent lymph nodes should be scanned if any thyroid abnormality is demonstrated, and in 2011 this was encouraged but not adhered to by all sonographers on all occasions".

101. In relation to scanning the adjacent lymph nodes, my expert, sonographer Ms Naomi Rasmussen, advised:

"In 2011 as it is now the protocol for scanning of the thyroid includes scanning the adjacent neck for lymph nodes. If no nodes are seen this is not always documented in an image. If a lump is mentioned on the request or by the patient this should be scanned and correlated with the documented images. Often you would label the image 'palpable lump' ...

Accepted practice would be to survey for lymph nodes although if normal these are not always documented. This would probably not be seen as a major departure from protocol.

It is concerning that [Mr B] in 2011 did not know to check for lymph nodes when doing a thyroid scan, particularly when there is pathology ...

Although due to human error this can sometimes be neglected or not documented when no nodes are identified, it is concerning that [Mr B] at that time by his own admission never looked for lymph nodes ... By admitting that he didn't ever take images of the lymph nodes he is showing that he was not aware of accepted New Zealand practice ...

Standard practice for sonographers in 2011 was to include at least a survey of the local lymph nodes when scanning the thyroid. Although if there were no abnormal nodes this was not always documented on imaging."

- 102. I accept my expert's advice and am therefore satisfied that accepted sonography practice in New Zealand in 2011 was at least to survey the adjacent lymph nodes when scanning the thyroid. In addition, Mr B's employer's expectation in 2011 was that adjacent lymph nodes should be scanned if any thyroid abnormality were demonstrated. I am critical of Mr B for not scanning the adjacent lymph nodes, and I consider his practice to be sub-optimal in this case.
- 103. I note that Mr B, in hindsight, has also acknowledged that on one of the images there was a partial nodule visible that he did not see at the time. However, I accept that the primary responsibility for reporting on the images lies with the radiologist (discussed above).
- 104. Ms Rasmussen advised that, overall, there was a mild departure from accepted standards.

#### Conclusion — standard of care

105. In relation to the ultrasound Mr B performed on 27 September 2011, he did not follow accepted professional practice and scan the lymph nodes adjacent to the thyroid gland. I note Mr B's response to my provisional report; however, I find his omission and lack of knowledge as to the need to scan the lymph nodes concerning. In my view, Mr B's care was suboptimal. I remain of the view that he failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

# Other comment — interaction with the patient

- 106. Ms A told HDC that she does not recall her 2011 appointment or Mr B. Likewise, Mr B could not recall the specific consultation, or whether Ms A discussed her lump with him. Accordingly, I am unable to make any finding regarding any discussions between Mr B and Ms A during the 2011 appointment.
- 107. However, I consider that comment regarding Mr B's stated interactions with consumers is warranted.

#### 108. Mr B stated:

"I am unaware of any protocol within the Company which deals specifically with requests by patients to scan areas at variance with those requested by the referring clinician. I cannot speak for any of my colleagues, but, I, personally do not scan areas at the behest of the patient."

109. I am also mindful of Mr B's employer's statement in this respect:

"Pacific Radiology always encourages sonographers to answer the clinical question that has been put to them as well as they can. They are health professionals in their own right, and the reporting radiologist is critically dependent on the way they scan the patient so that we have as much information as we can to inform our final opinion. Sometimes referral forms are non-specific, omit important clinical information and contain poorly framed questions. However, by the hands-on nature of the interaction between patient and sonographer further clinical details usually emerge and sonographers should use this information to extend the examination as they are trained and encouraged to do."

# 110. Ms Rasmussen advised me:

"Good Practice should have included questions to the patient if they could feel the lump to ensure it was covered in the examination and so correlation could have been made with the documented images."

111. I accept Ms Rasmussen's advice on this point. Talking to the patient and asking relevant questions about his or her presentation or clinical history supplements the clinical information supplied in the initial referral information received, and is part of the sonographer's stated responsibilities to a patient. I consider Mr B's attitude suboptimal in this regard.

# Opinion: Pacific Radiology Limited — Breach

Pacific Radiology had a responsibility for ensuring that Ms A received an appropriate standard of care. It needed to have adequate systems and procedures in place and to

- provide appropriate guidance to enable compliance with those systems and procedures.
- 113. In 2011, Dr C was an independent contractor for Pacific Radiology, and Mr B was an employee of Pacific Radiology. Pacific Radiology is a healthcare provider and an employing authority for the purposes of the Health and Disability Commissioner Act 1994. As such, it may be held directly liable for the care provided to Ms A, and it may be held vicariously liable for any actions or omissions of its employees and/or agents who are found in breach of the Code.
- 114. Dr Pandya advised that he reviewed the relevant policies in place at the time of these events and is satisfied that, for the most part, they constitute good clinical practice. However, he noted:

"With regards to the appropriateness of policies/procedures, there does appear to be some conflict.

Under '12.1.4 Procedure', no specific mention is made of the need to assess lymph nodes within the neck, however, the sonographer worksheet does clearly make provision for the documentation of lymph node status.

I would recommend making this statement explicit in future revisions of the neck ultrasound protocol."

- 115. I note that accepted sonography practice in 2011 was at least to survey the adjacent lymph nodes, and Pacific Radiology's expectation was that adjacent lymph nodes should be scanned if any thyroid abnormality were demonstrated. However, I agree with Dr Pandya's advice and consider that, at the time of the September 2011 ultrasound, an explicit reference in the protocol to the need to assess and/or scan lymph nodes adjacent to the thyroid in particular clinical circumstances would have provided helpful clarity regarding staff responsibilities. I am critical of the absence of such a reference in 2011.
- 116. I also note Pacific Radiology's comment that Mr B was regarded as a sonographer who would adequately fulfil the minimum requirements of an examination, rather than extend the examination. I am concerned that Pacific Radiology was aware of Mr B's practice in this regard, but did not take any action to ensure that he extended his examinations, in order to be consistent with accepted practice.
- 117. While Pacific Radiology's protocol documents outline its clinical practice, and it had peer review processes in place to review the work of its staff, I consider Pacific Radiology's tolerance for Mr B's sub-optimal practice to be sub-optimal in itself. I also note the conflict it its protocols (see paragraph 114) and the variability in the practice of its staff. In my view, Pacific Radiology failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.
- 118. I note that additions and changes to the wording of the thyroid ultrasound protocol took place as a result of this complaint.

# **Recommendations**

- 119. In my provisional report, I recommended that Dr C provide a formal written apology to Ms A. In response to my provisional report, Dr C provided an apology letter for forwarding to Ms A.
- 120. I also recommend that Dr C have an independent radiology peer perform a quality review of a random selection of thyroid ultrasound review reports he has completed in the last 12 months, and provide the results to HDC within three months of the date of this report.
- 121. I recommend that Mr B have an independent sonographer peer perform a quality review of a random selection of thyroid ultrasound scans and accompanying sonography worksheets he has completed in the last 12 months, and provide the results to HDC within three months of the date of this report.
- 122. In my provisional report, I recommended that the Medical Radiation Technologists Board consider whether a review of Mr B's competence is warranted. Having considered Mr B's response to my provisional report, as outlined above, I still consider this recommendation appropriate.
- 123. I recommend that the Medical Radiation Technologists Board consider taking steps to ensure that all New Zealand sonographers adopt a consistent approach to ultrasound scanning of the thyroid, including the adjacent lymph nodes, and clear documentation thereof. I recommend that it report back to HDC regarding its consideration of this issue within three months of the date of this report.
- 124. I recommend that Pacific Radiology audit compliance with the changes it has made to its ultrasound protocols to include a requirement for sonographers to assess and/or scan adjacent lymph nodes when scanning the thyroid gland. I recommend that Pacific Radiology Limited report back to HDC within three months of the date of this report.
- 125. I recommend, in light of clinical advice obtained on this matter, that:
  - a) The sub-regional clinical leadership group consider the clarity of local DHB guidelines surrounding indications for FNA in a patient presenting with a neck lump, and report back to HDC regarding any amendments, within three months of the date of this report.
  - b) The Ministry of Health consider the wording of the national guidelines for primary care, surrounding indications for FNA in a patient presenting with a neck lump, and report back to HDC regarding any amendments, within three months of the date of this report.

# Follow-up actions

126. A copy of this report with details identifying the parties removed, except the experts who advised on this case, and Pacific Radiology Limited, will be sent to the Medical

- Council of New Zealand, and it will be advised of Dr C's name in covering correspondence.
- 127. A copy of this report with details identifying the parties removed, except the experts who advised on this case, and Pacific Radiology Limited, will be sent to the Medical Radiation Technologists Board, and it will be advised of Mr B's name in covering correspondence.
- 128. A copy of this report with details identifying the parties removed, except the experts who advised on this case, and Pacific Radiology Limited, will be sent to the district health board, and it will be advised of Dr C's name and Mr B's name in covering correspondence.
- 129. A copy of this report with details identifying the parties removed, except the experts who advised on this case, and Pacific Radiology Limited, will be sent to the Royal Australian and New Zealand College of Radiologists, and it will be advised of Dr C's name in covering correspondence.
- 130. A copy of this report with details identifying the parties removed, except the experts who advised on this case, and Pacific Radiology Limited, will be sent to the Royal New Zealand College of General Practitioners, the Ministry of Health, and the subregional clinical leadership group's Health Services Development Programme, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

# Appendix A: Independent radiologist advice to the Commissioner

The following expert advice was obtained from a consultant radiologist, Dr Hament Pandya:

"I have reviewed the ultrasound scans of the neck performed on 27<sup>th</sup> September 2011 and 11<sup>th</sup> February 2014 at Pacific Radiology.

Based on the additional available information, I would offer the following comments for consideration regarding the role of Pacific Radiology:

Q: Given the ultrasound appearances noted in September 2011, particularly the size and nature of the two largest lesions identified, should a recommendation have been made that one or both of the lesions required further assessment with FNA or follow-up within a specified time frame?

During my work as part of the National Thyroid Cancer Tumours Standards Working Group 2013, the question of exactly which ultrasound findings should mandate a recommendation for FNA courted much debate amongst the various specialists.

I feel that it is important to take into account that accurate distinction between benign and malignant thyroid nodules using ultrasound, can be very difficult. Based on my experience it is unquestionably one of the areas of imaging that many non-specialist radiologists approach with some trepidation.

Although there are numerous international guidelines available, the practical difficulty lies in the fact that most of the features suggestive of malignancy are also often seen (to varying degrees) in benign nodules.

The judgement of whether a nodule may be malignant therefore has to be based on the cumulative probability of a number of imaging features being present within that nodule.

The main criteria being:

- Presence of microcalcification
- Poorly defined margins
- Prominent internal vascularity
- Absent halo around the nodule
- Nodule being 'taller than wide'
- Presence of abnormal cervical nodes

Based on my experience, the size of a given thyroid nodule as an independent feature is a poor discrimination of malignancy, as a significant proportion of benign nodules are often larger than 2cm.

I feel that it is also important to point out that the minimum number of features that are required for recommendation of FNA has not been stated in the Ministry of Health document 'Standard of Service Provision for Thyroid Cancer Patients in New Zealand 2013'. The creation of this document has drawn evidence from both current European and American thyroid nodule management guidelines.

Retrospective review of the images from September 2011 does reveal a suspicious 9mm lymph node causing an impression on the right internal jugular vein i.e. separate and lateral to the thyroid gland, which has not been commented upon. This node demonstrates loss of normal sonographic nodal architecture and contains some microcalcifications, features highly suggestive of metastatic papillary thyroid carcinoma.

It would therefore appear that 5 out of the 6 features above were present in 2011. On this basis, I would suggest that there has been a moderate departure from an accepted standard of care.

Accordingly, I would also agree with [Dr C's] assertion that FNA of the right sided thyroid nodule should have been suggested.

Q: There are multiple international guidelines on management of thyroid nodules, particularly relating to when FNA should be recommended. Do you feel these guidelines were followed appropriately by Pacific Radiology?

As above.

Q: Noting the history as described and the ultrasound findings in September 2011, should the ultrasound assessment at that time have been extended to involve the local lymph node groups?

Yes, I believe so. Adequate sonographic assessment of thyroid nodules should always include imaging of the local lymph node groups, which is widely accepted as standard procedure.

The images on the initial scan from September 2011 appear to focus solely on the thyroid gland. There are no images to suggest that a wider survey of the lymph nodes in the lower neck or supraclavicular fossae has been performed.

Furthermore (in retrospect) a suspicious right sided lymph node was present on the previous ultrasound scan from 2011. The significance of this observation was likely not realised by the sonographer during the scan, who would have presumably been prompted to look for additional abnormal nodes.

Q: [Dr C] has commented that, on review of the thyroid images from September 2011, the right lower lobe nodule showed suspicious findings and he should have recommended biopsy. After reviewing the ultrasound images from September 2011, do you feel that failure by [Dr C] to note the findings and make the recommendations he alludes to represents a departure from expected standards and, if so, to what degree?

As commented above, I agree with [Dr C's] assertion that FNA should probably have been recommended based on the presence of a number of suspicious ultrasound findings that were present in September 2011.

As also commented above, sonographic assessment of thyroid nodules can be difficult and therefore the lack of such recommendation probably represents a mild to moderate departure from expected standards.

Q: What role did Pacific Radiology play in the delay of [Ms A's] diagnosis? Based on the above, there does appear to have been an initial delay in the radiological diagnosis of the right sided thyroid tumour with local lymph node

metastases. This appears to have been compounded by the lack of appropriate further action by the patient GP's.

From a radiological perspective, my impression is that the main contributory factors have been inadequate evaluation of the local lymph nodes groups draining the thyroid gland and failure to recognise a number of suspicious sonographic features related to the thyroid nodule and within the right lower neck.

I hope that these comments help with your deliberations.

Kind regards

# Dr Hament Pandya

Consultant Radiologist

MCNZ: [...]"

Dr Pandya provided the following further advice:

"I confirm that I have read and agree to follow the guidelines for independent advisors provided. I have previously undergone specialist fellowship training in head and neck imaging in the UK during 2005. Subsequently, I have been a consultant radiologist since January 2006 having a major subspecialty interest in head and neck imaging, particularly thyroid imaging. Since 2013, I have been part of the New Zealand National Cancer Thyroid Tumour Standards Working Group.

I have reviewed the following documentation provided:

- 1. Complaint details supplied to HDC.
- 2. Initial Pacific Radiology Ltd response (undated).
- 3. My initial expert advice dated 4<sup>th</sup> September 2014.
- 4. HDC letters of notification dated 21st October 2014.
- 5. Response from Pacific Radiology Ltd dated 17<sup>th</sup> November 2014
- 6. Response from [Dr C], Radiologist, dated 5<sup>th</sup> November 2014.
- 7. Further input from Pacific Radiology Ltd dated 2<sup>nd</sup> April 2015.

I have been requested to *comment* on the following:

1. Whether [I] wish to make any changes or additions to [my] expert advice dated  $4^{th}$  September 2014 in light of the additional information and responses detailed above that [I] have not previously had the opportunity to review.

*Response*: I do not wish to make any changes to previously provided advice.

- 2. The overall standard of care provided by:
  - *i*) [Dr C]
  - ii) Pacific Radiology Limited

## Response:

i) [Dr C]

As previously stated in my response dated 4<sup>th</sup> September 2014, the ultrasound scan performed in September 2011, demonstrated 5 out of 6 criteria for designating a thyroid nodule as being suspicious.

The main criteria being:-

- Presence of microcalcification
- Poorly defined margins
- Prominent internal vascularity
- Absent halo around the nodule
- Nodule being 'taller than wide'
- Presence of abnormal cervical nodes

On this basis, (as [Dr C] has also previously asserted), FNA of the right sided thyroid nodule should have been suggested. A non-enlarged 9mm lymph node demonstrating abnormal echotexture was also present at the time of scanning.

I would therefore suggest that there has been a moderate departure from generally accepted practice.

# ii) Pacific Radiology Limited

With specific regard to the ultrasound scan performed on 27<sup>th</sup> September 2011, and based on the above, I suggest that there has been a moderate departure from an accepted standard of care provided.

Regarding the subsequent ultrasound examination and biopsies performed on 11<sup>th</sup> February 2014, I believe that the care provided constituted an acceptable standard of care.

On the basis of statements provided by the student sonographer and [Dr G], it would appear that following initial scanning by the student sonographer, [Dr G] also evaluated the thyroid and noted a separate abnormality away from the thyroid. The lesion in the thyroid gland and separate abnormal lymph node were then appropriately biopsied leading to a final diagnosis.

3. The appropriateness of policies and procedures in place at Pacific Radiology Limited in this case.

I would assert that including evaluation of at least the lower cervical and supraclavicular lymph nodes during sonographic assessment of thyroid nodules constitutes widely accepted practice.

This has also been indicated [in Pacific Radiology's] letter dated 2<sup>nd</sup> April 2015,

'When a patient complains of a lump in the neck ... this should prompt a review of the neck lymph nodes, especially when the thyroid gland itself is not normal in appearance.'

I have reviewed the thyroid ultrasound procedure protocol provided by Pacific Radiology Ltd (issue date: 8<sup>th</sup> October 2009).

Under '12.1.4 Procedure' the first point indicates 'note any neck lumps, get a clinical history e.g. difficulty swallowing.'

I think that this constitutes good clinical practice. If followed appropriately, this should minimize the risk of missing potentially relevant pathology.

Based on the information provided, however, it is unclear whether the thyroid nodule or the separate mass was the original lump noticed by [Ms A].

With regards to the appropriateness of policies/procedures, there does appear to be some conflict.

Under '12.1.4 Procedure', no specific mention is made of the need to assess lymph nodes within the neck, however, the sonographer worksheet does clearly make provision for the documentation of lymph node status.

I would recommend making this statement explicit in future revisions of the neck ultrasound protocol.

It remains a fact, however, that no comments were recorded by the sonographer in these spaces in September 2011. In addition, there were no representative images to indicate that further focused search for abnormal neck nodes had been performed at the time of initial ultrasound.

Overall, I think that most of my peers would agree with [Pacific Radiology's] assertion that '[when a patient presents with a neck lump] ... this should prompt a review of the neck lymph nodes, especially when the thyroid gland itself is not normal in appearance'. In this regard, I believe that the sonographer should have performed further focused evaluation of at least the perithyroidal, lower cervical and supraclavicular lymph nodes.

I hope that these comments help with your deliberations.

Kind Regards,

#### **Dr Hament Pandya**

Consultant Radiologist"

# **Appendix B: Independent sonographer advice to the Commissioner**

The following expert advice was obtained from a sonographer, Naomi Rasmussen:

"As a Sonographer I will endeavour to answer your questions or give my opinion regarding the care provided by sonographer [Mr B] for [Ms A] in 2011.

Your questions are listed below **A-G.** 

# A) The overall standard of sonography care provided to [Ms A] by [Mr B] in 2011

- a. In 2011 as it is now the protocol for scanning of the thyroid includes scanning the adjacent neck for lymph nodes. If no nodes are seen this is not always documented in an image. If a lump is mentioned on the request or by the patient this should be scanned and correlated with the documented images. Often you would label the image 'palpable lump'.
- b. The images of the thyroid gland are adequate although the largest nodule is often measured in 3 dimensions to allow comparison for future imaging. Accepted practice would be to survey for lymph nodes although if normal these are not always documented.
- c. This would probably not be seen as a major departure from protocol. It is concerning that [Mr B] in 2011 did not know to check for lymph nodes when doing a thyroid scan, particularly when there is pathology. 'I made no attempt to image them during the scan in question, nor did I image them on any of my thyroid scans at the time' Quote from [Mr B's] letter dated 10/2/15.

# B) [Mr B's] response to the description and criticisms of his care that his employer provided in point 2 dated 10/11/14

In the Hospital and Private Practice I worked at in 2011 it was normal protocol to check for lymph nodes on a thyroid scan. Although due to human error this can sometimes be neglected or not documented when no nodes are identified, it is concerning that [Mr B] at that time by his own admission never looked for lymph nodes.

It is a valid comment of [Mr B] that he had not been contacted regarding his lack of images or lack of comments on lymph nodes on other patients especially if there was pathology.

I understand he would have been doing this until 2014 when he was alerted to this case.

I agree with [Mr B] in that in some instances we do not scan the area of the patient's concern, especially if it is an abdomen scan and the region of concern is bowel which is not imaged well by Ultrasound. But even in these cases it is worth having a quick look where the patient's pain or area of concern is.

With small parts ultrasound such as thyroid, scrotum, breast or a soft tissue lump it is particularly important to cover the area of the patient's concern, pain or palpable lump.

As a sonographer it is good to see that in [Mr B's] second letter dated 7/4/15 that he immediately changed his scanning technique to always include images of the neck nodes, after he was alerted to this case.

# C) [Mr B's] interpretation of the Pacific Radiology sonographer protocols.

The Thyroid Protocol supplied by Pacific Radiology dated 8/10/09 does not specifically say the lymph nodes should be assessed but it does say 'Note any neck lumps, get a clinical history'.

In which case, if he was following their protocol he would have questioned the patient about her lump.

# D) Comments on [Mr B's] response to the relevant excerpt of Dr Pandya's advice to HDC

I would agree with Dr Pandya's advice that adequate assessment of the thyroid should always include imaging of the local lymph nodes and this would have been accepted practice to my knowledge in 2011. I couldn't find any direct response from [Mr B] in the information provided to me on the excerpt of Dr Pandya's advice to HDC.

# E) [Mr B's] explanation why no images of local lymph nodes were taken as part of the examination on 27<sup>th</sup> September 2011

[Mr B] by his own admission said that in 2011 at the time of the scan in question, he did not extend his thyroid scans to look for lymph nodes.

# F) My opinion of [Mr B's] understanding of accepted sonography practices and professional standards that were in place in 2011.

By admitting that he didn't ever take images of the lymph nodes he is showing that he was not aware of accepted New Zealand practice.

# G) [Mr B's] explanation why no mention is made of local lymph nodes in the appropriate spaces on his corresponding worksheet.

When I use work sheets I don't always fill in all the boxes, but they do prompt you to comment if there is relevant pathology. It is difficult to understand [Mr B's] explanation.

## **Conclusion:**

Standard practice for Sonographers in 2011 was to include at least a survey of the local lymph nodes when scanning the thyroid. Although if there were no abnormal nodes this was not always documented on imaging.

Good Practice should have included questions to the patient if they could feel the lump to ensure it was covered in the examination and so correlation could have been made with the documented images.

[Section removed not relevant to decision]

Yours Sincerely

Naomi Rasmussen Sonographer DMU"

Ms Rasmussen was asked to clarify her view of the degree of departure from accepted practice or professional standards. She advised that there was a mild departure from accepted standards.

Ms Rasmussen also provided the following further comment:

"The Sonographer has limited knowledge of pathology when compared to a Radiologist. But their training should provide enough knowledge to understand the request form and where to extend the examination if required. They should also be able to appreciate when they require more help or guidance from the Radiologist. Unlike CT and MRI where the images aren't mechanically produced in set slices. If the Sonographer doesn't image Pathology it can't be reported by the Radiologist.

The Sonographer fills in a worksheet which outlines the pathology they have seen and describes it in ultrasound terms. Often discussion between the Sonographer and Radiologist can help understanding for both.

The ultimate responsibility for the report lies with the Radiologist, but having said that the Radiologist can only report from the images and worksheet provided unless they scan themselves or discuss the findings with the Sonographer. It is good to have a close working relationship between the Sonographer and Radiologist.

I would agree that when you are focused on one area or organ it is quite possible to miss pathology even if it is on the image you have recorded. It is not uncommon for something to be identified on an image in retrospect that had previously not been recognized.

I'm not sure of the differences between surveying and scanning. In my report I have used 'Survey' to mean scanning in real time through the neck. Generally when you survey for nodes you only take a few representative images of the largest nodes unless pathology was visualized, in which case more documentation is required. Imaging means documenting with an image. I hope this helps. Please contact me again if I haven't answered your questions adequately.

Regards

Naomi Rasmussen"