Radiologist, Dr E

Radiologist, Dr D

Otolaryngologist, Dr F

Surgeon, Dr C

A Public Hospital

A Report by the

Health and Disability Commissioner

(Case 03HDC08493)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer (deceased)
Mr B	Consumer's son
Dr C	Provider / Otolaryngology surgeon
Dr D	Provider / Radiology consultant
Dr E	Provider / Radiology registrar
Dr F	Provider / Otolaryngology registrar
Dr G	Consumer's general practitioner

Complaint

On 10 June 2003 the Commissioner received a complaint from Advocacy Network Services Trust, on behalf of Mrs A, about the standard of service provided to Mrs A by Dr E, Dr F and Dr C. Mrs A's complaint was summarised as follows:

Dr E
Dr E, radiology registrar, did not provide services of an appropriate standard in reviewing Mrs A's CT scan of 25 July 2002, and his advice on the basis of that reading (that she required a follow-up scan in three months) was inappropriate in the circumstances.

Dr F
Dr F, otolaryngology registrar, did not:

- *provide services of an appropriate standard in his management of Mrs A's condition. In particular, he did not formulate an appropriate management plan on the basis of her presenting condition and the CT scan reported to him on 25 July 2002;*

- *inform Mrs A of the results of her 25 July 2002 CT scan, and did not ensure that Mrs A was adequately informed of his management plan.*

Dr C
Dr C, otolaryngologist – head and neck surgeon, did not:

- *provide services of an appropriate standard by proceeding with the laser laryngoscopy on Mrs A on the basis of the CT scan result dated 25 July 2002;*

- *instigate an appropriate and timely management plan for Mrs A following the laryngoscopy on 23 August 2002;*

- *provide Mrs A with accurate information when she asked him on 12 September 2002 if there was any sign of cancer.*

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

An investigation was commenced on 11 September 2003.

Dr D
On 14 January 2004, as a result of additional information provided by Dr E, the Commissioner's investigation was extended to include Dr D, consultant radiologist. The issues investigated in regard to Dr D were:

- *whether [he] provided services of an appropriate standard when he reviewed Mrs A's CT scan of 25 July 2002; and*

- *whether his advice on the basis of that reading (that Mrs A required a follow-up scan in three months) was appropriate in the circumstances.*

Information reviewed

- Complaint from Mrs A together with medical records summarised by her support person, (a nurse)
- Information from Mrs A's husband
- Information from Mr B (Mrs A's son)
- Information from Dr D
- Information from Dr E
- Information from Dr C including digital video imaging pictures
- Information from Dr F
- Information from a public hospital
- Mrs A's clinical records from the public hospital
- Mrs A's X-ray and CT scan images
- Mrs A's general practitioner records from Dr G
- Correspondence from ACC Medical Misadventure Unit including Claim Decision and Medical Misadventure Report to Claimant dated 21 June 2004 and Report of the independent advisor to ACC
- Policy statement from the Royal Australian and New Zealand College of Radiologists

Independent expert advice was obtained from Dr Robert Allison, an otolaryngologist – head and neck surgeon (report dated 13 January 2004) and Dr David Milne, a radiologist (reports dated 14 December 2003 and 22 April 2004).

Information gathered during investigation

Overview

In June 2002 Mrs A (who was then 63 years old) advised her general practitioner, Dr G, that she had neck and shoulder pain, difficulty swallowing, loss of voice and shortness of breath. Dr G referred Mrs A to a public hospital for investigations to identify the cause of her symptoms. Mrs A was seen by Dr F, an otolaryngology registrar, and Dr C, an otolaryngology consultant.

On 25 July 2002, they referred her for a CT scan. Dr E, a radiology registrar in his third year of training, studied the CT scan and discussed it with his supervising consultant, Dr D. Dr E dictated and signed the scan report, noting "fibrotic changes" and recommending a follow-up scan in three months. Mrs A was subsequently seen regularly by Dr C at the Ear, Nose and Throat (ENT) Clinic at the public hospital. He found that Mrs A's hoarseness was continuing despite treatment, and in December 2002 he referred her for a further CT scan. Mrs A was subsequently telephoned by an unidentified registrar from the public hospital who allegedly informed her that the follow-up CT scan showed she had cancer, and that a mass had also been evident on the first scan taken in July. Mrs A complained to the Commissioner that in July or August 2002, Dr E, Dr C and Dr F must have known she had cancer but had not informed her of the diagnosis. Mrs A also complained that by December 2002, it was too late for her to have treatment. Mrs A died on 8 October 2003.

Background

Mrs A's medical history is significant. In 1973, she had breast cancer. This had been treated by a left mastectomy and radiotherapy. She had experienced extensive radiation damage to her left axillary [armpit] area, and had undergone corrective surgery. She had also suffered considerable neurovascular injuries to her left arm in a motor vehicle accident in 1980, as a result of which "left sided external carotid to brachial artery surgery" and skin grafting was required. In June 2002, Mrs A was a heavy smoker who suffered from chronic obstructive respiratory disease [CORD] and asthma, for which she was on medication. She had recently lost 20kg in weight and had been experiencing difficulty breathing and swallowing.

Chronology of events

GP consultations
On 18 June 2002 Mrs A consulted her GP, Dr G, because she had left cheek pain, her throat was sore when she swallowed, and her voice was hoarse. Dr G examined her neck and found that her jaw was tender, but she did not have swollen glands. He recommended that she try an anti-inflammatory drug and gave her Vioxx 12.5mg. He told Mrs A to come back if her voice did not improve.

On 28 June Mrs A returned to see Dr G. She told him that she still had a hoarse voice and it felt like she had a lump in her throat. Her left-sided facial and neck pain had recurred after she stopped taking Vioxx. Dr G referred her to the ENT clinic at the public hospital to

investigate the cause of her hoarse voice. Dr G's referral letter to the ENT clinic dated 11 July 2002, states:

> "[Mrs A] has [been] hoarse for the last 2 months. There was no initial virus infection. She smoked (?smokes?) and has CORD. Also had Ca [cancer] left breast many years ago, with no recurrence. There is radiation damage to structures going through the left axilla, all stable. Recent CXR [chest X-ray] nad [no abnormality detected]. She has reflux, well controlled on Losec. I would be grateful for your help with further investigations and treatment."

On 17 July Mrs A consulted her GP again and told him that her voice had become very much more hoarse within a very short time. Dr G noted that Losec, the drug Mrs A was using to control her reflux, caused her throat to burn. He observed that she had some stridor, and decided to refer her urgently to the ENT clinic. Dr G's second letter to the ENT clinic, dated 17 July 2002, states:

> "She has had a hoarse voice for the last 2 months and I have organized a referral to your clinic, but she has now developed stridor and cannot lie flat and has trouble clearing phlegm. … She has radiation damage to her left axillary vessels with some CXR changes as well, but recent CXR normal otherwise. There is a tender rt [right] neck gland and she has had pain rt jaw area. I would appreciate your urgent opinion."

"Stridor" is a clinical term referring to a shrill or harsh high-pitched respiratory sound heard when patients breathe in; it can indicate an acute laryngeal obstruction.

First consultation with Dr F, ENT clinic
On 18 July 2002 Mrs A was seen at the ENT clinic by Dr F. After the consultation he wrote to Dr G as follows:

> "She has difficulty in swallowing with a feeling of aspiration [inhaling foreign material]. She has had a marked weight loss from 90 to 69kg. She has been troubled by stridor over the last few days and is getting short of breath when she lies [down]. She has had some dyspnoea [difficulty breathing].
>
> She is on multiple medications ... She has had multiple operations including repair of a vascular injury to her left arm. This involved a carotid to branchial cortex graft. She subsequently had some skin necrosis over her left chest wall, which has been repaired with a latissimus dorsi myocutaneous flap. She had breast cancer in 1973.
>
> …
>
> **On examination** she has a large surgical scar on her left neck. No masses were palpable in the neck. She has a hoarse and quiet voice and no stridor. On examination of the cords with a nasendoscope she has paralysis of the left vocal cord. There is lots of redundant mucosa of the supraglottis. The left vocal cord was in the paramedian position.

Impression – Left vocal cord paralysis. I am unsure of the cause but I think that there is every likelihood that this will be neoplastic [malignant] in nature.

Plan – I have arranged for her to have a CT scan of her chest and abdomen on an urgent basis. I will review her again next Tuesday. I have requested that she present herself immediately should she be troubled by significant dyspnoea."

The radiology request form completed by Dr F is dated 18 July 2002 and is very clearly marked "urgent". It contains the following information under the heading "Clinical Summary":

"L [left] vocal cord palsy
hoarse voice + + 1/12 [one month]
difficulty swallowing
stridor
weight loss + +
smoker – stopped 1/12 ago
Ca breast – 1973
?neoplastic cause of palsy
for URGENT CT neck and chest"

Mrs A attended the public hospital again on 25 July and, before her second appointment with Dr F, she had the CT scan he had ordered.

CT scan and report – 25 July 2002
The CT scan of Mrs A's neck and chest was performed by a radiographer at the public hospital's radiology department. Dr E, who in July 2002 was half way through his third year of radiology registrar training at the hospital, was the first person to study the CT films that day. He informed me that after his initial review, "as per standard practice, I reviewed these films with Dr D, consultant radiologist [and Dr E's supervisor]. We discussed the important findings and agreed on the summary points."

Dr E dictated a report the same day. He informed me that after the report was typed he reviewed it, made the necessary corrections and signed the report "as the finalized document". On 29 July 2002 the report was entered into the hospital computer system and a copy sent to the doctor at the ENT outpatients' department who had been on call on the day Mrs A attended the clinic. A copy was also sent to Dr G. Dr D did not see the report during this process. The report read as follows:

"AZD5449 [Mrs A] [DOB]
25/07/2002 […]

Copy for: Dr G

OP

#30 CT NECK AND CHEST: (REVIEWED WITH [DR D])

INDICATIONS:
Previous breast Ca 1973. Hoarse voice. Weight loss.

REPORT:
An intravenous contrast enhanced CT scan of the neck and chest was performed.
Within the neck no mass lesion or lymphadenopathy is demonstrated. There is no evidence of tracheal narrowing. No mass lesion is seen at the level of the vocal cords. The right lobe of thyroid is enlarged, no discrete nodules are identified, this could be further evaluated with an ultrasound if indicated.

Within the chest a left mastectomy is noted. The left hilum is elevated and there is loss of volume in the left upper zone with fibrotic change in keeping with previous radiation treatment. There is a 2 x 2cm area of soft tissue posteriorly in the left upper zone sited adjacent to the descending thoracic aorta medially and just above the branching of the left main bronchus. Superior and continuous with this lesion are more linear areas of stranding consistent with fibrosis. The pleura posterior to the lesion is also thickened in keeping with fibrosis. The soft tissue lesion is seen to abut the medial aspect of the left horizontal fissure. There is crowding of vessels and fibrotic change at the left apex. No further parenchymal or pleural nodules are identified. The lung bases appear clear. Within the upper abdomen the liver appears normal. A 1.5cm area of low density in the left adrenal would be consistent with an adenoma. No upper abdominal para-aortic lymphadenopathy is seen.

SUMMARY: No cause for hoarseness or stridor demonstrated. A 3cm lesion is seen in the left upper zone posteriorly. Given the associated surrounding changes and the previous radiotherapy this most likely represents an area of fibrosis which is more focal in part. However I cannot exclude an underlying malignancy. This lesion would be difficult to biopsy due to its close proximity to the descending thoracic aorta. Initially a follow up CT scan in 3 months time is recommended to further view the lesion. I cannot identify it on either a frontal or lateral chest film.

Radiologist [Dr E] – Registrar 25 JUL 2002"

Issues arising from Mrs A's complaint insofar as they relate to Dr E and Dr D include the allegation that she was "never contacted by anyone to inform me of the results of the CT scan", and that Dr E and Dr D did not provide services of an appropriate standard when they reviewed the scan and advised follow-up in three months. Responding to these issues, Dr E stated:

"I have reviewed the images and formal report. In the report issued there is minor discrepancy in measurements between the body of the report and the summary (2 x 2cm vs 3cm). Neither measurement is inaccurate, but reflects the ill defined nature of the tissue identified. The salient points in the summary I believe are accurate and the imaging follow up recommended appropriate. As recorded, an area of abnormality was detected in the left lung upper lobe posteriorly. With the history of previous breast cancer and volume loss this was felt more likely to be fibrosis secondary to radiotherapy

> although malignancy could not be excluded. As the tissue was centrally located and difficult to biopsy a short term follow up CT scan was recommended in three months time.
>
> Reports are not usually discussed with the referring doctor unless immediate medical or surgical management is required or the case is examined at a clinical specialty radiology meeting. Formal reports are not discussed with the patient by radiology consultants or registrars. Occasionally an informal verbal result is given to the patient immediately after the examination at the discretion of the consultant or registrar.
>
> When a recommendation of follow-up imaging is made, the patient must be referred by the clinician back to the radiology department with a new request form. Radiologists do not arrange repeat imaging examinations without discussion with the patient's clinical team."

The manager of Diagnostic and Allied Health Services at the hospital also confirmed that it is not the practice of the Radiology Service to convey CT findings directly to the patient, nor to routinely discuss the findings of individual cases with the referring clinician unless such cases are brought to a specialist radiology conference. With regard to Dr E's report on Mrs A's scan, the manager said:

> "[W]hile not offering a differential diagnosis, [it] does detail the anatomical changes associated with the lesion described within the upper lobe of the left lung … [Dr E] was unable to 'exclude an underlying malignancy'. The normal course of action in similar cases would be to recommend the biopsy of such a lesion, however in this case this was considered too risky due to the close association with the major blood vessel within the chest. [Dr E] goes on to recommend a further follow up CT scan in 3 months … It is felt that this recommendation was entirely appropriate in this instance."

Dr D advised me:

> "I was the supervising radiologist for the general CT list that was performed on 25 July 2002. [Mrs A's] CT was reported at that time. I was responsible for providing specific oversight to [Dr E], Registrar. This entailed a discussion with [Dr E] over the findings on [Mrs A's] CT. This was a consultation only.
>
> Please note that the reports are <u>not</u> dictated on direct instruction … The usual process is that following the consultation the registrar dictates a report. This may occur either at the time of the study, shortly after the study has been performed, or at a later date. The report is then typed by the medical typists and placed in the registrars' box for checking. In the past, once the registrar had checked the report it was signed off as a permanent record.
>
> In terms of this complaint, the usual practice at [the public hospital] at the time was that the supervising consultant did not usually review the final report. That was the situation in July 2002. I was therefore unaware of the language used or the relevant conclusion

stated in [Mrs A's] reported CT findings. I relied on [Dr E's] ability to accurately represent the findings that we had discussed during our consultation / discussion.

However, since then, I have changed my policy in respect of checking registrars' reports. This change resulted from a discussion in the national radiology literature about consultant oversight in the supervision of registrars and checking reports. Accordingly, I now check all reports issued by registrars under my supervision prior to them being finalised.

It is the responsibility of registrars at [the public hospital] to accurately report the discussed radiological findings. However, I note that it is not routine practice for radiology consultants at [the public hospital] to specifically review every dictated report …

I have reviewed the CT scan of 25 July 2002 and read [Dr E's] report. There are inconsistencies between what I believe should have been dictated and what was in fact dictated. Whilst there are comments made in the report about the volume loss, hilum elevation and pleural thickening, those matters are poorly described. It is noted that a 'mass' is present and continuous with stranding. This soft tissue should have been dictated as – 'in the mediastinum adjacent to the aorta (Aortopulmonary region)'. Also, the first statement in the conclusion part of the report should refer to the 'neck' and not the 'chest'.

However, despite the above issues it is clearly apparent that there are a series of abnormalities reported in the CT report.

In my opinion it was reasonable to conclude that – a) fibrosis could be the cause; b) malignancy could not be excluded; and c) a short term follow up should be performed in 3 months, given the potential difficulty in obtaining a biopsy."

Management by Dr F and Dr C– 25 July

Dr F reviewed Mrs A's CT scans in the radiology department on 25 July 2002. He informed me that it is his customary practice to review unreported CT scans with a radiologist; however, given the time that has passed since these events occurred he can not specifically remember whether a radiologist was present on this occasion.

Having reviewed the scans, Dr F saw Mrs A in the ENT outpatients' clinic the same afternoon. During the consultation, Mrs A was referred to Dr C, who performed a video laryngoscopy [an examination of Mrs A's vocal cords], in the presence of Dr F. This procedure was recorded in order that it could be shown to Mrs A immediately, and reviewed by the clinical team at a later date.

Dr F recorded in Mrs A's clinical notes findings of leukoplakia of her right true vocal cord, and paresis of the left true vocal cord. "Leukoplakia" refers to thickened white patches on a patient's vocal cord(s), which have a "pronounced tendency to become malignant"; paresis means slight or "partial" paralysis, in this case, of the vocal cord(s).

Dr F considered that Mrs A's vocal cord paresis may have been longstanding and might have resulted from one of the many left cervical vascular procedures that had previously been performed to correct the radiation damage to her left axillary artery. He also believed that her hoarse voice (dysphonia) may have been caused by the leukoplakia and possible reflux laryngitis.

Dr C stated:

> "[I]t was clear that [Mrs A] had a mild vocal paresis on the left but there were marked leukoplakic changes on both vocal cords. In association with her strong smoking history it was deemed essential to perform laryngoscopy. At this time these areas would be removed, the main purpose being to provide biopsies for histological diagnosis and a secondary purpose being stripping to allow new epithelial in-growth and thus improve her voice."

At the end of this appointment, Mrs A was prescribed proton pump inhibitor medication and listed for a further procedure known as "vocal cord stripping". Dr F completed a Waiting List Referral form for Mrs A asking her to be placed on the waiting list for "panendoscopy/ stripping of vocal cords / mitomycin C".

Dr F wrote to Dr G summarising this consultation as follows:

> "**Present problems –** leukoplakia of true vocal cords. Paralysis of left vocal cord.
>
> … [Mrs A] had a CT scan of her neck and chest this morning which was normal. Laryngoscopy was repeated by [Dr C] this afternoon at which was seen leukoplakia of the right true vocal cord. There was slight irregularity of the edge of the left true vocal cord. The left cord did not move as much as the right.
>
> **Plan –**
>
> 1. I have listed her for stripping of her vocal cords.
> 2. I have given her a prescription for Pantoprazole …
> 3. I have referred her to our Speech Therapist … "

The speech and language therapist, to whom Dr F referred Mrs A also received a copy of Dr F's letter.

Subsequent management – August 2002
Clinical notes recording Mrs A's consultation at a pre-admission clinic on 12 August 2002 state that she "[didn't] know the result" of the previous procedures, including the CT scan. It is also recorded that she was at that time smoking three cigarettes per day, still experiencing a change in the quality of her voice, "sometimes unable to talk", had pain in her jaw, difficulty swallowing and "problems talking and breathing". It is not clear who made these notes.

I have reviewed a "Reference Form" completed by a clinician, recording Mrs A's "extreme shortness of breath … ? cause" and referring Mrs A for spirometry tests (to measure her breathing capacity). Mrs A advised me that she was also not given the results of these tests.

On 23 August 2002, Dr C performed a laser laryngoscopy to examine Mrs A's vocal cords. Mrs A was placed under general anaesthetic, biopsies were taken and the leukoplakic areas were vaporised. Dr C's operation summary, copied to Dr G, states:

> "The leukoplakia has improved since what was seen at her clinic visit and which was photographed at that time. Under general anaesthesia the Kleinsasser C laryngoscope is introduced and fixed in suspension system. The patient is draped for laser. A small amount of saline is injected below the mucosa of the vocal cords thus raising them and the superficial layer of the vocal cord is stripped leaving the conus elasticus and vocalis intact below. These central areas which have been stripped are submitted into separate bottles. After this Mitomycin C 0.4mg was placed on the vocal cords for 6 minutes.
>
> **Post Op:** The patient must have voice rest for one week also humidification and should not whisper. I would like to see her in three to four weeks in clinic."

A histopathology report prepared by the pathologist on 30 August 2002 contained the following information in relation to the samples biopsied by Dr C on 23 August:

> "VOCAL CORD TISSUE, RT [Right] … The specimen consists of brown irregular tissue fragment measuring 2mm in maximum dimension. All embedded …
>
> DIAGNOSIS: Squamous epithelium with scanty stroma showing extensive diathermy artifact [making accurate assessment of morphology virtually impossible].
>
> VOCAL CORD TISSUE, LT [Left] … The specimen consists of brown irregular tissue fragment measuring 2mm in maximum dimension. All embedded …
>
> DIAGNOSIS: The appearances are consistent with squamous cell hyperplasia without any dysplastic changes."

Mrs A complained that Dr F and Dr C's management of her condition throughout July and August 2002 was not of an appropriate standard (they "failed to take more aggressive action") and that they failed to fully inform her about what was happening and what they had found. For example, she said that she was not told what vocal cord stripping involved: "I was just told that they would be having a look." More significantly, she alleged that as a result of the procedures performed during this time, Dr F and Dr C must have been able to identify a malignant area, which they failed to tell her about. In response to these particular concerns, Dr F informed me:

> "I did not recognise a tumour arising within the area of fibrosis in the upper lobe of the left lung. [Dr G's] referral letter describes longstanding changes on [Mrs A's] chest X-ray secondary to radiotherapy for breast cancer …

> On reviewing my contemporaneously made notes and correspondence I feel that the management plan I formulated in conjunction with [Dr C] on 25 July 2002 was appropriate given that the neoplastic change within the area of apical fibrosis was not clear to myself (as it was not clear to the consultant radiologist who subsequently reported these CT scans) …
>
> All patients in [Dr C's] clinic who undergo videolaryngoscopy have their tapes played back to them immediately after they are taken so that their clinical findings can be demonstrated to them. Their management plans are then discussed in the light of these findings. I did not inform [Mrs A] of the changes on her CT scan as I did not recognise a tumour."

Dr C advised me:

> "… [A]s the copy of the radiologist's CT report will show, there is no mention of any cause for hoarseness or stridor, but it does mention a 3cm lesion in the left upper zone [of the chest], which was thought to be representative of radiation fibrosis which had been known to be present before.
>
> It was however felt that this area would be best investigated by re-imaging in three months time as it was an extremely difficult area for biopsy."

Subsequent management – Dr C

Mrs A also complained that at a subsequent appointment on 12 September 2002, Dr C did not provide her with accurate information when she asked him directly whether there was any sign of cancer.

Mrs A said that on that date:

> "[Dr C] inserted a scope down [my] throat and took more photos. I asked 'was there any sign of cancer' – [Dr C] replied 'No sign of any cancer – isn't that good'. I replied 'that makes me happy'."

In response, Dr C informed me that he had reviewed Dr E's report of 25 July, filed in the notes, and commented:

> "Though I cannot specifically recall that I mentioned [to Mrs A] the finding of an area of pulmonary fibrosis … I believe I must have done so because I always dictate immediately after seeing the patient, and I did mention to the GP exactly what I had said to [her]. Though I accept that [Mrs A] asked if there was any cancer, and I must have said 'No', this is because we were discussing the findings in relation to the vocal cord changes at that time and indeed it was appropriate to reassure her in that regard. It is relevant that any causal connection between a mass in the chest pressing on the recurrent laryngeal nerve and hoarseness is not an intuitive one. Also, having had the report from the original CT in which the findings were 'no cause for hoarseness' it would seem inappropriate to cause speculative alarm. At the same time it was necessary to correctly inform the patient that an investigation needed to be repeated."

The letter sent to Dr G by Dr C on 12 September 2002 includes the following information:

> "[The vocal cord stripping] operation went well and on looking at her vocal cords today they are healing well. Also you will have had [Dr F's] report saying that the CT scan did not show any seriously suspicious lesion however there was reported a 3cm lesion in the left upper zone which was thought to represent an area of fibrosis. This may explain the left partial recurrent nerve lesion however the recommendation at that time was to repeat the CT scan in three months time which we will do … I am sending you a copy of her vocal cord pictures, the last one being the post-operative one. The histology of the removed epithelium shows only some thickening but no malignant changes."

Dr C also advised me:

> "We extensively informed the patient's general practitioner and I can assure you that extensive discussion took place with the patient and her husband at all times when she visited the clinic. We were however able to reassure the patient that there was no tumour present within her vocal cords.
>
> I can assure you that at all times both my registrar, [Dr F], and myself made great efforts to ensure that optimal treatment was given to this patient. This included some reassurance that no tumour was found within her larynx. The changes initially seen on CT scan were not reinforced in our numerous discussions with [Mrs A] as we felt at that time that it was appropriate to reassure her that no active tumour had been found which was indeed the case at that time. Sadly, as it now appears that the tumour had been responsible for her gradually worsening vocal cord paralysis it would already have been at an inoperable stage at that first CT examination [25 July 2002] and no curative treatment could have been given even at that early stage. We do always endeavour to keep the patient fully informed. However, we do apologise if in an attempt to give at least some reassurance where no certainty of malignancy is present one unintentionally creates a false sense of reassurance. In communicating such issues to patients, the balance is very fine."

Dr C's clinical opinion, at the appointment on 12 September 2002, was that Mrs A's hoarseness was due to the leukoplakia seen at the initial laryngoscopy performed on 25 July. The subsequent image of the vocal cords taken on 12 September indicated that the area was gradually healing and, in Dr C's view, the paralysis of the left vocal cord was "rather mild."

By late September, Mrs A's speech and language therapist had reported to Dr C that Mrs A was "employing a whisper which is proving to be resistant to most of the therapy techniques used. Voice was briefly achieved but not sustained, but it was sufficient for Mrs A to appreciate that the voice was there." The therapist advised Dr C that she had given Mrs A a therapy programme and a further appointment had been arranged to review her progress.

Mrs A was next seen by Dr C on 24 October 2002. In a letter written to Dr G that day, Dr C noted that she remained hoarse and commented:

> "[F]urther examination today … reveals that she has developed a left sided vocal cord paralysis … There is no doubt that she is a poor voice user and that she had these thickenings or so called 'calluses' of her vocal cords which we have now removed … The treatment I think will remain speech therapy for the next several months and if it recovers her voice will come back. If not, we will have to consider some surgery to correct the vocal cord paralysis. I think however the chances of its recovering are very high."

However, at Mrs A's next appointment with Dr C on 16 December 2002, he noted that her vocal cord paralysis had "definitely increased". Because of this, and (he states) in light of Dr E's original comments in the radiology report of 25 July, he arranged for an urgent repeat CT scan, along with an urgent referral to the respiratory medicine team. Dr C's radiology request form states:

> "**EXAMINATION:** CT Thorax
>
> **CLINICAL SUMMARY:** ensuing L [left] vocal cord palsy due to ? Rec [recurrent] nerve compression L mass seen on CT July 2002 – asked for repeat – 3/12 URGENT PLEASE."

Dr C's letter to Dr G dated 16 December 2002 advises:

> "[W]e have now established that [Mrs A] has a definite vocal cord paralysis which has gradually got worse and is now complete. However, her voice is much better following the speech therapy which she has had of late. I think that she definitely would require thyroplasty to correct the position of that vocal cord which would help both her cough reflux and her voice. Also I note that on the CT scan performed in July there was a left upper zone mass which was reported but was thought to be fibrosis. However it was recommended that this be repeated and I have asked for that to be done now. She also tells me that she has had some haemoptysis [coughing blood as a result of respiratory tract bleeding] of late. I think that we will await the results of the CT scan before acting any further on the haemoptysis."

Initially, Dr C completed a waiting list referral form asking Mrs A to be placed on the waiting list for a thyroplasty procedure. Subsequently, he asked for this to be cancelled and Mrs A taken off the waiting list. The referral form is crossed through and a note states, "not to proceed. Has lung problems".

CT scan – 24 December 2002

Dr C had informed Mrs A that she probably would not be able to get a CT scan done until the New Year. However, on 23 December 2002, a staff member from a radiology department telephoned and asked Mrs A to attend for her scan at 1.30pm on 24 December 2002. Mrs A did so.

The CT scan was reported by a radiologist, on 31 December 2002. The report, which was faxed to Dr G on 8 January 2003, noted:

> "Left sided mediastinal mass on previous CT, July 2002. Repeat scan for further assessment.
>
> Although the scans are not quite comparable … I am sure there is a slight increase in the bulk of the left sided mediastinal mass alongside the aortic arch. There is also significantly more pleural thickening associated with this, running up medially and posteriorly towards the apex of the lung. This is likely to be a slow to moderately growing malignant process, therefore. I note there has been a left mastectomy and secondary breast carcinoma is quite likely. A small mass just posterior to the left main pulmonary artery is still present, and this may have increased very slightly in size, although it is difficult to be sure of this."

Mrs A informed me that in the second week of January 2003 a registrar, whose name is not known, telephoned her from the public hospital to tell her that a mass had been seen on the follow-up CT scan. When Mrs A remarked that she had previously been told that the scan taken in July was clear, the registrar allegedly told her that the mass had been present since July 2002 and that her case would be discussed with a respiratory physician when he returned from holiday.

Management, 2003

On 29 January 2003 Mrs A was seen by the respiratory physician. He performed a bronchoscopy, which identified that the left main bronchus was narrowed with marked inflammation, and distortion. He also reported that the left upper lobe bronchus had a tumour mass but was very difficult to enter or biopsy because of the distortion. His record of this procedure notes that the washings and brushings, and some tentative biopsies, had been performed "with great difficulty … [and] I was unable to get a needle anywhere near the lesion to take a biopsy". Subsequently, adenocarcinoma was confirmed, with further tests identifying a primary lung tumour.

The respiratory physician referred Mrs A's case to a Chest Conference on 5 February 2003 for review and an opinion regarding further management. On 4 March Mrs A was assessed by a medical oncologist. He reported to the respiratory physician, Dr C and Dr G that Mrs A had "locally advanced adenocarcinoma [of the] lung", but was not a candidate for radiation therapy because of the extensive radiation she had received in the past. He discussed with Mrs A the possibility of chemotherapy, and noted that if she declined chemotherapy he would ask the palliative care physicians to take over her care. As Mrs A was in significant pain at that time, he started her on MST 30mg (morphine) twice daily and Sevredol 100mg as required up to four hourly for pain control.

Mrs A was referred to a palliative care specialist, who she saw on 17 March. Her ongoing care was managed by this specialist, the Cancer Society, and Dr G. Mrs A died at her home on 8 October 2003.

In summing up his response to Mrs A's complaint, Dr C said:

> "We do deeply regret that there was any delay at all in making the diagnosis that [Mrs A] had a malignancy within the fibrosed previously radiated area of her left lung apex. However, I believe that any delay was related to the diagnostic difficulties and at no time indicates inadequate standards of diagnosis or management. Until that time although we [had] considered recurrent neoplasia as a possible diagnosis the fact that she had leukoplakia of her vocal cords and had been a long term smoker determined that laryngoscopy and biopsy was essential, and all other appropriate diagnostic steps were also taken. The mild paresis on the left could have been accounted for by fibrosis and previous surgery to correct arterial radiation damage on that side. We proceeded to treat the vocal cords successfully for the changes which were there which were determined not to be malignant …
>
> As I have said, we deeply regret that this diagnosis was in existence from the very beginning but I think it is clear that we performed every possible investigation and attempted to apply good clinical practice at all times."

Accident Compensation Corporation

Mrs A's family filed a claim with ACC's Medical Misadventure Unit, alleging that the providers involved in her care had failed to diagnose lung cancer following the CT scan of 25 July 2002. On 21 June 2004, ACC's Clinical Advisor informed me that the claim had been declined because ACC was unable to establish that Mrs A's death was related to any failure of a health professional to "provide skill and care reasonably to be expected in the circumstances".

In reaching its decision, ACC considered the following advice of a consultant radiologist:

> "The soft tissue windows show a thoracic pre-aortic soft tissue mass. This measures approximately 20mm in transverse diameter. A second soft tissue mass is seen in the superior mediastinum adjacent to the left carotid origin. This measures approximately 15mm in transverse diameter. Third soft tissue mass is seen adjacent to the left side of the descending thoracic aorta posterior to the left main pulmonary artery. This measures approximately 12mm in diameter. Lung windows demonstrate pleural thickening in a reticular pattern in the apices of the left lung. … The abdominal images show a large low density medial limb of the left supra renal gland. …
>
> <u>Conclusion</u>
>
> ... The appearances of the soft tissue masses in the mediastinum may represent neoplasia or possibly post-radiotherapy changes. … Biopsy, follow-up imaging or correlation with old imaging would all be reasonable alternatives. …

Discussion

The reporting radiologists [Dr E] and [Dr D] gave an appropriate and reasonable report on the above CT imaging, noting that the appearances in the lung and mediastinum were consistent with malignancy but this was uncertain due to the co-existing changes secondary to radiotherapy. The reporting Radiologist raised the possibility of biopsy (although difficult) and made a reasonable recommendation of a follow-up CT scan in 3 months time.

Comment

In my opinion this is a reasonable appropriate and accurate report on the CT images presented to [Drs E and D]. … [The] follow up scan did not occur until five months after the original CT scan … It is not the responsibility of the reporting radiologist to organize the follow up imaging, this falls on the referring clinician and the clinical circumstances. It is also uncertain as to whether this delay led to personal injury (an oncological opinion could be sought to clarify this).

… The CT (25/07/02) was appropriately reported, and therefore there is no evidence of error. …"

ACC declined Mrs A's claim on the basis that the CT was "appropriately reported and there is no evidence of medical error".

Independent advice to Commissioner

Otolaryngologist – head and neck surgeon
The following expert advice was obtained from Dr Robert Allison, an otolaryngologist – head and neck surgeon:

"**In Confidence**

I have been asked to provide an opinion to the Commissioner on Case Number 03-08493-22S. I have read and agreed to follow the Commissioner's Guidelines for Independent Advisors.

Qualifications:

I am a Specialist Otolaryngologist. My qualifications are MBChB – 1976, Diploma Child Health 1980, FRACS (Otolaryngology) 1986. I have been in clinical practice as an otolaryngologist for 18 years with a particular interest in the management of head and neck cancer and voice disorders.

Sources of Information:

My report is based on the information supplied from the Health and Disability Commissioner's Office, specifically:

- Letter of complaint and supporting documentation from [Mrs A], forwarded by Advocacy Network Services Trust and received [by the Commissioner] on 10 June 2003, marked with an 'A'. (Pages 1-57)
- [Mrs A's] clinical records received from [Dr G], general practitioner, on 22 September 2003, marked with a 'B'. (Pages 58-86)
- Letter of response from [Dr E,] forwarded by [the public hospital], on 7 October 2003, marked with a 'C'. (Pages 87-97)
- Letter of response from [Dr F], received [by the Commissioner] on 7 October 2003, marked with a 'D'. (Pages 98-100)
- Letter of response from [Dr C], with supporting documentation, forwarded by [the public hospital], on 10 October 2003, marked with an 'E'. (Pages 101-111)
- [Mrs A's] clinical records received from [the public hospital] 28 October 2003, marked with an 'F'. (Pages 112-208).

Factual Summary:

The factual summary of events is essentially as provided by [the] Senior Investigator, with some minor changes.

In July 2002 [Mrs A] consulted her GP, [Dr G], because she had developed a hoarse voice, stridor, tender gland on the right side of her neck, right sided jaw pain, trouble clearing her throat and had lost 30kg in weight. [Dr G] referred [Mrs A] urgently to the ENT outpatients' clinic, where she was seen on 18 July by [Dr F], otolaryngology registrar.

[Mrs A] was diagnosed as having paralysis of the left vocal cord and redundant mucosa of the supraglottis. In view of the left vocal cord paralysis, she was sent for an urgent CT scan of the chest and abdomen, because of a possible underlying mediastinal malignancy.

On 25 July [Dr E], radiology registrar, reported fibrotic changes in the vicinity of the descending thoracic aorta and branch of the left main bronchus. He noted that she had had previous radiotherapy (for breast cancer) which could have been the cause of the fibrotic changes, but a possibility of malignancy could not be ruled out.

Later that afternoon [Mrs A] was seen by [Dr F] and [Dr C], who arranged an appointment for her to have her vocal cords stripped and a referral to a speech therapist. [Mrs A] alleges that [Dr F] informed her that the CT was normal.

[Mrs A] saw [Dr C] on 23 August and had a laser laryngoscopy. Histological examination of the material removed from the vocal cords showed no evidence of dysplasia or malignancy.

In September [Mrs A], accompanied by her husband, saw [Dr C] for further consultation. [Mrs A] asked [Dr C] if she had cancer. She alleges that he told her there was no sign of cancer. On 12 September, [Dr C] wrote to [Dr G] to inform him that there was no evidence of malignant change in the material removed from the vocal cords, but since the CT scan showed a 3cm lesion in the left upper zone, a repeat CT scan would be arranged as recommended.

On 16 December [Dr C] referred [Mrs A] for a repeat CT scan of the thorax for follow up of the mass seen on the CT scan carried out in July the same year. At this point, her left vocal cord paralysis had deteriorated and she was now experiencing haemoptysis.

In the second week of January 2003 [Mrs A] was telephoned by a … registrar and was told that there was a mass on the recent scan. [Mrs A] recalled that she was informed by the registrar that the lesion had been present since July/August the previous year. She was informed that she would be referred for a bronchoscopy and FNA [fine needle aspiration].

[Mrs A] was examined by on 29 January 2003 and was told that she had adenocarcinoma of the upper lobe of the left lung. [Mrs A] was referred to [a doctor], [at the oncology department]. He felt that she was not a candidate for radiation therapy because of extensive prior therapy. She would tolerate Cisplatin-Gemcitabine chemotherapy poorly because of aortic stenosis, and she was prescribed Carboplatin/Taxol to achieve a modest chance of disease restraint.

Specific Questions Posed by The Commissioner

[Whether] [Dr F] provided [Mrs A] with services of an appropriate standard. In particular:

- *What is the accepted treatment for leukoplakia and paresis of the true vocal cords?*

Firstly, leukoplakia and paresis of the true vocal cords are separate, unrelated conditions. Leukoplakia of the vocal cords refers to whitened patches which appear on the vocal cords and may indicate a pre-malignant condition, or early cancer of the vocal cords. The usual treatment of leukoplakia is microlaryngoscopy under general anaesthetic and removal of the abnormal areas with submission of all removed material, or representative samples, for histology because of the risk of underlying pre-malignancy or early cancer. Patients with leukoplakia of the vocal cords are often kept under long term review because of the risk of developing cancer of the vocal cords.

'Paralysis' or 'paresis' of the vocal cords are terms which are often used inter-changeably. The dictionary definition suggests that 'paralysis' means a complete loss of contraction. The term 'paresis' is often used to indicate a partial paralysis. Clinically, it

can be very difficult to differentiate between an incomplete and complete paralysis of the vocal cord. Reduction of vocal cord movement is associated with a lesion affecting the recurrent laryngeal nerve. The left vocal cord is affected more than the right since the left recurrent laryngeal nerve has a longer course, extending from the neck down into the superior mediastinum (within the chest) then up again towards the larynx. A wide range of pathological processes can cause vocal cord paresis. Approximately 50% are associated with malignancy within the chest or lower neck. Other causes are radiation fibrosis, 'viral', following trauma to the nerve, following surgery, particularly to the thyroid gland, and also 'unknown' or 'idiopathic' causes.

The accepted management of a patient with a vocal cord palsy is firstly, obtaining a history which may give a lead as to any possible causes (for example a history of previous surgery in the neck, radiotherapy etc). Secondly, a CT scan of the mediastinum and neck is standard investigation looking for any lesions which may affect the nerve along its course in the lower part of the neck and upper chest. Management of the patient then depends on the cause of the vocal cord palsy. If there is a benign cause, and the nerve does not recover spontaneously, then the patient's quality of voice can often be improved by a vocal cord medialisation procedure. If the underlying cause for the paralysis is a malignancy, then treatment will depend on the type and stage of malignancy although, in the vast majority of cases in which a tumour has involved the recurrent laryngeal nerve, treatment is usually palliative.

- *Is there any evidence that [Dr F] did not follow accepted procedures in [Mrs A's] case in relation to these conditions?*

I do not believe there is any evidence that [Dr F] did not follow accepted procedure in [Mrs A's] case. Firstly, with regard to her left vocal cord paralysis/paresis, he had obtained an adequate history, carried out an examination, and arranged the appropriate investigation which was a CT scan of the neck and chest. With regard to the leukoplakia of her vocal cords, after consultation with his consultant, [Dr C], he arranged for a microlaryngoscopy and vocal cord stripping for histological assessment of the leukoplakia.

- *Should [Dr F] have been suspicious that [Mrs A's] problems were due to a malignancy?*

In view of her smoking history, and previous breast carcinoma, he should have been suspicious of a possible malignancy causing her left vocal cord weakness and this is in fact confirmed by his letter to the GP, [Dr G], (18 July 2002) in which he mentions 'Impression – left vocal cord paralysis. I am unsure of the cause of this but I think that there is every likelihood that this will be neoplastic in nature.' ('Neoplasm' indicating malignancy.)

- *Was [Dr F's] management of [Mrs A's] condition appropriate?*

I believe his management was appropriate as mentioned above in that, in view of his concern about an underlying malignancy, he arranged the appropriate investigation which was a CT scan of the neck and chest. This was primarily to assess the cause of the left vocal cord paralysis. With regards to the leukoplakia of her vocal cords (which may have been pre-malignant or an early malignancy) after consultation with [Dr C], he arranged for microlaryngoscopy and stripping of the vocal cords.

However, [Dr F] did mention in his letter dated 25 July, 'She had a CT scan of her neck and chest this morning which was normal.' This comment was made following [Dr F's] review of the CT scan, but presumably prior to receiving the radiologist's formal report. Rather than saying that her CT scan was 'normal' he should have mentioned to [Mrs A] that there was shadowing in the left upper zone, consistent with her previous radiation, but that the possibility of an underlying malignancy could not be excluded.

- *Should [Dr F] have informed [Mrs A] that there was a suspicious 3cm lesion identified in the left lung on the CT scan of 25 July?*

Following the CT scan being performed on 25 July, the films were reviewed by Dr F prior to her outpatient appointment later that day. [Dr F] reported the CT findings to [Dr C] as the radiologist's report was not yet available at that stage. Although not directly stated in [Dr F's] letter, he implies that he was aware of longstanding changes in her left upper chest secondary to radiotherapy for breast cancer some 30 years earlier. This would have accounted for the changes noted on the CT scan and he did not recognise a tumour arising within the area of fibrosis in the left upper lobe of the lung.

The subsequent CT report (reported by [Dr E] with review by [Dr D]) showed 'No cause for hoarseness or stridor demonstrated. A 3cm lesion is seen in the left upper zone posteriorly. Given the associated surrounding changes and previous radiotherapy this most likely represents an area of fibrosis which is more focal in part. However I cannot exclude an underlying malignancy. This lesion would be difficult to biopsy due to its close proximity to the descending thoracic aorta. Initially a follow-up CT scan in three months' time is recommended to further view the lesion.'

The CT findings were consistent with her previous chest X-rays, and past history of radiotherapy to this area. The CT report suggests that the changes were 'most likely' to be due to fibrosis and, with this report, one could argue whether the possibility of a malignancy, without more concrete evidence, should have been raised with [Mrs A]. However, on balance, I think she should have been informed that the CT scan did show some 'shadowing' in the left upper lobe which was likely to be related to her previous radiotherapy but, because an underlying malignancy could not be excluded, she should have a repeat CT scan in three months. This approach would have kept [Mrs A] fully informed of the results of all her investigations but, if she had not turned out to have a malignancy, may have led to unnecessary anxiety.

[Whether] [Dr C] provided [Mrs A] with services of an appropriate standard. In particular:

- *Should [Dr C] have been suspicious that [Mrs A's] problem was due to a malignancy?*

[Dr F] discussed [Mrs A] with [Dr C] on 25 July. At this stage, the CT scan had been reviewed by [Dr F] and no definite evidence of malignancy noted in the chest. The main emphasis of that consultation was on the condition of her vocal cords and, in view of the areas of leukoplakia involving mainly the left, but also the right cord, appropriately, arrangements were made to carry out microlaryngoscopy and stripping of the vocal cords for histological diagnosis to exclude the possibility of a pre-malignant or early malignant condition of the vocal cords themselves.

When [Dr C] saw [Mrs A] again on 12 September (following vocal cord stripping), the appearance of the vocal cords was improved. In his letter to [Dr G] he mentioned the 3cm lesion in the left upper zone on the CT scan and although this was thought to represent an area of fibrosis, as recommended in the CT report, he planned to request a repeat CT scan in three months' time.

- *Was [Dr C's] management of [Mrs A's] condition appropriate?*

As mentioned above, I think his management was entirely appropriate.

- *Should [Dr C] have informed [Mrs A] that there was a suspicious 3cm lesion identified in the left lung by the CT scan of 25 July?*

According to [Dr C's] report, he believes he would have mentioned to [Mrs A] the fact that she had an area of fibrosis demonstrated on the CT scan, since he did mention this in the letter to her GP, [Dr G]. In retrospect he should have mentioned that, since there was a possibility of underlying malignancy, the radiologists had recommended a repeat CT scan which he would arrange. He does accept that, when he was asked if there was any cancer he had said 'no' but he was referring to the biopsies from the vocal cords. He does not appear to have clarified with her the reason for requesting a repeat CT scan.

- *Any other comments you consider relevant which may be of assistance?*

1. [Mrs A] implied in her complaint that, if the tumour had been picked up earlier, in July or August 2002, she may have been able to have more effective treatment. Unfortunately, the fact that she was noted to have a left vocal cord weakness, or paralysis, at the time of presentation implies that the tumour had extended outside the lung and into the superior mediastinum to involve the recurrent laryngeal nerve. In the vast majority of cases of lung cancer, this would imply that treatment at this stage would palliative, rather than carried out with curative intent. I have discussed this issue with […], Cardiothoracic Surgeon, who agrees that, once the cancer had extended beyond the lung into the mediastinum the chances of achieving a cure would be very remote.

2. It is unfortunate that her lung cancer occurred within an area which was radiologically difficult to assess because of her previous radiotherapy. In a proportion of patients who undergo CT scan of the lung, for a variety of reasons, 'shadows' often show up which have non-specific features and it can be impossible to differentiate fibrosis from underlying cancer. In areas in which it is difficult, or risky, to get tissue for histological purposes, it is common practice to carry out repeat CT scanning some months later to see whether there has been any change in the radiological abnormality.

SUMMARY

Overall I believe [Mrs A's] management by [Dr F] and [Dr C] was appropriate in terms of the investigations and procedures that she underwent. The only minor concern is that, after she had the CT scan of her chest, she should have been informed of the radiological changes which had been demonstrated, and the reasons for requesting a repeat CT scan some months later. This would have kept [Mrs A] better informed, but her management would have been unchanged and unfortunately the outcome would not have been different."

Radiologist

The following expert advice was obtained from Dr David Milne, a radiologist:

"I have been asked to provide independent advice to the Commissioner about whether [Mrs A] received an appropriate standard of treatment from [Dr E] (case 03/08493/WS)

My name is David Grant Milne, NZMC registration number 12986. I am a Diagnostic Radiologist and Fellow of the Royal Australian and New Zealand College of Radiologists since 1992. I am a subspecialist thoracic radiologist with post graduate training at The Royal Brompton Hospital in London. I am currently an examiner for RANZCR in cardiothoracic imaging. My practice of radiology has been predominantly thoracic radiology since 1992. I believe that I am qualified to give an expert opinion on this case.

My specific brief is to advise the Commissioner whether, in my professional opinion:

- [Dr E] provided [Mrs A] with services of an appropriate standard. In particular:
  - Was [Dr E's] conclusion about the 3cm lesion in [Mrs A's] left lung reasonable in the circumstances?
  - Should [Dr E] have recommended more urgent follow up diagnostic procedures given [Mrs A's] history and current symptoms?
- Were there any other professional, ethical and other relevant standards that apply and, in my opinion, were they complied with.

I was asked to make any other comment I considered relevant that may be of assistance.

This advice is to aid the Commissioner resolve the complaint that:

[Dr E], radiologist, did not provide services of an appropriate standard in reviewing [Mrs A's] CT scan of 25 July 2002, and his advice on the basis of that reading (that she required a follow up scan in three months) was inappropriate in the circumstances.

I have reviewed all the information supplied by the Commissioner. This includes:

- Letter of complaint and supporting documentation from [Mrs A], forwarded by Advocacy Network Services Trust and received [by the Commissioner] on 10 June 2003, marked with an 'A'. (Pages 1-57)
- [Mrs A's] clinical records received from [Dr G], general practitioner, on 22 September 2003, marked with a 'B'. (Pages 58-86)
- Letter of response from [Dr E], forwarded by [the public hospital], on 7 October 2003, marked with a 'C'. (Pages 87-97)
- Letter of response from [Dr F], received [by the Commissioner] on 7 October 2003, marked with a 'D'. (Pages 98-100)
- Letter of response from [Dr C], with supporting documentation, forwarded by [the public hospital], on 10 October 2003, marked with an 'E'. (Pages 101-111)
- [Mrs A's] clinical records received from [the public hospital] 28 October 2003, marked with an 'F'. (Pages 112-208)
- Two X-ray plates of chest/neck images of [Mrs A] taken 2003
- Nine plates of CT scan images taken of [Mrs A] 25 July 2002

A brief factual summary has been presented by [the] Senior Investigator, Office of the Health and Disability Commissioner. I have read this account and the supporting documentation and feel that it is a true representation of the facts. I enclose this summary.

[…]

My opinion

1. Qualifications of [Dr E]

In the complaint, [Dr E] is referred to as a radiologist. [Dr E] is **not** vocationally registered as a radiologist. As is the case of all registrars in training, [Dr E] is a registered medical practitioner practising under oversight. The specific oversight in this case was provided by [Dr D] FRANZCR, Radiologist, as is described in the CT report heading dictated by [Dr E]:

'CT Neck and Chest: (reviewed with [Dr D])'

The general oversight for [Dr E] was provided by the radiologist in charge of registrar training at [the public hospital]. I do not know who this is.

I can find no written report by [Dr D] in response to this complaint filed by [Mrs A] in the supplied documentation. A report from [Dr D] would seem more relevant than any report from [Dr E]. In my examination of the CT report, I will address the report as that of [Dr E] **and** [Dr D].

2. [Dr E's] and [Dr D's] report on the CT scan of 25/7/02

A CT scan report should comprise a section on observations where the viewing radiologist describes their findings, hopefully in an orderly fashion. Following these observations, there should be a conclusion where the observations are interpreted in light of clinical information supplied on the referral form or directly from the patient or clinician. A favoured diagnosis is advanced and if no favoured diagnosis is apparent, then typically some suggestions to the referring clinicians would be offered to aid the clinician in reaching a diagnosis.

I will examine the CT report concentrating on

A. The technical aspects of the CT scan
B. My interpretation of the scan
C. [Dr E's] / [Dr D's] observations
D. [Dr E's] / [Dr D's] conclusions
E. [Dr E's] / [Dr D's] suggestions to further management.

A. The technical aspects of the CT scan

A CT examination of the neck and thorax has been performed on a single slice helical CT/i scanner (GE Milwaukee). The scan has utilized intravenous contrast via the right arm. Scanning was performed from above the skull base to the thoracic inlet with 3mm collimation with the arms at the patient's sides, then from the thoracic inlet to the lower border of the liver using 5mm collimation with the patient's arms raised. Windowing/ centering is in keeping with standard protocols. The scan is technically of good quality for diagnosis.

B. My observations of the scan

In the neck, there is adduction of the left arytenoid cartilage and the left vocal cord in keeping with vocal cord paralysis and strongly suggesting a left recurrent laryngeal nerve [RLN] lesion. The course of the left RLN in the thorax is such that it arises off the left vagus nerve, passes under the aortic arch and ascends to the larynx in a left paratracheal position. The nerve is vulnerable to lymph node enlargement in the aorto-pulmonary window (Station 5).

In the thorax, there is a 2cm spiculated mass medially in the apical segment of the left lower lobe with extrinsic compression to the apical segment bronchus. There is abnormal mediastinal soft tissue consistent with lymphadenopathy against the left lateral aspect of the aortic arch and extending by continuity into the space between the top of the main

pulmonary artery and the aortic arch; the aorto-pulmonary window. This is a recognized lymph node station, station 5 (1, 2).

In addition, there is volume loss in the left upper lobe and left para-mediastinal scarring with an increase in left sided mediastinal fat. Pleural calcification is seen anteriorly in the left mid to upper thorax. These changes are likely the result of previous radiotherapy although previous trauma with haemorrhage into the pleural space would be a less likely differential. I understand that both of these causes were possible in this patient.

There is a left mastectomy, loss of subcutaneous fat over the upper left chest wall consistent with radiotherapy and skin grafting. There is mild bilateral adrenal hyperplasia.

C. [Dr E's] / [Dr D's] observations of the scan

The report is descriptive and makes a number of observations indicating that the scan has been well considered.

Some relevant observations have been missed.

1. The left RLN paralysis was not described. This is a minor omission in description as the lesion was clinically apparent and had been suggested on the referral form for the CT scan.

2. The abnormal soft tissue in the aorto-pulmonary window (station 5) extending onto the left lateral aspect of the Aortic Arch [has been missed]. The lack of appreciation of the abnormal soft tissue in station 5, the tissue which would be expected to cause the left RLN palsy as this lay in the course of this nerve, was crucial to securing a diagnosis of malignancy and explaining adequately the recent onset of left RLN palsy. I consider this to be a major failure in terms of the importance of the lesion to securing a diagnosis, and that the failure to make this observation would incur moderate disapproval from peers.

One key observation was misinterpreted.

> The 2cm mass in the apical segment of the left lower lobe was misinterpreted as more likely fibrosis than a cancer. This lesion is in continuity with scarring in the posterior upper left paramediastinal lung tissue and this presumably led to the misinterpretation.
>
> *'A 3cm lesion is seen in the left upper zone posteriorly. Given the associated surrounding changes and the previous radiotherapy this most likely represents an area of fibrosis which is more focal in part.'*

Other observations on the report include an error in description. The mass is described as:

'The soft tissue lesion is seen to abut the medial aspect of the left horizontal fissure.'

There is no left horizontal fissure described in 'normal' anatomy and I presume this is a descriptive error referring to the upper left oblique fissure.

Note was made of a low density adrenal lesion on the left. In fact there is bilateral mild adrenal enlargement.

To judge peer opinion on these failed and misinterpreted observations, I showed the scans to 3 radiologists and 2 radiology registrars. Each was presented the CT scans independently and given the same potted history:

'This 63 year old woman with a significant smoking history presents with a one to two month history of hoarse voice. She has significant weight loss. She has a past history of left breast cancer 20-30 years ago treated with mastectomy and radiotherapy with significant post radiation injury requiring skin grafting. There was an injury to her axillary vessels on the left which required surgical repair. Clinically there is a left vocal cord palsy.'

All five observers reached their conclusions within 2 minutes and all noted the 2cm mass in the apical segment of the left lower lobe and all observed the abnormal tissue in the aorto-pulmonary window (station 5). All 5 observers favoured a malignant diagnosis.

D. [Dr E's] / [Dr D's] conclusions on the scan

The failure to make one major observation and to correctly interpret the observation of a 2cm mass in the left lung resulted in the report conclusions being weighted towards a benign explanation for the appearances i.e. that the changes were on the basis of the patient's previous extensive radiotherapy.

Despite the benign weighting, malignancy was not dismissed:

'However, I cannot exclude an underlying malignancy'.

This would be a reasonable conclusion given the observations that were missed.

E. [Dr E's] / [Dr D's] suggestions to further management

The observation that the 2cm mass,

'Would be technically difficult to biopsy due to its close proximity to the descending Thoracic Aorta'

is presumably a reference to CT guided fine needle aspiration biopsy performed typically by a radiologist. I agree that the lesion would be technically difficult to biopsy but I would not agree that it was impossible. I would have been happy to attempt a biopsy of this mass.

Having concluded that the lesion was most likely benign and that they were not happy to biopsy it, 3 month follow up was advised.

'Initially a follow up CT scan in 3 months time is recommended to further view the lesion.'

In the circumstances of the major missed observation and the misinterpretation of a major observation where the Radiologists felt that the lesion was inaccessible to biopsy, this is reasonable. Lesions considered indeterminate on CT and inaccessible to biopsy are often monitored by CT surveillance. There are many models for CT surveillance but I prefer to use that established for the Early Lung Cancer Action Project (ELCAP) (4). This is a study designed to exclude lung cancer in a screening population of smokers rather than in people presenting with symptoms. Indeterminate lesions are monitored at 3, 6, 12 and 24 months and if stable after this period are considered benign. Although studies with multislice scanners are currently being published showing ability to detect change in malignant lesions at intervals less than 3 months, it would be unreasonable to rescan any patient for this purpose at an interval of less than 3 months on a single slice CT/i GE scanner, particularly in the absence of specific nodule assessment software.

There was no other imaging modality they could have considered in the context of common New Zealand practice. Magnetic Resonance Imaging (MRI) can be of use in differentiating normal lymph nodes from malignant lymph nodes in the chest (3) but is not in common use for this purpose in this country. It is likely that MRI of the thorax in this patient would have a high sensitivity for malignancy but all the relevant findings were available on the CT examination. Similarly, Positron Emission Tomography (PET) scanning would have likely identified the primary and metastatic nodal disease (5), but this technology is not available in New Zealand.

3. Summary of my opinion on the CT scan report

[Drs E and D] reported on a technically adequate CT examination.

They missed 2 relevant observations

1. Lt [left] recurrent laryngeal nerve palsy. Minor failure which would attract minor disapproval from peers.

2. Station 5 lymph node/abnormal tissue. Major failure which would attract moderate disapproval from peers.

They misinterpreted one observation, that the 2cm mass was fibrosis rather than a malignant mass. Major failure which would attract moderate disapproval from peers.

4. My advice to the Commissioner

Drs [E] and [D] did not provide [Mrs A] with services of an appropriate standard. In particular, their conclusions about the 2cm lesion in [Mrs A's] left lung were biased

towards the lesion being benign when I believe there was substantial evidence that it was malignant.

Having agreed to a benign bias in their report, however, the decision to review the lesion in 3 months time was not unreasonable on the grounds that:

1. They were clearly uncomfortable with performing a biopsy of this lesion. I accept that biopsy would require an experienced operator

2. There was no other commonly performed diagnostic imaging test available to them, MRI being uncommonly practised for this indication in New Zealand and PET scanning was not available in this country

3. Protocols for following up questionable lesions were established in the literature and many used a 3 month interval scan.

5. General comments

In a patient with a smoking history, left vocal cord paralysis, stridor and weight loss of recent onset, malignancy in the thorax should be actively excluded. The patient's previous mastectomy, radiotherapy and axillary vessel reconstruction on the left was clearly a distraction for the clinicians and radiologists. The patient's symptoms however were new and poorly explained by the minor abnormalities seen at laryngoscopy by the ORL surgical team.

A CT examination of the thorax is a useful tool for imaging the lungs and mediastinum but does not typically define histology of visualised lesions. 'CT scanning does not stage lung cancer, rather it directs the surgical staging of lung cancer' (quote from Mr Peter Goldstraw, Chief Thoracic Surgeon, Royal Brompton Hospital, London). Having concluded that the CT of the thorax was not normal, in a high risk patient, consideration should have been given to bronchoscopy with washings at an earlier stage in an attempt to define the histology of the abnormal tissue seen on the CT scan of 12/7/02 and interpreted at that time as probable fibrosis. The decision to proceed to bronchoscopy however would be a clinical one and would not typically be promoted in the radiology report.

I would be interested in the opinion of a respiratory physician as to whether the failure to proceed to bronchoscopy at an earlier time was an inappropriate standard of care.

6. References

1. Mountain C, Dresler C. Regional lymph node classification for lung cancer staging. *Chest.* 1997 Jun; 111(6): 1718-1723

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College of Radiologists
I contacted the Royal Australian and New Zealand College of Radiologists, to seek its view on the role and responsibilities of a radiology registrar signing off reports, when working under the supervision of a consultant. The College informed me:

> "The College's Accreditation Standards for Diagnostic and Interventional Radiology state that 'a qualified radiologist must be available to provide appropriate on site direct supervision of trainee radiologists at all times in hours, and be available to provide advice and backup at all times out of hours'. However, the College expects that the degree of consultant supervision required should reflect the degree of seniority and experience of the registrar and this can best be determined within the training department. The level of supervision required relates to the ability of the registrar, which comes from experience and the registrar's confidence and skills which develop at different speeds in different individuals."

Responses to independent advice

Dr D
Dr D was provided with a copy of Dr Milne's independent advice, to which he responded as follows:

> "It is Dr Milne's opinion that there is a 2cm spiculated mass in the apical segment of the left lower lobe with extrinsic compression to the apical segment bronchus. I note that the tumour at bronchoscopy was in fact in the left upper lobe bronchus not in the left lower lobe as indicated by Dr Milne and his 5 observers.
>
> I am certain that I did not miss the soft tissue in the aortopulmonary window, which is clearly obvious in the CT film. However, I acknowledge it was not adequately described in the CT report, as it is referred to in that as 'areas of stranding'.
>
> …

The CT scans were reviewed at [the public hospital] in the weekly Radiology Chest conference, which was attended by a radiologist, chest physicians and cardiothoracic surgeons. Based on the CT scans, there was some confusion around what was tumour and what was fibrosis. Everyone agreed that it would be difficult to get at surgically, and it was felt that the main lesion was in the upper lobe. The consensus of opinion was that it would be possible with some difficulty to obtain a fine needle aspiration if bronchoscopy failed.

I have also [shown] 4 radiologists [Mrs A's] CT scan of 25/7/2002 with the history on the form and I asked them for their independent opinions. They all agreed that there was evidence of radiation injury; they identified the mediastinal soft tissue although they did not agree that it was obviously lymph nodes; and they commented on the mass. There was a consensus of opinion that the differential would include fibrosis; malignancy should also be entertained; and it was agreed that there would be difficulty in biopsing this mass. In their opinions a follow-up scan was not inappropriate.

Conclusion

In summary, I provided the supervision for the report that [Dr E] indicated on 25/7/2002, as was the current practice at the time. Following a discussion of the findings, [Dr E] dictated a report, which he subsequently checked and then finalised. I did not see the final report nor do I agree with the way the findings have been presented. They are not as I would have presented them. I believe I did not miss the finding indicated by Dr Milne, although I acknowledge that it was poorly described in the report.

There was sufficient evidence of significant radiation effect in the pleura, lung and mediastinum. It was not inappropriate to draw the conclusions made in the report in regards to a) radiation having caused nerve injury; b) the differential of radiation fibrosis; and c) the inability to exclude malignancy.

Given the difficulty in doing a biopsy, I consider that it was appropriate to suggest short-term follow-up in 3 months. Dr Milne seems to agree with this suggestion. While there may be some disagreement about the reported scan findings, this does not in my view constitute a failure to provide services of an appropriate standard.

It is however unfortunate that [Mrs A] was told the CT was normal and that the recommendation of a 3 month follow-up scan was never requested by the referring clinicians, because it seems to me that this is the more important issue."

Dr E

Dr E was also provided with a copy of Dr Milne's advice, to which he responded as follows:

"…

2. I note that Dr Milne correctly observes that in this case I was under the direct supervision of [Dr D], a consultant radiologist. In July 2002 the supervising consultant would review all CT cases individually with the radiology registrar with whom they were working. Practically this meant that I would review the scans with [Dr D], discuss our observations, conclusions and suggestions for further management if required. I would then dictate the report, edit and sign it. The final form of the report was not checked by [Dr D]. This was and I understand is still the standard practice of CT reporting in the [the public hospital's] Radiology Department.

3. In the case of [Mrs A's] CT, I have a good recollection of our discussions because the scans were difficult to interpret given the extensive radiotherapy related scarring present. The observations, conclusions, and the clinical recommendations were all discussed with [Dr D]. In particular [Dr D] and I discussed:

   (a) [Mrs A's] history of radiotherapy, and the manifestations of radiation injury affecting the lung, pleura and mediastinum demonstrated on the study.

   (b) The soft tissue in the Aorto-pulmonary window. This is not well described in my report. I refer to this as 'superior and continuous with this lesion are more linear areas of stranding consistent with fibrosis'.

   (c) The soft tissue area which I have described as a 3cm lesion in the report, in the left upper zone posteriorly. Given the surrounding changes which appeared to be the result of tissue damage from radiotherapy, [Dr D] favoured fibrosis as the cause but emphasised that malignancy could not be excluded.

   (d) Follow up. [Dr D] was of the view that given the difficulty and risks associated with biopsy, the appropriate further action was a follow up CT scan within three months.

I summarised these key points in the report in accordance with [Dr D's] opinion.

There are some points in Dr Milne's report on which I would like to comment:

4. Dr Milne describes soft tissue contiguous into the AP window which 'was crucial in securing a diagnosis of malignancy'. He later refers to this area as 'abnormal soft tissue', and that the radiological panel recognised 'abnormal tissue in this region'. I accept my description of the tissue in the aortopulmonary window could have been improved, however it is noted in the report as referred to above (3(b)). The variable way in which Dr Milne and his panel describe this area suggests that it is not definitively lymphadenopathy. Given the history of radiotherapy, fibrosis certainly can appear as abnormal soft tissue, and is a further plausible explanation for the appearances here.

5. A malignant diagnosis cannot be made from a CT examination. This requires a tissue sample and histological assessment by a pathologist.

6. Dr Milne refers to the more focal lesion as a 'spiculated' and 'malignant mass'. The report I issued after review with [Dr D], favoured a benign fibrotic cause for this area but stated that 'malignancy cannot be excluded'. As cancer has not been ruled out, despite a benign weighting, I do not believe this represents a misinterpretation.

7. In addition, the respiratory physician who performed the bronchoscopy describes a tumour in the left upper lobe bronchus.

   'The left upper lobe bronchus has a tumour mass appearing in its orifice but is very difficult to enter as it is markedly distorted superiorly.'

   I understand that the 2cm lesion that Dr Milne describes in the left lower lobe is unchanged on the follow-up examination, raising the question, was that area in fact related to the upper lobe adenocarcinoma at all.

8. On the second page of the report Dr Milne refers to having reviewed CT images and X-ray plates dated 25 July 2003. I assume that this is a typographical error, however I would be grateful if you would clarify this with Dr Milne, as subsequent X-ray and CT examinations were performed on [Mrs A].

[A letter to Dr Milne from my office dated 30 March 2004 confirmed that this was a typographical error which occurred when the list of material for him to review was prepared. The images and plates reviewed by Dr Milne were dated 25 July 2002.]

9. On the third page of the report it is noted that a follow-up CT was not arranged until the 24th of December. In my July 25th report, a follow-up CT scan was recommended within three months of that date. Another issue in relation to the clinical follow-up is that it is documented in the clinical notes by [Dr F] that the CT scan is normal. This appears on the same day as the scan was performed. [Dr F] may have reviewed the scan himself as this was not how the CT scan was reported.

10. When Dr C decided to repeat the CT examination he quotes the initial CT report in [Mrs A's] outpatient notes '… ?fibrosis ?neoplasia …'. This suggests that the CT report had never been read until that time.

I maintain that the CT report is of appropriate standard and the short interval follow-up CT reasonable in the circumstances."

In addition, [Dr E's] legal counsel, made the following observations in relation to Dr Milne's report:

"1. The most significant criticism by Dr Milne of the report is a missed observation of abnormal tissue in the AP window. [Dr E] has clarified that this was not a missed observation, but rather that he has described this in language, which he concedes is not as accurate as that used by Dr Milne. …

2. Dr Milne's second criticism is of a failure to diagnose, as a malignancy, a mass in the apical segment of the left lower lobe. However, the tumour identified on bronchoscopy is in the left upper lobe bronchus and the bronchoscopy report records 'the left lower lobe bronchus appears to be otherwise normal although narrowed.' In light of this it is possible that Dr Milne is incorrect in characterising the mass in the apical segment as being malignant.

3. It is apparent that what [Drs D and E] are criticised for is a question of weighting. The CT report clearly raises the possible diagnosis of a malignancy, whilst preferring a benign explanation. Dr Milne himself is unable to be definitive that it is a malignancy. It is suggested that no firm diagnosis could be reached without a clearer clinical picture (which Dr Milne had the benefit of by the time he came to review these films) or some histological verification.

In summary, the response to the conclusions of Dr Milne are that the observations he claimed were missed, were not missed. As to the misrepresentation, the lesion was not categorically diagnosed as fibrosis. Given the history of radiotherapy, Drs [D and E] favoured a benign explanation, whilst not excluding the possibility of malignancy.

…

Perhaps the most significant issue arising from Dr Milne's report is his accurate observation that [Dr E] was supervised in the preparation of his report by Dr D. At the relevant time [Dr E] was a registrar in his third year of training. As a registrar in training, Dr E was required to work under the supervision of a vocationally registered radiologist. The requirement for supervision of registrars is a recognition that a trainee doctor does not have the full range of experience, skill and logic as a vocationally registered supervisor. …

Dr E says that he discussed the case at some length with Dr D and issued a report in accordance with Dr D's opinion of the case, including the recommendation for follow up imaging. In these circumstances, it is submitted that Dr E complied with the relevant standard of care expected of him. He diligently reviewed the CT, appropriately involved his supervisor, and produced a report in accordance with the supervising radiologist's radiological findings and recommendations."

Further advice to Commissioner

Dr Milne was provided with copies of Dr D and Dr E's responses to his advice, and a copy of the Royal Australian and New Zealand College of Radiologists' letter. I asked Dr Milne whether that information gave him any reason to alter his initial advice. My further questions, and Dr Milne's answers, are set out below in the body of his further advice dated 22 April 2004, as follows:

"On 31/3/04, I provided an opinion on whether [Mrs A] received an appropriate standard of treatment from [Dr E] (case 03/08493/WS). My opinion was that the scope of the investigation should be widened to include [Dr E's] supervising radiologist [Dr D].

I have been asked to provide further advice to the Commissioner following reply from Drs [E]and [D].

…

[Dr E[

1. *Is [Dr E's] comment that he did not miss 'some relevant observations' in his report on [Mrs A's] scan, but inaccurately described his observation, reasonable?*

   [Dr E's] description of the mediastinal findings in his report of the CT scan of 25/7/02 gives me no confidence that he made the observation of the abnormal soft tissue in the aorto-pulmonary (nodal station 5).

   He suggests that he has not well described the soft tissue in the aorto-pulmonary window in his correspondence of 10/3/04 and that he has referred to this abnormality as more 'linear areas of stranding consistent with fibrosis'. This is inconsistent with my observations and I remain of the opinion that he did not observe this abnormal soft tissue mass.

   The adducted left vocal cord was not described in the report and therefore it is likely that this observation was missed.

2. *Is [Dr E's] comment that his report, which favoured a benign fibrotic cause for the focal lesion but does not represent a misinterpretation, reasonable?*

   [Dr E] and his legal representative both express the opinion that much of my criticism of the CT report is a question of the relative weighting that the abnormalities are benign or malignant in etiology. This is correct. In hindsight, the abnormalities are clearly malignant as [Mrs A] has biopsy proven inoperable lung malignancy. Prospectively, my opinion remains that the balance of probabilities was very strongly in favour of a malignant cause for the patient's recent onset symptoms. Observations that recurrent laryngeal nerve lesions may rarely occur many years following radiotherapy are of little consequence when you are making a CT report on a clinical case with significant pre-test probability of malignancy and CT findings of a lung mass and abnormal mediastinal tissue in the course of that nerve.

3. *[Dr E] was a registrar in his third year of training. Was his report appropriate for his level of training?*

   I accept that [Dr E's] report on the CT scan of 25/7/02 is within the range of reports that I would expect from a third year Radiology Registrar but as the formal report

going into the patient's notes on this examination, the report is unsatisfactory. I note that the report is not that of [Dr E's] on his own but followed consultation with [Dr D].

[Dr D]

1. *Is [Dr D's] comment, that although he acknowledges disagreement about the reported scan findings, this does not constitute a failure to provide services of an appropriate standard, reasonable?*

   There are 2 issues here. The first is that [Dr D] suggests in his reply that [Dr E] misrepresented the discussion they had about the case in his report on the CT of 25/7/02. I am not going to speculate as to what was or was not said in that discussion as this cannot be verified. My personal experience with registrar supervision is that registrars may omit or misrepresent observations in their reports but the 'flavour' of the conclusion and subsequent recommendations are usually well remembered and represented.

   The second issue relates to the relative weighting of benign vs malignant diagnosis in the report. My opinion on this is already outlined in section 2 of my reply to [Dr E].

   I believe that the report falls short of an appropriate standard of care.

2. *Was [Dr D's] involvement in the assessment and reporting of [Mrs A's] CT scan appropriate in the circumstances?*

   I was not there at the time of the CT examination or at the discussion between [Dr D] and [Dr E] prior to the report being dictated. I had assumed that [Dr D] would have reviewed the final report prior to release to assure himself that it contained the relevant observations and conclusions. It is apparent from [Dr D's] reply that the system in place for verification of dictated radiology reports at [the public hospital] depended on the Radiology Registrar's review of the report rather than the Consultant's. This clearly is inadequate and places the Consultant at great medico-legal risk in that their opinion may not be accurately represented, as has been suggested by [Dr D] in this instance.

   My opinion is that [Dr D] cannot be personally held accountable for this inadequacy as it was department culture or department system that this occurred. I am pleased to read that this has been recently changed so that Consultants can now co-validate reports they have supervised but not directly dictated.

Comment:

In conclusion, I stand by my previous appraisal of the report on [Mrs A's] CT examination of 25/7/02.

It is not my role to speculate as to what was discussed between [Dr D] and [Dr E] prior to the report being dictated. This cannot be verified. The only hard copy record is the typed report on the examination, which was apparently not verified by [Dr D]. In that report, observations were missed and misinterpreted. Misinterpretations are common in radiology but there are typically clinical meetings and forums where patient management decisions are made on review of the radiology images, reports and the clinical presentation. Such a meeting is alluded to in [Dr D's] reply. We typically minute the discussions of such meetings and file these in the patients' notes as a consensus opinion. Was there record of this?

My opinion remains that in a patient with a smoking history, left vocal cord paralysis, stridor and weight loss of recent onset, malignancy in the thorax should be actively excluded. The patient's previous mastectomy, radiotherapy and axillary vessel reconstruction on the left was clearly a distraction for the clinicians and radiologists. The patient's symptoms however were new and poorly explained by the minor abnormalities seen at laryngoscopy by the ORL surgical team.

However, I repeat from my previous summary of this case. A CT examination of the thorax is a useful tool for imaging the lungs and mediastinum but does not typically define histology of visualized lesions. 'CT scanning does not stage lung cancer, rather it directs the surgical staging of lung cancer' (quote from Mr Peter Goldstraw, Chief Thoracic Surgeon, Royal Brompton Hospital, London). Having concluded that the CT of the thorax was not normal, in a high risk patient, consideration should have been given to bronchoscopy with washings at an earlier stage in an attempt to define the histology of the abnormal tissue seen on the CT scan of 12/7/02 and interpreted at that time as probable fibrosis. The decision to proceed to bronchoscopy however would be a clinical one and would not typically be promoted in the radiology report."

Response to provisional opinion – [Dr E]

On 9 August 2004, through subsequent legal counsel, Dr E responded to my provisional opinion that he had breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code). Dr E's legal advisor raised the following issues which he asked me to consider when finalising my opinion:

"The report cites in support of [a finding that [Dr E] breached the Code] Dr Milne's opinion that the lack of appreciation of the abnormal soft tissue in the aorto-pulmonary window was 'a major failure [which] would incur moderate disapproval from peers.'

With respect, that opinion was expressed in Dr Milne's initial report before he had read the material provided by [Dr E] and [Dr D] earlier this year. In his supplementary opinion provided in the light of this further information, Dr Milne was asked

specifically to address the issue whether Dr E had reached the standard reasonably expected of a third year radiology registrar. In his supplementary opinion, Dr Milne responded:

'I accept that [Dr E's] report on the CT scan of 25/7/02 is within the range of reports that I would expect from a third year radiology registrar but as the formal report going into the patient's notes on his examination, the report is unsatisfactory. I note the report is not that of [Dr E] on his own but follows consultation with [Dr D].'

Thus, Dr Milne's view was clearly that [Dr E] had not breached the requisite standard of care, but that the report was not satisfactory as the final report going on the patient's notes. He thus clearly signals that the key issue is that of supervision by [Dr D]. Later in his report he addresses this matter and concludes that the supervision issue is systemic …

The report also calls in aid of this [breach] finding material that Dr Milne put together as to a review of the reports by two radiology registrars. On behalf of [Dr E] it is said that this is no proper basis for the Commissioner to reach a finding of a breach. Firstly, Dr Milne who obtained this information, himself did not see this as a basis for reaching that view. Second, it would be grossly unfair to [Dr E] were that information to be taken into account at all by the Commissioner. These registrars were not retained as experts by the Commissioner but were polled by Dr Milne. Although Dr Milne tells us of the background information that he gave as to the patient we have no information as to the circumstances in which the polling arose. We can however be sure that the polling would have arisen outside of the normal run of events, such that it would be unsafe to rely upon.

It is also not clear why this ad hoc polling should be [given] more weight than that undertaken by [Dr D]. …

[Mrs A's] scan was carefully reviewed and discussed at length with [Dr D] before the report was issued. [Dr E] says that the findings and conclusions drawn accurately reflect that discussion. [Dr D] has stated:

'I did not see the final report nor do I agree with the way the findings have been presented. They were not as I would have presented them. I believe I did not miss the finding indicated by Dr Milne, although I acknowledge that it was poorly described in the report.'

It is apparent from his account that [Dr D] cannot specifically recall the case and this must be significant in terms of the weight to be attached to his account of events. Dr Milne says in connection with [Dr D's] attempt to distance himself from the report:

'[Dr D] suggests in his reply that [Dr E] misrepresented the discussion they had about the case in his report of the CT of 25/7/02 … My personal experience with registrar's supervision is that registrars may omit or misrepresent observations in

their reports but the 'flavour' of the conclusion and subsequent recommendations are usually well remembered and represented'."

Dr E's legal advisor also asked me to consider the following comment from the judgment of Glidewell LJ in *Wilshire v Essex AHA* (CA) [1987] 730, 774:

" … [I]n my view, the inexperienced doctor called upon to exercise a specialist skill will, as part of that skill, seek the advice and help of his superiors when he does or may need it. If he does seek such help, he will often have satisfied the test [ie met the required standard of care], even though he may himself have made a mistake."

In conclusion, Dr E's legal advisor noted:

"[Dr E] is at a training phase of his career. He properly involved his consultant in accordance with the systems in place at [the public hospital]. There is no evidence that he acted in any way in dereliction of duty. As he is at a training stage of his career, the impact of a finding of breach upon him is very significant. He has already this year experienced real difficulties in continuing his vocational training in Australia because of this ongoing investigation …"

Code of Health and Disability Services Consumers' Rights

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

RIGHT 4
Right to Services of an Appropriate Standard

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

RIGHT 6
Right to be Fully Informed

1) *Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including –*
   a) An explanation of his or her condition; and
   …
   f) The results of tests; …

…

3) Every consumer has the right to honest and accurate answers to questions relating to services …

Opinion: No breach – Dr F / Dr C

Management of Mrs A's condition
Right 4 of the Code affirms every patient's right to services of an appropriate standard. Right 4(1) specifically provides patients with the right to have services provided with reasonable care and skill.

Mrs A complained that Dr F failed to provide her with services of an appropriate standard, and in particular that on 25 July 2002, he did not formulate a management plan appropriate to her presenting condition and the CT scan findings. She also complained that Dr C did not provide her with services of an appropriate standard when, based on Dr F's review of the CT scan, he proceeded with laser laryngoscopy. Mrs A further alleged that Dr C did not instigate an appropriate and timely management plan for her, following the second laryngoscopy on 23 August 2002.

The issue for determination is whether Dr F and Dr C managed Mrs A's treatment with reasonable care and skill. Having carefully considered all the information available to me, particularly the advice of Dr Allison, my expert in otolaryngology, I consider that they did so, for the following reasons.

It is evident that when Dr F first saw Mrs A on 18 July 2002, his initial impression was that she had left vocal cord paralysis, possibly caused by neoplasm, ie, malignancy. There are a number of pathological causes of complete and partial paralysis of the vocal cords. Approximately 50% are associated with malignancy within the chest or lower neck. Dr F was rightly suspicious of a malignant cause for Mrs A's condition, as demonstrated by his note to Dr G, Mrs H's general practitioner: "Impression – left vocal cord paralysis. I am unsure of the cause of this but I think that there is every likelihood that this will be neoplastic [malignant] in nature."

The accepted management of a patient with vocal cord palsy or paralysis is first, obtaining a history, and second, performing a CT scan of the mediastinum and neck to look for any lesions that may be affecting the recurrent laryngeal nerve. Management of the patient thereafter depends on the cause of the vocal cord palsy.

I am satisfied that Dr F obtained an adequate history from Mrs A, as evidenced by his clinical notes. In view of his concern about an underlying malignancy, he carried out an appropriate examination and arranged the appropriate investigation, ie, a CT scan of Mrs A's neck and chest. His plan was for the scan to be carried out on 25 July prior to Mrs A's next appointment with him, so that the results would be available for review. Dr Allison's advice was that these steps and Dr F's management plan were appropriate and in keeping with accepted standards of practice.

On 25 July Dr F reviewed the CT scan and noted that although there was no identified cause of Mrs A's hoarseness and stridor, a 3cm lesion or area of shadow could be seen in the upper zone of the scan. However, his impression was that the CT scan was "normal" and that the lesion was most likely an area of fibrosis caused by Mrs A's previous radiation

therapy. Dr F told me that he "did not recognise a tumour within the area of fibrosis". It is significant that at this time, Dr E had not prepared his written report on the CT scan. I cannot determine whether Dr F and Dr E discussed the scan together.

Dr F did go on to discuss his impression of the scan with his consultant, Dr C. Their main focus was the condition of Mrs A's vocal cords and the cause of her hoarseness and stridor. They considered that Mrs A might have leukoplakia. A video laryngoscopy carried out by Dr C that afternoon confirmed this – white, leukoplakic patches could be seen on Mrs A's vocal cords. It was appropriate to proceed with this procedure, given that both doctors were anxious to discover the cause of Mrs A's symptoms.

The usual treatment for leukoplakia is microlaryngoscopy under general anaesthetic, and removal of the abnormal areas for histological examination. It is significant that leukoplakia is common among smokers, and may indicate a pre-malignant condition or early cancer. Given Mrs A's presenting symptoms and long history of smoking, Dr F and Dr C decided to schedule Mrs A for "panendoscopy / stripping of vocal cords". On 23 August, Dr C performed laser laryngoscopy, took biopsies and removed the leukoplakic areas from Mrs A's vocal cords. His operation note recorded that the "leukoplakia has improved since what was seen at her clinic visit and which was photographed at that time". I am satisfied that the decision to perform these procedures was appropriate and in keeping with accepted standards of practice.

Mrs A believed that Dr F and Dr C should have provided her with more "aggressive" treatment. However, it is important to note that the histopathology report of the samples biopsied by Dr C on 23 August confirmed that there was no evidence of dysplasia (abnormality of development) or malignancy. Dr C advised Dr G that the "histology of the removed epithelium shows only some thickening but no malignant changes". It is clear that Dr F and Dr C were reassured that no further active treatment was necessary at that time. In the circumstances, this seems to have been appropriate.

Dr Allison noted that patients with leukoplakia require long-term review because of the risk of developing cancer of the vocal cords. It is clear that Dr F and Dr C were alert to this and that they continued to review Mrs A. On 12 September, Dr C saw her and considered that the appearance of her vocal cords had improved and they were healing well. He was reassured by this, and by the conclusions set out in the August histopathology report. In retrospect, up to this point he had also perhaps been falsely reassured by Dr E's and Dr F' impressions that the identified 3cm lesion in the left upper zone was fibrosis.

It is significant that by this time, two months had passed since the first CT scan. Dr E's written report, which Dr C had not initially seen, was by then in Mrs A's clinical record and Dr C was able to read it. He would have seen Dr E's recommendation for a follow-up scan in three months, ie, in October. He would also have seen Dr E's comment that malignancy could not be excluded. However, I am satisfied that at this time, Dr C did not believe that there was a malignant cause for Mrs A's symptoms.

Dr C's management plan formulated at the 12 September consultation was not to arrange a repeat scan for October, but to request one for December (ie, three months from September and five months on from the date of Dr E's recommendation). Dr Allison's advice is helpful in understanding why Dr C took this approach. Dr Allison noted:

> "[I]t is unfortunate that [Mrs A's] lung cancer occurred within an area which was radiologically difficult to assess because of her previous radiotherapy. In a proportion of patients who undergo CT scan of the lung, for a variety of reasons, 'shadows' often show up which have non-specific features and it can be impossible to differentiate fibrosis from underlying cancer. In areas in which it is difficult, or risky, to get tissue for histological purposes, it is common practice to carry out repeat scanning some months later to see whether there had been any change in the radiological abnormality." [my emphasis]

It is clear that despite feeling reassured by Mrs A's presenting condition in September, Dr C was alert to the need to keep his patient under review. Accordingly, he felt that a follow-up CT scan three months from September would be helpful. In the circumstances as he believed them to be at the time, this was, as Dr Allison noted, "entirely appropriate" and a safe, precautionary measure.

It follows, therefore, that when Dr C saw Mrs A on 16 December 2002, and noted that her vocal cord paralysis had increased, his urgent request for a repeat CT scan and referral to the respiratory medicine team was also appropriate and necessary management.

Sadly, even if Mrs A's lung tumour had been identified in July or August, the outcome would not have been different; her initial presentation with left vocal cord weakness implies that her lung cancer had already advanced to an incurable stage.

I consider that Dr F's and Dr C's overall management of Mrs A was appropriate. They formulated adequate management plans for their patient and arranged or undertook the necessary investigative procedures consistent with those plans. They provided services to their patient with reasonable care and skill. Accordingly, Dr F and Dr C did not breach Right 4(1) of the Code.

Opinion: Breach – Dr F

Information provided to Mrs A

Right 6(1) of the Code affirms every patient's right to information that a reasonable patient, in that patient's circumstances, would expect to receive. Rights 6(1)(a) and 6(1)(f) specifically confer the right to an explanation of one's condition and test results respectively.

Mrs A complained that Dr F did not inform her of the results of her 25 July 2002 CT scan and did not ensure that she was adequately informed of his management plan.

The crucial information contained in Dr E's report of the 25 July CT scan was that a 3cm lesion could be seen in the left upper zone and, "given the associated surrounding changes and previous radiotherapy this most likely represents an area of fibrosis which is more focal in part. However I cannot exclude malignancy." It is clear that this information was not given to Mrs A. However, Dr F had not seen the written report at the time of his consultation with Mrs A on the afternoon of 25 July 2002. The question is whether, in the circumstances, Dr F should have provided more information to Mrs A about the possibility of a malignant cause of her symptoms.

Dr F had seen the CT scan. He may have discussed it with Dr E or Dr D, although he cannot remember this. He subsequently advised Dr G that the CT scan was "normal". I have not received any conclusive evidence that indicates exactly what he told Mrs A about the scan although it is quite possible he also told her that it was "normal". I believe that this is likely given that Dr F's management plan then involved a further investigative test (laryngoscopy) focusing on a suspected diagnosis of leukoplakia.

In my opinion, if Dr F believed Mrs A's symptoms were caused by leukoplakia, a condition that is known to be linked to malignancy, he should have told his patient that a malignant cause for her variety of symptoms could not be excluded. I appreciate that he was properly cautious in balancing Mrs A's right to be fully informed of her condition (or possible condition) against his wish to avoid causing her unnecessary anxiety (should malignancy ultimately be excluded). On balance, however, I agree with the advice of my expert, Dr Allison, that Mrs A should have been told that the CT scan had revealed an area of shadowing that was likely to be related to her previous radiotherapy but which could possibly be malignant. I also agree with my expert that it was not appropriate for Dr F to inform Dr G that the CT scan was "normal", particularly without seeing Dr E's report or further discussing the matter with his consultant, Dr C.

The key factor in reaching my opinion on this issue is that Mrs A had previously had breast cancer. While it was reasonable for Dr F to infer that the shadowed area on the CT scan may have been present as a result of previous extensive treatment for cancer, that was the very reason why Mrs A needed to be told that underlying malignancy could not be excluded. Mrs A's expectation that such information would be discussed with her is clear from her later direct questioning of Dr C; she wanted to know if she had cancer.

A patient such as Mrs A, with a history of breast cancer, extensive radiotherapy, adverse consequences of that therapy, a long-standing and continuing smoking habit and presenting symptoms that included loss of voice and shortness of breath, should have been told that ongoing review of her condition, including a repeat CT scan in three months, was needed. The fact that Dr F had not seen Dr E's actual recommendation for a three-month follow-up scan does not alter my view that the information Dr F conveyed to both his patient and her GP was insufficient in the circumstances.

It appears that Mrs A did not fully understand the nature of the procedures that Dr F had planned in order to further investigate the cause of her symptoms. For example, she was not sure what "vocal cord stripping" involved. Dr F informed me that management plans are

discussed with patients and he believes that following the video laryngoscopy performed by Dr C on 25 July, the plan for Mrs A would have been discussed with her. However, without further evidence of exactly what was discussed, I am unable to form an opinion on this issue.

In my opinion, in relation to the possibility of a malignant cause for her symptoms, Dr F failed to provide Mrs A with sufficient information following his review of her CT scan, and therefore breached Rights 6(1)(a) and 6(1)(f) of the Code.

Opinion: Breach – Dr C

Information provided to Mrs A

Right 6(3) of the Code gives every patient the right to honest and accurate answers to questions relating to services. When Mrs A asked Dr C on 12 September 2002 if she had cancer, he said "no". He told her that he believed her hoarseness had been due to leukoplakia, which he had treated. His focus was on the condition of her vocal cords and whether they were healing. He had seen the histopathology report on the August biopsies of tissue from her vocal cords, which confirmed that no malignant cells were present. His response to Mrs A was based on his honest belief that she did not have cancer of her vocal cords. Although the information he conveyed turned out to be inaccurate, doctors cannot be held to a standard of perfection in the face of diagnostic uncertainty. Dr C took reasonable steps to answer Mrs A's question honestly and accurately, and therefore did not breach Right 6(3) of the Code.

The more difficult question is the extent to which Dr C, in explaining Mrs A's condition, should have explained that an underlying malignancy could not be ruled out. In my view, given Mrs A's history, a reasonable patient in her circumstances would have expected to be told that although the vocal cord stripping procedure and biopsies performed in August had not revealed any malignant cause for her hoarseness and stridor, the CT scan report had not excluded malignancy and a repeat CT scan was needed. Dr C advised me:

> " … [H]aving had the report from the original CT scan in which the findings were 'no cause for hoarseness' it would seem inappropriate to cause speculative alarm. At the same time it was necessary to correctly inform the patient that an investigation needed to be repeated."

It is not possible to know whether telling Mrs A about the presence of a shadowed area on the scan and that an underlying malignancy could not be ruled out would have caused her "speculative alarm". She may well have been worried – but she was entitled to be told.

Dr C believes that he may have told Mrs A about the fibrosis (because he mentioned it in his letter to Dr G), but he cannot specifically recall doing so. It appears that he did not explain to Mrs A that she needed a repeat CT scan, or why this was so.

I note Dr C's comment, "[W]e do apologise if in an attempt to give at least some assurance where no certainty of malignancy is present one ultimately creates a false sense of reassurance. In communicating such issues to patients, the balance is fine."

I agree that the balance is fine. However, the Code requires doctors to give every patient the information that a reasonable patient in that patient's circumstances would expect to receive. I consider that Mrs A had the right to expect more information than she was given by Dr C. Accordingly, in my opinion, Dr C breached Rights 6(1)(a) and 6(1)(f) of the Code.

Opinion: Dr E, Dr D, the Public Hospital

Introduction
Right 4(1) of the Code affirms the right of every patient to have services provided with reasonable care and skill. When reading X-rays and dictating reports, a radiologist has a responsibility to ensure that the report is accurate and the recommendations are appropriate.

Mrs A complained that Dr E's reading of her CT scan on 25 July 2002, and his advice based on that reading, was not of an appropriate standard. At the time, Dr E was not a vocationally registered radiologist but a registered medical practitioner working as a third-year radiology registrar. He was, in his words, "under the direct supervision of Dr D, a consultant radiologist". General oversight was provided by the radiologist in charge of registrar training at the public hospital.

The procedure for CT reporting at the public hospital's Radiology Department in July 2002 was that the supervising consultant would review all CT scans individually with the radiology registrar with whom they were working. Dr E accordingly reviewed Mrs A's scan with Dr D, and they discussed their observations, conclusions and suggestions for her further management. Dr E dictated the report, edited and signed it. The final form of the report was not checked by Dr D before it went into Mrs A's medical file. This was standard practice at the time.

As a result of this information, I considered it necessary to widen the scope of my investigation to include not only Dr E, but also Dr D and the public hospital.

Opinion: No Breach – Dr E and Dr D

Observations and findings
Mrs A's complaint raises the question whether the review of her CT scan by Dr E and Dr D was carried out with reasonable care and skill. Was a malignant cause for Mrs A's symptoms evident on her scan yet missed? As the CT scan was discussed by Dr E and Dr D together, I have treated the observations and findings as being made by both clinicians.

Dr Milne noted that the scan report was "descriptive and makes a number of observations indicating that the scan has been well considered". However, he remarked that one relevant observation, "abnormal tissue in the aorto-pulmonary window (nodal station 5)", appeared to have been missed, and that another observation, a "2cm spiculated mass in the apical segment of the left lower lobe with extrinsic compression" had been misrepresented.

Dr D responded that he is "certain" that he did not miss the abnormal tissue in the aorto-pulmonary window. He acknowledges that the way Dr E described this aspect of their findings is not as he would have done. Dr E also responded that he did not miss the abnormal tissue in nodal station 5, but admits he described it in language that is not as accurate as it could have been.

Dr D and Dr E both say they observed the area that Dr Milne has identified in the left lower lobe, and disagree that their assessment that it was fibrosis is a misrepresentation. In support of their view, Dr D and Dr E note that at bronchoscopy, the tumour was in fact in the left upper lobe bronchus. Dr E also notes that the bronchoscopy report said "the left lower lobe bronchus appears to be otherwise normal although narrowed". Dr E's legal counsel suggests "it is possible that Dr Milne is incorrect in characterising the mass in the apical segment as being malignant" and that he has relied too heavily on hindsight.

When preparing his initial report, Dr Milne asked two radiology registrars to review Mrs A's scan. He advised that they both noted the 2cm mass in the apical segment of the left lower lobe and observed the abnormal tissue in the aorto-pulmonary window. They favoured a malignant diagnosis. Dr E's counsel argued that it would be "grossly unfair" if this information was taken into account in forming the Commissioner's opinion, and noted that Dr D had polled four radiologists whose consensus opinion was that "the differential would include fibrosis; malignancy should also be entertained".

Experts advising the Commissioner, and providers under investigation, often canvas their peers for their views of the expected standard of care in a particular situation. I appreciate that such polling may provide helpful background information for the expert or the provider. However, polling carries the risk that those polled do not have all the facts and/or approach the issue under consideration with heightened (and therefore artificial) suspicion. Accordingly, I have placed no reliance on the 'polling information' in forming my final opinion.

I note Dr Milne's comment that Dr E and Dr D's observations "resulted in the report conclusions being weighted towards a benign explanation for the appearances i.e. that the changes were on the basis of the patient's previous extensive radiotherapy", while in Dr Milne's view there was substantial evidence that there was a malignant cause for Mrs A's symptoms. Dr Milne noted that "in a patient with a smoking history, left vocal cord paralysis, stridor and weight loss of recent onset, malignancy in the thorax should be actively excluded".

However, I also acknowledge Dr D's view that there was "sufficient evidence of significant radiation effect" in Mrs A's chest that it was not inappropriate to draw the conclusion that

the lesion was radiation fibrosis. Dr E commented that "a malignant diagnosis can not be made from a CT examination. This requires a tissue sample and histological assessment by a pathologist." This point is in keeping with Dr Milne's quote from the Chief Thoracic Surgeon at Royal Bromptom Hospital, London, that "CT scanning does not stage lung cancer, rather it directs the surgical staging of lung cancer".

I am unable to verify exactly what Dr E and Dr D discussed on 25 July 2002. The key point is that Dr E and Dr D considered that malignancy could not be excluded. Despite his concerns as to missed or misrepresented observations, Dr Milne is satisfied that this was a reasonable conclusion. I note that ACC's advisor similarly concluded that "the appearances of the soft tissue masses in the mediastinum may represent neoplasia or possibly post-radiotherapy changes. … Dr E and Dr D gave an appropriate and reasonable report … noting that the appearances in the lung and mediastinum were consistent with malignancy but this was uncertain due to the co-existing changes secondary to radiotherapy." Overall, I am satisfied that their observations and findings were reasonable and that they did not breach Right 4(1) of the Code.

Recommendation for future management
Mrs A's complaint also raised the issue that Dr D and Dr E's recommendation for a follow-up CT scan in three months' time was inappropriate. It is important to assess the appropriateness of the recommendation in light of the information available to both radiologists at the time, without the benefit of hindsight.

Dr Milne advised that given the "benign bias" in their report, Dr E and Dr D's decision for future management was not unreasonable. He commented that "despite the benign weighting, malignancy was not dismissed … This would be a reasonable conclusion given the observations that were missed."

A biopsy of the lesion identified on the CT scan was one option that could have been taken to further investigate the cause of Mrs A's symptoms. However, Dr E and Dr D were reluctant to carry out this procedure and elected not to do so. Dr E considered that the 2cm mass "would be technically difficult to biopsy due to its close proximity to the descending Thoracic Aorta". Dr D also thought that "given the difficulty in doing a biopsy … it was appropriate to suggest short-term follow-up in 3 months".

My expert advisor, Dr Milne, agreed that the lesion in Mrs A's lung would have been technically difficult, but not impossible, to biopsy. However, I am satisfied that the position

taken by Dr E and Dr D was reasonable, particularly in light of the comments of the medical oncologist who described the biopsy of the lesion that he performed in January 2003 as "extremely difficult."

Having concluded that the lesion was most likely benign and that they were reluctant to biopsy it, Dr E and Dr D recommended a follow-up scan in three months. Dr Milne advised me that this was a "reasonable" recommendation and confirmed that lesions that are considered indeterminate on CT and inaccessible to biopsy are often monitored by CT

surveillance. Dr D pointed out that it is "unfortunate that Mrs A was told the CT was normal and that the recommendation of a 3 month follow-up scan was never requested by the referring clinicians, because it seems to me that this is the more important issue." I agree with that view.

Dr Milne advised me that one guideline for CT surveillance, the Early Lung Cancer Action Project, approves monitoring of "indeterminate" lesions at intervals of three months, for up to 24 months. He noted that in the absence of more technologically advanced assessment software, it would be unreasonable to rescan a patient for the purpose of detecting changes in malignant lesions at intervals of less than three months. Significantly, Dr Milne advised that in the context of New Zealand radiology practice at the time, there was no other imaging process available or commonly used to further review a condition such as Mrs A's.

I accept Dr Milne's advice on this point. Accordingly, in relation to their recommendation for future management of Mrs A, Dr E and Dr D did not breach Right 4(1) of the Code.

Opinion: Breach – Dr E, Dr D, the Public Hospital

CT scan report – Dr E
Dr Milne advised me that standard reporting practice requires a CT scan report to comprise a section on observations, where the viewing radiologist describes his or her findings, followed by a conclusion where the observations are interpreted in light of the clinical information obtained from the patient and/or clinician. The report should include the radiologist's favoured diagnosis; if no favoured diagnosis is apparent, suggestions would usually be offered to help the treating clinician reach a diagnosis.

Dr Milne confirmed in his supplementary advice that the CT scan report drafted by Dr E is "within the range of reports that I would expect from a third year Radiology Registrar", but described it as "unsatisfactory". However, the ACC's advisor considered the report to be "a reasonable appropriate and accurate report on the CT images".

In my view, the first issue for determination is whether the report was accurate and of an acceptable standard. Clearly the report contained inaccuracies, as both Dr E and Dr D concede.

Dr Milne noted the following areas where relevant observations appear to have been missed or misinterpreted by Dr E:

(a) the left RLN paralysis was not described;

(b) the presence of abnormal soft tissue in the aorto-pulmonary window extending onto the left lateral aspect of the Aortic Arch was missed;

(c) the 2cm mass in the apical segment of the left lower lobe was misinterpreted as more likely fibrosis than cancer;

(d) the "soft tissue lesion" is described as abutting the "medial aspect of the left horizontal fissure", yet in normal anatomy there is no left horizontal fissure – it appears that the reference should have been to the upper left oblique fissure;

(e) a "low density adrenal lesion on the left" is reported, yet there is in fact "bilateral mild adrenal enlargement".

Dr Milne stated that Dr E's failure to describe the left RLN paralysis was a "minor omission". However, he described the lack of appreciation of abnormal soft tissue in the aorto-pulmonary window as "crucial to securing a diagnosis of malignancy" and "a major failure [which] would incur moderate disapproval from peers". As noted above, Dr E's response is that he did not miss the abnormal soft tissue in the aorto-pulmonary window but rather had inaccurately described it.

In relation to this issue, Dr D also observed that the report contained "inconsistencies between what I believe should have been dictated and what was in fact dictated. Whilst there are comments made in the report about the volume loss, hilum elevation and pleural thickening, those matters are poorly described. It is noted that a 'mass' is present and continuous with stranding. This soft tissue should have been dictated as – 'in the mediastinum adjacent to the aorta (Aortopulmonary region)'".

Dr D and the public hospital have admitted that the supervision of the report writing was not adequate. My advisor, Dr Milne, described the report as "unsatisfactory". In these circumstances, I do not share the view of ACC's advisor that the report was "a reasonable appropriate and accurate report". Patients are entitled to expect reasonable care and skill in the reporting of radiology findings, and the fact that one independent radiologist would excuse a report's shortcomings, does not convince me that it was adequate or acceptable.

The second issue is whether Dr E can be exonerated from responsibility for the substandard report on the basis that it was "within the range of reports" expected from third-year radiology registrars, according to Dr Milne – even though one infers that it would be near the bottom of the range. Legal counsel submitted that Dr E had not breached the requisite standard of care, and cited the *Wilsher* decision of the English Court of Appeal to suggest that an inexperienced doctor "will often have satisfied the test even though he may himself have made a mistake" if he does "seek the advice and help of his superiors".[1]

[1] *Wilsher v Essex Area Health Authority* [1987] QB 730, 774, per Glidewell LJ.

[2] *McKenzie v Medical Practitioners Disciplinary Tribunal* (High Court, Auckland, No. CIV2002-404-153-02,12 June 2003), para. 73, quoting para. 92 of the District Court judgment

The difficulty with this submission is that although Dr E sought his consultant's help in reviewing the findings of the CT scan, he did not check that he had reported the findings accurately. As noted by Dr D, he "relied on Dr E's ability to accurately report the findings" they had discussed, but the report contained "inconsistencies between what I believe should have been dictated and what was in fact dictated".

Notwithstanding the absence of a system for mandatory checking of registrars' reports by their supervisors (discussed below), if Dr E was unsure whether he had accurately described the observations and findings, he should have sought Dr D's further "advice and help" and shown him the report before it was finalised, signed and placed on Mrs A's file. Dr D's role as Dr E's supervisor, and the systems in place at the public hospital, are certainly relevant issues in this case, but Dr E cannot invoke them to avoid responsibility for his own standard of report drafting.

In my view, the relevant legal standard is that affirmed by Venning J in *McKenzie v Medical Practitioners Disciplinary Tribunal*:[2]

> "A doctor accepting appointment as a registrar is required to bring to that role the requisite levels of competence, skill and experience necessary for the proper discharge of [his] responsibilities. It cannot be correct that where a failure to meet proper standard is concerned that a doctor should be able to excuse [himself] on the basis that [he] lacked expertise or experience."

Having carefully considered the comments of Dr E and Dr D, and the expert advice of Dr Milne and the ACC's advisor, my conclusion is that Dr E's report of Mrs A's CT scan was not of a satisfactory standard.

Ultimately, the question whether there has been a breach of the Code by a particular provider is a matter for the Commissioner's determination. In my opinion, Dr E failed to reach the standard reasonably expected of a third-year radiology registrar. I do not believe that his lapses can be excused by the fact that Dr D did not review the draft report before it was finalised and signed, or that other registrars could have made the same mistakes. If Dr E was unsure whether he had accurately captured the discussion with Dr D, he should have asked him to read the draft report. He did not do so. In these circumstances, Dr E failed to meet the standard of a junior doctor as described in the *Wilsher* and *McKenzie* cases. Accordingly, Dr E breached Right 4(1) of the Code.

Review of CT scan – Dr D
Dr D was Dr E's supervising consultant. He discussed the CT scan with Dr E but he did not see the report, which Dr E dictated before it was finalised.

Dr D informed me that the findings in the report did not meet his personal standard. He commented:

> "Please note that the reports are not dictated on direct instruction. The usual process is that following the consultation the registrar dictates a report. This may occur either at the time of the study, shortly after the study has been performed, or at a later date. The report is then typed by the medical typists and placed in the registrar's box for checking. In the past, once the registrar had checked the report it was signed off as a permanent record.
>
> In terms of this complaint, the usual practice at [the public hospital] at that time was that the supervising consultant did not usually review the final report. That was the situation in July 2002. I was therefore unaware of the language used or the relevant conclusion stated in [Mrs A's] reported CT findings. I relied on [Dr E's] ability to accurately represent the findings that we had discussed during our consultation/discussion.
>
> However, since then, I have changed my policy in respect of checking registrars' reports. This change resulted from a discussion in the national radiology literature about consultant oversight in the supervision of registrars and checking reports. Accordingly, I now check all reports issued by registrars under my supervision prior to them being finalised."

Dr D had a responsibility to exercise reasonable care and skill in reviewing the CT scan with his registrar, and retained ultimate consultant responsibility for the quality of the report. Dr D delegated his responsibility for ensuring the standard of radiology reports.

Public hospitals in New Zealand rely heavily on junior doctors, including registrars, for the provision of patient care. After a suitable period of assessment, consultants should be able to rely on the accuracy of registrars' report writing, particularly registrars in their third year of training, such as Dr E. However, in the absence of evidence that it was reasonable to delegate his responsibility to Dr E, Dr D must accept responsibility for the findings in the report. In these circumstances, Dr D breached Right 4(1) of the Code.

The Public Hospital radiology reporting system

In July 2002, the system in place at the public hospital for radiology reporting did not require a consultant radiologist to approve and double-check a registrar's report. As Dr Milne commented, "verification of dictated radiology reports at the public hospital depended on the radiology registrar's review of the report rather than the consultant's. This clearly is inadequate and places the consultant at … risk in that their opinion may not be accurately represented, as has been suggested by Dr D in this instance."

I agree that the public hospital reporting system was flawed. It allowed a report containing errors by a radiology registrar to be placed in the medical record and released to other treating clinicians, without being checked by the consultant radiologist. Dr D was not required to review the final report prior to its release, to ensure that it contained the relevant observations and conclusions and that they had been correctly expressed and described.

Dr D advised me that he has changed his practice and now checks his registrars' reports. A discussion in the national radiology literature regarding consultant oversight and the supervision of registrars and checking reports persuaded him that this was necessary.

In my opinion, the absence of a system for mandatory review of reports from radiology registrars constituted a breach of Right 4(1) of the Code by the public hospital.

Actions taken

In my provisional opinion, I recommended that Dr F, Dr C, Dr D, Dr E and the public hospital provide written apologies to Mrs A's family. I also recommended that the public hospital review its systems for radiology reports to ensure that reports from junior medical staff are reviewed by a consultant, and review its systems for the supervision of radiology registrars in training. I recommended that Dr F and Dr C review their practice in relation to the provision of information to patients, in light of my report.

All of the providers in this case, with the exception of Dr E, have acted on these recommendations.

Dr F
In response to my provisional opinion, Dr F provided the following written apology to Mrs A's family:

> "The Commissioner has found that in [Mrs A's] circumstances I did not convey sufficient information either to her or to her general practitioner. I accept the Commissioner's opinion and I wish to apologise for the distress which my role in the management of [Mrs A's] final illness has caused you, and to offer my condolences on her loss."

Dr C
Dr C's response to my provisional opinion included the following statement:

> "Though at the time I felt I had made a finely balanced decision as to what degree of information I provided, in the belief that I could have caused 'speculative alarm', I now unequivocally accept that I did not balance that decision appropriately – I should have provided more information."

Dr C provided a written apology to Mrs A's family, in which he commented that he has "reviewed the extent of information I provide patients in light of [the Commissioner's] decision, particularly where there is a possibility of malignant disease".

Dr D
Responding to my provisional opinion, Dr D stated:

> "Delegation of some clinical responsibilities to more junior staff is an essential component in the functioning of any large public hospital. It has always been a responsibility of the senior doctor to provide sufficient over-sight of such delegation in order to ensure clinical standards. I accept that the supervision of this delegated responsibility was not adequate in this instance. I acknowledge and accept the Commissioner's finding that I had the final responsibility for the findings in [Dr E's] X-ray report. I therefore wish to sincerely apologise for this shortcoming. I would like to reassure you that I have reviewed my practice in light of this matter. Systems have been improved in order to prevent such short-comings in the future".

The Public Hospital
On behalf of the public hospital, the Chief Executive accepted my finding that the absence of a system for mandatory review of reports from radiology registrars constituted a breach of Right 4(1) of the Code. The public hospital provided a written apology to Mrs A's family, in which she confirmed that the reporting of radiological findings by junior medical staff and the supervision of radiology registrars in training is being reviewed. The public hospital informed me:

> "The Radiology Department has reviewed the need for greater oversight of junior medical staff in respect of radiological film examination and reporting. Draft reports by junior medical staff are now reviewed by a consultant radiologist until the Director of Training, in consultation with other senior medical staff, is satisfied that the individual registrar is competent to do so without such supervision.
>
> The Radiology Department intends undertaking a review of registrar training at [the public hospital] later this year in October/November, subsequent to the advertisement and appointment of a new Director of Training. While we do not know what changes will fall out of the review, our goal is to put greater structure in place to provide a more modular approach to the teaching, supervision and evaluation of Resident Medical Officers. Should any changes fall out of the review, we aim to implement them in the new training year, which commences on 13 December 2004. The timing of this review is intended to minimise the impact on current registrars within the training programme at [the public hospital].
>
> We will provide you with evidence to show that all recommendations have been implemented by January 2005."

Recommendations

I recommend that Dr E apologise in writing to the family of Mrs A, for his breach of the Code. This apology is to be sent to the Commissioner and will be forwarded to Mr B (Mrs A's son).

Follow-up actions

- A copy of my final report will be sent to the Medical Council of New Zealand, the Accident Compensation Corporation, the Royal Australian and New Zealand College of Radiologists, and the Royal Australasian College of Surgeons.

- A copy of my final report, with details identifying the parties removed, will be sent to the Chief Medical Advisors of all District Health Boards and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.