Pathologist, Dr C

A Report by the

Health and Disability Commissioner

(Case 04HDC02992)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer
Dr B	General Practitioner
Dr C	Provider/Pathologist
Dr D	Surgeon
Dr E	Radiologist
Dr F	Consultant otorhynolaryngologist
Dr G	Plastic surgeon registrar
Dr H	Plastic surgeon registrar
Dr I	Histopathologist
Dr J	Pathologist
Dr K	Histopathologist

Complaint

On 26 February 2004 the Commissioner received a complaint from Mrs A about the services provided by Dr C, pathologist. The following issues were identified for investigation:

Whether in May 2002 Dr C provided Mrs A with services of an appropriate standard. In particular:

- *whether Dr C adequately assessed the pathology of the fine needle aspirate performed on 9 May 2002;*
- *whether Dr C reported his findings appropriately.*

An investigation was commenced on 31 March 2004.

Information reviewed

Information from:

- Mrs A
- Dr C
- Dr D, surgeon
- A District Health Board
- Dr B, general practitioner
- ACC.

Independent expert advice was obtained from Dr Peter Fitzgerald, pathologist.

Information gathered during investigation

Background
On 6 May 2002, 54-year-old Mrs A attended her general practitioner, Dr B, complaining of a lump in her neck. Dr B prescribed antibiotics. He also arranged for an ultrasound scan (USS) and a USS-guided fine needle aspiration (FNA) to diagnose the lump. Dr B's request form stated:

> "Initially small lump on [right] side of neck. Swelling has [decreased] but lump has remained. Lump is [illegible] size it originally was. Has [squamous cell carcinoma] on [right] ear."

The USS and FNA were performed by radiologist Dr E on 9 May 2002. Dr E concluded in her report:

> "Appearances are consistent with lymphadenopathy. The purulent appearing FNA is likely to be from a necrotic node. Appearances are all consistent with metastatic squamous cell carcinoma with definitive cytology awaited."

The pathology request form completed by Dr E for the FNA histology states:

> "[FNA] of neck node — assume necrotic not infected. Prob Sq Cell Ca met nodes [Probably squamous cell carcinoma metastatic nodes]."

On 9 May 2002, pathologist Dr C reported the FNA, and stated:

> "In my opinion, the appearances are consistent with the clinical suggestion of necrotic metastatic squamous cell carcinoma."

Having received the result of the USS and the histology of the FNA, Dr B arranged for Mrs A to be seen by the plastic surgery team at the public hospital, headed by Dr D. Mrs A was already known to Dr D, as she was on the waiting list for the removal of a basal cell carcinoma on her right ear. This operation was planned for 22 May 2002.

On 13 May 2002, Mrs A was seen by a plastic surgery registrar. In her letter to Dr B, the plastic surgeon registrar stated:

> "Over the past three weeks [Mrs A] has noticed a right neck mass and ultrasound guided FNA suggested metastatic SCC [squamous cell carcinoma] … On examination she has a 2cm ulcerated SCC over the right helical fold which is fixed to the underlying cartilage. She has a 2 x 2cm hard, fixed mass over the right neck anterior to the sternomastoid.
>
> I have arranged for her to have an urgent CT for staging and to see [Dr D] in his Outpatient Clinic as soon as possible for excision of the right ear lesion plus right neck dissection."

On 21 May 2002, Mrs A had a magnetic resonance imaging (MRI) scan. This was reported by a radiologist and reviewed by a second radiologist. They concluded:

> "10mm metastatic node adjacent to the SCM muscle just below the angle of the jaw. Multiple probable reactive small lymph nodes in levels 2B bilaterally and level 5 on the left."

Mrs A attended Dr D's clinic on 10 June 2002. He wrote to Dr B:

> "[Mrs A] was seen in clinic today. She has been seen by our registrar with the history of a sudden swelling occurring on the right upper neck. She has been seen by yourself and you have sent her for full biopsies and all revealed SCC of the nodes. I have looked into the site and it is resolving now and I could feel a vague swelling under the angle of the jaw and another 10mm diameter node below that. As we have confirmed that it is SCC I couldn't find any skin SCC which can relate to the metastases to it. I have arranged for her to be seen by an ENT consultant to check the airway for a primary lesion before we embark on dissection of the neck, which she is going to need anyway."

Dr D referred Mrs A to Dr F, consultant otorhynolaryngologist and head and neck surgeon. Dr D's request form stated:

> "I would be grateful if you see this nice lady who developed sudden swelling in her [right] upper neck with inflammation proved to be SCC, although we have done few excision of [basal cell carcinomas] from her face and ear we cannot link that metastatic mass to skin cancer. I would be grateful if you assess for ENT search of primary."

On 17 June 2002, Mrs A was seen by Dr F. He wrote to Dr D:

> "Thank you for referring [Mrs A]. Her history is well known to you. She has had numerous SCCs and BCCs removed from both her facial skin and other exposed skin areas. She represented recently with a mass in the right side of her neck which FNA has shown to be suspicious of squamous cell carcinoma. Since the FNA and the antibiotics the size of her mass has significantly reduced, however MRI does reveal a number of masses on that side …
>
> This examination has not revealed any sign of a primary lesion to explain the secondary nodes on the right side of the neck."

Mrs A was seen on 24 June 2002 by Dr G, plastic surgery registrar, who wrote to Dr B:

> "This lady has been undergoing a sequence of investigations for her recently diagnosed right angle of jaw neck mass. … Examination of her oronasal pharynx did not reveal any sign of a primary lesion to explain the node in the right side of her neck.
>
> The MRI identified a 10mm node adjacent to the SCM just below the angle of the jaw with multiple, probably reactive lymph nodes in level 2B bilaterally and level 5 on the left.
>
> [Mrs A] thinks that the node has actually gone down and clinically it is difficult to feel today …

> The plan at this stage is to perform a right supraomohyoid neck dissection with excision of the lesion on the ear at the same time and excision of lesions on her right arm … We will try and do the surgery as soon as possible. I have explained to her that she will most likely be in hospital for 4–5 days."

On 25 June 2002, the day after Mrs A's consultation with Dr G, Mrs A consulted Dr B, concerned about the operation that had been proposed. Dr B wrote to the Plastic Surgery Department on 28 June 2002:

> "[Mr and Mrs A] came to see me today re her upcoming operation — they are understandably concerned re her planned neck dissection. We discussed the operation in depth and I wondered if a frozen section during the procedure may play a role in helping to limit the amount of surgery done. Thank you for all the help you have given [Mrs A] and thank you for your expert opinion."

There is no record of Dr B's letter within Mrs A's hospital notes. Dr D informed me that doing an operation such as Dr B suggested was not an option:

> "Doing a simpler operation in a case like this will not be seen as adequate surgery by most surgeons."

On 27 June 2002, at the public hospital Combined Head and Neck Oncology Group meeting, Mrs A's case was discussed. Those present included Dr F, Dr D and a number of registrars from surgery, ENT and oncology. Although recorded as having attended, Dr […] had left the meeting by the time Mrs A's case was discussed. The note of the meeting was taken by Dr H, plastic surgery registrar, and the plan recorded:

> "[Right] level I, II, III, IV neck dissection (selective) [with] EUA [examination under anaesthetic] — [right] tonsillectomy and biopsy of base of tongue.
>
> Post-op radiation may be considered on the basis of histology that may be to the entire upper orodigestive tract."

On 3 July 2002 Mrs A was admitted to the public hospital. Dr H attended her and he discussed in detail the operation, possible complications and postoperative recovery. The consent form was signed by Mrs A. Dr H advised that the information provided to Mrs A included:

> "the procedure/treatment;
> the risks, benefits and side effects associated with such a procedure;
> available options;
> where possible, the estimated time in which the service will be provided …"

Dr D stated:

> "The consent for surgery has been done by [Dr H] [on 3 July 2002] and I understand that [Dr H] has given her all the information necessary for her operation, about incisions, operative details, recovery period, postoperative recovery and relevant possible complications, and spent a good amount of time answering all her questions."

As there were no beds available in the hospital, Mrs A spent the night of 3 July 2002 in hostel accommodation, and presented herself to the day surgery unit on the morning of 4 July 2002.

On 4 July 2002 Dr D performed a right modified neck dissection with preservation of levels I, II, III and IV. The lesion on Mrs A's ear was removed, as were four lesions on her right forearm.

Histopathologist Dr I reported the histology specimens. In relation to all specimens taken from the neck surgery, no evidence of malignancy was found.

On 1 November 2002 the FNA slides were reviewed by Dr J, pathologist at the public hospital. The conclusion of his report stated:

> "In my opinion this is a lymph node with occasional atypical cells."

ACC

On 28 November 2002, Mrs A submitted a claim to the Medical Misadventure Unit of ACC, which was accepted as medical error on the part of Dr C. In reaching its decision, ACC considered advice provided by a pathologist, who summarised in his letter (undated) to ACC:

> "The Combined Head and Neck Oncology Group who discussed this case before the surgery … did not include a pathologist. It would be usual practice in most institutions for a pathologist to be a member of such a group. …
>
> It would be reasonable to expect a pathologist to have correctly diagnosed this specimen as negative for malignancy or at most inconclusive. In my opinion diagnosis of this specimen as malignant falls below a standard of care and skill to be reasonably expected in the circumstances."

ACC received advice on the surgical aspects of Mrs A's treatment from a plastic and reconstructive surgeon, who advised ACC in a letter dated 3 July 2003:

> "[T]he correct diagnostic pathways were followed. It has been shown that following positive FNA diagnoses, if further interference of the surgical field is made by node biopsy, the chance of spread of the tumour to the surgical wound is significant. The correct surgical approach therefore is to confirm the diagnosis of metastatic cancer by FNA, followed by a complete block dissection."

The ACC decision recording the error finding on the part of Dr C stated that Dr C's terminology "could lead to no other conclusion than a diagnosis of probable cancer".

Dr C applied for a review of the decision, and submitted that his report did not provide an unequivocal malignant diagnosis.

Dr K, histopathologist, wrote to Dr C on 13 October 2003 in support of his application for a review. Dr C provided a copy of this letter to ACC. Dr K stated:

> "[I]t is common practice in our laboratory to use terms such as 'consistent with' … in cases where there is an element of doubt about the diagnosis. … Experience has shown that communication of exact shades of meaning is sometimes difficult in a formal report and discussion between the clinician and pathologist often clarifies the situation."

Dr I, histopathologist, in his advice to ACC dated 2 February 2004, stated:

> "[T]he term 'consistent with' to me indicates that it is not possible to make a 100% confident histological diagnosis on the material being reviewed, but on the balance of probabilities taking into account all the available information, a particular diagnosis is favoured."

Dr D stated in a letter to ACC dated 11 December 2003:

> "[Mrs A] has been presented to a panel at the Head and Neck Meeting, at [the public hospital]. The FNA report, clinical presentation plus previous head and neck cancer make it unnecessary to repeat the FNA as the procedure we used might be indicated even before any cervical lymph nodes involvement in bad head and neck cancer (preventative). In [Mrs A's] case we call it suspicious of 'unknown primary' for diagnosis, grading, treatment.
>
> The decision has been made on several factors including the [FNA], clinical presentation and previous cancers of facial skin.
>
> Negative result may make one repeat the FNA several times and we might have gone with the procedure anyway, as there is no space for delay."

In a letter dated 28 January 2004, ACC's Clinical Advisor commented on Dr D's letter of 11 December 2003:

> "While it is clear that [Dr D] understood the [FNA] was a positive reading, this did not impact upon his decision given the wider clinical picture.
>
> In light of the specific comments made by [Dr D], ACC will be revoking the decision of medical error."

On 5 February 2004 the decision of medical error against Dr C was revoked.

On 7 December 2004, ACC accepted Mrs A's claim as medical mishap. The "Medical Misadventure Report to Claimant" stated:

> "ACC accepts on the balance of probability that you have suffered an injury caused by the neck dissection surgery, being an axonal lesion of the right accessory nerve and damage to the laryngeal nerve."

Other information
In responding to the notification of Mrs A's complaint, Dr C stated:

> "It was my view that there was some evidence in the [FNA specimen] which would support that proposition [of metastatic squamous cell carcinoma], but I accept with hindsight that is not so. There is a well recognised false positive rate in this regard."

Response to provisional opinion
Dr C stated that it has always been his position that he did not make a firm, unequivocal diagnosis of metastatic cancer, and that his use of the words "consistent with" indicated some doubt as to the correctness of that proposition.

Dr C stated that he no longer practises cytopathology and that he apologised in person to Mrs A at the ACC review hearing.

Independent advice to Commissioner

Original advice
The following expert advice was obtained from Dr Peter Fitzgerald, pathologist:

> "I have been asked to write an opinion to the Commissioner on Case Number 04/02992/WS. I have read and agreed to follow the Commissioner's guidelines for independent advisors.
>
> I am a registered Medical Practitioner and a Fellow of the Royal Australasian College of Pathologists. I have a Postgraduate qualification (Fellow of the International Academy of Cytology) in Cytopathology. I have been a member of the Royal Australasian College of Pathologists Cytopathology Advisory Committee since 2001. My clinical practice is focussed on the area of Cytopathology. My area of expertise in Cytopathology is relevant to this report.
>
> **Expert Advice Required**
>
> 1. Was the report issued by [Dr C] on the FNA accurate? If not, please indicate the extent of departure from an accurate report, and comment on any details not reported.
> 2. In what circumstances should an FNA be repeated, and should a further FNA (or any other tests) have been recommended by [Dr C] in this case?
>
> General questions:
>
> 3. To what extent would a request form, with clinical details attached, affect a pathologist's report?
> 4. Should a pathologist be present at a multi-disciplinary meeting where a plan of treatment is decided that followed on from clinical presentation, examination, radiology and pathology?
>
> I have received a request form for an FNA dated 8 May 2002 ([Dr E]). The report of FNA dated 9 May 2002 ([Dr C]). FNA slides were given to me directly by […].

Background

On 6 May 2002 [Mrs A] consulted [Dr B], GP, complaining of a lump in her neck. She was prescribed antibiotics and an ultrasound scan and FNA were arranged. On 9 May 2002, [Dr E], radiologist, performed a scan, reporting as 'appearances are all consistent with metastatic squamous cell carcinoma … definitive cytology awaited'. [Dr E] performed an FNA, which was reported on the same day by [Dr C], pathologist, as 'the appearances are consistent with the clinical suggestion of metastatic squamous cell carcinoma'.

1. *Was the report issued by [Dr C] on the FNA accurate?*
   The report mentions several smears as being received. I have received two smears for review and assume that these represent all case material. The report is largely accurate with respect to its description. Lymphoid cells are not seen in the smears that I received. I would not interpret the single cells with eosinophilic cytoplasm as having hyperchromatic nuclei. There is insufficient cytologic evidence for a definite diagnosis of metastatic squamous cell carcinoma.

2. *In what circumstances should an FNA be repeated, and should a further FNA (or any other tests) have been recommended by [Dr C] in this case?*
   The two most important circumstances in which an FNA should be repeated are where there is insufficient diagnostic material or where the cytology does not adequately answer the clinical question. Both situations represent doubtful sample adequacy. Clinical information is critical to ensure optimal FNA results. In this case, clinical information provided to [Dr C] was strongly suggestive of metastatic squamous cell carcinoma. The interpretation of the FNA material by [Dr C] was consistent with a clinical suggestion of squamous cell carcinoma. Providing this interpretation was justified a repeat FNA (or any other test) should not be required.

3. *To what extent would a request form, with clinical details attached, affect a pathologist's report?*
   The clinical information provided by the referring doctor should have a major effect on the pathologist's report. Where there is a discrepancy between the clinical and the cytologic findings, review of the case is prudent.

4. *Should a pathologist be present at a multi-disciplinary meeting where a plan of treatment is decided that followed on from clinical presentation, examination, radiology and pathology?*
   It is optimal for a pathologist to be present. However, in practice this is not always practical. Where there is discrepancy between clinical presentation, examination, radiology and pathology it would be prudent to ask for case review. FNA of cystic head and neck lesions is a recognised area of difficulty. In particular, cystic well differentiated squamous cell carcinoma presents a major challenge for the cytopathologist. Squamous cells may be sparse and not show the usual nuclear criteria of malignancy. A number of benign conditions, particularly branchial cleft cyst may mimic cystic well differentiated squamous cell carcinoma.

   In this particular case, providing that I have received all the smears, there was insufficient cytologic evidence for definitive diagnosis of squamous cell carcinoma.

However there are a number of poorly preserved cells which show squamoid features. Confident benign categorisation should not be given on this cytology. These poorly preserved [cells] (described as atypical by [Dr J]) suggest the possibility of an underlying squamous cell carcinoma. A repeat FNA or excision of the lesion in question prior to definitive surgery would have been the optimal interpretation given from the cytology findings.

In conclusion, I do not think that [Dr C's] diagnosis represents a major deviation from an appropriate standard of care. Cystic head and neck lesions represent a major FNA diagnostic challenge. Distinguishing between well differentiated squamous cell carcinoma and other benign conditions particularly branchial cleft cysts is not straight forward. Small numbers of poorly preserved squamoid cells are present in these aspirates. Such cells could be reasonably interpreted as suggestive of squamous cell carcinoma. However I do not think there is sufficient evidence for a definitive diagnosis of squamous cell carcinoma."

Further advice

Further advice was obtained from Dr Fitzgerald to provide clarification of points within his earlier report:

"Re: [Mrs A] — Reference No. 04-02992/ws

To specifically answer your questions:-

1. [Dr C's] report deviates from an appropriate standard of care to a moderate degree.

2. Yes, [Dr C's] report of the 9th May 2002 could be reasonably considered to be a definitive diagnosis of metastatic squamous cell carcinoma.

3. There is nothing in [ACC's pathologist advisor's advice] to the ACC that would cause me to amend my report to the Commissioner dated 9th February 2005.

I have further reviewed the literature with respect to the diagnosis of squamous cell carcinoma in the head and neck region. I have also consulted local clinical specialists in head and neck oncology.

If an equivocal FNA report had been issued then a repeat FNA or excision of the lesion with intraoperative consultation (frozen section) would both have been reasonable next steps. Choice would be influenced by quality of the local FNA service. Where the surgeon was confident with his or her local service a repeat FNA would be optimum. However, it is possible in some localities in New Zealand this might not be the case and lesion excision with intraoperative consultation would be chosen by the surgeon. It is difficult to be dogmatic about this. However, where FNA expertise is available a repeat FNA would be best.

A pathologist should be present at a multi-disciplinary meeting planning treatment for head and neck malignancy. However, in practice this is not always the case. This might be for a variety of reasons including sickness, leave, etc. However, it is worth

noting in this case that there appeared not to be discrepancy between clinical presentation, examination, radiology and pathology. It is probable that the pathologist was over-influenced by the clinical and radiologic information that was presented to him at the time he reviewed the slides. Thus he over-interpreted the cytologic changes as representing malignancy. In this situation unless the multi-disciplinary meetings involved a cytopathologist different to [Dr C] it is likely that the original findings would have been upheld and subsequent management confirmed even though it had been discussed at a multi-disciplinary meeting. So perhaps the question should be rephrased 'should an independent pathologist be present at a multi-disciplinary meeting where a plan of treatment is decided?' The answer to this question is 'yes'.

In summary, having reread my own report and compared it to [ACC's pathologist advisor's] the reports differ only in emphasis. [Dr C's] diagnosis represents moderate deviation from an appropriate standard of care. The report could be reasonably considered to be a definitive diagnosis of metastatic squamous cell carcinoma. An independent pathologist should be present at a multi-disciplinary meeting where a plan of treatment is being planned for head and neck oncology patients. In my experience such meetings are usually held within the public hospital sector and I assume this would also be the case in [this town]."

Additional advice
Further clarification was sought from Dr Fitzgerald following Dr C's response to my provisional opinion.

Dr Fitzgerald stated that the sample reviewed by Dr C "fell well short of being consistent with squamous cell carcinoma, and was certainly not diagnostic of squamous cell carcinoma". However, Dr Fitzgerald stated that there were some "poorly preserved cells" present in the sample, and that Dr C's error was "understandable" and "not a major error".

Dr Fitzgerald also stated that there was variation within New Zealand over how pathologists make their reports, with "no uniform approach". Although Dr Fitzgerald would not have used the words "consistent with" to describe the sample, it is necessary to "gauge the relationship between specialists to understand the use of words within a report".

Code of Health and Disability Services Consumers' Rights

The following Right in the Code of Health and Disability Services Consumers' Rights is 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.

Opinion: No breach — Dr C

FNA report
Under Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) Mrs A was entitled to have services provided with reasonable care and skill. Accordingly, Dr C was required to report to an acceptable standard the FNA sample taken by Dr E on 9 May 2002.

When reporting the FNA sample, the only clinical information available to Dr C was the request form from Dr E, on which was stated that the radiological indication of Mrs A's lump was that it was "probably" a squamous cell carcinoma metastatic node. Dr Peter Fitzgerald, my independent pathology advisor, stated in his first report:

> "Clinical information is critical to ensure optimal FNA results. In this case, clinical information provided to [Dr C] was strongly suggestive of metastatic squamous cell carcinoma."

In his further report, Dr Fitzgerald stated:

> "It is probable that [Dr C] was over-influenced by the clinical and radiologic information that was presented to him at the time he reviewed the slides. Thus he over-interpreted the cytologic changes as representing malignancy."

In advising ACC, ACC's pathology expert considered that the FNA should have been reported as inconclusive at most. Dr J, reviewing the FNA for the public hospital, also reported that there were atypical cells present, which according to my expert Dr Fitzgerald "suggest the possibility" of an underlying malignancy. Dr C, following a further review of the FNA slides, stated:

> "It was my view that there was some evidence in the [FNA specimen] which would support that proposition [of metastatic squamous cell carcinoma], but I accept with hindsight that is not so."

Dr C also stated that his report was not a definitive diagnosis of metastatic squamous cell carcinoma, considering that his use of the words "consistent with" indicated this.

I believe that the important issue is the emphasis given in the report. Although Dr C did not report an unequivocal malignant diagnosis, his report could easily be interpreted as supportive of the working diagnosis of a malignant disease. I do not accept Dr C's view, stated in response to my provisional opinion, that without further qualification his use of the words "consistent with" does not indicate a probability of a diagnosis rather than a possibility. He should have been aware that reporting this specimen as he did would have an influence on the course of treatment for Mrs A. I consider that the use of such words was incautious. Subsequent to Dr C's report, the FNA sample was accepted as indicating the likelihood of squamous cell carcinoma by Mrs A's clinicians. If Dr C meant to indicate that there was some doubt, he failed to do so, and for this he needs to accept some responsibility.

My view is supported by my expert, Dr Fitzgerald, who advised that the FNA slides showed some changes that were "suggestive" of an underlying malignancy, but that in his view the FNA sample "fell well short" of being "consistent with" squamous cell carcinoma.

I have taken into account Dr Fitzgerald's statement that there is variation within New Zealand in the language that is used in pathology reports, and that Dr C's error was not a major error. I have also considered Dr Fitzgerald's advice that Dr C's interpretation of the FNA was "understandable" given the circumstances of the abnormalities seen, and also the emphasis in Dr E's request form. Consequently, although I am critical of Dr C's report, in all the circumstances I find that he did not breach the Code.

Other comments

Consistency of language in pathology reports
This case highlights the importance of the use of consistent terminology by pathologists in their reports. Consistency in the language used is necessary for consistent interpretation and appropriate treatment decisions. There appears to be a lack of clarity which the Royal College of Pathologists of Australasia would be best placed to address. I recommend that the College review the manner in which FNA samples are reported in New Zealand to ensure consistency.

Presence of pathologist at multidisciplinary meetings
As noted by my expert, an independent pathologist should be present at multidisciplinary group meetings where treatment is planned on the basis of pathology reports.

Recommendations

- I recommend that the Royal College of Pathologists of Australasia review the language used in FNA reports in New Zealand, in order to ensure consistency.

- I recommend that the District Health Board ensure that whenever possible an independent pathologist is present at multidisciplinary meetings where treatment is planned on the basis of pathology reports.

Follow-up actions

- A copy of this report will be sent to the Medical Council of New Zealand, the District Health Board, and the Royal College of Pathologists of Australasia.
- A copy of this report, with details identifying the parties removed, will be sent to all District Health Boards and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.