# Pathologist, Dr B General Practitioner, Dr C

## A Report by the Health and Disability Commissioner

(Case 10HDC00540)



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#### **Executive summary**

#### **Complaint**

- In June 2006, general practitioner, Dr C, completed a medical examination for Mr A (then aged 45 years), as part of Mr A's application for New Zealand residency. Dr C noted Mr A's relevant medical history, which included the removal of a melanoma in 1990. Three months later, Mr A enrolled as a regular patient at the practice where Dr C worked.
- 2. In September 2008, Dr C excised a mole from Mr A's back, and the specimen was sent to the medical laboratory (Laboratory X). The histology report, completed by pathologist Dr B, confirmed that it was a melanoma and stated that it had been "completely excised". Dr C was aware that wider excision was usually recommended for melanomas, and he telephoned Laboratory X to confirm the result. He was advised again that the excision was complete, and recorded also that no further surgery was required. A few days later, Dr C saw Mr A to remove the sutures and discuss the histology. No other follow-up was arranged.
- 3. In September 2009, Mr A went to see Dr C about a lump in his left armpit. Dr C referred Mr A to general surgeon Dr E. There was no reference to Mr A's melanoma history in the referral letter. Ten days later, Dr E reviewed Mr A and sent him for a fine needle aspirate test. The cytology was reported by Dr B.<sup>2</sup> It was noted that the sample was of "low cellularity" but that there was no sign of any malignant cells and that features were consistent with a lipoma (ie, benign).<sup>3</sup> Dr E arranged to see Mr A on Mr A's return from a forthcoming overseas trip, for a surgical excision of the lump.
- 4. When Dr E reviewed Mr A in December 2009, the lump was firmer in nature and Dr E thought that it might be a lymph node. The lump was removed under general anaesthetic 13 days later. The biopsy confirmed that it was malignant, and further tests revealed that Mr A had Stage IV malignant metastatic melanoma with brain, liver and lung metastases. Mr A died a few months later.

#### **Findings**

5. Dr C was found in breach of Rights 4(1) and 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).<sup>4</sup>

<sup>&</sup>lt;sup>4</sup> Right 4(1) — Every consumer has the right to have services provided with reasonable care and skill. Right 4(2) — Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.



<sup>&</sup>lt;sup>1</sup> Histology is the study of the structure of tissues by examination under a microscope.

<sup>&</sup>lt;sup>2</sup> Cytology is the study of the structure and function of cells.

<sup>&</sup>lt;sup>3</sup> Cellularity refers to the degree, quality or condition of cells present within tissue.

6. The Commissioner concluded that Dr B's reporting was reasonable and that there was insufficient evidence to conclude he had provided additional inaccurate verbal advice. Accordingly, Dr B was not found to have breached the Code.

#### **Complaint and investigation**

- 7. On 12 May 2010, the Commissioner received a complaint from Mrs A about the services provided to her husband by Dr C and Dr B. The following issues were identified for investigation:
  - The appropriateness of the care and treatment provided to Mr A by Dr C between September 2008 and December 2009.
  - The appropriateness of the services provided to Mr A by Dr B between September 2008 and October 2009.
  - The appropriateness of the services provided to Mr A by Laboratory X between September 2008 and October 2009.
- 8. An investigation was commenced on 18 October 2010.
- 9. HDC was subsequently advised that Dr B was employed by Laboratory Y rather than Laboratory X. On 10 May 2011, the scope of the investigation was amended accordingly. On 7 December 2011, HDC was advised that during the relevant period, Dr B was in fact employed by Laboratory Z. On further investigation, it transpired that Dr B's employment agreement was actually with Laboratory Y although he was paid by, and considered by those concerned to be working for, Laboratory Z. At the relevant time, Dr B was working at Laboratory X's premises. Laboratory X, Laboratory Y, and Laboratory Z are all wholly owned subsidiaries of a pathology company (the pathology company) and have the same directors and Chief Executive. The identity of Dr B's employer is thus unclear. However, given I have decided not to find Dr B's employer in breach of the Code, and the close relationship between the entities concerned, it is not necessary for me to resolve this issue. Under the circumstances, I have discontinued my investigation in relation to Laboratory Y but have not notified any alternative employing entity. My findings and reasons regarding employer liability are set out in paragraph 131.
- 10. The parties directly involved in the investigation were:

Mr A (dec) Consumer

Mrs A Consumer's wife/complainant

Dr C General practitioner

Dr B Pathologist A pathology company Provider

Dr D Dr B's clinical supervisor

Dr E General surgeon

Also mentioned in this report:

Dr F

#### General practitioner

- Information was reviewed from: Mrs A, Dr C, Dr B, the pathology company (including on behalf of its subsidiaries), Dr E, ACC, and Immigration New Zealand.
- 12. Expert clinical advice was provided by HDC's clinical advisor, Dr David Maplesden (**Appendix 1**) and expert pathology advice was provided by independent pathologist Dr Jonathan Allen (**Appendix 2**).

#### Information gathered during investigation

*Introduction* — *melanoma management* 

- 13. New Zealand and Australia have the highest incidence of melanoma in the world. It is the most serious form of skin cancer. While other types of skin cancer are more common, melanoma is responsible for about three-quarters of all skin cancer-related deaths. <sup>5</sup> Prevention, early diagnosis, and appropriate treatment are critical.
- 14. The Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand (Melanoma Guidelines)<sup>6</sup> were issued by the New Zealand Guidelines Group and the Australian Cancer Network in November 2008.<sup>7</sup> The Melanoma Guidelines reflect the accepted treatment and management of melanoma that existed during the time of the events covered in this investigation (ie, September 2008 to October 2009). Accepted practice included a clear emphasis on early diagnosis and a rigorous application of appropriate treatment. Other key aspects of accepted practice at the time were as follows:
  - When a doctor identifies a lesion suspicious for melanoma, usual practice is to excise it with a narrow margin of normal-looking skin.<sup>8</sup>
  - The specimen is sent for histology. Histological examination will determine whether the lesion is a melanoma and, if so, provide necessary information to guide further management. Relevant information includes the "level" of the melanoma, that is, the depth to which the melanoma cells have grown into the skin. The level is measured in millimetres and referred to as the "Breslow" thickness. The "stage" of a melanoma gives an indication as to how far the melanoma has spread. Stages I and II are confined to the skin, Stage III to the

<sup>&</sup>lt;sup>8</sup> A GP may refer to a plastic surgeon or general surgeon for such excision. There may be circumstances where partial biopsy is appropriate.



<sup>&</sup>lt;sup>5</sup> http://www.aafp.org/afp/20000715/357.html

<sup>6</sup> http://ebooks.nzgg.org.nz/melanoma guideline

<sup>&</sup>lt;sup>7</sup> In Australia, these guidelines were preceded by the *Clinical Practice Guidelines: the management of cutaneous melanoma*, issued in 1999 by the Australian Cancer Network in conjunction with the National Health and Medical Research Council.

lymph nodes, and Stage IV indicates spread to internal organs. Other details may be included in what is known as a "synoptic report".

- Once a primary melanoma is confirmed, it is usual practice in most cases to undertake wider excision. The recommended excision margins are based on the maximum Breslow thickness and other prognostic features.
- Patients who have had a melanoma excised should be followed up at regular intervals. The main purpose of follow-up is to detect any recurrences or new suspicious skin lesions early, so that early treatment can be undertaken. The frequency and duration of follow-up is dependent on how advanced the disease is at the time of presentation.

Initial GP contact — April 2006 to March 2008

- 15. Mr A came to New Zealand in February 2006.
- 16. On 21 June 2006, Mr A consulted general practitioner Dr C<sup>9</sup> at a medical centre for the purposes of obtaining the medical certificate Mr A required for his application to become a New Zealand resident. The medical certificate involved the completion of a 16-page report: a "Medical & Chest X-ray Certificate".
- 17. In response to a question in the report about previous hospitalisations, Dr C noted that Mr A had had a melanoma excised from his left leg in 1990. The melanoma was referred to in three further places in the report. In the section for the medical examiner's comment on the applicant's medical history, Dr C wrote "normal history melanoma 16 years ago cured".
- 18. In the medical centre's electronic record, Dr C recorded the consultation as "Immigration examination". There was a reference to orders for blood tests and a chest X-ray, but no record of the clinical examination.
- 19. Dr C subsequently stated that his consultation with Mr A at this time was solely for the purposes of completing the immigration assessment, and at that time Mr A was not a registered patient at the medical centre.
- 20. On 29 June, Dr C attached a letter with the results of Mr A's blood tests and chest X-ray to the "Medical & Chest X-ray Certificate", and it was forwarded to Immigration New Zealand. Aside from the brief record of the consultation in the medical centre's electronic database, the letter outlining blood test and chest X-ray results was the only other record relating to Mr A's examination retained by the practice.
- On 4 October 2006, Mr A returned to see Dr C as a registered patient, presenting with lesions on his lower back and left hand. A punch biopsy of the back lesion was

<sup>&</sup>lt;sup>10</sup> This was Mr A's second medical assessment for immigration purposes. He was first assessed on 27 February 2006 by a doctor in another region, when he was applying for a working visa.



<sup>&</sup>lt;sup>9</sup> Dr C completed his medical training overseas, and registered to practice in NZ around 17 years ago. At the time of these events Dr C was registered within a general scope of practice, which required that he work within a collegial relationship with another doctor registered within the same or related vocational scope.

performed and sent to Laboratory X for histology. Dr C subsequently told HDC that it is his usual practice with new patients to take a history — "as much as time would allow" — and to perform a complete physical examination. He believes that he would probably have completed a physical examination for Mr A. There is no documentation in the clinical records to confirm that a patient history was obtained or a complete physical examination performed.

- 22. The punch biopsy confirmed basal cell carcinoma and, on 12 October 2006, Dr C excised the lesion. This was also sent to Laboratory X for histology. Dr C's records show that at a follow-up appointment with Mr A on 19 October 2006, the stitches were removed and the histology, showing clear margins, was discussed.
- 23. Records show that Mr A saw Dr C four times in 2007, in relation to other concerns.
- On 26 March 2008, Mr A saw Dr C regarding swelling in his right knee. Dr C referred Mr A for an X-ray. His note for this consultation also states "LN [liquid nitrogen] lesions right foot, right leg and right arm--?tcb [to come back] for excision". There is no record that Mr A came back for this or that it was followed up.

*Mole excised* — *September 2008* 

25. On 19 September 2008, Mr A went to see Dr C about a mole on his back and a blocked ear. Dr C noted:

"ears syringed and tcb for excision mole bp [blood pressure] = 140/75, p [pulse] = reg [regular] at 64/min".

26. On 24 September 2008, Mr A returned to Dr C to have the mole excised. In the clinical record Dr C wrote "excision mole on left side of back". Dr C does not recall whether he asked Mr A about his personal or family history of melanoma at this time. The specimen was sent to Laboratory X for histology; the laboratory order stated: "Back".

Melanoma confirmed

- 27. On 29 September 2008, the specimen from Mr A's back was analysed and reported by pathologist Dr B.
- 28. A copy of the histology report completed by Dr B is attached as **Appendix 3**. Under "diagnosis", it states:

"SKIN, BACK, EXCISION MALIGNANT MELANOMA, COMPLETELY EXCISED"

29. Further details are provided under the heading "Vertical growth phase melanoma – Synoptic Report". It is noted that the melanoma type is nodular, <sup>11</sup> the Clark's level is IV, <sup>12</sup> and the Breslow thickness is 1.6mm. The excision margins are shown as:

<sup>&</sup>lt;sup>11</sup> Melanomas are described according to their appearance and behaviour, and can be categorised into several types. Nodular melanomas are the most aggressive and appear to be invasive from the outset.



Invasive component:

lateral margin: 4mm deep margin: 2mm

In situ component:

lateral margin: 4mm

30. When Dr B completed this report, he had been working for a subsidiary of the pathology company for three months. He recalls that, at this time, it was his usual practice to verify his interpretation of a result indicating melanoma with a senior colleague. Dr B considers that it is possible he did so in this case, although there is no documentation to confirm it. He stated that he usually completed the written reports and responded to any follow-up telephone queries without input from a senior colleague.

#### *Telephone follow-up*

- Dr C's clinical record shows that, on 29 September 2008, he telephoned Laboratory X about the histology report. Dr C wrote in Mr A's medical centre records: "spoke to [the] pathologist -- he feels the excision is complete.-- no further surgery required". 13
- 32. Dr C told my Office that he was prompted to make the call because a melanoma had been confirmed and, in his experience, it was normal for wider excision to be recommended for melanomas. As there was no such recommendation in this report, he telephoned the pathologist to check. Dr C states he remembers the pathologist saying they had got everything. He said he asked the pathologist whether he was sure, and the pathologist reassured him that he was.
- When Dr C was subsequently asked whether he understood from this conversation that the excision included the margins recommended for melanoma, he stated that he understood the pathologist to be saying that "he's had a good look at it, and his advice is that no further excision was needed". Dr C stated that with hindsight, maybe he was falsely reassured.
- 34. Dr C does not recall who he spoke with. In addition to Dr B, there was one other anatomical pathologist working at Laboratory X on 29 September 2008. A director of Laboratory X, Y and Z, and the pathology company, Dr D, explained that when a referring doctor telephones Laboratory X to discuss a report, the usual practice is that this discussion is with the reporting pathologist. Another pathologist would only discuss the case if the reporting pathologist was on leave or had resigned, and this

(Invasive melanoma occurs where cancerous cells have grown into the deeper layer of the skin, as opposed to melanoma in-situ, which occurs where the cancerous cells are confined to the skin's outer layer.) Although the primary cause of most melanomas is exposure to ultra-violet radiation in sunlight, nodular melanomas have little or no relationship to sun exposure.

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12 The Clark's Level (I to IV) refers to the anatomical layer at which cells are seen and is another measure of the "level" (in addition to the "Breslow" measure). This is different from the stages I-IV noted in paragraph 14.

<sup>&</sup>lt;sup>13</sup> The punctuation shown in this sentence is consistent with Dr C's record. The audit history of the record was checked and this confirmed the entry was made on the date specified, with no changes.

would require the deputising pathologist to access the slides, review the material microscopically, and review the wording of the original report.

- There is no contemporaneous record to confirm that the pathologist Dr C spoke to was Dr B. Dr B stated that it was common for GPs and specialists to seek further information or clarification in relation to pathology reports and results, and that he had many such conversations. He does not recall a telephone conversation with Dr C, but accepts that he may have been the pathologist in question.
- or B acknowledges that he was not aware that it was usual practice in New Zealand to undertake wider excision for melanoma. Accordingly, he considers it is entirely possible that he advised Dr C that further surgery was not needed. Dr B accepts that the information as recorded by Dr C (that the excision was complete and further surgery was not required) was consistent with his understanding at the time.
- When Dr B was subsequently asked by HDC for further information about the basis for his understanding in relation to clearance margins for melanoma, he stated:
  - "...I have no scientific basis nor did I ever claim to know definitively what any clinician should do or should have done therapeutically with any patient. If I implied any clinical guidance in any way, such implication would have been a medical misadventure on my part."

#### Dr C's follow-up with Mr A

- 38. Clinical records show that Dr C discussed the histology with Mr A at an appointment on 2 October 2008. Dr C noted: "histology discussed ROS [removal of sutures]". Dr C subsequently stated that he believes he would have shown Mr A the report, told him that he was a "lucky guy", and advised that they did not need to do anything further.
- 39. Mrs A recalls her husband telling her about the histology results at the time: he said that it was a malignant melanoma, but that it had been fully excised and there was nothing to worry about. She recalls him telling her that Dr C had shown him the pathology report on his computer.
- 40. Mrs A states that her husband was "au fait" with his health, he was a runner, and he was very fit and health conscious. She said that he was fair-skinned, and that they were both very aware of the need to be careful in the sun. She said the scar on his leg where he had had the melanoma removed in 1990 was a "massive thing".

#### September 2009

A year later, on 25 September 2009, Mr A consulted Dr C in relation to a lump in his left axilla (armpit). The clinical record shows:

"Subjective

lump left axilla — felt it yesterday for the first time".

Objective

 $2cm \times 2cm \text{ mobile lump} = = gland$ 

No other glands and skin, abdo, chest and ent [ears nose and throat] = nad [no abnormality detected] referred surgeon for biopsy"

42. Dr C referred Mr A to general surgeon, Dr E, the same day. The written referral states:

"Presenting problem: enlarged gland left axilla

Thank you for seeing [Mr A]

Relevant notes are as follows: This man is normally quite healthy and not on any medication. He now presents with a large mobile gland in his left axilla that he noticed only a few days ago. Your advice and suggestions regarding treatment will be appreciated -- ?? for biopsy."

- Dr C subsequently told HDC that he did not include the information about the melanoma in 2008 because "it didn't ring a bell". He said that for him, there was no relevance between the melanoma excised from Mr A's back the year before, and the lump under his arm. He also noted that Dr E was able to get the history himself. Dr C stated that his failure to mention the melanoma in his referral letter was therefore "academical [sic] and had no bearing on the outcome of this unfortunate event".
- 44. Later that day, a receptionist at the medical centre contacted Mr A to confirm an appointment with Dr E on 5 October 2009.

*Appointment with Dr E — 5 October 2009* 

- 45. Dr E reviewed Mr A as arranged. Mrs A attended the appointment with Mr A, but was not present when Dr E completed the physical examination. Following the consultation, Dr E sent Mr A for a fine needle aspirate (FNA) of the lump and repeat blood tests. 14
- 46. The FNA was reported by Dr B at Laboratory X the same day. It states that the smears were of low cellularity, with a few groups of benign fat cells raising the possibility of a lipoma. It was noted that there was no sign of any malignant cells. Under diagnosis, Dr B wrote "LOW CELLULARITY" and "FEATURES CONSISTENT WITH A LIPOMA".
- 47. In a letter to Dr C dated 6 October 2009, Dr E noted that Mr A had had a malignant melanoma removed from his leg in 1990, and a number of benign lesions removed from his back approximately three years previous. Dr E noted his examination findings: three surgical scars on Mr A's back, a 3cm palpable lump in his left axilla, and a palpable 5mm lymph node in his right axilla. It was noted that there were no suspicious skin lesions. Liver, spleen and kidneys were not palpable and there was no lymph adenopathy (swelling) in the groin.

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<sup>&</sup>lt;sup>14</sup> FNA is a minor surgical procedure in which a hollow needle is inserted into a mass or lump just under the skin, to extract cells for examination.

<sup>&</sup>lt;sup>15</sup> A benign tumour.

- At the end of his letter Dr E added that the result of the FNA suggested a lipoma. Mr A was due to go overseas on 9 October 2009, and Dr E noted that he would see Mr A on his return for a surgical excision of the lump.
- Mrs A recalls Dr E telling them that the FNA indicated the lump was benign. She recalls that her husband asked if he should cancel his trip, but that Dr E noted that the result indicated the lump was benign and that men in his age group do sometimes get benign lumps.
- Dr E subsequently told HDC that, when he saw Mr A on 5 October 2009, "both the patient and myself were not aware a melanoma had been removed from his back in 2008". 16 Dr E's handwritten consultation note includes reference to the 1990 melanoma, but there is no mention of the 2008 melanoma.<sup>17</sup>
- Mr A was away for about a month, and saw Dr E again on 2 December 2009. Dr E noted that the lump felt firmer in nature and that it might be a lymph node. Mr A was booked to have an excision of the left axillary lump at a private hospital on 15 December 2009. Mrs A recalls that this was the earliest appointment available.
- The operation proceeded as scheduled. Dr E excised a single 3x3cm lymph node, which was sent to Laboratory X for analysis.

#### Metastatic cancer confirmed

- At a follow-up appointment with Dr E on 24 December 2009, Mr and Mrs A were informed that the pathology report had confirmed metastatic malignant melanoma. Dr E referred Mr A for MRI scans of his head, neck, chest, abdomen and pelvis, and to the oncology clinic at the public hospital. In his follow-up letter to Dr C, Dr E noted his intention to ask for a review of the specimens excised from Mr A's back in the previous two to ten years.
- Mr A had CT and MRI scans on 12 January 2010, which confirmed metastatic disease within the left axilla, and further lesions in his lungs, liver, and brain.
- On 15 January, Dr C visited Mr and Mrs A at home to discuss the diagnosis.
- Mr A had a further appointment with Dr E on 18 January 2010. In his follow-up letter to Dr C, Dr E noted that he had reviewed the pathology reports and that it seemed the likely source of the metastatic melanoma was the lesion excised in September 2008.
- Mrs A recalls that after returning home from the hospital that day, she went to see Dr C and challenged him over his care of her husband. She recalls Dr C telling her that he considered he had exercised all reasonable care and that medicine was "not an exact science".

Dr E was subsequently asked whether he considers his management of Mr A would have been different if he had known about the recent melanoma. Dr E stated that he believes his approach would have been "a bit more aggressive".



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<sup>&</sup>lt;sup>16</sup> Dr E and Mrs A had conflicting impressions as to whether Mr A was aware that the 2008 lesion was a melanoma. When asked further, neither Dr E nor Mrs A could explain this discrepancy.

- 58. Over the following few months, Mr A was under the care of the oncology service at the public hospital, and received treatment including palliative radiotherapy and chemotherapy.
- 59. Mr A died in the middle of 2010.

#### Further information from Dr C

- 60. In his initial response to this complaint, Dr C advised that the first mention of the 1990 melanoma excision was in Dr E's letter of September 2009. Dr C stated, "There was nothing in either my notes could have been my mistake or in [Dr F's] notes, suggesting anything about the previous [1990] melanoma".
- 61. However, contrary to Dr C's assertion, it is clear that he had documented the 1990 melanoma on Mr A's immigration medical examination report in 2006. When a copy of this was obtained and drawn to Dr C's attention subsequently, he noted that this documentation was completed prior to Mr A registering at the medical centre, and therefore not retained by the practice. He noted that immigration forms are completed by hand and that "therefore no record is kept of the information therein".
- or C recalls that at some point he saw the scar on Mr A's leg where the lesion had been excised in 1990, and that it was quite big and noticeable. He does not recall when they discussed this. Dr C stated that he did not think it was something he had to deal with: "If somebody has been clear of a melanoma for ten or fifteen years, you accept that they've been cured".
- or C was asked whether it was his usual practice to review a patient's history prior to a consultation. He explained that he does not do this at the beginning of the day, as he does not necessarily know in advance who he will be seeing. He stated that if he is seeing a patient he has not seen before or for some time, he tries to have a quick look at the records before or during the consultation.
- 64. With regard to the care he provided to Mr A in September 2008, Dr C stated:

"From my point of view I took all precautions, firstly by excising the lesion and not waiting, secondly by sending the specimen away for histology and thirdly when the report came back I was not willing to accept a non-recommendation of wider excision and phoned the pathologist who gave me the assurance that no wider excision was needed. Besides overriding the pathologist's recommendation [there] was nothing else I could have done."

65. Dr C subsequently stated that with the benefit of hindsight he would have acted differently, and that his "failure to take action is to be blamed on taking the word of a qualified pathologist".

HX

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<sup>&</sup>lt;sup>18</sup> Dr F had seen Mr A in April 2006 at another practice for an employment medical. That practice was subsequently bought by the medical centre and the records for Dr F's patients were incorporated into the medical centre's records. However, patient records were not transferred until early 2009 (between January and April). Accordingly, Dr F's records were not available to Dr C when he saw Mr A in September 2008.

- Dr C noted that it is his usual practice to complete a physical examination of all patients at each appointment.
- Dr C noted the pressure that GPs work under, particularly the number of patients they see and the limited time available for consultations. He stated that he now makes an effort to spend more time obtaining information from patients, and documenting this and his findings.

Further information regarding Dr B

- Dr B was recruited from overseas, and had arrived in New Zealand with certification in histopathology and cytopathology. He was employed by a pathology company subsidiary on a fixed-term contract from mid 2008.
- Dr B was registered with the Medical Council of New Zealand (MCNZ) within a provisional general scope of practice, with the expectation that he would complete the necessary requirements to become a fully registered specialist pathologist.
- MCNZ requires doctors who have qualified in a comparable health system, and who are working within a provisional general scope of practice, to work under supervision for a minimum of 12 months. It is noted in the MCNZ guideline that was current at that time:

"Supervision is time limited and is flexible depending on the doctor's competence. Close supervision is required in the beginning, and decreases over time once the supervisor becomes comfortable about delegation and increasing the doctor's independence.<sup>19</sup>

The guideline states further:

"At a minimum, the supervisor is expected to meet the doctor:

- daily for the first week
- weekly for the first three months, and
- monthly after that."<sup>20</sup>
- Dr B was initially based at Laboratory Y.<sup>21</sup> He transferred to Laboratory X during the week beginning 22 September 2008. The pathology company stated that Dr B was initially located at Laboratory Y "where he could be closely supervised and made familiar with New Zealand specific guidelines and protocols". Dr B was found to have made good progress at which time the level of supervision was relaxed and he was transferred to Laboratory X.
- Dr B recalls that he was supervised daily for the first few months of his employment, either by his clinical supervisor, Dr D, or other senior colleagues. He states that he

<sup>&</sup>lt;sup>21</sup> Laboratory Y is also a subsidiary of the pathology company.



<sup>&</sup>lt;sup>19</sup> Medical Council of New Zealand, Induction and Supervision of Newly Registered Doctors (Wellington: Medical Council of New Zealand, May 2007), page 18.

Medical Council of New Zealand, Induction and Supervision of Newly Registered Doctors (Wellington: Medical Council of New Zealand, May 2007), page 19.

was started off with double signature reporting and a review of all of his work at a multi-headed microscope, in either Laboratory Y or X. Dr D advised that at the commencement of Dr B's contract there was double reporting of all his work, and that this had ceased by 1 September 2008. After that time, Dr D or another senior pathologist would review cases of interest or difficulty with Dr B on the multi-headed microscope. Dr D stated that the pathology company's guideline for all pathologists is for around 5% of cases to be reviewed with other pathologists.

- 74. Dr D noted that, in August 2008, he took up a full-time position as Clinical Director of Histology/Cytology, but that he continued to meet with Dr B for weekly supervision.
- 75. Dr B has stated that in light of this complaint, he has resolved to make a telephone diary record of telephone contact with referring doctors. He notes that this will enable him to recall details of cases after the telephone call, and allow him to review the material and any issues arising from the clinico-pathological correlation.

*Further information from the pathology company* 

- 76. At the time of these events, Dr B was in the process of applying for vocational registration through the Medical Council of New Zealand (MCNZ). The pathology company stated that they did not have formal induction and training policies and protocols in place, because of the MCNZ mandated orientation and supervision programme. It was also noted that Dr B was only the third pathologist they had employed who did not have automatic specialist registration in New Zealand.
- 77. Since these events, the pathology company has made several changes in relation to the recruitment and supervision of senior staff. Formal induction policies and protocols for pathologists have been developed. A copy of the "Induction and Supervision Plan" template now being used has been provided to HDC.

ACC

On 30 July 2010, a Treatment Injury Claim was submitted to ACC. ACC obtained expert clinical advice from a general practitioner and a pathologist. Both commented that the management of Mr A's melanoma was not in accordance with guidelines and/or accepted practice, but considered that it was not certain that this would have influenced the outcome for Mr A.

#### **Opinion: Breach — Dr C**

- 79. The focus of this investigation in relation to Dr C is the appropriateness of the care and treatment he provided to Mr A between September 2008 and December 2009.
- 80. I note that HDC clinical advisor Dr Maplesden, my pathology expert Dr Allen, and ACC's expert advisors all acknowledge that even if Mr A's treatment had been in accordance with expected standards and/or relevant guidelines, the final outcome may

have been no different. It is not the Commissioner's role to determine or comment on whether the care and treatment provided to Mr A altered the outcome — in particular, whether Mr A's death could have been prevented or delayed. However, I do find that Dr C failed to provide Mr A with services of an appropriate standard during this period, in several respects.

Melanoma excision and referral to Laboratory X — September 2008

- The Melanoma Guidelines had not been published when Dr C excised the mole from Mr A's back in September 2008. Accordingly, I have considered the care and treatment provided by Dr C in relation to accepted practice at that time. Dr Maplesden confirms that the Melanoma Guidelines did not recommend different treatment or management from that which was accepted and usual practice in September 2008.
- 82. On 19 September 2008, Mr A consulted Dr C about a blocked ear and the mole on his lower back. Dr C states that he endeavours to review a patient's records prior to or during a consultation if he sees a new patient or a patient he has not seen recently. If he had reviewed Mr A's records, he would have been reminded that Mr A had had lesions removed two years previously, and six months previously. However, there was nothing in the records to remind Dr C of Mr A's 1990 melanoma.
- 83. Dr C does not recall whether he asked Mr A about his melanoma history at this time. There is no evidence in the clinical record to indicate that he did so. Dr Maplesden states:

"It would be common practice to ask about a personal or family history of melanoma when an abnormal pigmented lesion is detected as occurred on 19 September 2008. Melanoma is a significant lesion that requires a full and frank discussion with the patient if detected."

- 84. Mr A's melanoma history was important in two respects. Firstly, while most recurrences occur within three years, there have been reports of recurrence up to 46 years later. 22 Secondly, as Dr Maplesden notes, a history of previous melanoma or non-melanoma skin cancer increases the risk of subsequent melanoma. Dr C is incorrect in his assertion that a melanoma more than ten or fifteen years previously is of no relevance.
- 85. On 24 September 2008, Dr C excised the lesion and sent it to Laboratory X. The information Dr C provided with the specimen was minimal, indicating only "Back". As Dr Maplesden states, this was inadequate. There should have been some description of the lesion and, ideally, relevant patient history.
- 86. The Medical Council of New Zealand's publication "Good Medical Practice A guide for doctors" (2008) sets a professional standard for referring patients. It states:



<sup>&</sup>lt;sup>22</sup> Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand (New Zealand Guidelines Group, 2008).

"When you refer a patient, provide all relevant information about the patient's history and present condition." <sup>23</sup>

- 87. A pathology request is a crucial communication document between treating physicians and histopathologists. A lack of information in the request compromises the pathologist's ability to correctly report specimens.
- 88. While, in this instance, the paucity of information provided by Dr C may not have influenced the diagnosis, this cannot justify practice that does not comply with professional standards, and has the potential to compromise patient care and safety.

Communication with pathologist

89. Dr Maplesden states in his advice:

"[I]t is my opinion that most GPs would be aware of the prognostic implications of a thick nodular melanoma (in [Mr A's] case Breslow depth 1.6mm) and the realisation that wide excision and specialist review is generally recommended in these cases."

- 90. Dr C received the pathology report on 29 September 2008. This confirmed a melanoma, which it stated had been "completely excised". In light of his previous experience with melanomas, Dr C expected to see a recommendation for wider excision. As there was no such recommendation, Dr C telephoned Laboratory X for clarification, and spoke with a pathologist.
- The only contemporaneous record of this conversation is Dr C's entry in the medical centre's records, which indicated that the pathologist considered that the excision was complete. On the basis of this conversation, Dr C noted also, "no further surgery required". It is not clear whether the pathologist explicitly stated that further surgery was not required, or whether Dr C inferred this.
- 92. If the pathologist stated explicitly that further surgery was not needed, Dr Maplesden's advice on this point becomes pertinent. Dr Maplesden states that in these circumstances, Dr C's actions were in accordance with the practice of obtaining and following advice from a specialist when in doubt, and therefore cannot be deemed a departure from expected practice. Commenting on the basis that Dr C was told that further surgery (wider excision) was not needed, Dr Maplesden states:

"[Dr C's] decision was made in good faith and on the advice of a specialist and although many of my peers would have questioned such advice, a significant number may have been reassured by it."

93. However, if the pathologist confirmed only what was in the written report, that is, that the melanoma had been completely excised, the problem lay in Dr C's interpretation of that information.

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<sup>&</sup>lt;sup>23</sup> Medical Council of New Zealand, *Good Medical Practice: A guide for doctors* (Wellington: Medical Council of New Zealand, 2008), page 16.

While Dr C recalls his understanding at the end of this conversation, his entry in the clinical record is ambiguous. In these circumstances, I do not consider that I have sufficient information to determine definitively whether the issue is one of misleading information from the pathologist, or misinterpretation by Dr C.

#### *Lack of appropriate follow-up*

- 95. Irrespective of the question of whether further excision was required, there is the matter of other follow-up after the melanoma was diagnosed in September 2008.
- 96. It is unfortunate that Dr C did not seek specialist advice or review from a plastic surgeon or a dermatologist, rather than a pathologist. As discussed further in relation to Dr B, it is not usually a pathologist's role to make treatment recommendations.
- 97. As stated above, specialist review is recommended in cases such as Mr A's. Dr Maplesden considers that a significant proportion of GPs would have sought plastic surgery or dermatology expertise in deciding on an appropriate level of ongoing surveillance. No such advice was sought.
- 98. Dr Maplesden states that "it is common knowledge in general practice that formal follow-up of patients with melanoma is indicated and, if there is no specialist involvement, this task is undertaken by the GP". Accordingly, if Dr C did not seek specialist review, he should have arranged to provide appropriate follow-up himself.
- There is no evidence of any follow-up with Mr A, planned or actual, after he had his sutures removed on 2 October 2008. Dr C stated that, in light of the pathologist's reassurance, he understood that the melanoma had been completely excised and that he was not required to do anything further. This was not an acceptable approach to take. Dr C should have recognised the need for some form of follow-up for the period following the excision of the melanoma. I agree with Dr Maplesden that the follow-up arrangements put in place by Dr C were inadequate.

#### Information provided to Mr A

- 100. It is puzzling that Mr A told Dr E that he had had lesions removed in recent years and about the 1990 melanoma, but apparently did not mention the melanoma removed the previous year, even in the context of Dr E conducting a physical examination and noting the surgical scars on his back.
- 101. However, Mrs A recalls that her husband talked about the melanoma diagnosis following his appointment with Dr C on 2 October 2008. On the basis of Mrs A's recollection and noting Dr C's clinical record, while I cannot explain why Mr A did not mention it to Dr E, I accept that Mr A had been informed by Dr C that the lesion removed in September 2008 was a melanoma.

#### Inadequate referral — September 2009

102. When Mr A presented a year later with an axillary lump, Dr C immediately referred him to Dr E. Dr Maplesden notes this was consistent with expected practice. However, the referral information provided to Dr E was incomplete. As stated above,

referring doctors are required to include all relevant information about a patient's history and condition in a referral.

- 103. It is perhaps not surprising that Dr C did not document anything in relation to the 1990 melanoma, as he had no record of this in his own notes. However, he also failed to include any reference to the melanoma he himself had excised the year before. Dr C stated that it "didn't ring a bell". It should have. As Dr Maplesden states, it would be expected practice for such relevant history to be included in a referral letter. I reject Dr C's submission that this had no bearing on the outcome for Mr A and is therefore "academical" (sic). This information should have been provided to Dr E.
- 104. I note that Dr E believes his approach would have been "a bit more aggressive" if he had known about the recent melanoma. I am aware that this is speculative, but the fact remains that when Dr E discussed his proposed management plan with Mr and Mrs A, he did not have all of the relevant information to hand. This was in part due to a failure by Dr C.

#### **Documentation**

- 105. The need for general practitioners to document their care appropriately has been highlighted in a number of previous investigations.<sup>24</sup>
- 106. As outlined in the Medical Council of New Zealand's publication Good Medical Practice — A guide for doctors (2008): "Records form an integral part of any medical practice; they help ensure good care for patients and also become critical in any future dispute or investigation."<sup>25</sup> The standard in relation to documentation requires doctors to keep clear and accurate patient records that report: relevant clinical findings; decisions made; information given to patients; and any drugs or other treatment provided. As stated in a previous opinion: "Proper record keeping is an essential part of good quality care and is one aspect of practice that is basic to clinical competence". 26
- 107. Dr C's clinical documentation was suboptimal. Dr Maplesden comments on Dr C's documentation in September 2008, when he excised the lesion on Mr A's back:

"There is no description of the lesion in question (size, colour, evolution etc) in the notes. The minor operation note does not include any reference to consent, anaesthesia, sutures, lesion being sent for histology or post-operative management or advice. There is no documented plan for ongoing melanoma surveillance [...] or that melanoma history was enquired after, either before the lesion was excised or once the histology was known."

<sup>&</sup>lt;sup>24</sup> eg, Opinions 06HDC12164 (29 February 2008), 07HDC01315 (27 July 2007), and 06HDC11343 (27 June 2007).

<sup>&</sup>lt;sup>25</sup> Medical Council of New Zealand, *Good Medical Practice: A guide for doctors* (Wellington: Medical Council of New Zealand, 2008), page 6.

<sup>&</sup>lt;sup>26</sup> Opinion 06HDC12164 (29 February 2008), page 20.

- 108. Dr C's documentation of his conversation with the pathologist at Laboratory X was also inadequate. It failed to detail who he spoke with, and failed to clearly describe the content of the conversation.
- 109. Dr C's documentation was not consistent with expected standards.

#### *Summary*

- 110. Mr A had a right to a better standard of care than he received from Dr C, in several respects.
- 111. When Dr C saw Mr A in September 2008 and identified a lesion suspicious for melanoma, he should have asked Mr A about his personal and family history of melanoma, and documented the response.
- I am unable to determine whether Dr C's decision not to undertake further excision of the melanoma in September 2008 was made on the direct advice of a pathologist, or whether Dr C reached this conclusion himself based on his interpretation of what the pathologist said. However, this did not excuse Dr C from arranging other follow-up, either by referring Mr A to a specialist plastic surgeon or dermatologist, or by taking responsibility for Mr A's follow-up himself. At the very least, Dr C should have had a clear and documented plan for the ongoing monitoring of Mr A in relation to his melanoma. In these circumstances, I find that Dr C failed to provide services with reasonable care and skill. This was a breach of Right 4(1) of the Code.
- 113. Dr C provided minimal information in his referral to Laboratory X in September 2008, omitted important information from his referral to Dr E in September 2009, and kept inadequate documentation. This was not consistent with the professional standards for referrals or documentation, and was a breach of Right 4(2) of the Code.

#### Opinion: No breach — Dr B

- 114. Dr B was the pathologist responsible for reporting on both the lesion excised from Mr A's back in September 2008, and the FNA from his axilla in October 2009.
- 115. A position statement from the Royal College of Pathologists of Australasia (RCPA) on the role of the pathologist states:

"The primary role of the pathologist is to perform or supervise tests on blood, other body fluids, body secretions and samples of tissue taken at surgery or as a part of a medical examination or autopsy. Where appropriate, the pathologist may render a clinical interpretation or consultation based on the results of the test." <sup>27</sup>

116. My pathology expert, Dr Jonathan Allen, has also referred to the Melanoma Guidelines. However, as noted previously, these were not published until after the



<sup>&</sup>lt;sup>27</sup> http://www.rcpa.edu.au

excision and reporting of Mr A's melanoma in September 2008 but are regarded as consistent with accepted practice at that time.

Biopsy report — September 2008

- On 29 September 2008, Dr B reported on the specimen that had been excised from Mr A's back by Dr C five days earlier. Dr Allen notes that Dr B's findings are presented in a proforma report in accordance with best practice. Dr Allen agrees with the significant prognostic findings: Clark's level IV, Breslow thickness 1.6mm, and no ulceration.
- Dr Allen advises that he measured the lateral clearances and found this to be 2.7mm at its narrowest point. This is in contrast with Dr B's measurement of 4mm. However, Dr Allen also states that, as the lesion is not seen to reach the surgical margins in the sections, it is "perfectly accurate to describe the lesion as completely excised". Dr Allen notes that, for a melanoma with a Breslow thickness of 1.0–2.0mm, a further 1.0–2.0cms should be excised.
- 119. There are no recommendations regarding further treatment in Dr B's written report. As noted by Dr Allen:
  - "I do not think it is mandatory or even advisable for the pathologist to include treatment recommendations, as these are properly the province of the managing primary care physician and/or surgeon, and may depend on circumstances of which the pathologist is unaware. In general, the pathologist may, at his or her discretion, add a comment or advice on treatment to the report but must take responsibility for the accuracy of this. [...] I do not consider the absence of a specific treatment recommendation in this report to be a significant omission."
- 120. Points 2 and 3 from the RCPA policy statement on the provision of specific anatomical pathology reports note:
  - "2. Any additional comment or recommendations should be carefully worded to clarify important information that may modify the management of that patient and should not make specific recommendations for management unless this has been agreed to by the clinician in clear terms.
  - 3. Consideration should be given to documenting the consultation either as a private entry or in the report."
- 121. I accept Dr Allen's advice that Dr B was correct in stating that the lesion had been completely excised, and also that Dr B was not required to provide guidance on further treatment, including the need for re-excision. Dr B's role in this situation was to accurately report the findings.

*Telephone follow-up* 

122. On 29 September 2008, Dr C telephoned Laboratory X and recalls speaking with a pathologist. He does not recall the name of the pathologist with whom he spoke, and Dr B does not recall a telephone conversation with Dr C. Dr B accepts that he

commonly speaks with referring doctors about pathology reports and results, and the pathology company advised that its usual process is for referring doctors to discuss pathology reports with the reporting pathologist. It is thus possible that Dr B spoke with Dr C, and Dr B accepts that he may well have done so.

- 123. As outlined in paragraphs 90–94, I do not consider that I have or can obtain sufficient information to determine whether, in the course of this conversation, the pathologist with whom Dr C spoke explicitly stated that further surgery (wider excision) was not required, or whether Dr C inferred this from the pathologist's confirmation that Mr A's lesion had been completely excised.
- 124. I accept Dr Allen's advice that recommendations for treatment are properly the responsibility of the referring clinician. However, if Dr B chose to give advice, either written or verbal, it was his responsibility to ensure the advice was accurate. Accordingly, if Dr B did speak with Dr C and tell him that further surgery was not required, it would have been inaccurate and misleading, and not in accordance with accepted practice. While the lesion itself was completely excised, with clearance margins of less than 10mm it was not, in terms of recommended practice, *adequately* excised.

Fine needle aspirate — October 2009

- When Mr A went to see Dr E in October 2009 with regard to the axillary lump, he was sent for a FNA. This was also reported by Dr B at Laboratory X.
- Dr Allen notes that his review of these slides was compromised by storage artefact, but that he saw no malignant cells in the specimen. He finds that in the circumstances, lipoma was a likely clinical diagnosis and, in the absence of any other cellular element in the aspirate, a reasonable suggestion.
- 127. Dr Allen suggests Dr B's report might have contained a more explicit comment, but nevertheless found that the report was not inaccurate and did comment on the low cellularity of the specimen, both in the text and the diagnosis lines.
- 128. I accept that Dr B's reporting in this instance was not inaccurate. However, as Dr Allen notes, it might have been more helpful if the non-specificity of the cytological findings had been emphasised.

#### *Summary*

129. I accept Dr Allen's advice that Dr B accurately described Mr A's melanoma as "completely excised" in the pathology report dated 29 September 2008. I note that Dr B's reporting of the FNA in 2009 was also reasonable, but could have been more helpful.

130. There was no requirement for Dr B to provide treatment advice when he reported Mr A's melanoma in September 2008. I have acknowledged the possibility that Dr B advised Dr C verbally that further surgery was not needed. If he did so, this was contrary to accepted practice. However, in the absence of sufficient evidence on this matter, I do not find that Dr B breached the Code.

#### Other comment — The pathology company

- As noted previously (see paragraph 9), Laboratory X, a subsidiary of the pathology company, was notified in relation to this investigation. This was in recognition of the fact that an employer may be held directly and/or vicariously liable for a breach of the Code by its employee. The scope of the investigation was subsequently amended, when HDC was advised that Dr B's employer was another subsidiary, Laboratory Y. HDC was then informed that during the period relevant to this complaint, Dr B was in fact employed by a third subsidiary, Laboratory Z, but his only employment agreement was with Laboratory Y. There remains ambiguity about Dr B's employment situation.
- 132. As outlined in the previous section, I have considered Dr B's reporting of Mr A's lesion in September 2008 and a Laboratory X pathologist's follow-up conversation with Dr C. I have also considered Dr B's reporting of Mr A's FNA in October 2009. While I have not found Dr B in breach of the Code, I note that the information he provided could have been improved. In these circumstances, and noting that when Dr B reported on Mr A's lesion in September 2008, he was a fairly recent arrival to New Zealand working under a provisional general scope of practice, I make the following comments.
- 133. I have identified no issues relevant to this investigation arising from the structure of the group of companies or the fact that Dr B worked at two sites. The companies responsible for the premises at which Dr B worked and the company which employed him were all under the same umbrella.
- 134. Dr B was recruited from overseas as a qualified pathologist. He commenced work at Laboratory Y on 30 June 2008. Dr B was registered by MCNZ under a provisional general scope of practice, and as such, was required to participate in an orientation and supervision programme under the auspices of the MCNZ, which he did.
- 135. Dr B was initially based at Laboratory Y so that he could be made familiar with guidelines and protocols specific to New Zealand, and for close supervision. He then moved to Laboratory X. At both locations he worked alongside vocationally registered pathologists and received regular supervision.
- 136. I note that there was no formal process in place for Dr B's induction and orientation. While Dr B was required to participate in the MCNZ program, there also needed to be an arrangement in place to ensure issues and information specific to the employer and

place of work were covered. I consider it appropriate that the pathology company has now developed formal induction policies and protocols for use with pathologists in Dr B's situation.

137. Dr Allen states that in relation to treatment, pathologists cannot be expected to have the clinical expertise to cover the range of relevant conditions. Dr B's role in this situation was to accurately report the findings. On this basis, I accept that as long as Dr B did not give advice on the treatment and management of melanoma, he was not required to be familiar with the recommended practice for treatment and management in New Zealand. Accordingly, his employer was not obliged to include information about this in his induction and orientation.

#### Other Comment — Communication between providers

- I have some concern about the potential for miscommunication between GPs and pathologists if they do not share the same understanding and expectations in relation to the pathologist's role in the provision of information to guide treatment or management. Dr C states that he expected a recommendation for wider excision, on the basis of previous reports he had received containing such advice.
- 139. Dr Allen highlights the potential risks with pathologists providing treatment advice or recommendations, given that this may depend on circumstances of which the pathologist is not aware. Where such advice is given, pathologists must ensure the accuracy of the information they provide. However, it is important that referring doctors do not misinterpret the absence of such information. If they are in any doubt as to how to proceed, advice should be sought from an appropriate specialist. The responsibility to follow up test results appropriately lies with the person who ordered the test.

#### Recommendations

- 140. I note that since these events, Dr C has retired from medical practice. I recommend that Dr C:
  - provide a written apology for his breaches of the Code, to be sent to HDC by 21 May 2012 for forwarding to Mrs A.

#### **Follow-up actions**

- A copy of the final report with details identifying the parties removed, except the
  experts who advised on this case, will be sent to the Medical Council of New
  Zealand and it will be advised of Dr C's and Dr B's names, with a
  recommendation that it considers a review of Dr C's competence should he seek
  to practice again in the future.
- A copy of the final report with details identifying the parties removed, except the experts who advised on this case, will be sent to the DHB and the Royal New Zealand College of GPs, and they will be advised of Dr C's name.
- A copy of the final report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Royal College of Pathologists of Australasia, the Health Quality and Safety Commission and the Ministry of Health, and placed on the Health and Disability Commissioner website, <a href="https://www.hdc.org.nz">www.hdc.org.nz</a>, for educational purposes.

#### Appendix 1 — Clinical advice

The following advice was provided by HDC clinical advisor Dr David Maplesden on 1 July 2010.

"Thank you for the request that I provide clinical advice in relation to the complaint from [Mrs A] about the care provided to her husband, [Mr A], by [Dr C]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest.

#### 1. **Documents reviewed**

- 1.1 Complaint from [Mrs A] received 12 May 2010
- 1.2 Response from [Dr C] received 16 June 2010
- 1.3 GP notes for [Mr A] including histology reports and letters from [Dr E]

#### 2. Complaint Summary

[Deleted for brevity]

#### 3. **Provider response(s)**

- 3.1 [Dr C] states that neither my records or that of their previous doctor...reflect the fact that any statement was made regarding previous excision of a melanoma. The first mention of this was made in a letter from [Dr E] in September 2009.
- 3.2 [Dr C] notes that he took all appropriate precautions in [Mr A's] care by excising the lesion and not waiting...by sending the specimen away for histology and...when the report came back I was not willing to accept a recommendation of wider excision and phoned the pathologist who gave me the assurance that no wider excision was needed. [Dr C] notes that he is to a large extent dependent on, and followed, the specialist recommendation in this instance, and that he kept [Mr A] informed of these decisions. He notes that he is dependent on the pathologist interpretation of specimens received, as was [Dr E] when the fine needle aspiration (FNA) he undertook on [Mr A's] axillary lump showed no evidence of malignancy.
- 3.3 [Dr C] notes that he immediately referred [Mr A] for excision of the axillary lump when it was detected and both he and [Dr E] were initially reassured by the FNA report that suggested it was a benign lipoma.

#### 4. Review of clinical records

4.1 GP notes are generally very brief. Those for 19 September 2008 state *mole back and left ear blocked...ears syringed and tcb for excision mole*. Blood pressure and pulse are recorded. The notes for 24 September 2008 read, in their entirety, *excision mole on left side back*. Note for 29 September 2008

- states spoke to [the] pathologist he feels the excision is complete no further surgery is required. On 2 October 2008 histology discussed—ROS. I cannot see anywhere that formal melanoma follow-up was arranged or undertaken.
- 4.2 Histology report 24 September 2008: the clinical details are recorded as *Back*. I presume these are the details provided by [Dr C] to the pathologist on the histology request form. Diagnosis is recorded as *Malignant melanoma*, *completely excised...vertical growth phase melanoma synoptic report...Melanoma type: nodular, Clark's level IV, Breslow's thickness: 1.6mm*. There is no lymphovascular invasion seen but the lesion extends into the mid-reticular dermis. Excision margins are 4mm laterally and 2mm depth. There is no management advice recorded on the report.
- 4.3 A swollen knee is recorded on 26 March 2008 and eventually leads to orthopedic referral. An MRI of the right knee is undertaken on April 2009 and shows osteoarthritis and loose bodies. Conservative management is recommended by the orthopedic surgeon. There are consultations recorded on 28 July 2009 (lower back strain) and 8 August 2009 (stress).
- 4.4 Note for 25 September 2009: lump left axilla felt it yesterday for first time...2cmx2cm mobile lump==gland, no other glands and skin, abdo, chest and ent=nad, referred surgeon for biopsy. The referral note is dated 29 September 2009 with the history, in its entirety, being This man is normally quite healthy and not on any medication. He now presents with a large mobile gland in his left axilla that he noticed only a few days ago. Your advice and suggestions regarding treatment will be appreciated ??for biopsy.
- 4.5 Report from surgeon [Dr E] dated 6 October 2009 notes *Thank you for referring [Mr A] with a left axillary lump for a week's duration...He had a malignant melanoma excised from his left leg in 1990 while [overseas]. Follow up had been normal. He also had a number of benign lesions removed from his back approximately three years ago...A 3cm palpable mobile lump was noted in the left axilla...examination was otherwise unremarkable...I have sent him for a fine needle aspirate of the left axillary lump...PS The FNA done on the 5<sup>th</sup> October 2009 suggested a lipoma. [Mr A] is going [overseas] on the 9<sup>th</sup> October 2009. He will contact me when he is back for surgical excision of the lump. Review takes place on 8 December 2009 where [Dr E] notes the lump to be firmer in nature and may be a lymph node. Excision at [a private] Hospital is undertaken on 15 December 2009. This unfortunately confirms metastatic malignant melanoma and CT and MRI scans on 12 January 2010 show brain, liver and lung metastases.*
- 4.6 Histology of the fine needle aspirate is reported on 5 October 2009 by Dr B. Clinical details are *History of melanoma left leg now with lump in*

subcutis of left axilla. Diagnosis is Low cellularity, features consistent with a lipoma.

4.7 In a letter from [Dr E] to [Dr C] dated 5 January 2010, [Dr E] notes the unexpected finding of melanoma in the axillary gland and reiterates: He had a melanoma excised from the left leg in 1990 [overseas]. He has a number of benign skin lesions removed from his chest and back in the last 2-10 years. I will try to get the pathologist to review these specimens. In a letter to [Dr C] dated 19 January 2009, [Dr E] states I have reviewed his pathology reports. It does seem the likely source of the metastatic melanoma was the lesion from the left back which was reported as Clark's level IV, Breslow thickness 1.6mm malignant melanoma, dated 2008. [Dr E] refers [Mr A] for oncology review and palliative radiation for the brain disease is commenced in March 2010 after [Mr A] becomes symptomatic having been previously very well (running up to 20km at a time). Any further care is palliative in nature.

#### 5. Comments

5.1 Background and initial clinical management:

There are local guidelines relevant to this case<sup>28</sup>. [New Zealand and Australia have the highest incidence of melanoma in the world. It is my impression that there is a high level of awareness of the disease in primary care, although I would not expect all GPs to be aware of the clinical guidelines or to access them. However, it is my opinion that most GPs would be aware of the prognostic implications of a thick nodular melanoma (in [Mr A's] case Breslow depth 1.6mm) and the realisation that wide excision and specialist review is generally recommended in these cases, and that some form of formal follow-up is generally undertaken for a period following excision. At the same time, I acknowledge that [Dr C] did seek specialist (pathologist) advice regarding the immediate management of the lesion following diagnosis specifically the need for further excision. He was evidently advised that such excision was not required which is inconsistent with the guidelines. He cannot be blamed for being given such advice, which he subsequently followed, although it is my opinion that a significant proportion of my peers would have sought plastic surgical or dermatology expertise in deciding what surveillance was recommended (separate to the question of re-excision) and it is likely [Mr A's] subsequent management would have been quite different had such advice been sought. It should also be noted that a history of previous melanoma or non-melanoma skin cancer increases the risk of subsequent melanoma and the guidelines advise 6-

<sup>&</sup>lt;sup>28</sup> NZGG. Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand. Published November 2008. In relation to the key issues relevant to Mr A's situation, the Melanoma Guidelines did not recommend different treatment or management from that which was accepted and usual practice in primary care in September 2008 when Mr A's lesion was removed.

monthly clinical review of the skin in such patients. This emphasises the importance of actively obtaining relevant history in patients with skin lesions. Other extracts from the guidelines relevant to this case are noted below:

- (i) Following the diagnosis of primary cutaneous melanoma, (stage I, II) routine investigations are not required for asymptomatic patients. This advice was followed.
- (ii) Patients suspected of having lymph node metastasis from cutaneous melanoma should undergo fine needle aspiration biopsy, with ultrasound or radiological guidance when required, to confirm the presence of stage III disease. I note this was undertaken in [Mr A].
- (iii) Treatment of primary melanoma: The optimal biopsy approach is complete excision with a 2mm margin and upper subcutis this approach was taken by [Dr C]. After initial excision biopsy; the radial excision margins, measured clinically from the edge of the melanoma, should be:
  - 1. (pTis) Melanoma *in situ*: margin 5mm
  - 2. (pT1) Melanoma < 1.0mm: margin 1cm
  - 3. (pT2) Melanoma 1.0–2.0mm: margin 1–2cm
  - 4. (pT3) Melanoma 2.0–4.0mm: margin 1–2cm
  - 5. (pT4) Melanoma > 4.0mm: margin 2cm

Lesions excised with a margin less than those defined above should be re-excised as soon as practicable to achieve these margins. Depth of excision in usual clinical practice is excision down to but not including the deep fascia unless it is involved. [Mr A's] lesion was pT2 with a recommended margin of 1-2cm. The histological margin was 2-4mm and was therefore less than that recommended, although the pathologist evidently advised [Dr C] that no further excision was required.

- (iv) Treatment of most melanomas can be achieved on an outpatient or day-surgery basis, under local anaesthesia, unless nodal surgery is required. It was therefore appropriate for [Mr A's] initial treatment to be undertaken by [Dr C].
- (v) Melanoma is a risk factor for new primary melanoma(s) and also has the potential to recur or metastasise. For patients with deeper invasive melanomas (> 1mm thick [Mr A's] lesion was 1.6mm), referral to a specialised melanoma centre should be considered to ensure that best practice is implemented and for the collection of national outcome data. This may present logistic difficulties in regional and remote areas, but specialist care is recommended. There was no formal specialist referral of [Mr A] for further

management following the initial diagnosis, although this decision may have been influenced by the advice from the pathologist.

(vi) The AJCC/UICC (2001) system has been recommended for melanoma staging. Sentinel node biopsy (SNB) is an important prognostic factor for melanoma but there is debate about its use in treatment. SNB should be considered in patients with primary melanomas > 1.2mm thick, who want to be as informed as soon as possible about their prognosis. SNB should be performed before wider local excision.

Patients with a melanoma greater than 1.0mm in thickness should be given the opportunity to discuss sentinel lymph node biopsy to provide staging and prognostic information. This aspect of management was not evidently discussed with [Mr A].

(vii) Follow-up intervals are preferably six-monthly for five years for patients with stage I disease, three-monthly or four-monthly for five years for patients with stage II or III disease, and yearly thereafter for all patients. Ultrasound may be used in conjunction with clinical examination only in the follow-up of patients with more advanced primary disease. For patients enrolled in clinical trials, the above recommendations may vary in accordance with the follow-up protocols of these trials.

While it is important that clinicians weigh up the advantages and disadvantages of undertaking routine follow-up, individual patient's needs should be considered before appropriate follow-up is offered. It is not apparent that [Mr A] was offered any formal follow-up once he had had his sutures removed.

In summary, and taking into account this discussion, it is clear that [Dr C] followed recommended guidelines in terms of his decision to perform an excision biopsy with at least 2mm margins of a (presumably) suspicious lesion. The fact that he did not seek and obtain a history of previous skin malignancy is not ideal, but is probably at most a mild departure from accepted practice. The pathologist considers, to some extent, the data provided by the clinician when a histology specimen is submitted. The accompanying description of Back (see 4.2) is inadequate – expected practice would be that there is some description of the lesion eg changing pigmented lesion or suspicious pigmented lesion etc, and ideally relevant past history should be included. However, in this case the paucity of accompanying data did not influence the diagnosis. The decision by [Dr C] not to undertake a wider excision was not consistent with accepted guidelines but was made after consultation with a relevant specialist. As such, I do not think this action can be deemed a departure from accepted practice (ie, the practice of obtaining and following a specialist recommendation when in doubt), but I recommend that an expert pathologist opinion be obtained regarding this aspect of [Mr A's] care after a response from [Dr B] has been received. It is not clear whether follow-up or surveillance advice was given by the pathologist, and the overall content of the advice given to [Dr C] may be clarified in [Dr B's] response. Based on the information available to me, it is my opinion that the follow-up arrangements put in place by [Dr C] were inadequate and departed from expected practice to a moderate degree. It is unclear whether surveillance as per the guidelines would have altered [Mr A's] final outcome but it is apparent he was denied the chance to consider specialist assessment and follow-up and early sentinel node biopsy.

#### 5.2 Clinical documentation:

Clinical documentation by [Dr C] is sub-optimal. There is no description of the lesion in question (size, colour, evolution etc) in the notes. The minor operation note does not include any reference to consent, anaesthesia, sutures, lesion being sent for histology or post-operative management or advice. There is no documented plan for ongoing melanoma surveillance (see above) or that melanoma history was enquired after, either before the lesion was excised or once the histology was known. While I agree with [Dr C] that his approach in immediately excising the lesion and sending it for histology was consistent with best practice, the supporting clinical documentation departed from accepted practice to a mild to moderate degree.

#### 5.3 Subsequent management:

[Dr C's] approach of immediately referring [Mr A] to [Dr E] when an axillary lump was detected was consistent with expected practice. [Mr A] was apparently very well and active with the lump being his only complaint. However, it is clear from [Dr E's] letters to [Dr C] in January 2010 that he was not aware of [Mr A's] history of nodular melanoma excision in 2008 until he ordered a pathologist review of the skin lesions [Mr A] had had removed in the preceding few years. [Dr E] was conscientious in gaining a history of melanoma some two decades previously. It is somewhat puzzling that [Mr A] did not recount the more recent melanoma history given the discussions with [Dr C] that had taken place after excision of the lesion. I am not sure whether [Dr E] would have altered his management of [Mr A] had he been aware of this history, and it may be difficult to gain his opinion without the influence of hindsight. Nevertheless, I think there is some value in obtaining his response as it is my opinion that this piece of history (without the benefit of hindsight) had the potential to be very relevant to [Mr A's] management and should have been included in the referral letter. In my opinion, failure to include such relevant information in a referral letter would be met with moderate disapproval by my peers. Management undertaken by [Dr E] was consistent with expected practice - the axillary lump did not feel malignant and FNA was consistent with a lipoma. It was therefore reasonable to adopt a semi-urgent approach to excision of the lump and allow [Mr A] to complete his planned overseas trip before excision took place. It is unclear whether [Dr E] would have been more aggressive with his management had he been aware of [Mr A's] more recent history of nodular melanoma.

#### 6. Clinical advice

- 6.1 On the basis of the records available to me, and referring to comments in section 5, I am of the opinion that the clinical management of [Mr A] by [Dr C] departed from expected standards to a mild to moderate degree with respect to aspects of his clinical documentation discussed above, and his failure to institute appropriate post-diagnosis surveillance of [Mr A]. [This section has been redacted as it is not relevant to the clinical advice] [Dr C's] decision not to undertake a wider excision of [Mr A's] melanoma was made in good faith and on the advice of a specialist and although many of my peers would have questioned such advice, a significant number may have been reassured by it.
- 6.2 On the basis of the records available to me, and referring to comments in section 5, I am of the opinion that the clinical management of [Mr A] by [Dr B] requires expert review following receipt of a response from [Dr B]. The content of the advice given by [Dr B] to [Dr C], and the basis for this advice, needs to be clarified. There may be some value in a reexamination of the FNA sample undertaken by [Dr E] and interpreted by [Dr B] on 5 October 2009.

Dr David Maplesden
Clinical Advisor
Health and Disability Commissioner
Auckland."

The following advice was provided by HDC clinical advisor Dr David Maplesden on 20 August 2010, after further clinical records had been obtained from Dr C.

"Thank you for requesting comments on the further clinical GP notes received regarding [Mr A]. I have examined these and make the following comments:

1. The additional notes run from April 2006 to the end of 2007. On 21 June 2006, [Dr C] performed an Immigration Medical examination on [Mr A] and on 29 June 2006, he records finalising the immigration report. Part of the immigration medical involves completion of quite a detailed personal and family medical history including specific questions regarding a history of skin disorders, operations or cancer. Unless [Mr A] deliberately withheld the information regarding his history of melanoma removal from his leg at this point, it is my opinion that such history would have been obtained by [Dr C] and ideally should have been recorded in his file. I can see no such record in the notes available to me. However, without seeking a copy of the immigration medical notes from the relevant government department, it is impossible to confirm whether the information was obtained.

- 2. [Dr C] performed a punch biopsy of a lesion on [Mr A's] back on 4 October 2006. The lesion was a basal cell carcinoma and was excised by [Dr C] on 12 October 2006 with histology explained to [Mr A] on 19 October 2006. Written consent for surgery was obtained on this occasion. There is no recording of the past history of melanoma on this occasion.
- 3. There is no additional information in the notes examined. There are several puzzling aspects relating to the issue of [Mr A] recounting his history of melanoma in this case. It would be common practice to ask about a history of skin lesions or cancers when an abnormal lesion is detected as occurred in October 2006. It would be common practice to ask about a personal or family history of melanoma when an abnormal pigmented lesion is detected as occurred on 19 September 2008. Melanoma is a significant lesion that requires a full and frank discussion with the patient if detected. [Dr C] records *histology discussed* when he saw [Mr A] on 2 October 2008 following the second melanoma removal yet again there was apparently no mention of the previous history of melanoma. Even more puzzling was the fact that when [Mr A] saw [Dr E] in October 2009 he readily admitted to the history of leg melanoma in 1990 but seemed to be under the impression that no significant lesions had been removed since then. I can state these facts but I am unable to comment further.
- 4. In summary, there appear to have been several opportunities at which I would have expected the past history of leg melanoma to have been obtained by [Dr C]. However, it is certainly not unheard of for patients to withhold information either because they do not think it is relevant or for other unstated reasons so it cannot be assumed that the information was supplied but not recorded by [Dr C]."

The following advice was provided by HDC clinical advisor Dr David Maplesden on 9 September 2010, after further information was obtained from Immigration New Zealand.

"Thank you for providing documentation from NZ Immigration regarding this case. I make the following comments:

- 1. On 21 June 2006, [Dr C] has signed an immigration medical form for [Mr A]. This implies that he has assisted [Mr A] in completing the medical questionnaire and/or reviewed the content of the medical questionnaire in order to make the comments required later in the form regarding any medical recommendations. It also implies he has personally undertaken a medical examination of [Mr A].
- 2. Facts provided by [Mr A] in the medical questionnaire, and recorded by [Dr C], include:
  - (i) section B1 excision melanoma L leg (1990)

- (ii) section B22 melanoma excision L leg in 1990
- (iii) section B24 melanoma (already mentioned)
- 3. In the section "Medical Examiner's comment (if any) on applicant's medical history, [Dr C] has written *normal history melanoma 16 years ago cured*. Pages 8 and 9 of the document have not been provided this includes the majority of the medical examination including observation of scars. <sup>29</sup> However, under the examination summary comments [Dr C] has recorded *normal examination*.
- 4. For some reason [Mr A] had undergone an identical examination by [another doctor], on 27 February 2006.<sup>30</sup> In her summary of the medical history she included the comment *previous melanoma* in 1990 No recurrence. He has been monitored since the surgery. In her examination summary comments she states [Mr A] needs regular skin checks in view of his previous melanoma history. Mole mapping would be useful. It is unlikely that [Dr C] had access to these previous immigration medical notes.
- 5. In my opinion, it is clear from the documentation supplied that [Dr C] was aware of [Mr A's] past history of melanoma in 1990 having recorded it four times in the course of the immigration medical. This is significant medical history as it increases [Mr A's] risk of recurrent or new melanoma, even after 16 years. This history should have been incorporated into [Mr A's] medical file. The comments made by [the doctor on 27 February 2006] were in keeping with expected practice in terms of follow-up advice."

## The following advice was provided by HDC clinical advisor Dr David Maplesden on 16 November 2010.

"Thank you for forwarding Dr C's response to my original advice. I make the following comments:

1. I am aware the Immigration Medical documentation of 21 and 29 June 2006 was completed by hand and this is normal practice. I note [Mr A] was seen as a casual patient rather than an enrolled patient for this examination. However, an entry was made in the electronic notes that the examination had taken place. In my experience, it is common for relevant past medical history, including medication allergies, to be recorded even when a patient is seen on a casual basis. Certainly when a patient is seen for the first time as an enrolled patient, as [Mr A] was by [Dr C] in October 2006, it would be accepted practice to ask about and record any relevant past medical history whether or not old notes

<sup>&</sup>lt;sup>29</sup> A copy of pages 8 and 9 was subsequently obtained from NZ Immigration. These contained no further reference to Mr A's previous melanoma and no information regarding scars.

<sup>&</sup>lt;sup>30</sup> Mrs A subsequently explained that the first examination was completed for the purposes of obtaining a work permit, and the second examination was for her husband's application for residency.

were available. Furthermore, when a potentially abnormal pigmented skin lesion has been identified, as noted by [Dr C] in September 2008, it would be accepted practice to ask about any personal or family history of melanoma and certainly to clarify such history if current melanoma was confirmed. Thus there were several opportunities to record in the electronic notes [Mr A's] relevant past history of melanoma yet no such recording was made.

- 2. [Dr C] relied on verbal advice from a pathologist regarding the need for further excision of [Mr A's] lesion. While the advice given was not consistent with New Zealand guidelines I accept that it was probably reasonable for [Dr C] to accept the advice although I am of the opinion that a significant proportion of my peers would have recognised the need for specialist referral for wider excision and follow-up given the nature of the histology. However, I feel it is common knowledge in general practice that formal follow-up of patients with melanoma is indicated and, if there is no specialist involvement, this task is undertaken by the GP. There was no such arrangement for formal follow-up in [Mr A's] case.
- 3. [Dr C] failed to document in his referral letter to [Dr E] that [Mr A] had a recent diagnosis of melanoma removed from his back. This was highly relevant history not obtained by [Dr E] (it is unclear why [Mr A] was not aware of the diagnosis and this must raise some concerns about the adequacy of communication between [Dr C] and [Mr A] regarding the nature of the lesion) until he sought copies of the histology of [Mr A's] back lesion some three months after initially seeing him. It would be expected practice for such relevant history to be included in a referral letter. [Dr C] states *my failure to mention* recent diagnosis of melanoma] *in my referral to* [Dr E] *is therefore academical and had no bearing on the outcome of this unfortunate event.* I do not regard this as a valid excuse for failing to provide appropriate information had the relevant history been made available to [Dr E] it may well have influenced his initial conservative approach in October 2009 although I agree that the prognosis for [Mr A] would still have been poor.
- 4. I am aware of the complexities involved in providing good quality medical care in the face of time constraints and administrative burdens, and I sympathise with [Dr C] that this complaint has come as he finishes his career in medicine. However, I do not see any reason to change my original advice and recommendations which take into consideration accepted medical practice in New Zealand."

#### Appendix 2 — Independent expert pathology advice

The following advice was provided by anatomical pathologist Dr Jonathan Allen, prior to start of the formal investigation.

"I am writing to provide preliminary expert advice to the Commissioner in regard to [Mrs A's] complaint about Pathologist [Dr B].

I received a number of documents in addition to the letter of complaint, including histology reports for the excised skin lesion and lymph nodes, a cytology report for axillary FNA and cytology report for imprint of axillary lymph node. The documents also include correspondence to and from [Dr B], [Dr D], [Dr C] and [Dr E], surgeon.

I have reviewed the histological sections from the skin lesion 08A4110231 and from the axillary node 09A5398342. I have also looked at the cytology slide 09A4293604 but the material is insufficient for assessment.

#### Adequacy of [Dr B's] interpretation of the slides

The histological sections of the skin lesion show a malignant melanoma and I agree with the significant prognostic findings, i.e. the Clarke level is 4, Breslow thickness 1.6mm, and there is no ulceration. I have measured the lateral clearances and the narrowest lateral margin to my eye is 2.7mm. The deep margin clearance is 2mm. Apart from the lateral margin clearance discrepancy, I consider [Dr B's] report to be satisfactory. It is presented as a proforma report, which is in accordance with best practice and it is perfectly accurate to describe the lesion as completely excised, as it is not seen to reach the surgical margins in the sections.

The sections of the axillary lymph node confirm the presence of metastatic melanoma, as reported by [the pathologist].

#### Advice and recommendations

The most recent Clinical Practice Guidelines for Management of Melanoma in Australia and New Zealand (referred to subsequently as Guidelines document) recommend that after initial excision biopsy, the radial excision margins measured clinically from the edge of the melanoma be 1-2cms for a melanoma of Breslow thickness 1.0mm to 2.0mm. These recommendations also state that sentinel node biopsy may be considered in patients with primary melanoma of greater than 1mm Breslow thickness or Clarke level 4.

I note that no recommendations regarding further treatment are included in the written histology report. However I do not think it is mandatory or even advisable for the pathologist to include treatment recommendations, as these are properly the province of the managing primary care physician and/or surgeon, and may depend on circumstances of which the pathologist is unaware. In general, the pathologist may, at his or her discretion, add a comment or advice on treatment to the report but must take responsibility for the accuracy of this. I enclose a policy statement on the provision of specific treatment recommendation on anatomical pathology reports from the Royal College of Pathologists of Australasia. I do not consider the absence of a specific treatment recommendation in this report to be a significant omission.

I am unsure as to the exact nature of any verbal advice given in this case. In the ACC request for information form, which I assume was completed by [Dr B], he states "I can't speak to treatment" and "I don't know" on questions I and 2 from the client relating to treatment. Question 3 implies that the client believed that pathologist is required to recommend further excision, whereas this is a treatment decision to be made by the clinician. The pathologist's advice may be sought but I cannot see exactly what that was, as there is no specific treatment recommendation in the report. it is not clear to me whether the recommendation that no further surgery was required was [Dr B]'s guidance or [Dr C's] inference from a report which (accurately) stated complete excision. If [Dr B] did give advice that no further excision or assessment was warranted, then that is not in keeping with current recommendations.

#### Effect of treatment on prognosis in this case

My understanding is that wider excision of primary melanoma is to reduce the incidence of local recurrence (i.e. recurrence adjacent to the site of excision) and that it is unlikely that this makes any difference to the rate of metastasis, which is the main determinant of long term survival. I also note, from the Guidelines document, that there are two randomised controlled trials that show no evidence that a margin greater than 1cm offers any survival advantage. From the same document, it is also noted that systematic review indicates there are inadequate data to confirm a mortality difference between wider and narrower excision for primary invasive melanoma. In this case, the appearance of metastasis without any evidence of local recurrence would support the hypothesis that wider excision would have been unlikely to have altered [Mr A's] prognosis for survival.

The Guidelines also recommend that sentinel node biopsies should be discussed with patients who have a primary tumour 1.2mm to 3.5mm thick. In the Guidelines document, the multicenter selective lymphadenectomy trial has not demonstrated an overall survival advantage for patients undergoing sentinel node biopsies. Therefore, I am unable to assert that a sentinel node biopsy performed on [Mr A] would have improved his prognosis.

#### **Summary**

The histology report on the primary skin lesion is well presented and includes the prognostically important variables. The measurements of radial clearance I would correct to 2.7mm. I agree that as histologically defined, the lesion appears completely excised. Regardless of whether the lateral clearances are 2.7 or 4mm, current clinical treatment guidelines would recommend re-excision of this lesion, but I do not believe that [Dr B's] report was required to include that information.

I am not entirely clear in my own mind whether clear advice was given that no surgery was needed or whether there was a misunderstanding of the meaning of clear margins. In general, the pathologist may recommend treatment but is not required to, as this is properly the responsibility of the referring clinician. If the pathologist makes treatment recommendations, it is his or her responsibility to be aware of current recommendations.

I do not think re-excision of the primary site wound or scar would have been likely to have influenced the final outcome in this case. I am unable to provide clear evidence

that a sentinel node biopsy would have improved the final prognosis, although best practice would be for this to have been discussed with the patient.

#### I attach:

Relevant pages from Clinical Practice Guidelines for Management of Melanoma in Australia and New Zealand provided by the New Zealand Guidelines Group.

[attachment deleted for brevity]

**RCPA Policy Statement** 

The Provision of Specific Treatment Recommendations on Written Anatomical Pathology Reports, November 2008

Elective Lymph Node Dissection for Melanoma Laid to Rest Yet Again

[attachment deleted for brevity]

Neal Ready, MD; Martin A. Weinstock, MD, Commentary on: Elective lymph node dissection in patients with melanoma: systematic review and meta of randomized controlled trials Lens MB, Dawes M, Goodacre T, Newton-Bishop JA Arch Surg. 2002;137:458-461

[attachment deleted for brevity]

Yours faithfully Dr Jonathan Paul Allen FRCPA Anatomical Pathologist Surgical Pathology Unit, North Shore Hospital"

## Additional comment was sought from Dr Allen in relation to the fine needle aspirate (left axilla) reported on 5 October 2009. On 4 October 2010, Dr Allen advised by email:

"[...] The slides you sent from the FNA 09A4293604 showed some storage artefact, compromising assessment, and as the lump was excised soon afterwards, I did not consider further comment to be necessary. I can confirm that I saw no malignant cells in this specimen.

An FNA which contains scanty cellular material but includes a few adipose cells may indicate a lipoma, but the cells that would be obtained from a lipoma are identical to the cells obtained from fatty tissue which is normally present in the subcutaneous tissue. Your initial email states that the FNA was performed by the surgeon and the clinical information, as documented in the FNA report was "History of melanoma left leg now with lump in subcutis left axilla". In these circumstances, lipoma is a likely clinical diagnosis and in the absence of any other cellular element in the aspirate is a reasonable suggestion. However there is always a substantial false negative rate in fine needle aspiration biopsy inherent in the biopsy technique, a fact well appreciated by surgeons and pathologists. A final diagnosis of lipoma would therefore require clinical correlation or excision. In this case, excision was performed as the clinical

suspicion of recurrent malignancy remained especially as the lesion continued to grow.

The report might have more explicitly contained a comment along the lines of: "The material is scanty and, although consistent with a lipoma, may represent subcutaneous tissue adjacent to a lesion which has not been sampled. Clinical correlation is required". However as it stands the report is not inaccurate and it does comment on the low cellularity of the specimen, both in the text and in the diagnosis line.

It is reasonable and accurate to state that there was "no sign of any malignant cells" and "features consistent with a lipoma". The decision to re-biopsy or excise the lesion is properly made by the surgeon in the light of his clinical judgement and in this case the lesion was excised. It might have been more helpful if the non specificity of the cytological findings had been emphasised but this cannot replace clinical judgment."

## Further advice from Dr Allen in relation to the orientation/induction of overseastrained pathologists, provided verbally 1 December 2010:

"Dr Allen noted that it was reasonable to expect that any qualified pathologist is competent. Many pathologists are employed from overseas and they would not necessarily be expected to be familiar with specific New Zealand guidelines (as distinct from international best practice or guidelines from their own country). Dr Allen noted that it is not his practice to include the guidelines for melanoma management in his induction/orientation of overseas-trained pathologists.

Dr Allen reiterated that in his view, it is not necessary for pathologists to make recommendations in relation to treatment. They cannot be expected to have the clinical expertise to cover the range of relevant conditions, and many clinicians do not like to receive advice on treatment from pathologists. The pathologist's role is to accurately report the findings. However, as noted in his written report, if a pathologist does give treatment advice he or she is responsible for the accuracy of this.

Dr Allen also noted that there is a school of thought that there is no survival benefit in wider excision, and that in [Mr A's] case, there was no evidence of local recurrence."

The Royal College of Pathologists of Australasia ABN 52 000 173 231

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#### **Policy**

Subject:

The Provision of Specific Treatment Recommendations on

Written Anatomical Pathology Reports

Approval Date:

November 2008

Review Date:

March 2012

Review By:

**PPAC** 3/2008

Number:

When providing Anatomical Pathology reports it is recommended that the following principles

- 1. Prior to providing any treatment recommendations on any written Anatomical Pathology Report it is recommended that a verbal consultation with the clinician be
- 2. Any additional comment or recommendations should be carefully worded to clarify important information that may modify the management of that patient and should not make specific recommendations for management unless this has been agreed to by the clinician in clear terms.
- 3. Consideration should be given to documenting the consultation either as a private entry or in the report.
- 4. The only extra information which should be added to a report without consultation should be general information about the condition or lesion or to highlight specific features which may affect management but without offering specific management recommendations.

#### Appendix 3 — Pathology Report — 29 September 2008

#### HISTOLOGY / CYTOLOGY REPORT

OFFICE

INTERNAL MAIL ONLY

Accession number: Patient reference: NHI: Referring practitioner: Date collected: Date reported: Copy to:

Report on:

Sex: Male

Age:47

Date of birth:

Clinical details

Back.

Gross description

The specimen consists of an ellipse of skin measuring 15 x 7 x 3 mm in depth. There is a dark lesion which is either pigmented or a collection of blood slightly beneath the skin surface measuring 4 x 4

Microscopic description

Sections are of skin excised into the deep reticular dermis. Present is a malignant melanoma.

Diagnosis

SKIN, BACK, EXCISION

MALIGNANT MELANOMA, COMPLETELY EXCISED

VERTICAL GROWTH PHASE MELANOMA - SYNOPTIC REPORT

Melanoma type:

Clark's level (I - V): Breslow's thickness (mm):

nodular

1.6mm

Tumour infiltrating lymphocytes: Mitotic rate (# /mm2 or 5 HPF):

scant 1 / 5 hpf None

Regression (radial component):

Lymphovascular invasion:

None none seen

Other features:

Extends into mid reticular dermis

Excision margins (mm):

Invasive component:

lateral margin: deep margin: In situ component:

4mm 2mm

lateral margin:

4mm

Reported by: