Dr B, General Practitioner

A Medical Centre

A Report by the

Health and Disability Commissioner

(Case 13HDC00031)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. In March 2010 Mr A attended his general practice, (the medical centre) and had a consultation with general practitioner (GP) Dr B.[1] Dr B removed a mole from Mr A's right thigh. The subsequent histology report showed that the mole was "an atypical compound neavus amounting to in situ melanoma".[2]

2. On 14 May 2012 Mr A saw Dr B about a lump in his right groin. Dr B ordered an ultrasound of the lump. The subsequent ultrasound report stated that the lump was probably a reactive lymph node[3] and that options for further management would include a fine needle aspiration biopsy at that time or a follow-up ultrasound scan in four weeks' time.

3. On 18 May 2012 Mr A had a follow-up consultation with Dr B. Dr B told Mr A that the lump was benign and to return if he had any concerns. Dr B did not inform Mr A about the equivocal nature of the ultrasound report, including the suggested options for further follow-up. In addition, Dr B did not organise any structured follow-up.

4. By October 2012 the lump had grown and become painful. Mr A saw another GP at the medical centre, and was subsequently diagnosed with metastatic melanoma.

Findings

5. A reasonable consumer in Mr A's circumstances would have expected to be told about the equivocal nature of the ultrasound report. By failing to provide that information to Mr A, Dr B breached Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[4]

6. In failing to adequately consider differential diagnoses and organise structured follow-up for Mr A following the ultrasound report, Dr B did not provide services with appropriate care and skill and so breached Right 4(1) of the Code.[5]

7. Adverse comment was made about the standard of Dr B's documentation, and he was reminded of the importance of accurate and comprehensive record-keeping.

8. The Commissioner found that the medical centre did not breach the Code.

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[1] Dr B is a vocationally registered general practitioner.
[2] An atypical compound naevus is a mole with unusual features that is benign. Melanoma in situ is a superficial type of melanoma (a type of skin cancer arising from the malignant growth of pigment cells called melanocytes), wherein the melanoma cells are confined to the epidermis.
[3] A reactive lymph node is a lymph node that becomes enlarged owing to a nearby infection.
[4] Right 6(1) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive."
[5] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

Complaint and investigation

9. The Commissioner received a complaint from Mr A about the services provided to him by Dr B. The following issues were identified for investigation:

- *Whether Dr B provided an appropriate standard of care to Mr A between February 2010 and December 2012.*
- *Whether the medical centre provided an appropriate standard of care to Mr A between February 2010 and December 2012.*

10. An investigation was commenced on 7 June 2013.

11. The parties directly involved in the investigation were:

Mr A	Consumer/Complainant
Dr B	General practitioner
A medical centre	

Also mentioned in this report:

Dr C	General practitioner

12. Information from the district health board was also reviewed.

13. Independent expert advice was obtained from general practitioner Dr Jim Vause (**Appendix A**).

Information gathered during investigation

Background

14. Mr A, aged 53 years at the time of these events, had many risk factors for melanoma.

15. Mr A attended a medical centre where he usually saw GP Dr B, although on occasion he also had consultations with other GPs employed there.

Atypical compound naevus (amounting to in situ melanoma)

16. An atypical compound naevus is a mole with unusual features. According to DermNet NZ (www.dermnetnz.org), atypical naevi "are actually harmless (benign) and do not need to be removed".

17. Melanoma in situ is a superficial form of melanoma where all melanoma cells are confined to the outside layer of skin (the epidermis). According to DermNet NZ:

> "Melanoma in situ is always cured by excision because it has no potential to spread round the body … Melanoma in situ is not dangerous; it only becomes potentially life threatening if an invasive melanoma develops within it."

Mole excision in March 2010

18. On 25 March 2010 Mr A consulted Dr B to have a mole on his inner right thigh checked. Dr B recorded in the clinical notes that he considered that the mole might be a melanoma, and discussed its excision with Mr A. Mr A recalls Dr B saying something like, "Just as well you came to see me," but not that he suspected melanoma.

19. On 29 March 2010 Dr B removed the mole from Mr A's inner right thigh. The clinical records include a statement that "informed verbal consent [was] obtained" and that there was an "[e]xplanation of … results of tests/procedures".

20. Mr A told HDC that he thought that if the test results were serious, Dr B would call him.

21. The histology report following the excision of the mole stated:

> "[T]his lesion is best regarded as representing in situ melanoma. There is no evidence of invasive malignancy in the sections examined. Excision is complete by about 2.5mm of the nearest peripheral margin.
>
> […]
>
> Diagnosis
> ATYPICAL COMPOUND NAEVUS (amounting to IN SITU MELANOMA)"

22. Dr B told HDC:

> "I was reassured by this report that I had completely excised the lesion, and because it was melanoma in situ with no evidence of invasion, that the margin of excision was adequate."

23. Mr A stated that he was never informed that the mole was melanoma in situ. In contrast, Dr B told HDC:

> "I am certain that [Mr A] was informed of his results. For patients where urgent follow up is required either a nurse or I will contact the patient. Otherwise where there is a plan to [remove] suture[s], then the results will be discussed at this time, in the first instance by the nurse. I would then discuss the results if further treatment or follow up is indicated. It is usual and expected that the removal of sutures will be documented by the nurse."

24. The clinical notes record on 29 March 2010 that Mr A was due to return for the removal of the sutures in 12 days' time. However, there is no documentation regarding Mr A returning for removal of the sutures or that the test result was communicated to Mr A. According to the clinical records, Mr A next attended the medical centre for an unrelated matter on 15 April 2010. Mr A told HDC that he cannot recall how the sutures were removed, but he thought that his daughter, who is a registered nurse, may have removed them.

25. Over the next two years, Mr A attended the medical centre on a number of occasions for various matters.

Ultrasound in May 2012

26. On 14 May 2012 Mr A saw Dr B about a lump in his right groin. The clinical notes record that Mr A presented with a "tender lumplt [sic] groin, o/e [on examination] 2cm dia [diameter] tender lump left lt [left] fem [femoral] canal. ? l/node [query lymph node]". The clinical note incorrectly refers to the left groin.

27. Dr B told HDC that he thought the lump might be a lymph node or a femoral hernia, so he ordered an ultrasound of the lump. The subsequent ultrasound report, dated 14 May 2012, refers to the right groin and states:

> "The palpable lump is a lymph node which is probably a reactive node. It is not pathologically enlarged.
>
> Options for further management would include FNA [fine needle aspiration] biopsy under ultrasound guidance now, or alternatively given the node is likely to be reactive rather than malignant, a follow up ultrasound scan in 4 weeks time.
>
> If it remains abnormal at that point then FNA biopsy would definitely be indicated."

Follow-up consultation

28. On 18 May 2012 Mr A had a further consultation with Dr B. Dr B told HDC that, as he believed Mr A had a reactive (ie, benign) lymph node, he prescribed antibiotics and advised Mr A to return if he had any concerns. Dr B stated:

> "On looking at the ultrasound report and recommendation for follow up now, I regret that I did not specifically arrange this follow up. I can only say that I believed the lymph node was reactive rather than something more sinister."

29. Mr A stated that during this consultation, Dr B informed him that the ultrasound results showed that the lump was benign, and he said that it should improve in three to four months. Mr A does not recall that he was prescribed antibiotics.

30. The relevant clinical notes of this consultation were recorded on 21 May 2012 and state: "[L]ump rt [right] groin l/node [lymph node] reassured pt [patient], happy see sos [according to need]."

31. There is no reference in the clinical notes to the prescription of antibiotics. The practice administrator stated on behalf of Dr B that "this is unfortunate but does not confirm that no prescription was given … it is possible that the prescription was generated by hand but not recorded in the computerized notes".

Subsequent events

32. Mr A told HDC that after about four months he noticed that the lump had grown and become painful. On 4 October 2012 he had a consultation at the medical centre with GP Dr C, as Dr B was away.

33. Mr A stated that Dr C asked him what his follow-up ultrasound scan had shown (as referred to in the histology results dated 14 May 2012). Mr A informed Dr C that he had not had a follow-up ultrasound and was not told that he needed one. Dr C referred Mr A for a follow-up ultrasound. The results of that ultrasound, dated 29 October 2012, state: "Significant growth and change in the echotexture in the right groin node. It looks malignant and urgent FNA is required."

34. In November 2012 Mr A was referred to a specialist for treatment of metastatic melanoma.

35. Mr A advised that, since his diagnosis of metastatic melanoma, he met with Dr B, and Dr B apologised to him.

36. Sadly, Mr A passed away in 2013.

37. In response to the facts gathered section of my provisional opinion, Mr A's wife described his deterioration following his diagnosis as "traumatic". She stated her belief that health providers and consumers need to be more aware about the dangers of melanoma, including the extent to and the rapidity with which it can spread throughout the body.

The medical centre's policies and procedures

38. At the time of these events, the medical centre had a "Patient test results & reports" policy.[6] The policy stated:

> "3.3 Patients are provided with information about the practice procedure for notification of test results. …
>
> 6.1 The provider is responsible for ensuring the patient is made aware of significant results, even if the patient may delay or cancel follow-up consultations. …
>
> 6.7 All communications regarding test results should be documented in the patient's notes."

39. The medical centre advised HDC that, following Mr A's complaint, it has introduced a new system to document minor operations such as mole removals. Under the new system:

- a nurse books all minor operation procedures, as well as a histology/result appointment with the relevant doctor;
- the doctor then books a follow-up appointment for three months' time or earlier;
- the patient's histology results are classified as "diagnostic" in the clinical records for ease of reference; and
- a doctor then signs off that the above steps have been completed.

[6] The policy was reviewed in July 2012.

Changes to practice

40. Dr B advised HDC that, following Mr A's complaint, he has:

- discussed his treatment of Mr A, including the communication of test results, at a peer review meeting;
- reviewed relevant literature on the diagnosis and management of melanoma;
- met with senior staff at the medical centre and discussed the advice of my independent expert GP, Dr Jim Vause (dated 6 May 2013), as well as the medical centre's updated "Informed consent" and "Clinical investigations" policies; and
- reflected on his use of "automatic keys" to enter information (such as informed consent) into patients' clinical records, and resolved not to rely on them (although he will continue to use them in some circumstances).

41. In response to my provisional opinion Dr B stated that he:

- now keeps a log book for minor surgical procedures, which is completed by the nurse who attends the minor surgical clinic with him and documents the nature of the procedure, the date it is performed, the summarised histological findings following the procedure, when and how the results are notified to patients, and a follow-up appointment date; and
- has attended a seminar on melanoma chaired by a dermatologist; a full day workshop concerning risk management, shared decision-making and managing adverse outcomes; and regular educative and peer review meetings.

Opinion: Dr B

Mole excision follow-up — No breach

42. In March 2010 Dr B excised a mole from Mr A's inner right thigh. The histology report recorded that the mole was an atypical compound naevus amounting to melanoma in situ, with no evidence of invasive malignancy.

43. I note the view of my independent expert advisor, GP Dr Jim Vause, that "difficulties arise from the somewhat confusing nature of the diagnostic label [atypical compound naevus amounting to melanoma in situ]". Dr Vause references DermNet NZ (www.dermnetnz.org), which states that an atypical naevus is "actually harmless (benign) and [does] not need to be removed", and that melanoma in situ "is not dangerous; it only becomes potentially life threatening if an invasive melanoma develops within it".

44. The report also stated that the excision of the mole was complete by about 2.5mm of the nearest peripheral margin. Dr B told HDC that he was reassured by the histology report that he had excised the mole completely and that the margin of excision was adequate.

45. My expert referred me to the Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand (the Guidelines).[7] Dr Vause noted that while the Guidelines state that excision by a 5mm margin is the standard following histology identifying a mole as melanoma in situ, in this case there would have been difficulties ascertaining the true margins because of likely biopsy shrinkage. Dr Vause further noted that the Guidelines state that it is generally accepted that no follow-up is required for melanoma in situ. He concluded that he "cannot fault [Dr B's] decision to not take further steps" following the histology report.

46. In light of Dr Vause's advice, I accept that, following excision of the mole, no further follow-up was required.

Communication of test results following mole excision — No breach

47. Mr A told HDC that he was not informed that the mole excised in March 2010 was melanoma in situ. He said he thought that if the test results were serious, Dr B would call him.

48. Dr B stated that he is "certain that [Mr A] was informed of his results". Dr B said that normal practice at the medical centre was that, where there was a plan to remove sutures (as the clinical records indicate there was in Mr A's case), test results not requiring follow-up were communicated to patients by the nurse removing the sutures. The clinical notes record that Mr A was due to return for removal of his sutures 12 days after the excision, but there is no evidence that he did so.

49. The medical centre's policy requires that all communication regarding test results should be documented in the relevant patient's notes, and that patients should be "made aware of significant results, even if the patients may delay or cancel follow-up consultations".

50. There is no record in Mr A's clinical notes that he was informed that the excised mole was melanoma in situ. I therefore find it more likely than not that Mr A was not informed that the excised mole was a compound naevus amounting to melanoma in situ.

51. No follow-up was required following the excision. As cited above, melanoma in situ "is not dangerous" unless an invasive melanoma develops within it, and the histology report stated that there was "no evidence of invasive malignancy".

52. Mr A did not attend the medical centre for the removal of his sutures, which is when results not requiring follow-up are normally communicated to patients. Furthermore, he was aware that he would be contacted if the results were serious. The results in March 2010 did not warrant further follow-up and I accept that, at the time, they were not considered serious.

Communication of ultrasound result and recommendation — Breach

53. On 14 May 2012 Mr A presented to Dr B with a lump in his right groin, and Dr B ordered an ultrasound. The ultrasound report stated that the lump was "probably a

[7] Australian Cancer Network Melanoma Guidelines Revision Working Party. Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand. The Cancer Council Australia and Australian Cancer Network, Sydney and New Zealand Guidelines Group, Wellington (2008).

reactive [lymph] node" and that options for further management would include an FNA biopsy at the time or a follow-up ultrasound scan four weeks later. The report further stated that if the lump remained abnormal following a follow-up ultrasound, "then FNA biopsy would definitely be indicated".

54. On 18 May 2012 Mr A had a follow-up consultation with Dr B. Dr B told HDC that he prescribed Mr A antibiotics as he believed that the lump was a reactive lymph node and would respond to antibiotics. Dr B also stated that he told Mr A to return if he had ongoing concerns about the lump.

55. In contrast, Mr A stated that Dr B told him that the lump was benign and should resolve in three to four months. Mr A did not recall being prescribed antibiotics. In light of Dr B's and Mr A's differing recollections, I consider it appropriate to rely on the clinical notes to determine what took place at this consultation. The clinical records state that Dr B "reassured" Mr A and told him to return "sos [according to need]".

56. There is no record in the clinical notes that Dr B prescribed antibiotics. The Medical Council of New Zealand's standards require that doctors must keep clear and accurate patient records that report, among other things, any drug or treatment prescribed.[8] Baragwanath J stated in *Patient A v Nelson–Marlborough District Health Board*[9] that it is through the medical record that healthcare providers have the power to produce definitive proof of a particular matter. This Office has previously stated that[10] "this applies to all health professionals who are obliged to keep appropriate patient records. Health professionals whose evidence is based solely on their subsequent recollections (in the absence of written records offering definitive proof) may find their evidence discounted."

57. Therefore, in the absence of any record in the clinical notes regarding Dr B's prescription of antibiotics on 18 May 2012, I accept Mr A's account that Dr B did not prescribe him antibiotics.

58. There is also no evidence that Dr B informed Mr A that the ultrasound report stated that the lump was "probably" a reactive lymph node. In addition, Dr B did not inform Mr A that the ultrasound report suggested follow-up investigations — namely an FNA at the time, or a follow-up ultrasound four weeks later. In my view, the equivocal nature of the ultrasound report diagnosis and the suggested follow-up investigations indicated a degree of uncertainty about the diagnosis of the lump.

59. I consider that the level of uncertainty about the diagnosis was information that a reasonable consumer in Mr A's circumstances would expect to receive. I therefore find that, in failing to provide Mr A with that information, Dr B breached Right 6(1) of the Code.

Ultrasound follow-up — Breach

60. Dr B did not organise for Mr A to have an immediate FNA, follow-up ultrasound, or specific follow-up consultation after 18 May 2012. As stated above, Dr B told HDC

[8] Medical Council of New Zealand, *Good medical practice*. See also the Medical Council of New Zealand publication "The maintenance and retention of patient records" (August 2008).
[9] *Patient A v Nelson–Marlborough District Health Board* (HC BLE CIV–2003–204–14, 15 March 2005).
[10] Opinion 08HDC10236, 28 November 2008, at page 11.

that he thought the lump was a reactive lymph node that would respond to antibiotics. However, there is no evidence that he prescribed Mr A antibiotics at that time. Furthermore, he did not organise structured follow-up (in the form of a follow-up consultation or follow-up ultrasound) in order to monitor whether the lump actually was a reactive lymph node.

61. In my view, Dr B's failure to organise structured follow-up illustrates that he failed to consider the differential diagnoses sufficiently. Dr Vause advised me that, on seeing the ultrasound report recommendation for an immediate FNA or follow-up ultrasound in four weeks' time, "any GP should be putting cancer on his/her differential diagnosis list".

62. In light of Dr Vause's advice I am concerned by Dr B's failure to organise structured follow-up. GPs owe their patients a duty to provide services with reasonable care and skill. In this case, the ultrasound report was equivocal but recognised the need for structured follow-up. In my view, Dr B was overly casual in his treatment of Mr A. While Dr B believed the lump was a reactive lymph node, the differential diagnosis was potentially very serious for his patient. Follow-up to exclude that possibility ought to have occurred as suggested in the radiologist's report.

63. Accordingly, I find that in failing to consider differential diagnoses adequately and organise structured follow-up for Mr A, Dr B failed to provide services to Mr A with reasonable care and skill and, in doing so, breached Right 4(1) of the Code.

Documentation — Adverse comment

64. In reviewing Mr A's clinical records I note a number of instances where Dr B's documentation was incomplete or incorrect.

65. For example, at the time the mole was excised, the clinical notes record that Mr A was given an "explanation of … results of tests/procedures". This record does not provide sufficient detail about the conversation that took place between Mr A and Dr B regarding the communication of Mr A's test results. On 14 May 2012 the clinical notes incorrectly state that Mr A presented with a lump in his left groin (rather than his right groin).

66. As I have noted previously, the importance of good record-keeping (including comprehensive consultation notes) cannot be overstated, particularly where patients may be seen by other practitioners.[11] In my view, Dr B should be mindful of his professional obligation[12] to keep comprehensive and accurate records.

Opinion: The medical centre

67. Dr B's failures in his communication and follow-up with Mr A following the ultrasound scan on 14 May 2012 were matters of individual clinical judgement. Mr A was appropriately referred for a follow-up ultrasound when he attended another GP at

[11] Opinion 10HDC00610, 29 February 2012 at page 10.
[12] Medical Council of New Zealand, *Good Medical Practice*. See also the Medical Council of New Zealand publication "The maintenance and retention of patient records" (August 2008).

the practice, Dr C. There is no evidence that the medical centre's policies or practices contributed to Dr B's errors of judgement. Therefore I do not find that the medical centre is vicariously liable for Dr B's breaches of the Code, or directly liable for any breach of the Code.

Recommendations

68. In accordance with the proposed recommendation in my provisional report, Dr B has undertaken an audit of his patients' clinical records, in order to identify any patients who may require follow-up and have not received it, and reported to HDC on the results. Dr B told HDC that all patients requiring follow-up had received it or been advised that follow-up will be arranged on receipt of relevant laboratory results, and that "no gaps were found".

Follow-up actions

- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand. The Council will be advised of Dr B's name, with a recommendation that it consider undertaking a competency review of Dr B's practice focussed on record-keeping, communication with patients, and test result follow-up.

- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Royal New Zealand College of General Practitioners and the district health board, and they will be advised of Dr B's name.

- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent advice to the Commissioner

The following expert advice was obtained from general practitioner Dr Jim Vause on 6 May 2013:

"Thank you for your request for advice on [Dr B's] care of [Mr A], HDC case C13HDC0031.

I have read the following documentation:

- Letter from [Dr B] dated 21 March 2013
- Print out of [Mr A's] computerised clinical records from [the medical centre].
- [The] District Health board records of [Mr A's] admission for surgery on 11 Dec 2012.
- HDC Complaint submitted by [Mr A] on [date]

I am a vocationally registered general practitioner, having graduated MBChB from Otago University in 1976. I have practised as a general practitioner since 1979 and gained Membership of the Royal New Zealand College of General Practitioners in 1990, Fellowship in 1998 and was awarded a Distinguished Fellowship in 2006. In 2001, I gained a Diploma of General Practice from Otago University. I initially practiced for 5 years in rural practice and then since 1985 in my current position in a provincial 6 doctor general practice.

Documentation

With respect to the documentation put before me,

Concerning possible conflict of interest:

I do not know any of the persons referred to in the documentation presented to me and do not know any other information of this case.

The case can be divided into two parts: These are

1. The initial treatment and follow-up of the lesion removed from [Mr A's] left thigh by [Dr B] on 29-03-10, and

2. The actions subsequent to the first ultrasound requested by [Dr B] in 14-05-12

On the matter of the first

An important consideration is whether the primary site of [Mr A's] metastatic melanoma was the lesion [Dr B] removed from his right thigh, this being reported by histology as being an atypical compound naevus. The percentage of such lesions that subsequently evolve into metastatic melanoma is not accurately known but is likely to be very low, in the magnitude of 1 in 100,000.[1] There are significant problems with applying this statistic to [Mr A's] case, ranging from the low quality of observational studies from which this statistic is derived, through to variables such as the greater the number of dysplastic naevi a person has, the more

[1] Naeyaert JM, Brochez L. Clinical practice. Dysplastic nevi. N Engl J Med. 2003 Dec 4;349(23):2233–40.

likely the development of melanoma. [Mr A's] melanoma could well have arisen from a different mole to that excised by [Dr B], as it is not unusual for the primary site of a malignant melanoma to be unknown.

Further to consider is

- The difficulties with histological diagnosis of moles, namely the significant blurring between atypical naevi, melanoma in situ and melanoma itself and,
- The labelling problems which I explain below.

To contextualise the diagnosis, prognosis and management in this case, good reliable empirical research in primary care is inconsistent across these three realms. There are many gaps in medical knowledge and frequently the quality of the research is not high.

Re [Mr A's] complaint that he wasn't informed of his thigh biopsy results:

There is no record in the documentation of [Mr A] being informed of the results of his first excision biopsy on 29 March 2010.

The most likely methods for [Mr A] to be informed of the biopsy histology results would have been either in a 'pushed' manner, that is for the practice to forward the result to [Mr A] upon its receipt, either by phone, mail or electronic means, or in a pulled manner i.e. the results given face to face at a consultation or [Mr A] contacting the surgery for the result, either after being informed of its arrival at the clinic or at a prearranged time based on the likely time of its arrival at the clinic.

Whatever the method, the practice and [Dr B] had a responsibility, at the time of conducting the biopsy, to assure that [Mr A] was aware of how he would be informed of the results. This standard is stipulated in indicator D.10:3 (page 68) of the RNZCGP Aiming for Excellence Standards 2009.[2]

At [Mr A's] biopsy excision consultation on 29-03-10, I would expect that he would have been informed of this process, either by [Dr B] or his nurse or on written information given to him by the practice.

Possibly [Dr B] may have relied upon signage in the practice informing patients of this. [The medical centre], as an RNZCGP Cornerstone Accredited practice, should have displayed signs for patients on how test results will be communicated to them. I cannot determine if, in March 2010, the practice was Cornerstone accredited but given that [the network] of practices has been involved for a number of years in Cornerstone, I suspect they would have met this requirement at the time. However, given the fact that excision biopsies are often performed in general practice to assure that a suspicious mole is not cancer; I would expect [Dr B] to not rely on signage.

Another suitable occasion for [Mr A] to be informed of the results would have been when he had the sutures removed from the biopsy site on his leg. The removal of sutures (ROS) consult is a useful time to discuss the biopsy histology with the patient. The instruction ROS appears on page 6 of [Mr A's] [medical

[2] 'Aiming for Excellence' 2009. Royal New Zealand college of General Practitioners. 88 The Terrace, Wellington.

centre] records, this being due 12 days after 29-3-10. Unfortunately there is no record of this occurring in the notes which might be because the ROS was performed elsewhere or was done at the clinic but not recorded.

The record of obtaining informed consent for the excision procedure should normally include information for the patient on how to access results. There is an entry in the clinical records by [Dr B], some 29 words long, covering key aspects to the procedure and informed consent being obtained. Unfortunately, this is identical, character to character, with entries made by [Dr B] on four other occasions when he performed minor procedures on [Mr A]. I suspect this is an automated 'macro' data entry that can be set up in the practice computer Patient Management System (PMS). Therefore I cannot conclude from this entry whether [Mr A] was informed appropriately on how to access his results.

There is record of [Mr A] being phoned by [initials] who appears to be a nurse, with histology results from a skin biopsy on 7 October 2011 after [Dr B] requested, on 22 September, for [Mr A] to be informed of the results. Thus the practice had, a year later, a system for informing patients and I suspect would have had this at the time of [Mr A's] initial mole excision.

Therefore I conclude that [Dr B] did not adequately inform [Mr A] of how he could access the biopsy results.

Were the excision margins sufficient:

[Dr B], in his letter of 21 March 2013 states that he felt the excision margin of 2.5mm was adequate for a melanoma in situ.

The 2008 Australasian Melanoma Guidelines,[3] an appropriate standard to judge this case, state that a 2.5mm margin is satisfactory for a mole that is suspected of being a melanoma (that is prior to the histology results). However, the guidelines state that a 5mm margin is the standard once the histology has identified that the lesion was a melanoma in situ. This would imply, in [Mr A's] case, a need for a further excision.

[A plastic surgeon] from the [public] Hospital Plastic Surgery Department, also indicates in his letter to HDC on 6 March 2013, that a 5mm margin would have been ideal, but highlights the difficulties around ascertaining the true margins in this case due to likely biopsy shrinkage.

Further difficulties arise from the somewhat confusing nature of the diagnostic label in the histology results. This concludes with the diagnosis:

'atypical compound naevi (amounting to in situ melanoma)'

For a GP, and according to DermNet NZ, a very good online resource popular amongst GPs and to which [Dr B] refers, states:

[3] Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand. Available online at http://www.health.govt.nz/publication/clinical-practice-guidelines-management-melanoma-austraila-and-new-zealand.

> 'Atypical naevi are actually harmless (benign) and do not need to be removed.'[4]

However the report addition 'Amounting to in situ melanoma' swings the clinical thoughts towards a further excision.

To quote the fore mentioned DermNet

> 'Melanoma in situ is not dangerous; it only becomes potentially life threatening if an invasive melanoma develops within it'

The Australasian Melanoma Guidelines, on page 43, identify that immunohistochemistry (testing the biopsy for specific markers) may be helpful in distinguishing between melanoma and atypical naevi.

Thus there is uncertainty as to whether melanoma in situ and atypical compound naevi are one and the same.

Possibly if the report had given clearer advice to the GP on appropriate action (as for example, the ultrasound report below provided) it may have clarified this situation. Ultimately, [Dr B], in his letter of 21 March 2013, acknowledges that he based his action on the melanoma in situ diagnosis,

> '… because it was melanoma in situ with no evidence of invasion, that the margin of the excision was adequate'

I use the above diagnostic labelling uncertainty, the excision margins uncertainty and a standard that is largely opinion based, to draw a conclusion that I cannot fault [Dr B's] decision to not take further steps. Possibly he could have checked with an appropriate specialist as to whether his management was appropriate, but not doing so is also acceptable.

An appendum: There is a report in the notes [on] page 27 which provides the findings of a review of the microscopic description in the histology report conducted at a Colorectal Clinicopathological meeting on 27 November 2012 at the request of [a] general surgeon at [the public hospital]. The results were confirmed. For some reason, this report from 2012 is presented in the documentation as being entered into the notes on 29 March 2010 and is correct sequential record for this date. This is unusual but has no bearing on my findings.

Follow-up:

Should [Dr B] have organised further follow-up based on the diagnosis?

The British Association of Dermatologists recommends follow-up based on tumour stage and for

> 'in situ melanoma, no follow-up is required'.

This is similarly reflected in the Australasian Guidelines pg. 121.

One consideration is whether [Dr B] evaluated [Mr A's] risk of melanoma. I note comment on this in [the plastic surgeon's] letter to HDC on 6 March 2013. There is no record of such risk assessment being undertaken by [Dr B].

[4] http://www.dermnetnz.org/lesions/atypical-naevi.html.

In his letter of 21st March 2013 [Dr B] states

> "I understand from my discussions that there should be no theoretical possibility of invasion from the in situ melanoma to the lymph nodes."

This statement also is in [the plastic surgeon's] letter as above.

While 'no theoretical possibility' fails to acknowledge the uncertainty of melanoma development, the absolute risk is low but this risk is also dependent upon the number of dysplastic naevi a person might have, along with their history of sunlight exposure. Possibly if [Dr B] has made a more formal assessment of [Mr A's] risk he may have organised further follow-up but given there is no research showing benefit from such follow-up, I cannot see how it would have made any difference to the outcome in terms of metastatic disease.

In conclusion, [Dr B's] decision not to follow-up [Mr A's] initial diagnosis was appropriate.

On number 2, the ultrasound follow-up

The ultrasound findings as reported on 14 May 2012 (Page 20 of clinical notes) was inconclusive but gives clear guidance on next steps, namely either further investigation by obtaining an FNA (Fine Needle Aspirate) or

> '… a follow up ultrasound scan in 4 weeks' time.'

This advice was entirely appropriate and is typical of that a GP would receive from a radiologist when ultrasound findings such as this are inconclusive.

On the 21 May 2012, the clinical notes record [Dr B] reassuring [Mr A] on his right groin lump. There is no record of discussion of the need for further action as per the report and no indication that [Dr B] planned any further investigation. There is no record of a referral for FNA or a referral for a repeat ultrasound.

If [Dr B] had presented [Mr A] with the complete ultrasound report including the radiologists' recommendations then it would be unlikely for [Mr A] to be 'reassured' and 'happy' as [Dr B] recorded in his notes. This was [Dr B's] key failing and where his conduct as a general practitioner falls below an accepted standard.

I cannot assess whether [Mr A] had any discussion with the ultra-sonographer of the ultrasound imaging or the need for a follow-up scan but I would doubt whether she would have been in a position to make such a clinical judgement, for the advice to [Dr B] on further action came from [the radiologist] rather than the ultra-sonographer.

In conclusion:

[Dr B] failed to provide the standard of care to be expected of a general practitioner in three realms:

1. To ensure that [Mr A] was informed of how he could access his initial leg biopsy results.
2. To discuss in an appropriate and transparent manner with [Mr A], the recommendations of the ultrasound report

3. To follow the advice from the radiologist and organise and ensure a repeat ultrasound of [Mr A's] groin lymph node was performed.

Recommendations:

I have three quality improvement suggestions for this case.

1. [Dr B] reviews his communication of test results with his patients by way of a peer review with an appropriately skilled RNZCGP GPEP tutor.
2. [Dr B] ceases to use automated data entry in the PMS he uses and discusses this in his peer group to ensure consistency with his peers.
3. [The medical centre] conducts a clinical review of its informed consent policy and implementation thereof, including the content of written information it gives patients undergoing minor surgery."

Further advice

Dr Vause provided the following additional advice to the Commissioner on 9 October 2013:

"In consideration of the proposal that [the] Commissioner were to find that

1. [Mr A] was told following his mole excision on 29 March 2010 that the mole was a compound naevus

   Were this to be the case, then my conclusion on [Dr B's] departure from an accepted standard when informing [Mr A] of how he could access his test results, becomes inappropriate. My previous judgement on this matter was based on there being no record in the clinical notes of a removal of sutures or any other communication with [Mr A] on the histology results. [Dr B's] 'Response to questions, number one' in his letter of 26 June that he believed this 'removal of sutures' was conducted by his nurse and not recorded in the notes seems appropriate and, without triangulation statements on the matter from the nurse or [Mr A], I accept this explanation.

With respect to the second finding (2) and also the similar finding (3) in the email of 27-08-13

2. [Dr B] discussed [Mr A's] ultrasound results with him on 21 May 2012, prescribed [Mr A] antibiotics and told [Mr A] to return if the lump in his groin continued to concern him, but although the lump remained and was tender, [Mr A] did not represent until 4 October 2012,
3. [Dr B] told [Mr A] that the lump was most likely benign and should resolve itself in 3 to 4 months, and to return if it did not, would you consider [Dr B] departed from expected standards?

The radiologist recommendation on the ultrasound report of 14 May 2012 clearly states:

   'Options for further management would include FNA biopsy under ultrasound guidance now, or alternatively given the node is likely to be reactive rather than malignant, a follow-up ultrasound scan in 4 weeks' time'

There are only two options and a clear explicit timeframe of an immediate FNA (Fine Needle Aspirate) or a repeat scan in 4 weeks. This recommendation is typical of such ultrasound reports and in line with what a GP might expect.

[Dr B's] explanations in 2 or 3 do not address my conclusion 2 from my report, namely that it appears the contents of the ultrasound report, in particular the radiologist's recommendations, were not discussed with [Mr A] in an appropriate and transparent manner and [Dr B] did not take heed of the radiologists report advice on further action.

While it was entirely acceptable for [Dr B] to tell [Mr A] that the lump was 'most likely benign', the ultrasound report is not conclusive and clearly indicated further investigation or follow up was essential. Even if the radiologist's description of the lymph node ultrasound findings led [Dr B] to conclude the lump was benign, the radiologist option for an FNA should have raised [Dr B's] alertness to the possibility that it was necessary to be more assured diagnostically than the findings of one ultrasound result. An FNA obtains cells from the lymph node and provides a substantially more accurate diagnosis of the exact nature of the lump than an ultrasound. Next to a surgical biopsy this is the best test. On seeing this report recommendation, any GP should be putting cancer in his/her differential diagnosis list.

[Dr B's] suggestion of a time frame of 3 to 4 months for follow up to [Mr A] was inappropriate considering the report and the clinical circumstance. While a benign lump may well have taken a few months to settle, quoting this timeframe to the patient in no way reduced [Dr B's] responsibility to check on the lump earlier. If [Dr B's] decision had been to follow up this lump (rather than organise the FNA 'now') he should have either arranged to see [Mr A] in one month or ordered a repeat ultrasound scan for four weeks time.

Going back to [Dr B's] clinical records of 21 May 2012, these record that he discussed the ultrasound results with [Mr A] as follows:

> 'lump rt groin l/node reassured pt. Happy see sos'

which I interpret as meaning he ([Dr B]) told [Mr A] that the right groin lump was a lymph node, not of any consequence and that the follow up would be at his ([Mr A's]) behest. The time frame is 'sos', that is according to need, in this case the patient's perception of need. The patient does not appear to have been informed of the suggested 4 week time frame for a repeat ultrasound. There is no recording of [Dr B] telling [Mr A] of the radiologist recommendation for either an FNA biopsy OR a follow-up ultrasound in order to exclude malignancy.

[Dr B], in choosing to reject the radiologist advice and in believing that this lump was reactive and to give antibiotics (I can find no record in the notes of this prescribing, nor any other), indicates a greater faith in his clinical skills than the information in the notes and his letters support. Other than the radiologist's report, there is no history or findings of skin or other infection on [Mr A's] leg that might have made this node 'reactive'. Furthermore the blood test taken on the 14 May 2012 showing an ESR of 2 and no white blood cell reaction, does not suggest any infection or cause for lymph node reactivity. This clinical judgement is of debatable quality but in the uncertain world of general practice, acceptable BUT it

cannot exclude the need to heed the radiologist advice and to follow good practice in terms of follow-up.

Thus the departure from acceptable care is focused on [Dr B's] rejection of the radiologist advice, his failure to recognise the significant error rate of the ultrasound result, the failure to put malignancy higher on his diagnostic list and the reliance on a diagnosis that was poorly supported by the clinical findings. This is a significant departure from accepted care.

In judging the severity of this departure, it is not mild, for there is not one error of judgement and knowledge, but a number. It is possible to conclude that [Dr B] may have deliberately misled [Mr A] on the radiologist report but equally he may not have read the report correctly for a number of different reasons such as the clinical workspace in the practice and the IT system. Thus I cannot clearly identify any deliberate mal-action [sic] on [Dr B's] part, as at other times his care [for] [Mr A] has been appropriate.

Thus I find that this is a moderate departure."