General Practitioner, Dr B A District Health Board

A Report by the Health and Disability Commissioner

(Case 12HDC01533)



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Executive summary

Background

- 1. On 18 December 2008, Ms A, then aged 41 years, presented to general practitioner Dr B at a medical centre because she had an irregular shaped lesion¹ on her lower right leg, which had changed in shape and size. Dr B examined the lesion with dermoscopy.² He stated that the lesion "appeared to be a seborrhaeic wart³ (keratosis) type lesion that clinically and dermoscopically appeared benign".
- 2. Dr B excised the lesion and sent a sample for histology testing. The histology result stated that melanoma could not be excluded in the tissue examined.
- 3. Ms A said that Dr B did not tell her the histology result or give her a copy of the report, and did not offer to re-excise the lesion. Dr B's clinical notes are ambiguous as to whether he fully informed Ms A of the histology result and her option of having the lesion re-excised. The record suggests that Dr B told Ms A that the lesion was clinically benign.
- 4. Dr B said he felt that it was reasonable not to re-excise the lesion and to proceed with a plan to observe it closely and to re-excise it if he had any concerns, because the lesion was clinically and dermoscopically benign and there was no sign of residual lesion.
- 5. On 7 September 2009, Ms A drew Dr B's attention to two lesions at the surgical site. Dermoscopy of the lesions was suspicious so, on 15 September 2009, Dr B performed a re-excision of the lesion. The histology report confirmed that the lesion was "in situ lentigo maligna melanoma".⁴ On 6 October 2009, Dr B performed a further reexcision of the surgical scar with a wide clinical margin of 5–7mm.⁵
- 6. The histology report confirmed that there was no residual melanoma. No review arrangements were put in place following the wide excision.
- 7. On 23 September 2010, Ms A saw Dr B and said that the lesion was growing back. Dr B performed a full skin check including dermoscopy. He was satisfied that there was no recurrence of the lesion.
- 8. On 19 April 2011, Ms A saw Dr B with a new lesion within the surgical scar where the previous excisions had taken place. Dr B again examined Ms A's lower leg using dermoscopy and observed no suspicious features.



¹ A lesion is an area of tissue with impaired function as a result of damage by disease or wounding.

² Dermoscopy or dermatoscopy refers to the examination of the skin using surface microscopy, and is used mainly in the evaluation of pigmented skin lesions.

³ Seborrhoeic warts are non-cancerous (benign) warty growths that occur on the skin. Usually they do not need any treatment.

⁴ In situ lentigo maligna is a potentially serious form of skin cancer in which malignant melanoma cells have invaded the dermis and deeper layers of the skin.

⁵ The recommended clinical margin for melanoma *in situ* is 5mm.

- 9. On 2 July 2012, Ms A attended a further consultation with Dr B because she had a new irregular lesion on the site of the previous excisions. Dr B noted that the lesion had grown and become irregular with suspicious dermoscopic features.
- ^{10.} Dr B sent an urgent referral to the plastic surgery department at the hospital. On 9 August 2012, a plastic surgery registrar, Dr C, performed an excision biopsy of the lesion. The results showed a 0.45mm invasive melanoma with no ulceration. Dr C recommended that Ms A have a wider excision, including reconstruction with a split skin graft.⁶
- 11. Prior to the surgery, Ms A was not given the DHB's information sheet, which advises that the surgery requires complete rest for a week with the leg elevated, and no standing, other than to go to the bathroom. However, the information was provided after the surgery.
- 12. On 20 September 2012, Ms A underwent a wide local excision with a split skin graft, performed by plastic surgery registrar Dr E.
- 13. Ms A was discharged from the hospital later that day and subsequently attended the the hospital's dressing clinic, where the skin graft was checked. Ms A then attended the medical centre for dressing changes. The wound became infected and was treated with antibiotics.
- 14. On 1 November 2012, Ms A was reviewed by a plastic surgery registrar, Dr F, who noted that there had been loss of the skin graft. Ms A returned to the hospital a further two to three times. Eventually the wound healed, but Ms A was left with a severe scar.

Findings

- 15. Dr B's decision on 15 January 2009 to observe the lesion rather than to re-excise it was unsafe, and a departure from the accepted standard of care. Dr B failed to provide services to Ms A with reasonable care and skill and breached Right 4(1)⁷ of the Code of Health and Disability Services Consumers' Rights (the Code).
- 16. On 15 January 2009 Dr B should have ensured that Ms A was aware, and understood, that the histology report stated that melanoma could not be excluded. He should also have discussed the option of a re-excision of the lesion, including the risks and benefits of that option, and clearly documented the discussion. This was information that a reasonable consumer in Ms A's circumstances would expect to receive. Dr B breached Right 6(1)⁸ of the Code for failing to provide Ms A with that information.

⁶ This refers to a split-thickness skin graft (STSG), which is a skin graft including the epidermis and part of the dermis. Its thickness depends on the donor site and the needs of the patient.

⁷ Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

 $^{^{8}}$ Right 6(1) states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including —

a) an explanation of his or her condition; and

b) an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and ...

Names have been removed (except the expert who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

- 17. Dr B's failure to put in place a structured monitoring plan for Ms A from January 2009 was suboptimal and a departure from accepted standards of care. Dr B failed to take sufficient steps to minimise the risk of harm to Ms A and, accordingly, breached Right $4(4)^9$ of the Code.
- 18. The delay from 19 April 2011, when Ms A expressed concern about a new lesion, until 2 July 2012, when Ms A was referred to the hospital by Dr B, was a severe departure from accepted standards of care. Dr B failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.
- 19. Adverse comment was made about the DHB's communication with Ms A prior to her surgery.

Complaint and investigation

- 20. The Commissioner received a complaint from Ms A about the services provided by general practitioner (GP) Dr B¹⁰ and a public hospital. The following issues were identified for investigation:
 - Whether Dr B provided an appropriate standard of care to Ms A between 2008 and 2012.
 - Whether the DHB provided an appropriate standard of care to Ms A in 2012.
- 21. An investigation was commenced on 13 August 2013.
- 22. The parties directly involved in the investigation were:

Ms A	Consumer/Complainant
Dr B	Provider
The DHB	Provider

- 23. Information was also reviewed from a consultant dermatologist, Dr D, and the Accident Compensation Corporation.
- 24. Also mentioned in this report are:

Dr C	Plastic surgery registrar
Dr E	Plastic surgery registrar
Dr F	Plastic surgery registrar
Dr G	General practitioner
Dr H	Plastic surgery consultant

f) the results of tests; ..."

30 June 2014



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⁹ Right 4(4) states: "Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer."
¹⁰ Dr B is a vocationally registered general practitioner.

25. Independent expert advice was obtained from general practitioner Dr Philip Monnington (**Appendix A**).

Information gathered during investigation

Background

- ^{26.} Dr B is a GP with a special interest in skin cancer management.¹¹ In 2010 Dr B gained a post-graduate qualification in skin cancer medicine. Dr B practises at a medical centre.
- 27. Dr B is also the Clinical Director of a clinic which has a special focus on appearance medicine and skin cancer management. Dr B works in a collegial relationship with a consultant dermatologist, Dr D, who consults in the clinic on a monthly basis.

Ms A

28. Ms A has been a patient of Dr B at the medical centre since 2003. She has no family history of melanoma. At the time of these events she had sole responsibility for her two young children.

Initial consultation and excision

- 29. On 18 December 2008, Ms A, then aged 41 years, consulted Dr B regarding an irregular shaped lesion¹² on her lower right leg, which was causing her concern because it had changed in shape and size. Dr B examined the lesion with dermoscopy.¹³ He stated that the lesion "appeared to be a seborrhaeic wart¹⁴ (keratosis) type lesion that clinically and dermoscopically appeared benign".
- 30. Dr B stated that the treatment he recommended was curettage¹⁵ and cautery¹⁶ with a radiofrequency device. In response to the provisional opinion, Ms A told HDC that Dr B explained to her that this was a cosmetic procedure costing \$360.00, and that he would send the mole away to get it checked. Dr B excised the lesion by way of curettage biopsy, and a sample was sent for histology testing.
- 31. On 19 December 2008, Ms A attended a follow-up appointment with Dr B. He checked the wound and advised a change of dressing. On 24 December 2008, Ms A attended an appointment with the medical centre's practice nurse who checked the wound and provided Ms A with Bactroban ointment (a topical antibiotic), because the wound was showing a slight discharge. The practice nurse made a note to "chase [histology] result".

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¹⁶An agent or instrument used to destroy abnormal tissue by burning, searing, or scarring.



¹¹ Dr B has been registered with the Medical Council of New Zealand for over 20 years.

¹² See above n 1.

¹³ See above n 2.

¹⁴ See above n 3.

¹⁵ Curettage refers to the use of a sharp spoon-like instrument to scrape off a predominantly epidermal superficial skin lesion.

Histology result

32. The histology result, received at the medical centre on 15 January 2009, states:

"Sections show artefactually distorted superficially biopsied melanocytic lesion¹⁷ which is architecturally atypical and in which cytologic definition is obscured by cautery artefact. Melanoma cannot be excluded in the tissue examined."

Decision not to re-excise — 15 January 2009

33. On 15 January 2009, Ms A attended an appointment with Dr B, who noted:

"[W]ound well healed — will fade — no residual melanocytic lesion present hito (histology) not clear but was clin [clinically] benign and discussed [my] feeling is observe — [Ms A] happy — if concern happy to reexcise nc."

34. Dr B stated that "it is very clear" from this record that he offered re-excision at that time. He stated that the histology result, "Melanoma cannot be excluded", was not diagnostic, and said:

"This result was discussed with [Ms A] and an offer to excise the lesion was made but declined by her. [Ms A] was reluctant to undertake further surgery so closely after the recent excision and when the wound had just recovered."

- 35. Ms A said that Dr B did not tell her the histology result or give her a copy of the report. She said that if he had done so, it would have "rung alarm bells" for her. She stated further that he did not offer to re-excise the lesion and that, if he had done so, she would have agreed to re-excision. In response to the provisional opinion, Dr B stated that he is sure he discussed the histology results and that his practice is always to offer options for management of skin lesions.
- 36. Dr B said he felt that it was reasonable not to re-excise the lesion and to proceed with a plan to observe it closely and to re-excise it if he had any concerns, because the lesion was clinically and dermoscopically benign, and there was no sign of residual lesion. In response to the provisional opinion, Dr B stated that, in retrospect, his decision "not to either re-excise or refer for re-excision was not the best option", and he accepted that the decision was below the accepted standard of care.
- 37. No follow-up or surveillance plan is documented in Ms A's clinical notes. Ms A said that Dr B made no monitoring arrangements with her. Dr B advised HDC: "[A]lthough the frequency [of observation] was not specified, I considered that every 6 months would be safe. I was seeing [Ms A] regularly for [another medical matter] so did not consider she needed a formal reminder for a skin check."

Consultation — 28 May 2009

^{38.} The next consultation between Ms A and Dr B was on 28 May 2009. Dr B reviewed the lesion and noted "leg good". Dr B told HDC that Ms A's leg was healing nicely with no sign of re-occurrence of the lesion.



¹⁷ A melanocytic nevus (commonly called a "mole") is a lesion that contains pigment cells called melanocytes.

³⁰ June 2014

Re-excision — 15 September 2009

- 39. On 7 September 2009, Dr B reviewed the lesion. Ms A drew Dr B's attention to two smaller lesions at the surgical site. Dr B stated that dermoscopy of the lesions was suspicious, so he advised Ms A that re-excision would be the most appropriate action to take.
- 40. On 15 September 2009, Dr B performed a re-excision of the lesion on Ms A's lower right leg. A sample of the lesion was sent to the laboratory for testing. The histology report confirmed that the lesion was "in situ lentigo maligna melanoma".¹⁸
- 41. Dr B then discussed the case with Dr D.

Further re-excision — 6 October 2009

- 42. On 6 October 2009, Dr B performed a further re-excision of the surgical scar with a wide clinical margin of 5–7mm.¹⁹ Dr B said that Dr D assisted him, because of the position of the lesion, which was just above Ms A's ankle.
- 43. The histology report confirmed that there was "no residual melanoma"²⁰ and, on 18 January 2010, Dr B reviewed the lesion and noted "leg good". Dr B stated that no formal review arrangements were put in place following the wide excision on 6 October 2009. However, he advised HDC that he informed Ms A that she would require regular checks of her skin and the surgical area on her leg for any recurrence.
- 44. Ms A said that no monitoring or surveillance arrangements were put in place at any time.
- 45. Between February and September 2010, Ms A attended the medical centre regarding unrelated medical matters.

Further assessments — 23 September 2010 and 19 April 2011

- ^{46.} On 23 September 2010, Ms A attended an appointment at the medical centre with Dr B and told him that she was worried that the lesion was growing back. Dr B performed a full skin check including dermoscopy. He said he was satisfied that the area was benign in appearance and that there was no recurrence of the lesion. He did not undertake a further re-excision. He discussed with Ms A the use of sublock and the need for regular skin checks.
- 47. On 19 April 2011, Ms A consulted Dr B regarding what appeared to be a new lesion within the surgical scar where the previous excisions had taken place. Dr B again examined Ms A's lower leg using dermoscopy and noted: "[M]ole in scar where prev melanoma excised gmb dermoscopy no suspicious features." He did not perform a further re-excision at that time and did not document a surveillance or follow-up plan in Ms A's clinical notes.

²⁰ Residual melanoma refers to melanoma cells that exist outside of the main lesion.



¹⁸ See above n 4.

¹⁹ See above n 5.

In response to the provisional opinion, Dr B stated that he did not ignore the lesion. Rather, he examined it under the dermoscope but did not think it had any sinister features at that time. He stated that he "reached a decision that was in retrospect not correct", and accepted that it was a departure from accepted standards of care. He said he does not consider it was a severe departure because "serial digital dermoscopy" would have been an acceptable alternative to re-excision at that time. However, the records show no evidence of further dermoscopy having been performed after 19 April 2011.

Consultations May 2011–July 2012

- 48. On 23 May 2011, Ms A attended a consultation with Dr B's colleague, GP Dr G. Ms A discussed her concerns regarding the mole on the scar site. Dr G told Ms A to monitor the scar site and organise a consultation with Dr B if she noticed any changes in the area.
- 49. Ms A attended the medical centre for unrelated medical issues between May 2011 and June 2012.

Referral to hospital

- ^{50.} On 2 July 2012, Ms A consulted Dr B because she had a new irregular lesion on the site of the previous excisions. Dr B assessed the area and noted that the lesion had grown and become irregular with suspicious dermoscopic features.
- 51. Ms A requested a referral to the public hospital. She said that at this consultation she had a friend with her, who insisted that Ms A be referred to a specialist.
- 52. Dr B facilitated an urgent referral to the plastic surgery department for investigation and further excision of the lesion. Dr B advised that usual practice was for all referrals involving melanoma to be marked as "urgent".

The hospital

- 53. The DHB advised HDC that the hospital received the referral from Dr B on 3 July 2012 and, on 6 July 2012, assigned it an urgent priority. Ms A was placed under the care of plastic surgery consultant Dr H.
- 54. On 25 July 2012, Dr H saw Ms A at the melanoma clinic and discussed that the lesion might be an early melanoma. He advised Ms A that she would require an excision biopsy in the first instance, and that further management would depend on the initial result.
- 55. On 9 August 2012, plastic surgery registrar Dr C performed an excision biopsy of the lesion at the hospital. The results found a 0.45mm invasive melanoma with no ulceration. Dr H stated that, although it was an invasive melanoma, it was the earliest type of invasive lesion. Ms A was advised to have a wider excision, including reconstruction with a split skin graft.²¹



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²¹ See above n 6.

³⁰ June 2014

^{56.} On 28 August 2012, Dr C wrote to Ms A and Dr B outlining the findings. Dr C recorded that histology confirmed that Ms A had a "radial growth phase invasive malignant melanoma with adjacent intraepidermal component of superficial spreading type Clark level II".²² Dr C's letter stated: "This means that you will need a wide local excision of the area with a split skin graft."

Information provided

- 57. The DHB advised that, prior to undergoing a split skin graft, every patient is provided with an information sheet with their waiting list papers. The DHB provided the information sheet, which advises that the surgery requires complete rest for a week with the leg elevated, and no standing, other than to go to the bathroom. The sheet states: "You should be prepared to be **house bound** for **one week**" (emphasis in original).
- 58. The DHB advised that their admission book notes when a patient has been admitted for a split skin graft, and said that a tick is placed next to the patient's name indicating that the information pamphlet has been provided to the patient. However, the DHB was unable to confirm that the booking office provided the pamphlet to Ms A prior to her admission.
- 59. Ms A said that she was not given the pamphlet prior to the surgery, and had no idea that she would be required to be off her feet for one week after the split skin graft.

Surgery 20 September 2012

- 60. On 20 September 2012, a plastic surgery registrar, Dr E, performed a wide local excision with a split skin graft on Ms A's leg.²³
- 61. Ms A stated that, after the procedure, DHB staff advised her that the surgery required complete rest for a week with the leg elevated, and no standing, other than to go to the bathroom. Ms A stated that on receiving that information she was distressed and burst into tears because she had two young children at home and no way to care for them.
- 62. The DHB stated that it appears that it was not made clear to Ms A before the surgery that she would have a skin graft and would be unable to walk or drive a car for a period of time afterwards. The DHB apologised and noted that Ms A was "clearly not adequately prepared for her surgery before she came to us".
- 63. The DHB stated that it raised these issues with the Clinical Nurse Manager and Dr H, who offered to meet with Ms A to discuss her concerns.
- 64. Ms A was discharged later that day (20 September 2012). Ms A said that no arrangements had been made for her to return home, so she had to lie on the back seat of her daughter's car, while her daughter drove home.
- 65. On 27 September 2012, Ms A attended the hospital's dressing clinic, and the skin graft was checked. That day, Dr C reported to Dr B that Ms A had presented for a

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²² A melanoma with an excellent prognosis but a small risk of metastatic disease.

²³ Ms A signed a consent form for the procedure on 20 September 2012.

change of her dressing. The skin graft appeared healthy and there was no melanoma seen. The DHB stated that further dressings were to be supervised by Dr B's practice nurse, as is its normal procedure.

66. Ms A then attended the medical centre for dressing changes. Dr B stated that Ms A decided that it was more cost effective to have the dressings done at the medical centre rather than travelling to the dressing clinic at the hospital. In contrast, Ms A said that the hospital sent her back to the medical centre for her dressings.

District nurse

- 67. In her complaint, Ms A said that she had suffered financial and emotional stress because no home help or district nurse assistance was arranged. Ms A said that the medical centre staff made no arrangements for assistance for her, and she did not know that help might be available. Ms A's daughter had to move into Ms A's house with her young baby in order to care for Ms A and the other two children.
- 68. The DHB advised HDC that "the decision whether or not to involve the district nurse is initiated by the GP", and that a practice nurse at a doctor's surgery can request district nursing support if the patient is eligible.

Wound treatment

- 69. The wound subsequently became infected and was treated with antibiotics. Ms A said that the medical centre staff did not tell her that the graft had failed.
- 70. On 1 November 2012, Ms A was reviewed by a plastic surgery registrar, Dr F, at Dr H's melanoma clinic. Dr F recorded that there had been loss of the skin graft. Dr H stated that prior to that date the service had not been aware of the loss of the skin graft or the infection.
- 71. Dr H advised HDC that 70% of skin grafts on lower limbs have poor healing to some extent, including partial or complete graft loss, and have the highest risk of secondary infection of any outpatient procedure performed by the Plastics Unit.
- 72. Dr F arranged review of the wound by the dressing clinic nurses, who instituted appropriate treatment. Ms A said that she returned to the hospital two or three times subsequently and, eventually, the wound healed. The hospital recommended follow-up at the melanoma clinic in six months' time.

Further information from Ms A

73. Ms A said that she now has a big dent in her lower leg, which looks awful and causes her a lot of pain in cold weather, because the nerves in her leg have been damaged.

Subsequent action taken by Dr B

- 74. Dr B stated that he has undertaken the following actions:
 - He has reviewed his management of Ms A's treatment and discussed the matter with Dr D.
 - He has upgraded his dermoscope to enable electronic images to be collected and stored.



- He has reviewed how the practice follows up patients for regular reviews. The practice is considering incorporating a recall system for follow-up of skin cancers, similar to the recall system used for smears.
- He has initiated a recall system for skin checks.
- He has transferred most of his clinical practice in this area to his specialised clinic so that consultations are targeted and limited to the management of skin cancers.
- He has undertaken educational activities related to diagnosis and treatment of skin cancer.
- He has regular monthly face-to-face meetings with Dr D to discuss complex cases.
- 75. Dr B further advised HDC:

"In going over my management of [Ms A's] skin lesions, I have considered whether I should have relied on the benign appearances on the dermoscope when I examined the lesion on 19th April 2011. I am aware that usual recommended practice would be to arrange excision of any lesion that has appeared at the site of a previously excised melanoma ... in any future cases of lesions appearing at the site of a previous melanoma I will arrange excision rather than relying on dermoscope appearances."

76. In response to the provisional opinion, Dr B noted that there is advice that suggests that Ms A is unlikely to have suffered any increased morbidity or mortality due to the deficiencies in his care.

Melanoma Guidelines

- 77. The *Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand*²⁴ (the Guidelines) set out the accepted treatment and management of melanoma that existed during the time of these events. The Guidelines include a clear emphasis on early diagnosis and a rigorous application of appropriate treatment.
- 78. Other key aspects of the Guidelines are 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.²⁵
 - 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

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²⁴ The Cancer Council Australia and Australian Cancer Network, Sydney and New Zealand Guidelines Group, Wellington (2008).

 $^{^{25}}$ A GP may refer to a plastic surgeon or general surgeon for such excision. There may be circumstances where partial biopsy is appropriate.

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.

Responses to provisional opinion

- 79. Responses to the provisional opinion were received from Ms A and Dr B. These have been incorporated into the "information gathered" section where relevant.
- 80. A response to the provisional decision was also received from the DHB. The DHB advised that the plastic surgery booking staff have met with their manager to discuss this case, and will ensure that a copy of the appropriate information brochure is included whenever an appointment is made for surgery. The DHB stated that it regrets that Ms A did not receive the appropriate information preoperatively.

Opinion: Dr B

Introduction

- 81. Skin cancer is the most common type of cancer to affect New Zealanders. New Zealand and Australia have the highest melanoma skin cancer rates in the world.²⁶ Prevention, early diagnosis, appropriate treatment and follow-up are vital.
- 82. Ms A had the right to expect that Dr B would act proactively and competently when she presented with lesions on her leg. I consider that Dr B failed to provide care to Ms A of an appropriate standard.

Treatment 18 September 2008 — No breach

- 83. On 18 December 2008, Ms A consulted Dr B about an irregular shaped lesion on her lower right leg that had changed in shape and size. Dr B examined the lesion with dermoscopy. He stated that the lesion "appeared to be a seborrhaeic wart (keratosis) type lesion that clinically and dermoscopically appeared benign".
- 84. Dr B excised the lesion by way of curettage biopsy, and a sample was sent for histology testing.



²⁶ <u>http://www.cancernz.org.nz/reducing-your-cancer-risk/sunsmart/about-skin-cancer/skin-cancer-facts-and-figures/</u>.

³⁰ June 2014

- 85. My expert advisor, GP Dr Philip Monnington, stated that it is appropriate to manage a confidently diagnosed seborrhoeic keratosis by shave biopsy and cautery. He noted that the laboratory testing of the excised specimen showed that Dr B's clinical diagnosis was incorrect; however, the fact that the lesion was clinically misdiagnosed was not in itself a departure from the accepted standard of care.
- ^{86.} I find that Dr B's management of the lesion on 18 December 2008 was not a departure from accepted standards and, therefore, Dr B did not breach the Code in this regard.

Management strategy following excision — Breach

87. The 15 January 2009 histology result states:

"Sections show artefactually distorted superficially biopsied melanocytic lesion which is architecturally atypical and in which cytologic definition is obscured by cautery artefact. Melanoma cannot be excluded in the tissue examined."

- 88. Dr B said that the histology result, "Melanoma cannot be excluded", was not diagnostic. He concluded that the lesion was benign and that there was no residual lesion. Accordingly, he felt that it was reasonable not to re-excise the lesion, and to proceed instead with close observation. He intended to re-excise the lesion later if he had any concerns.
- 89. Dr Monnington advised that shave biopsy and cautery remove only part of the thickness of the skin. He stated:

"In a situation where melanoma cannot be excluded in the tissue examined it is essential to ensure complete removal of the lesion with an adequate margin. It is not possible to determine with clinical examination and dermatoscopy whether or not there is melanoma remaining after a shave biopsy and cautery. The doctor should have been aware of this."

90. Dr Monnington further advised that there are a number of words and phrases in the histology report that raise serious concerns about the lesion and make it clear that Dr B's clinical diagnosis of a benign seborrhoeic wart was incorrect. In particular, Dr Monnington stated:

"Firstly the report makes it clear that the clinical diagnosis was incorrect. The lesion is described as melanocytic. This means it is composed of melanocytes. Melanocytes are pigment cells in the skin and in their benign form are present in moles or naevi. In melanoma the architecture is abnormal (or atypical) and the cells themselves show atypical features. The report indicates that the architecture is atypical but because of the method of removal of the lesion it is not possible to determine how abnormal the melanocytes are. The report clearly states that melanoma cannot be ruled out in the tissue examined. Therefore it cannot be safely assumed that the lesion is benign, regardless of the clinical appearance. In this situation the lesion should be treated as if it is a melanoma. This means re excision with at least a 5mm margin of normal skin."

91. I accept Dr Monnington's advice.



- 92. In response to the provisional opinion, Dr B stated that, in retrospect, his decision "not to either re-excise or refer for re-excision was not the best option", and he accepted that the decision was below the accepted standard of care.
- 93. I agree. In my view, the histology result should have alerted Dr B that he needed to reexcise the lesion with an adequate margin. I consider that Dr B's decision to observe the lesion rather than to re-excise it was unsafe and a departure from accepted standards of care. Accordingly, I find that Dr B failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

Discussion of histology and treatment options — Breach

- 94. On 15 January 2009, Ms A attended an appointment with Dr B. I am faced with a conflict of evidence as to what information Ms A was given at this time regarding her histology result and treatment options.
- 95. Ms A advised HDC that Dr B did not tell her the histology result or give her a copy of the report and that, had he done so, it would have "rung alarm bells" for her. Ms A further stated that Dr B did not offer to re-excise the lesion and that, had he done so, she would have agreed to re-excision.
- 96. In contrast, Dr B said:

"This result was discussed with [Ms A] and an offer to excise the lesion was made but declined by her. [Ms A] was reluctant to undertake further surgery so closely after the recent excision and when the wound had just recovered."

- 97. In response to the provisional opinion, Dr B stated that he is sure he discussed the histology results and that his practice is always to offer options for management of skin lesions.
- 98. Dr B recorded in the clinical notes at the time:

"[W]ound well healed — will fade — no residual melanocytic lesion present hito (histology) not clear but was clin [clinically] benign and discussed [my] feeling is observe — [Ms A] happy — if concern happy to reexcise nc."

- 99. Dr B stated that "it is very clear" from this record that he offered re-excision at that time. I disagree. I consider that Dr B's clinical notes are ambiguous as to whether he fully informed Ms A of the histology result and her option of having the lesion re-excised. The record suggests that Dr B told Ms A that the lesion was clinically benign. Dr Monnington advised that it could not have been safely assumed that the lesion was benign, regardless of the clinical appearance.
- 100. I remain of the view that Dr B's record suggests that he decided not to re-excise and advised Ms A as such, rather than that Ms A refused re-excision after receiving full information about the results and her treatment options. That view is supported by Dr B's response to my provisional opinion that his decision "not to either re-excise or refer for re-excision was not the best option". Accordingly, I accept Ms A's account



³⁰ June 2014

that Dr B did not discuss the histology report with her fully, and did not offer her the option of a re-excision.

101. In my view, Dr B should have ensured that Ms A understood that the histology report stated that melanoma could not be excluded. He should also have discussed the option of a re-excision of the lesion, including the risks and benefits of that option, and clearly documented the discussion. This was information that a reasonable consumer in Ms A's circumstances would expect to receive. I find that Dr B breached Right 6(1) of the Code for failing to provide Ms A with that information.

Re-excision October 2009 — No breach

- 102. On 7 September 2009, Ms A drew Dr B's attention to two smaller lesions at the surgical site on her leg. Dermoscopy of the lesions was suspicious, so Dr B advised Ms A that re-excision was the most appropriate action to take.
- 103. On 15 September 2009, Dr B re-excised the lesion on Ms A's leg and sent a sample of the lesion to the laboratory for testing. The histology report confirmed that the lesion was in situ lentigo maligna melanoma.
- 104. On 6 October 2009, Dr B, assisted by Dr D, performed a further re-excision of the surgical scar with a wide clinical margin of 5–7mm. The histology report confirmed that there was no residual melanoma present.
- 105. Dr Monnington advised that Dr B's management at that time was timely and appropriate. Dr Monnington stated that to remove the lesion with a 5–8mm margin was good medical practice and, although the notes are brief, they provide an adequate record of the essential facts of this operation.
- ^{106.} I find that Dr B's management of the re-excision in September and October 2009 was not a breach of the Code.

Monitoring — Breach

- 107. Dr B advised HDC that Ms A was informed that she would require regular checks of her skin and the surgical area on her leg for any recurrence. However, no follow-up arrangements were put in place following the wide excision on 6 October 2009. On 18 January 2010, Dr B reviewed the lesion and noted "leg good", but subsequently there was no monitoring of Ms A.
- 108. Dr Monnington advised that there are no good evidence-based guidelines for surveillance following excision of a melanoma, but common practice is three-monthly checks for a year, six-monthly for two years, and then annually. He advised that the risk of recurrence after wide local excision is extremely small, and that the risk of a new primary melanoma is higher. However, he advised that it is normal practice to examine the regional lymph nodes carefully, in this case the groin, in a patient with a previous melanoma and, in his view, "[t]here is very little documentation in the notes of that having been done with only one occasion being mentioned".

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- ^{109.} I have previously commented on the need for follow-up of patents with melanoma.²⁷ I do not consider that it was sufficient for Dr B to rely on Ms A presenting regularly for other medical conditions in place of formal follow-up and monitoring of her skin lesion.
- 110. In my opinion, Dr B's failure to put in place a structured monitoring plan for Ms A from January 2009 was suboptimal and a departure from accepted standards of care. I consider that Dr B failed to take sufficient steps to minimise the risk of harm to Ms A and, accordingly, breached Right 4(4) of the Code.

Assessments 23 September 2010 and 19 April 2011 — Breach

- 111. On 23 September 2010, Ms A told Dr B that she was worried that the lesion was growing back. Dr B performed a full skin check including dermoscopy. He was satisfied that the area was benign in appearance and that there was no recurrence of the lesion. Dr B did not undertake a further re-excision or arrange any follow-up.
- 112. On 19 April 2011, Ms A presented to Dr B with a new lesion within the surgical scar where the previous excisions had taken place. Dr B again examined Ms A's lower leg using dermoscopy and observed no suspicious features. Dr B noted: "[M]ole in scar where prev melanoma excised gmb dermoscopy no suspicious features." He did not suggest a further re-excision at that time or make any surveillance plan or arrangement for follow-up of Ms A. In response to the provisional opinion, Dr B stated that he did not ignore the lesion. Rather, he examined it under the dermoscope, but did not think it had any sinister features at that time. He stated that he "reached a decision that was in retrospect not correct". He accepted that this was a departure from accepted standards of care, but does not consider it to be a severe departure because "serial digital dermoscopy" would have been an acceptable alternative to re-excision at that time. However, the records provide no evidence of further dermoscopy having been performed after 19 April 2011.
- 113. Dr Monnington advised that the fact that this was a new mole arising in or adjacent to the scar from a previous melanoma excision overrode any dermoscopy findings, and mandated diagnostic excision. He advised that the appropriate management would have been to promptly re-excise all visibly abnormal skin with a 2mm margin. He stated that, in the circumstances, dermatoscopy would have been unreliable, which should have been known to a GP who had gained a post-graduate qualification in skin cancer medicine.
- 114. I agree with Dr Monnington that the delay from 19 April 2011, when Ms A expressed concern about the new lesion, until 2 July 2012, when she was referred to the hospital, was a severe departure from expected standards of care. Accordingly, I find that Dr B failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.



Names have been removed (except the expert who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

²⁷ Opinion 10HDC00540, available at www.hdc.org.nz.

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Adverse comment — The District Health Board

- 115. On 25 July 2012, Dr H saw Ms A at his DHB melanoma clinic and discussed with her that the lesion might be an early melanoma. He advised Ms A that she would require at least an excision biopsy in the first instance, and that further management would depend on the initial result.
- ^{116.} On 9 August 2012, Dr C performed an excision biopsy of the lesion at the hospital. The results found a 0.45mm invasive melanoma with no ulceration. Dr C recommended that Ms A have a wider excision, including reconstruction with a split skin graft.
- 117. On 28 August 2012, Dr C wrote to Ms A and Dr B outlining the findings. Dr C recorded that histology had confirmed that Ms A had a radial growth phase invasive malignant melanoma with an adjacent intraepidermal component of superficial spreading type Clark level II.
- ^{118.} The DHB advised that every patient is provided with an information sheet with their waiting list papers prior to undergoing a split skin graft. The information sheet advises that the surgery requires complete rest for a week with the leg elevated, and no standing other than to go to the bathroom. The sheet states: "You should be prepared to be **house bound** for **one week**" (emphasis in original).
- 119. The DHB was unable to confirm that the booking office provided the pamphlet to Ms A prior to her admission. Ms A said that she was not given a pamphlet and had no idea that she would need to be off her feet for a week after the split skin graft. The DHB stated: "It appears that the doctor who communicated with [Ms A] at that stage did not make it clear that she would have a skin graft and therefore would be unable to walk or drive a car for a period of time." The DHB apologised and noted that Ms A was "clearly not adequately prepared for her surgery before she came to us".
- 120. When the DHB staff told Ms A after the procedure that the surgery required complete rest for a week with the leg elevated, she was distressed and burst into tears because she had two young children at home and no way to care for them.
- 121. I agree with the DHB that Ms A was not adequately prepared for her surgery. In my view, this was suboptimal. Ms A should not have been put in the position of not having known that she needed to make arrangements for her young children.
- 122. In her complaint, Ms A said that she had suffered financial and emotional stress because no home help or district nurse assistance was arranged. The DHB advised HDC that "the decision whether or not to involve the district nurse is initiated by the GP", and that a practice nurse at a doctor's surgery can request district nursing support if the patient is eligible.
- 123. Dr Monnington advised me that normally if a patient is discharged from hospital and requires district nurse input (usually to change dressings in the patient's own home), the hospital would make those arrangements. However, in some cases the hospital will discharge the patient with instructions to visit the GP for follow-up. If ongoing

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dressings are then required, it is a joint decision between the general practice and the patient as to whether the patient continues to visit the practice for dressings, or whether a referral is made to the district nurse.

124. Dr Monnington noted that financial considerations will influence this decision, as a practice will normally charge for repeat dressings, whereas district nursing is fully funded by the district health board. Although I do not consider that it was necessarily the responsibility of the DHB to arrange support for Ms A, I consider that the DHB should have discussed the options with her and included the available options in Ms A's discharge planning.

Recommendations

125. Dr B has provided a written apology to Ms A. Dr B has also developed a recall system for skin checks in response to my recommendation in the provisional opinion.

126. I recommend that Dr B take the following actions:

- Review the relevant aspects of his practice in light of this report, particularly in relation to how the practice follows up patients for regular reviews, and provide evidence to this Office of the review and the subsequent changes he has made to his practice, within three months of the date of this report.
- Provide evidence of having undertaken further training on the diagnosis and treatment of melanoma, within three months of the date of this report.
- Review the application of the new recall system within three months of the date of this report.
- 127. I recommend that the Medical Council of New Zealand consider undertaking a competence review of Dr B.

128. I recommend that the DHB take the following actions:

- Provide a written apology to Ms A. This should be sent to HDC within three weeks of the date of this report, for forwarding to Ms A.
- Develop a system to ensure that discharge planning includes information, when required, regarding district nursing and other available supports for patients within three months of the date of this report.

Follow-up actions

129. 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, and it will be advised of Dr B's name, with a recommendation that it conduct a review of his competence.

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- 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 Dr B's District Health Board, and they will both 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, <u>www.hdc.org.nz</u>, for educational purposes.



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Appendix A — Independent expert advice to the Commissioner

The following independent expert advice was obtained from GP Dr Philip Monnington on 10 March 2014:

"I have been asked to provide an opinion to the Health and Disability Commissioner on Case number C12HDC01533.

My qualifications are MB ChB, FRNZCGP, M Med (skin cancer).

My training and experience relevant to the area of expertise is as follows.

I graduated from Manchester University Medical School in 1972.

I undertook some basic surgical training in Queensland hospitals between 1973 and 1976.

I entered the general practice in 1976 in Brisbane, Australia and moved to New Zealand in 1991. I was a full-time general practitioner from 1991 until 2013. During this time I developed a particular interest in skin cancer. I currently work part-time in a dedicated skin cancer clinic and part-time in a general practice.

I attended a weekend skin cancer and surgery workshop in Auckland in 1991.

I attended a weekend workshop in skin cancer medicine and surgery in Auckland in 2006.

I commenced a Master of Medicine degree in primary care skin cancer medicine as an external part time student with the University of Queensland in 2007. I graduated in 2009.

I completed the Australian Diploma of Dermoscopy in 2009.

I have treated 2000 skin cancers since 2007. This includes over 50 melanomas.

I am an active member of Skin Cancer College Australasia. I am currently a director, a tutor for the diploma of skin cancer medicine and surgery, and an assistant tutor at some of the certificate courses. I have previously been the coordinator and a tutor for the advanced skin cancer surgery workshop.

•••

I have not provided any advice or opinions regarding the care, treatment or management of the complainant by [the DHB].

. . .

In answer to the questions raised, I provide the following replies and opinions.

1. Please comment on the standard of the doctor's clinical documentation, particularly in relation to the consultation that took place on 18 December 2008.

In general the notes are brief but adequate. The notes pertaining to the aforementioned consultation are minimal, recording the basic facts without any



additional information as to how the diagnosis was reached. This is quite common in general practice. In my opinion the notes just meet an acceptable standard.

2. Was the decision to perform curette/electrocautery consistent with the expected standards given the clinical scenario?

The consultation notes dated 18 December 2008 state that the patient was concerned regarding a change in shape and size of a lesion on her right lower leg which is also described as irregular. A diagnosis of 'seb wart' (i.e. seborrhoeic keratosis) was made. The notes do not contain any further description of the lesion and whether or not dermatoscopy was performed. Management of a confidently diagnosed seborrhoeic keratosis by shave biopsy and cautery is appropriate.

Laboratory testing of the excised specimen showed that the clinical diagnosis was incorrect. A recent Australian study found that 1 in 300 specimens submitted for histology in which there was no clinical suspicion of malignancy (including lesions diagnosed as seborrhoeic keratosis) were unexpectedly found to be melanomas (1). Without digital images of the lesion it is not possible to state whether or not the diagnosis was reasonable. It would not have been standard practice in 2008 for general practitioners to take digital images of such lesions. Some melanomas are difficult to diagnose and can mimic other lesions including seborrhoeic keratoses. The fact that the lesion was clinically misdiagnosed is not per se a departure from the accepted standard of care in my opinion.

3. Was the management strategy to observe the lesion rather than re-excise consistent with expected standards? Is it apparent from the notes that adequate surveillance was undertaken if this was a reasonable management option?

The histology report from [the laboratory] reads as follows, 'Sections show an artefactually distorted superficially biopsied melanocytic lesion which is architecturally atypical and in which cytological definition is obscured by cautery artefact. Melanoma cannot be excluded in the tissue examined'.

There are a number of words and phrases in this report which raise serious concerns about the lesion. Firstly the report makes it clear that the clinical diagnosis was incorrect. The lesion is described as melanocytic. This means it is composed of melanocytes. Melanocytes are pigment cells in the skin and in their benign form are present in moles or naevi. In melanoma the architecture is abnormal (or atypical) and the cells themselves show atypical features. The report indicates that the architecture is atypical but because of the method of removal of the lesion it is not possible to determine how abnormal the melanocytes are. The report clearly states that melanoma cannot be ruled out in the tissue examined. Therefore it cannot be safely assumed that the lesion is benign, regardless of the clinical appearance. In this situation the lesion should be treated as if it is a melanoma. This means re excision with at least a 5mm margin of normal skin.

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In my opinion the management strategy to observe this lesion rather than to reexcise it is a moderate to severe departure from the expected standard of care. Shave biopsy and cautery only removes part of the thickness of the skin. In a situation where melanoma cannot be excluded in the tissue examined it is essential to ensure complete removal of the lesion with an adequate margin. It is not possible to determine with clinical examination and dermatoscopy whether or not there is melanoma remaining after a shave biopsy and cautery. The doctor should have been aware of this.

The notes pertaining to this decision are brief and state that there was no residual melanocytic lesion present. As discussed above, it is not possible to be certain of this. The notes go on to read, 'Histo not clear but was clinically benign and discussed'. The doctor's opinion that the lesion was clinically benign was shown to be incorrect by the histology report stating that there was architectural atypia and that melanoma could not be excluded. In this situation to take no further action and observe was unsafe.

In summary, the accepted standard of care is to fully excise the lesion with an appropriate margin of skin. This was not followed.

4. On 7 September 2009 the complainant drew her provider's attention to small pigmented lesions in the region of the previous excision. The doctor removed the lesions on 15 September 2009 and the histology returned as in situ lentigo maligna extending to within 0.8 mm at the nearest lateral resection margin. The doctor discussed management with a specialist colleague and re-excision with 5 to 8 mm margins was recommended and undertaken on 6 October 2009. There was no residual melanoma found in the tissue removed. Was the management on this occasion consistent with expected standards? Was post operative surveillance as evidenced by the clinical record consistent with expected standards?

The doctor's contemporaneous notes indicate that management here was timely and entirely appropriate. It was consistent with the 2008 guidelines for the management of melanoma in Australia and New Zealand (2). For a suspicious pigmented lesion, the recommendation is to excise with a 2mm clinical margin for diagnostic purposes. If melanoma is confirmed, then a second operation is performed to remove a wider margin of skin. For an in situ melanoma the recommended margin for wide excision is 5 mm. It is common practice to increase this margin for lentigo maligna melanoma as the margins of these lesions can be indistinct with abnormal melanocytes present beyond what appears to be the boundary of the lesion.

Therefore to remove the lesion with a 5 to 8mm margin was good medical practice. The actual operation note states that the margin was approximately 7 mm. Although the notes are brief they provide an adequate record of the essential facts of this operation.



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There are no good evidence based guidelines for surveillance following excision of a melanoma in situ. Common practice is three monthly checks for a year, six monthly for two years and then annually. However the risk of a melanoma in situ recurring after wide local excision is extremely small. The risk of a new primary melanoma is higher. There is a brief mention 'leg good' in the notes of a consultation dated 18 Jan 2010 but then no mention of any further surveillance until the patient presented on 23 September 2010 complaining that the mole was growing back. In my opinion this is only a minor departure from the standard of care.

It is possible that this was a new primary melanoma arising in adjacent skin as opposed to recurrence of the original melanoma which had been widely and completely excised and would not be expected to recur.

5. Was it reasonable to rely on the dermoscopic assessment as a means of confirming the lesion was most likely benign in the clinical scenario? Was the failure to excise the lesion in 2010/2011 a departure from expected standards and if so to what degree? Please comment on the recorded surveillance of this lesion after it was first viewed. Was the nature and degree of follow-up appropriate to the clinical scenario (monitoring of a recurrent pigmented lesion at the site of previous melanoma-in-situ excision)?

In my opinion the appropriate management is to promptly re-excise all visibly abnormal skin with a 2 mm margin. In this situation dermatoscopy is unreliable and this should have been known to a GP who had [gained a post-graduate qualification in skin cancer medicine]. The fact that this was a new mole arising in or adjacent to the scar from a previous melanoma excision overrides any dermatoscopy findings and mandates diagnostic excision. Brief mention is made of the recurrent mole in the notes for consultations on 19 April 2011 and 2 July 2012 at which visit she was referred for further surgery. This represents a 21 month delay in the correct management being instigated. In my opinion this is a fairly severe departure from expected standards of care.

6. In the complainant's situation would it have been expected practice for the *GP* or for the hospital to arrange the services of the district nurse?

Normally if a patient is discharged from hospital and requires district nurse input (usually to change dressings in the patient's own home) the hospital would make those arrangements. In some cases the hospital will discharge the patient with instructions to visit the GP for follow-up. If ongoing dressings are then required it is a joint decision between the general practice and the patient as to whether the patient continues to visit the practice for the practice nurse to do the dressings or whether a referral is made to the district nurse. In reality, financial considerations will influence this decision as a practice will normally charge for repeat dressings whereas district nursing is fully funded by the district health board. In my opinion there is no departure from the expected standard of care. The various accounts suggest that there has been a problem with communication and understanding of the patient's options.





7. Any other aspects of the care provided by the doctor and that you consider warrant additional comment.

It is normal practice to carefully examine the regional lymph nodes, in this case the groin, in a patient with a previous melanoma. There is very little documentation in the notes of this having been done with only one occasion being mentioned.

In my opinion, the fact that the lesion was not fully excised in December 2008 and subsequently recurred in September 2009 is not the cause of the events of September 2010 and subsequently. My reasoning for this is that the melanoma in situ had been fully excised in October 2009 with an appropriate margin, and the histology report confirmed that there was no residual melanoma. At that point in time, all the evidence was that the melanoma had been completely removed with the correct margin and recurrence would not be expected. It is possible that the melanoma that the patient developed on her leg in September 2010 was a new primary melanoma, and not a recurrence of the previous melanoma.

Despite the delay from September 2010 to July 2012 in the patient receiving appropriate treatment, she has a very good prognosis. The AJCC tables give a five-year survival for a stage T1a melanoma of better than 95% (3). As this was a 0.45mm thick melanoma and only Clarks level II, it is most unlikely that this melanoma will have spread internally during this period of time.

In summary, and in my opinion, there are 3 main issues.

- 1. The decision to observe rather than excise in January 2009. This falls short of the accepted standard of care.
- 2. The management of the recurrence in September 2009. The care in this instance was exemplary.
- 3. The decision to observe rather than excise between September 2010 and July 2012. This falls short of the accepted standard of care.

Signed, Philip Keith Monnington

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