General Practitioner, Dr B

A Report by the
Health and Disability Commissioner

(Case 10HDC01419)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive Summary

1. This report considers the care provided to Mr A by his general practitioner Dr B, in particular, whether Dr B exercised reasonable care in managing Mr A's test results.

2. In 2009, Mr A frequently consulted Dr B regarding his skin condition, and received referrals to dermatologists. In June 2010, Mr A also consulted a homeopath about his skin condition, and was asked to have a blood test prior to the consultation. Dr B organised this blood test and then received the results. The results were normal, except for the protein electrophoresis test[1] which indicated that further review and surveillance were necessary. Dr B discussed the results with Mr A and they decided to carry out follow-up tests.

3. In August 2010, Mr A (then aged 69 years) had follow-up blood and urine tests. The results were positive on the Bence Jones Protein[2] test, which is an indicator for multiple myeloma.[3] The test results were noted by Dr B as abnormal, but he accidentally misfiled the result. Dr B did not inform Mr A of the significant result, and did not refer Mr A for specialist advice.

4. While overseas on holiday, Mr A suffered from severe back pain and was hospitalised on several occasions. On his return to New Zealand, he was hospitalised again and diagnosed with multiple myeloma.

5. While Dr B correctly marked the Bence Jones Protein test as abnormal, he did not advise Mr A of the abnormality, or refer him to a specialist. In my view, by failing to inform Mr A of the test results, and failing to take appropriate action to ensure Mr A's abnormal test results were further investigated, Dr B breached Rights 4(1)[4] and 6(1)(f)[5] of the Code of Health and Disability Services Consumers' Rights (the Code).

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[1] A technique used in blood sampling that measures the major blood proteins.
[2] A protein of low molecular weight found in the urine of patients with multiple myeloma.
[3] Multiple myeloma is a bone marrow cancer involving a type of white blood cell called a plasma (or myeloma) cell.
[4] *RIGHT 4: Right to Services of an Appropriate Standard*
(1) Every consumer has the right to have services provided with reasonable care and skill.
[5] *RIGHT 6: Right to be Fully Informed*
(1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including —
(f) The results of tests; …

Investigation process

6. On 20 December 2010, the Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided to her husband Mr A, by general practitioner Dr B. The following issue was identified for investigation:

- *Whether Dr B provided an appropriate level of care to Mr A in 2009 and 2010, with particular reference to the management of his lesions, test results and to Dr B's clinical documentation.*

7. An investigation was commenced on 9 May 2011, following a period of preliminary assessment.

8. The parties directly involved in the investigation were:

Mr A	Consumer
Mrs A	Complainant
Dr B	Provider/General practitioner
A medical centre	Provider/Medical centre

Also mentioned in this report

Dr D	General practitioner
Dr E	Dermatologist
Dr F	Dermatologist
Dr G	General practitioner
Dr H	Pathologist

9. Information was also received from Ms C (support person for Mrs A).

10. Clinical advice was obtained from general practitioner Dr David Maplesden, and is set out in **Appendix 1**.

Information gathered during investigation

Background

11. Mr A became a registered patient at a medical centre in 2002. Dr B[6] was Mr A's primary doctor. When Dr B was not available, Mr A saw other doctors at the practice.

12. The practice is a group of six self-employed doctors with a cost-sharing arrangement, who share premises.

Chronology of events

Skin lesion

13. On 10 June 2009, Mr A consulted general practitioner Dr D (a GP also practicing at the medical centre) concerning a rash on his legs. Dr D made a provisional diagnosis of discoid eczema.[7]

[6] Dr B has been registered with the Medical Council of New Zealand for over 45 years.

14. Between that appointment and November 2009, Mr A consulted Dr B several times regarding the management of his eczema. For an appointment on 17 November 2009, the clinical notes state: "Itchy rash relieved by prednisone but has recurred." Dr B advised that he was concerned at the "refractory[8] nature of [Mr A's] skin condition", so he referred Mr A to dermatologist Dr E.

15. Dr E reviewed Mr A and, on 19 November 2009, wrote to Dr B. Dr E's letter to Dr B states that Mr A had "very unpleasant widespread discoid eczema", for which Dr E prescribed treatment. There is no mention of a pigmented lesion on Mr A's sternum.

16. Dr B recalled Mr A asking him to "check a couple of spots" on his skin at the end of the consultation on either 30 November 2009 or 2 March 2010. This request, and Dr B's examination and advice, is not documented. However, Dr B's recollection is that he examined a lesion on Mr A's sternum with the aid of a binocular magnifying loupe. He considered that the lesion had no malignant features, and that it was most likely a benign sebaceous keratosis.[9]

17. On 2 March 2010, due to Mr A's continuing skin problems, Dr B referred Mr A to another dermatologist, Dr F, for a second opinion.

18. Dr F reviewed Mr A, and on 4 March 2010 wrote to Dr B. He diagnosed a "6 month history of nummular eczema",[10] and provided Mr A with advice regarding the management of this. Additionally, Dr F examined Mr A's sternum lesion with a dermatoscope and advised that the lesion could be a melanoma and should be removed.

19. Dr G (a GP also practicing at the medical centre) removed the sternum lesion on 29 March 2010. The lesion was found to be a melanoma.

20. Dr B told HDC that he regretted not diagnosing the melanoma and wished to apologise to Mr A and his family. However, Dr B was surprised that Mr A had a melanoma because Dr B did not regard the lesion on Mr A as sinister. Dr B noted that melanomas can change rapidly, and he pointed out that Mr A's condition may have changed in the time between Dr B's examination and Dr F's. Dr B also noted that Dr F is a specialist in this field, whereas Dr B is not. He finally pointed to the fact that diagnostic errors do occur, even by competent, experienced practitioners.

21. Dr B has also acknowledged shortcomings in his clinical documentation relating to his review of Mr A's lesion. Dr B advised that he has changed his practice to include a review of his casenotes at the end of each consultation, to ensure full documentation.

22. Dr B stated that he never hesitates to refer patients for specialist follow-up when he has concerns.

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[7] Characterised by coin-shaped lesions (also called nummular eczema), *Oxford Concise Medical Dictionary, 6th edition*.
[8] Unresponsive to treatment, *Oxford Concise Medical Dictionary, 6th edition.*
[9] A horny overgrowth of the skin, *Oxford Concise Medical Dictionary, 6th edition.*
[10] See footnote (7) above.

Blood test results

23. Mr A decided to consult a homeopath about his skin condition. The homeopath required a full blood count prior to the appointment. On 24 June 2010, Mr A requested a blood test form from Dr B for this purpose, and the blood test was performed that day. The results of the blood test were normal except for the protein electrophoresis test which indicated monoclonal gammopathy.[11]

24. Dr B received a report on the blood test results from chemical pathologist, Dr H. Part of the report of 24 June 2010 stated:

> "… Initial review and regular surveillance (6 monthly, then 12 monthly if stable) should include clinical review, blood count, immunoglobin quantification, protein electrophoresis, renal function and calcium. If there is suspicion of myeloma or lymphoma referral to a Clinical Haematologist is recommended. Suggest a urine sample to check for the presence of monoclonal free light chains (Bence Jones Protein)."

25. On 29 June 2010, Mr A was asked to come in and see Dr B to discuss the results of his blood tests. Mr A consulted Dr B on 30 June. The clinical notes for this consultation read in part:

> "discussion re monoclonal antibody.
>
> P: blood review end of August (prior to departure [overseas])"

26. Dr B acknowledged that the extent of his consultation is not apparent from reading his brief consultation note. However, he told HDC that "in the absence of any symptoms, apart from [Mr A's] eczema and the normality of all his other blood tests", he decided that surveillance was appropriate. Dr B stated that rather than commence surveillance in six months (as he believed was indicated by the pathologist), out of caution he recommended the first surveillance blood test occur in six to eight weeks, prior to Mr A's planned trip overseas. Dr B supplied HDC with a copy of the laboratory form prepared on 30 June 2010, dated for 6 weeks later (9 August 2010). This included a request for a full blood count and urine test, including a test for Bence Jones Protein.

27. On 12 August 2010, Mr A underwent the first of these follow-up tests, including the Bence Jones Protein test. Mrs A advised HDC that Mr A had no memory of being told why he was having the urine test.

28. The Bence Jones Protein test was positive, which is suggestive of multiple myeloma.[12] Dr B received these results on 12 August and recognised that they were abnormal.

29. Dr B's clinical notes for 12 August read:

> "Ibx: Bence Jones Confirmation – note, abnormal."

[11] Monoclonal gammopathy is the presence of excessive amounts of a particular protein in the blood and denotes an underlying disorder.
[12] See footnote (3) above.

30. Dr B explained that his usual practice with abnormal test results is to leave them in his "Practitioner's In-box" (a folder within the practice management computer system) until he has determined the appropriate course of action to be taken. In this case however, Dr B inadvertently filed the result in Mr A's patient inbox. Dr B told HDC that when results are filed in a patient's inbox, they "are not accentuated unless the in-box is opened". Dr B did not attach a reminder to the result. As a consequence of these actions, Dr B stated that his "attention was diverted" and he did not inform Mr A of the results at that time, or refer him to a specialist.

31. Dr B considers that a feature of the practice management system which the medical centre use contributed to his misfiling. In particular, he claimed that the short-cut keys for filing a result are too close together (see paragraph 40).

32. On 30 August 2010 (a week before Mr A's overseas trip), Mr A saw Dr B regarding several issues. The clinical notes read:

> "has decided homeopathy ineffective. worried about eczema while on holiday. would like to try prednisone. has had relapse of longstanding lower back pain, following a coughing bout. had the flu about 6 weeks ago. cough persists.
>
> heart sounds dual, no murmurs, chest clear.
>
> P: prednisone commencing with 20mg tabs, then 5mgs as per Rx. rpt reg meds. use codalgin for back pain prn."

33. Dr B did not look at Mr A's inbox during what Dr B describes as a "relatively complex consultation". There was no prompt from the patient management system, or from Mr A to look at the test results. Consequently, Dr B did not tell Mr A of the positive Bence Jones Protein test.

34. Dr B accepts that he failed to advise Mr A of the abnormal findings of his blood and urine tests, suggestive of myeloma, and failed to refer him for specialist opinion.

Overseas trip

35. During Mr A's overseas trip, he developed increasingly severe back pain and required hospitalisation. He was diagnosed with a probable herniated disc.

36. On 16 October 2010, while still overseas, Mrs A emailed Dr B to inform him of Mr A's back issues and to let him know that their travel insurance company would be contacting him. Dr B replied, saying he would provide whatever the insurance company needed, and expressed his concern for Mr A's back. He did not mention the abnormal test result. Mrs A told HDC that this meant they continued to believe Mr A was suffering from a herniated disc. On 18 October 2010, Dr B completed a questionnaire relating to Mr A's travel insurance claim and returned it to them by fax.

Diagnosis and complaint

37. Mr A returned to New Zealand on 24 October 2010, and was admitted to hospital. He was diagnosed with collapse of several vertebrae secondary to multiple myeloma, and commenced chemotherapy. He has since been significantly disabled by the pain of his fractures.

38. On 1 November 2010, Dr I, Managing Associate for the medical centre, completed a Significant Event form, noting that an error had occurred, namely, the inadvertent filing of Mr A's abnormal result. The form confirmed that Mr A was receiving appropriate specialist follow-up, and that Dr B had been trying to contact Mr or Mrs A. Under the heading, "What has been done to prevent this happening again", it is noted: "[Dr B] to discuss with all Associate Drs to be aware of the potential to file results in error."

39. Mrs A arranged a meeting with Dr B on 29 November 2010. Mrs A took Ms C with her as her support person. During this meeting, Mrs A asked Dr B why tests were not carried out on Mr A before they left for their overseas trip. Dr B advised Mrs A that a Bence Jones Protein test had been carried out, and the result was positive. Dr B explained to Mrs A and Ms C that the test result had slipped his mind, and that he had accidentally pushed the wrong key on the computer. He apologised to Mrs A. Dr B explained that he believed features of the patient management system had contributed to this mistake. He noted that the shortcut keys to file laboratory results are too close, increasing the potential for inadvertent filing of abnormal results. He also mentioned that there is no warning when an abnormal result is filed. Mrs A felt that Dr B did not accept accountability for his actions.

40. On Ms C's suggestion, Dr B wrote to the practice management system company suggesting a modification of the keys used to file inbox documents. The practice management system company did not adopt his suggestion, and stated that the preferred method for filing inbox results is to use the mouse and click on the 'File' button when a particular lab result is being viewed.

41. Mrs A recalled Dr B saying during the meeting that Mr A did not ask about the result, and both Dr B and Mr A were excited about their upcoming trips. Ms C also recalled Dr B saying that he did not bring up the test results at the consultation, and that Mr A did not raise the issue either.

42. On 20 December 2010, Mrs A complained to HDC about the care and treatment Dr B provided to her husband. At that time, Mr A was requiring full-time care and had been in hospital for seven weeks, having four compression fractures.

43. Dr B told HDC of his regret that his actions had an adverse affect on Mr A's health and expressed "a wish to take any action that may mitigate those actions".

44. Dr B said that he attempted to contact Mr and Mrs A when he became aware of the diagnosis. He asked Mrs A at their meeting on 29 November to pass on his apology to Mr A for not having had an opportunity to speak directly with him. Dr B stated that he "formed the view, possibly unwarranted, that [Mr A] did not wish to have personal contact with me. For that reason, I did not pursue efforts to offer [Mr A] a personal apology, believing that my message via [Mrs A] had that effect." He stated in his response to HDC: "I am indeed very sorry for my omission and I apologise to [Mr and Mrs A]."

45. Mrs A recalled that Dr B left one telephone message on her and Mr A's answer phone during the period Mr A was in hospital.

46. Dr B indicated that he has discussed the issues in this complaint with his practice partners and with senior haematologists.

47. Dr B also advised HDC that he has now reviewed his management of patients with monoclonal gammopathy and has read the Waikato DHB's guidelines (referred to in Dr Maplesden's advice, see Appendix One). He noted that the previous testing provider "habitually provided individualised advice to clinicians concerning abnormal test results", whereas the current service provider does not. He remarked that this would have been useful in Mr A's case.

48. Dr B advised HDC that he has sold his practice, and has retired.

The medical centre

49. Dr I advised that at the medical centre it is the ordering doctor's responsibility to review all results and follow up abnormal results, unless the doctor is away and other arrangements are made (for example, a nurse may check the incoming results, or the doctor may arrange for a locum).

50. Dr I enclosed a copy of the medical centre's 'Practice policy to manage patient test results', which was in place at the time of the misfiling. This states:

> "Policy is that all Doctors check electronic results daily. If a Doctor is on leave, the Doctor's designated nurse reviews inbox and mail and alerts the day's Acute Doctor of any abnormal results. All mail is opened by reception and distributed to Doctors who sign and put back for scanning, and then electronically file.
>
> Ordering Doctors responsibility is to follow up test results. Doctors will use task list to remind themselves to follow-up significant results."

51. Dr I advised that the Policy was written in 2008 as part of the Cornerstone Accreditation Process, and was discussed at that time with the medical centre's doctors and nurses. Since then, the policy has been available to all staff in paper and electronic copy, and it is discussed with all new clinical staff during orientation.

52. Dr I also advised that any problems that arise with the management of test results are discussed as part of the medical centre's Significant Event Process.

53. Dr I confirmed that Dr B had discussed the error with the associate doctors, and that the locum doctors would also be alerted. Dr I also advised:

> "Since this complaint was received, we have extensively discussed the possibility of a misfiled result at our Associates Meeting and also at our [medical centre] Doctors Peer Group. All clinical staff are aware of the need for vigilance in the managing of Inbox results."

Opinion: Breach — Dr B

Diagnosis of melanoma

54. Dr B was asked to "check a couple of spots" on Mr A in late 2009 or early 2010, including a lesion on Mr A's sternum. Dr B considered that the lesion had no malignant features. This examination is not documented, and the sternal lesion was later diagnosed, by a dermatologist, as a melanoma. Dermatologists are generally able to diagnose skin lesions more accurately than general practitioners because of their specialist capacity and increased exposure to such lesions. In addition, Dr Maplesden notes:

> "…while it is clear that [Dr B] did misdiagnose the lesion, this does not mean he did not make a clinically sound decision based on his assessment of the evolution and appearance of the lesion at the time. Unfortunately, the lack of clinical documentation makes it impossible to qualify the actions of [Dr B] at the time."

55. In my view, Dr B's failure to document his examination represents a departure from expected standards. However, as noted by Dr Maplesden, on a review of the clinical notes there are several references to skin checks and removal of lesions that indicate that Dr B had "a generally conscientious and clinically sound approach to the examination and treatment of [Mr A's] skin lesions".

56. I accept that Dr B's omission in this case was not the result of a trend of suboptimal documentation. I also note that Dr B altered his practice to review his documentation at the end of each consultation. In my view, this quality improvement strategy will ensure that a good standard of documentation is maintained.

Test results

57. On 30 June 2010, Mr A attended a consultation with Dr B to discuss the results of his blood tests. The results indicated mild monoclonal gammopathy, which required follow-up. Dr B and Mr A discussed the results and follow-up arrangements were made. The chemical pathologist's report recommended "[i]nitial review and regular surveillance (6 monthly, then 12 monthly if stable)", and should include clinical review, blood count, immunoglobin quantification, protein electrophoresis, renal function and calcium. Dr B's interpretation of this report was that an initial review in six months would be appropriate. However, because Mr A was planning an overseas trip, Dr B recommended the initial review take place before that trip, in six to eight weeks' time.

58. Dr Maplesden advised me that the clinical review and the further testing, advised by the chemical pathologist, should have been undertaken at the time the first abnormal result was detected, with surveillance dependent on the results of the review and tests. Clinical review would generally involve a clinical assessment for unexplained weight loss, bone pain, night sweats, lymphadenopathy or splenomegaly. Dr Maplesden stated: "Any concerning features in the clinical assessment or on completion of the recommended tests should have led to discussion with a haematologist or appropriate further investigations such as lumbar spine X-ray or bone marrow biopsy."

59. Although the chemical pathologist's advice was ambiguous, it would have been appropriate for Dr B to have undertaken a focussed clinical assessment and further investigations shortly after the June blood test results were obtained. Nevertheless, I

accept that Dr B's planned management of Mr A, based on Dr B's interpretation of the pathologist's advice, was reasonable in the circumstances, particularly bearing in mind that Mr A was evidently reasonably well at this time.

Abnormal test result

60. Follow-up tests were performed on 12 August 2010, and the Bence Jones Protein test was abnormal. Dr B received the Bence Jones Protein test result in his inbox on 12 August 2010, and marked it as abnormal. However, Mr A was not informed of the abnormal result and further investigations into the abnormal result were not undertaken because: no reminder was put in place; the results were inadvertently filed; and the results were not recalled by Dr B when he saw Mr A two weeks later (30 August 2010). In October 2010 Dr B missed a further opportunity to review the notes when Mrs A emailed from overseas to advise him of Mr A's severe back pain.

61. Doctors owe patients a duty of care in handling patient test results, including advising patients of, and following up on, abnormal results.[13] The primary responsibility for following up abnormal results rests with the clinician who ordered the tests, in this case, Dr B.[14] Dr B's failure to inform Mr A of the significantly abnormal result and to follow up on that abnormal result in an appropriate manner was a severe departure from expected practice.

62. Dr B submitted that his failures in this case were due, in part, to his inadvertent misfiling of Mr A's abnormal result. Dr B submitted that a feature of the patient management system contributed to his filing mistake.

63. While, as stated by this Office in 2002, "doctors [should not] be held responsible for failures outside their control, such as testing facility delays, or a patient's decision not to attend for tests",[15] that was not the case here. Dr B's misfiling of the abnormal Bence Jones Protein result was only one of a series of avoidable errors that led to his overall failure to appropriately manage and respond to Mr A's abnormal result. Other factors include his failure to use an appropriate reminder system, and failure to recognise other opportunities to inform Mr A of the result and arrange appropriate follow up, for example, when he reviewed Mr A on 30 August and when he was contacted by Mrs A on 16 October.

64. I note that patient test result management systems may never be completely fail-safe, and do not exist in isolation from their users. As noted by the Institute of Medicine in a recent report on health information technology and patient safety, the challenges facing safer healthcare and safer use of information technology involve the people using the technology, as much as the technology itself.[16] To ensure patient safety, general practitioners and practices must remain especially vigilant when managing abnormal test results, and need to utilise methods available to them that reduce the possibility of human or technological error. In this case, that could have included using a computer mouse to file results rather than shortcut keys, and using a reminder system such as the patient and provider task manager, the recall module, and patient

[13] For example: 00HDC07636, 99HDC11494, 08HDC06165, 08HDC06359, 09HDC01505.
[14] See opinion 08HDC06359.
[15] *Patient Test Results Again*, Ron Paterson, 19 March 2002
[16] Institute of Medicine (2011) Health IT and Patient Safety: Building Safer Systems for Better Care. Washington, D.C: The National Academies Press.

alerts. Dr B did not utilise the methods available to him to ensure that he appropriately managed Mr A's abnormal test result, and this was unacceptable.

Patient responsibility

65. As part of his explanation for his failure to inform Mr A about the abnormal test result, Dr B told Mrs A that her husband did not ask about his test result. I appreciate that this was probably not meant to be interpreted as to lay any blame with Mr A. However, it is the referring practitioner's responsibility to follow up test results, not the patients. This responsibility has been emphasised in several previous HDC opinions.[17]

Action by Dr B

66. Dr B advised that he:

- reviewed his management of patients with monoclonal gammopathy, and has read the Waikato DHB Guidelines referred to in Dr Maplesden's advice;
- changed his practice to include a review of the casenotes at the end of each consultation;
- discussed the issues involved in the complaint with his practice partners and with senior haematologists;
- suggested to the practice management system company that the system be reviewed so that there is less risk that results be misfiled due to the closeness of the filing shortcut keys. The practice management system company considered his response, but declined his suggestion. The practice management system company suggested that the problem would be avoided by using a mouse rather than a keyboard when directing results for filing; and
- sold his practice and would retire at the end of 2011.

67. I acknowledge Dr B's attempts to express his apology to Mr A through Mrs A.

Summary

68. I accept that Dr B's failure to advise Mr A of the abnormal test result and failure to arrange appropriate follow up was, in part, because of his error in inadvertently filing the result. However, it is not this error alone that causes particular concern. Here, it was Dr B's failure to utilise the systems readily available to him to ensure that the test result was adequately managed and appropriately followed up. As noted by my clinical advisor: "The potential for failing to act appropriately on abnormal results or results due to be followed-up in the future can be lessened through appropriate use of various reminder systems present in the PMS (patient and provider task manager, recall module, patient alerts)."

69. In my view, Dr B did not exercise an appropriate degree of care in responding to Mr A's abnormal test result. While he correctly marked the Bence Jones Protein test as abnormal, he did not inform Mr A of the result and did not arrange appropriate follow up. Accordingly, in my view, Dr B breached Rights 4(1) and 6(1)(f) of the Code.

[17] For example, see Opinions 00HDC07636 and 08HDC06165.

70. Dr B has apologised to Mr and Mrs A for his breach of the Code.

Other comment

71. Medical Centres have a responsibility to have good systems in place to ensure patients receive good quality care. In particular, they are responsible for having effective policies for the handling of incoming results and patient follow-up.

72. The medical centre has a policy that states in part:[18]

> "Doctors will use task list to remind themselves to follow-up significant results."

73. Dr Maplesden is of the view that the "practice policy on management of patient test results has been viewed and is robust — it recommends the use of patient task manager as an additional safeguard to ensure timely management of abnormal results."

74. The medical centre advised that the policy, written in 2008, was discussed with all its doctors and nurses at the time, and is always available in paper and electronic form. It also advised that the policy is discussed with all new clinical staff during orientation.

75. Overall, in my view, the medical centre did have an effective policy in place for the handling of incoming results and patient follow-up at the time of these events.

Recommendation

- If Dr B practises in the future, I recommend that he use appropriate reminders on any abnormal result, to minimise the risk of such an error occurring again.

Follow-up actions

- A copy of the final 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.

- A copy of the final 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.

- A copy of the final 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.

[18] The full policy document was provided to HDC.

Appendix A - Clinical advice to Commissioner

The following expert advice was obtained from HDC's in-house clinical advisor, general practitioner Dr David Maplesden:

"**1. Documents reviewed**

1.1 Complaint from [Mrs A] received 20 December 2010

1.2 Response from [Dr B] received 23 February 2011

1.3 GP notes

2. Summary of complaint

(i) [Dr B] reassured [Mr A] that a mole on his throat was nothing to worry about. When he saw a dermatologist in March 2010, [Mr A] was told the spot was a melanoma and should be removed. The lesion was removed and was a melanoma.

(ii) [Mr A] had blood tests done in June 2010 that were abnormal. Follow-up tests were not done until August 2010 and these indicated [Mr A] might have multiple myeloma.[19] However, [Dr B] did not convey these results to [Mr A] at a consultation of 30 August 2010 just before [Mr A] was leaving on an overseas trip. [Mrs A] states *[Mr A's] whole focus at the 30 August 2010 appointment had been to ask for something to keep his eczema from flaring up while we were visiting our daughter overseas. [Dr B] prescribed Prednisone.*

(iii) [Mr A's] trip was complicated by the development of increasingly severe back pain and he required hospitalisation and doctors visits while away. On his return he went to [Hospital] and was diagnosed with collapse of several vertebrae secondary to multiple myeloma. He was commenced on chemotherapy and has since been significantly disabled by the pain of his fractures.

(iv) [Mrs A] complains that the diagnosis was not made in a timely fashion and led to [Mr A] travelling when he should not have, suffering severe discomfort and disability due to the delayed diagnosis, and financial distress from unforeseen medical expenses while away. [Dr B] has since explained the failure to follow up was due to a filing error.

3. Provider(s) response summary

3.1 [Dr B] recalls [Mr A] asking him to 'check a couple of spots' at the end of a consultation on either 30 November 2009 or 2 March 2010. He has not documented any reference to the request or his management. However, he recalls examining a lesion over [Mr A's] upper sternum with a magnifying loupe and felt that it had no malignant features and was most likely a benign sebaceous keratosis. [Mr A] was reassured. Dr F used his specialist experience and equipment (dermatoscope) to

[19] Commissioner's note: "multiple myeloma" and "underlying myeloma" are used interchangeably in Dr Maplesden's advice.

diagnose the possible melanoma. The lesion was removed by [Dr B's] colleague ([Dr G]) on 29 March 2010 and was a melanoma.

3.2 [Dr B] accepts that he misdiagnosed the lesion and apologises for this, but states that there were no features of concern at the time he examined it, and such lesions can sometimes change quite rapidly such that the appearance may have altered by the time he saw [Dr F].

3.3 [Dr B] agrees that he failed to advise [Mr A] of the abnormal findings of his blood and urine tests, suggestive of myeloma, in August 2010 and apologises for the delayed diagnosis and suffering [Mr A] underwent as a result of this delay. He apologised to [Mrs A] in person when she raised the issue at an appointment following the couple's return from overseas, but was under the impression [Mr A] did not want any further contact with [Dr B] following the delayed diagnosis and has therefore not apologised in person to [Mr A].

3.3 [Dr B] notes that [Mr A] developed a progressive rash from June 2009 and was seen by himself, a colleague at the medical centre (Dr D) and two dermatologists ([Drs E and F]) on several occasions over the next 12 months because the rash was severe and resistant to treatment. A diagnosis of myeloma as a contributor to the rash was never considered and there was no blood testing advised by the specialists. The rash was diagnosed as nummular eczema.

3.4 On 24 June 2010 [Mr A] requested a blood test form as he was seeing a homeopath for his skin condition and the homeopath wanted blood tests done. Results were essentially normal apart from protein electrophoresis which indicated a monoclonal gammopathy. [Dr B] interpreted the pathologist's advice as indicating the abnormality was unlikely to be significant and that the patient should be reviewed at 6-12-monthly intervals with specific tests to be done at these times. [Dr B] conveyed these results to [Mr A] on 30 June 2010 and, after establishing [Mr A] was well apart from his skin rash, decided that the 'recommended surveillance' was appropriate. He states *out of caution, I advised that the first such surveillance blood test should occur in six to eight weeks, prior to his planned trip, rather than in six months.*

3.5 The recommended tests were performed on 12 August 2010 – the monoclonal gammopathy had increased and Bence Jones protein was present in the urine (biochemical markers suggestive of underlying myeloma). The results were annotated by [Dr B] as abnormal but inadvertently filed, and therefore overlooked when [Mr A] presented for a review of other symptoms on 30 August 2010. [Dr B] has since written to the practice management system software provider, drawing their attention to the incident and the potential for such error (letter viewed). The provider has declined to alter the software instead suggesting [Dr B] use the mouse rather than keyboard when dealing with results. [Dr B] felt [the key combination to file a result was] close enough together to lead to errors. There was also no warning when an abnormal result was being filed].

3.6 On 30 August 2010 [Mr A] presented a week prior to his departure overseas. He had a cough of several weeks duration, requested prednisone in case his skin flared while he was away, and complained of recurrence of a longstanding problem with back pain that usually resolved with chiropractic attention. *He did not want further*

attention, but did want some strong analgesics to use should the need arise on his trip. He did not ask about his recent test results and [Dr B] did not check them during the consultation.

4. Review of clinical records and related comments

(i) Clinical notes are of reasonable quality, generally following the SOAP structure.

(ii) The notes show [Mr A] has been referred for specialist advice relating to various complaints (ophthalmologist 2006, ECG reporting May 2007, urologist September 2009, cardiologist October 2009 (blood pressure monitoring), dermatologist November 2009 ([Dr E]) and March 2010 ([Dr F]). There is no apparent reluctance by [Dr B] to refer for specialist advice when he feels this is clinically indicated.

(ii) Blood tests have been undertaken regularly, particularly with regard to monitoring of PSA levels and cardiovascular risk factors. Full cardiovascular risk assessment was undertaken on 13 November 2002 giving a 5-10% 5-year risk. Formal reassessment of risk is undertaken on 24 May 2007 and 9 May 2010. There is appropriate pharmaceutical management of risk factors (hypertension, hyperlipidaemia).

(iv) There are several references to skin checks and removal of lesions: 6 November 2002 basal cell carcinoma (BCC) removed from chest; liquid nitrogen treatment of seven lesions resembling superficial BCCs on 21 November 2003; liquid nitrogen treatment to a hyperkeratotic lesion on the left hand 22 March 2004; numerous superficial BCCs on trunk and scalp treated with liquid nitrogen 3 July 2006; liquid nitrogen treatment to lesions left arm and left flank; benign scalp lesion excised 20 December 2007; liquid nitrogen to left pectoral lesion 11 February 2008; excision of BCC anterior left shoulder and liquid nitrogen to two back lesions 3 September 2008; To me, these actions indicate [Dr B] took a generally conscientious and clinically sound approach to the examination and treatment of [Mr A's] skin lesions.

(v) [Mr A] is reviewed by dermatologist [Dr E] on 19 November 2009. He has examined [Mr A's] skin noting *very unpleasant widespread discoid eczema.* A dermatologist would normally be examining the entire skin when there is a widespread rash. There is no comment regarding the pigmented lesion on [Mr A's] upper sternum which was presumably present at this time. As indicated above, there is no documentation by [Dr B] referable to the melanoma in any 2009 consultations nor in 2010 until the consultation at which removal was undertaken on 29 March 2010. Histology confirmed a superficial spreading melanoma 0.85mm deep. The lesion is described (pathology report) macroscopically as a *raised keratotic brown lesion 11x7mm.* [Dr F] notes in his letter to [Dr B] dated 4 March 2010 *Of incidental concern is the irregularly pigmented brownish/black macule just over 1cm on longest diameter over his upper sternum.* Dermatoscopic features are described as consistent with *microscopic superficial melanoma over sternum* and [Dr F] notes he will discuss the features with [Mr A] at the next planned review. This review takes place on 23 March 2010 by which stage removal of the lesion has already been arranged.

(vi) Competent use of a dermatoscope can increase the accuracy of diagnosis of some skin lesions including melanoma. Some GPs have received training in use of the dermatoscope and use it often enough to remain competent but they would be in the

minority. I would not regard its competent use in primary care as commonplace. Dermatologists diagnose skin lesions more accurately than GPs with or without the use of a dermatoscope as would be expected in their specialist capacity and with increased exposure to such lesions. A majority of pigmented skin lesions removed in primary care are not melanoma and it is hoped increased use of dermoscopy and the associated technology of mole mapping might reduce the unnecessary removal of benign lesions in the future. [Dr B] did not record any features of the lesion in question nor that he examined it. Failure to document the examination and features is a moderate departure from expected standards although I have noted above a prior history of consistent documentation and treatment of [Mr A's] skin lesions. I have not seen the lesion and cannot comment on its appearance or evolution. [Dr B], in his response, describes it as like a sebaceous keratosis (a very common benign lesion in the elderly). The pathologist's macroscopic description could be consistent with a sebaceous keratosis, although [Dr F's] macroscopic observation of variable brown black pigmentation would be less characteristic. Features that might raise a suspicion of melanoma include: a higher risk patient (personal or family history of melanoma; personal history of high sun exposure; advanced age) — [Mr A] was probably at higher risk given his past history of numerous basal cell carcinomas indicating ultraviolet damage; an asymmetrical pigmented lesion; irregular or ill-defined borders to the lesion; variability in colour — present by the time [Dr F] reviewed the lesion; diameter > 8mm (yes); a pigmented lesion that is growing, changing in colour or bleeding (not clear). In summary, while it is clear [Dr B] did misdiagnose the lesion, this does not mean he did not make a clinically sound decision based on his assessment of the evolution and appearance of the lesion at the time. Unfortunately, the lack of clinical documentation makes it impossible to qualify the actions of [Dr B] at the time. However, in the context of previous documentation supporting a conscientious approach to the management of [Mr A's] skin lesions by [Dr B], and the fact that Dr E did not comment on the lesion as being unusual, I cannot state that [Dr B's] clinical management on the occasion in question departed from expected standards (other than the lack of documentation). He should reflect on his failure to document his actions in this instance, including no apparent advice to return should the lesion change in any way. I note he has apologised to [Mr A] in his written response.

(vii) Notes for 24 June 2010 state *eczema has flared and has decided to consult a homeopath. She wants him to have a 'full blood count'…* On 30 June 2010 *discussion re monoclonal antibody. P: blood review end of August (prior to departure for Europe)…* On 12 August 2010 a variety of results have been filed with comment against Bence Jones protein *note, abnormal* and against blood count *neutropaenia.* On 30 August 2010 *has decided homeopathy ineffective. Worried about eczema while on holiday. Would like to try prednisone. Has had relapse of longstanding lower back pain, following a coughing bout. Had the flu about 6 weeks ago. Cough persists. Heart sounds dual, no murmurs, chest clear. P: prednisone…use codalgin for back pain.* Prescriptions are given for prednisone and Codalgin in addition to regular medications. I could find no additional reference to chronic or recurrent back pain in the clinical notes.

(viii) Results from 24 June 2010 show normal calcium levels, normal liver function, albumin and globulin levels, essentially normal renal function and very mild neutropenia (pathologist comment *consider viral infections and review medication*).

ESR is normal at 9mm/hr with normal glucose and thyroid function. Immunoglobulins show a decrease in IgM at 0.2 g/L (normal range 0.4-2.5) with other immunoglobulin levels normal. Protein electrophoresis identifies a mild IgG monoclonal gammopathy. The pathologist comment is *This patient's monoclonal protein is small and is less likely to be clinically important, but the band size is not always predictive of clinical significance. IgG monoclonal proteins may be associated with myeloma and related lymphoproliferative disorders. Initial review and regular surveillance (6 monthly then 12 monthly if stable) should include clinical review* and a variety of specified tests including a urine sample looking for Bence Jones protein. Results of 12 August 2010 are similar with persistence and slight increase in the monoclonal band, and increase in the previous neutropaenia. Of most significance is that the Bence-Jones test is positive raising the possibility of underlying myeloma.

(ix) A review of the pathophysiology of myeloma[20] includes the following comments:

a) The diagnosis of MM is often suspected because of one (or more) of the following clinical presentations:

- *Bone pain with lytic lesions discovered on routine skeletal films* (not noted in [Mr A] until investigations for severe back pain)
- *An increased total serum protein concentration and/or the presence of a monoclonal protein in the urine or serum* (this was the first indication of [Mr A's] eventual diagnosis)
- *Systemic signs or symptoms suggestive of malignancy, such as unexplained anemia* (not present in [Mr A])
- *Hypercalcemia, which is either symptomatic or discovered incidentally* (not present in [Mr A])
- *Acute renal failure with a bland urinalysis or rarely the nephrotic syndrome due to concurrent primary amyloidosis.* (not present in [Mr A])

b) *Most patients with MM present with signs or symptoms related to the infiltration of plasma cells into the bone or other organs or to kidney damage from excess light chains. As an example, a retrospective analysis of 1027 sequential patients diagnosed with MM at a single institution found the following symptoms and signs at presentation:*

- *Anaemia — 73 percent* (not present in [Mr A])
- *Bone pain — 58 percent* (in retrospect [Mr A's] back pain noted on 30 August 2010 was likely related to the underlying myeloma)
- *Elevated creatinine — 48 percent* (not present in [Mr A])
- *Fatigue/generalized weakness — 32 percent* (not obviously present in [Mr A])
- *Hypercalcemia—- 28 percent* (not present in [Mr A])

[20] Rajkumar S. Clinical features, laboratory manifestations, and diagnosis of multiple myeloma. Uptodate. Last reviewed September 2010. www.uptodate.com

- *Weight loss — 24 percent, one-half of whom had lost ≥ 9 kg* (not present in [Mr A])

c) *As the use of "routine" bloodwork has become more common, patients are being diagnosed earlier in the disease course.* This is precisely the scenario in [Mr A's] case. There was no real clinical indication for protein electrophoresis to be ordered in June 2010 but, having ordered the test, [Dr B] had a responsibility to action the result appropriately.

(x) It is my opinion that [Dr B] has misinterpreted the pathologist comments relating to the initial monoclonal band detection (4(viii)). The relevant part of the comment is …***Initial review*** *and regular surveillance…* (my emphasis) which indicates a clinical review and the further testing advised should have been undertaken at the time the first abnormal result was detected, with surveillance dependent on the results of the review and tests. Review would generally involve a clinical assessment for unexplained weight loss, bone pain, night sweats, lymphadenopathy or splenomegaly. Any concerning features in the clinical assessment or on completion of the recommended tests should have led to discussion with a haematologist or appropriate further investigations such as lumbar spine X-ray or bone marrow biopsy. While myeloma is not a common presentation in primary care, the detection of paraproteinaemias is not uncommon and often benign in origin. In my own DHB, guidelines for management of monoclonal gammopathy[21] were distributed in 2007 and [Dr B] may want to review these. However, apart from the back pain which [Mr A] apparently attributed to a recurring injury, and that was usually responsive to manipulation (which would not be the case with myeloma related pain) [Mr A] was evidently reasonably well. It seems unlikely his skin condition was related to myeloma or if it was this would be an extremely rare presentation. There were certainly some atypical features of [Mr A's] presentation in that ESR is normally markedly elevated in myeloma yet was normal in [Mr A's] case, and there was no sign of anaemia, hypercalcaemia or impaired renal function.

(xi) Summarising the relevant issues, had [Mr A] not had a blood test done in June 2010 (for which there was no particular clinical indication), it is unlikely the myeloma would have been diagnosed prior to his departure overseas. Bony pain was, in retrospect, the main indication of underlying myeloma but this was not granted any particular significance by [Dr B] or [Mr A] because it was apparently a flare of a longstanding intermittent problem. The blood test results obtained in June 2010, apart from the monoclonal band, did not raise suspicion of any significant underlying pathology. However, it would have been appropriate for [Dr B] to have undertaken a focussed clinical assessment and further investigations shortly after the June results were obtained. The follow-up tests were eventually undertaken on 12 August 2010 and raised suspicion of underlying myeloma which [Dr B] noted and intended following up. At this point it would have been appropriate for [Mr A] to have been notified and a focussed clinical assessment undertaken. It is likely his complaint of back pain would then have been realised by [Dr B] as being possibly significant, appropriate further investigations undertaken and the diagnosis confirmed in time for [Mr A] to cancel his travel plans. This did not happen because the results were inadvertently filed, and not recalled by [Dr B] when he saw [Mr A] two weeks later. I

[21] Available at http://www.waikatodhb.govt.nz/file/fileid/7030

feel that the unfortunate outcome for [Mr A] was the result of suboptimal clinical management (delay in following up the first abnormal test result) and process error (inadvertent filing of an abnormal test result). [Dr B] has pursued the process error with the software provider although it appears no change will be made to the software and he will have to be more vigilant with his filing. The clinical management of [Mr A's] abnormal result from June 2010, putting aside the filing issue, was a mild departure from expected practice taking into account the atypical features of the case and the perhaps slightly ambiguous pathology advice given. The failure to inform a patient of significantly abnormal results and to act on these results in an appropriate manner (referring to the results of 12 August 2010 and consultation of 30 August 2010) was a severe departure from expected standards but must be noted in the context of the process error that led to the departure.

(xii) It would be appropriate for [Mr A] to receive a personal apology for the misdiagnosis of his melanoma and the delayed diagnosis of his myeloma, and an explanation as to how the latter situation occurred. It would be appropriate for [Dr B] to review his management of patients with monoclonal gammopathy, perhaps using the referenced guidelines as a starting point. I note that, on examination of [Mr A's] entire medical record, there were no additional features that raised concerns at [Dr B's] overall management of [Mr A] over the past nine years."

Further advice was received from general practitioner Dr David Maplesden:

"I have reviewed the responses to my initial advice from [Dr B] and Managing Associate for [the medical centre], [Dr I].

1. [Dr B] has acknowledged some shortcomings in his clinical documentation relating to the consultations in questions and has altered his practice to regularly review documentation at the end of each consulting session. As discussed in my original advice, [Dr B's] clinical documentation, on examination of [Mr A's] entire medical file, was generally very good and indicated a conscientious and clinically sound approach to [Mr A's] care. I am confident that the omissions identified in my advice were exceptions rather than representing a trend of suboptimal documentation, and therefore the quality improvement strategy planned by [Dr B] should be adequate to ensure his generally good standard of documentation is maintained.

2. [Dr B] has clarified the content of the consultation of 30 June 2010 which was not fully represented in his clinical notes. [Mr A's] results were discussed and follow-up arrangements formalised, with provision of a post-dated laboratory form. The pathologist advice on the initial blood result was somewhat ambiguous (as discussed in my original advice), and [Dr B] was following his perception of the advice given. He has since reviewed his management of patients with monoclonal gammopathy, the majority of whom will not have any sinister underlying disorder. I conclude that [Dr B's] planned management of [Mr A], based on his perception of the clinical advice offered by the pathologist, was reasonable and, had it been carried out as intended, would likely have resulted in the detection and appropriate management of [Mr A's] myeloma before he departed on his overseas trip.

3. It is acknowledged that [Dr B] filed the abnormal results of August 2010 in error, and there was no prompt from his PMS or from [Mr A] to discuss the results at the

appointment of 30 August 2010. The failure to convey a significantly abnormal result to a patient, in a timely fashion, is a severe departure from expected practice although such an occurrence is not uncommon in primary and secondary care for a variety of reasons. However, because an issue such as misfiling of results is not an uncommon occurrence, this does not make it an acceptable practice. In [Mr A's] case, the misfiling was in part due to potential shortcomings in the PMS as described in my original advice. [Dr B] has sought to address these issues with the PMS manufacturer, although the manufacturer feels the current system is acceptable and there is no better alternative. The potential for failing to act appropriately on abnormal results or results due to be followed-up in the future can be lessened through appropriate use of various reminder systems present in the PMS (patient and provider task manager, recall module, patient alerts). [Dr I] notes that this incident has been regarded as a 'Significant Event' and a full review taken place within the practice (relevant documentation viewed). The practice policy on management of patient test results has been viewed and is robust – it recommends the use of patient task manager as an additional safeguard to ensure timely management of abnormal results. In this case, I think there is a need to differentiate between [Dr B's] intention with respect to the results, which was clearly to act on them when he undertook the planned review of [Mr A] before he went oversees, and his failure to carry out this intention due to his error in misfiling the result and not having any back-up reminder to discuss them. This is really a procedural error leading to sub-optimal clinical practice rather than a primary clinical error. I presume [Dr B] will be making full use of the patient task manager in the future to minimise the risk of such an error occurring again. He has apologised to [Mr A] for the error. I have no recommendations regarding appropriate further actions."