Medical Centre

General Practitioner, Dr B

A Report by the

Health and Disability Commissioner

(Case 16HDC00508)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Mr A, aged 79 years, was registered with a medical centre and his regular GP was Dr B. In June and August 2012, Dr B tested Mr A's prostate-specific antigen (PSA) level. The results of each of these tests showed that Mr A's PSA levels were high.

2. On 10 August 2012, Mr A consulted Dr B to discuss his elevated PSA levels. During the consultation, Dr B examined Mr A's prostate and made the decision not to refer Mr A for further urological review. Instead, Dr B informed Mr A that she would test his PSA level again in six months' time.

3. Dr B did not take steps to make sure that a test was carried out in six months' time to check Mr A's PSA level. Although Mr A saw Dr B on several occasions after February 2013, after the follow-up blood test was due, and other blood tests were ordered, Dr B did not order a further PSA test. The patient management system in place at the practice and its Test Results and Medical Management Policy did not permit other doctors who had reviewed a patient to be alerted that a laboratory test was due. In February 2015, Mr A was diagnosed with prostate cancer with extensive widespread metastatic deposits.

Findings

4. By failing to take the necessary steps to retest Mr A's PSA level in six months' time as planned, Dr B failed to meet her obligation to ensure that the result was managed appropriately, and therefore she did not provide Mr A services with reasonable care and skill. Accordingly, Dr B breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[1]

5. The practice had taken reasonably practicable steps to prevent the particular error from occurring, and it was found not to be vicariously liable for Dr B's breach of the Code. However, the practice was criticised because its patient management system and its Test Results and Medical Management Policy did not permit other doctors who had reviewed a patient to be alerted that a laboratory test was due.

Recommendations

6. In response to the recommendation made in the provisional opinion, Dr B provided a written apology for Mr A's family.

7. It was recommended that the medical centre notify HDC of the dates of its test result audits for 2017 and, within three weeks of receiving this report, provide the results of the audit/s to HDC.

Complaint and investigation

8. The Commissioner received a complaint from Mr A regarding the services provided to him at the medical centre.

[1] Right 4(1) of the Code states that every consumer has the right to have services provided with reasonable care and skill.

9. The following issues were identified for investigation:

- *Whether the medical centre provided Mr A with an appropriate standard of care between June 2012 and November 2014.*
- *Whether Dr B provided Mr A with an appropriate standard of care between June 2012 and November 2014.*

10. This report is the opinion of Kevin Allan, Deputy Commissioner, and is made in accordance with the power delegated to him by the Commissioner.

11. The parties directly involved in the investigation were:

Mr A	Consumer
Dr B	General practitioner/provider
Medical centre	Provider

Also mentioned in this report:

Dr C	General practitioner
Dr E	General practitioner
Dr D	General practitioner
Dr F	General practitioner

12. Information from the District Health Board was also reviewed.

13. Independent expert advice was obtained from GP Dr Gerald Young (**Appendix A**).

Information gathered during investigation

Introduction

14. At the time of these events, Mr A (aged 79 years) was registered with the medical centre, and had been a patient of the practice since 2001. Dr B had been Mr A's regular GP since 2005. She is an employee of the company that owns the practice (the company).

Medical centre — PSA testing in 2012

15. On 21 June 2012, Mr A presented to Dr B for a routine consultation. During the consultation, Dr B ordered a test of Mr A's prostate-specific antigen (PSA) level.

16. The PSA test result received on 25 June 2012 was 8.9µg/L (normal range 0.0–6.5µg/L) and recorded by the laboratory as high. Dr B informed Mr A of his PSA result, and made a plan to repeat the PSA test in six weeks' time. She recorded in the medical notes: "Prostatic Markers — 8.9, rpt [repeat] in 6 [weeks]."

17. On 8 August 2012, Dr B ordered a further PSA test for Mr A. The PSA test result received on 9 August 2012 was 9.25µg/L and was recorded by the laboratory as high. On that day, Dr B recorded in the medical notes: "Prostatic Markers — 9.25, see GP."

18. On 10 August 2012, Mr A presented to Dr B to discuss his elevated PSA levels. Dr B documented in the medical notes that Mr A had had no pain on urinating and no change in urine flow over the last few years. Dr B performed a digital rectal examination (DRE) and recorded that Mr A had an "enlarged prostate, sulcus palpable, symmetrical[2]".

19. Dr B sought the views of her practice colleague, Dr C, on the threshold for referring Mr A for further review.

20. Dr B told HDC:

> "We [Dr C and Dr B] discussed with [Mr A] that our management options were restricted due to the guidelines from our DHB which would have made an acceptance for an appointment with the urology service very unlikely."

21. Dr C told HDC:

> "On 10 [August] 2012 when she had a consultation with [Mr A], [Dr B] asked my opinion about whether she should send a urology referral in view of his PSA being 9 … I told her that to the best of my knowledge, a referral for a non symptomatic man, over 70 years old with a PSA lower than 20–30 would probably not be accepted provided the rectal exam did not reveal any findings suspicious for cancer."

22. Dr B told HDC that she did not refer Mr A for further urological review because his PSA was mildly elevated and there was no change in his urinary pattern and no pain with urinating (dysuria). She considered that Mr A's PSA level was below the local criterion for referral for a man of his age who did not have suspicious findings on rectal examination. Dr B told HDC that "treatment would have been started when PSA reaches 75–100 or symptomatic disease as quoted by the local urologist".[3]

23. Dr B told HDC that she is unable to clarify which referral guidelines she considered at the consultation with Mr A on 10 August 2012 because of the time that has now elapsed since the consultation.

24. Dr B's documented plan was to test Mr A's PSA levels again in six months' time. However, Dr B did not send a task to the nurses' task box for a form to be generated by the nurse to be sent to Mr A to have a repeat blood test in six months' time. This repeat testing did not occur.

25. Dr B told HDC:

> "I have always agreed that having made the plan to check [Mr A's] PSA in 6 months, it was an error on my part not to repeat this.

[2] The ability to palpate the prostate's two relatively firm lobes with a distinct furrow (sulcus) between — a prostate that has not lost its symmetry.

[3] The company submitted to HDC information from a urologist dated 9 May 2016, including the following: "[I]n 2012 we would advise men over 75 to not have a biopsy as they wouldn't have any benefit and in fact [were] likely to suffer harm from both the biopsy and any treatment with curative intent. We would have advised them, as we still do, to start androgen deprivation therapy when the PSA reached 75–100 or there was clinical evidence of metastatic or locally advanced (symptomatic) disease."

…

I intended to repeat this in 6 months but I did not put a recall in for the repeat blood test. [Mr A] was aware that I intended to repeat the test but it clearly slipped both our minds. During the next two years [Mr A] did not report any worrying changes in his urinary pattern so there was no additional prompt for me to repeat the PSA."

26. Dr B stated that as Mr A's regular GP she was responsible for tracking repeat blood tests. She also told HDC:

"In 2012 there was no strict recall system in place for routine repeat blood tests (which was [Mr A's] PSA result). A recall for the PSA testing wasn't set … We realised that we can't only rely on our patients to remember when they should come in for a blood test and that we must also take responsibility for this."

27. After February 2013, when Mr A's follow-up blood test was due, he consulted Dr B for other matters on eight occasions, and Dr B ordered blood tests on at least three separate occasions between January 2013 and June 2014. However, Dr B did not order a further PSA test.

Test Results and Medical Report Management Policy — the medical centre

28. The Test Results and Medical Report Management Policy at the practice was implemented in March 2012 and was in operation until March 2016.

29. The policy states:

"All incoming medical reports are seen and actioned by the appropriate member of the practice team who requested these or a designated deputy.

…

- When a repeat test is required … A task is sent to the Nurses task box and a form is then generated for the patient. … In the case of serious results a recall note is sent to the Dr's task box to recheck the results have been repeated. If not a further contact is made to bring the patient back for a repeat test.

…

- The Dr who requested a test that needs following up will keep the test they have requested in their task box as a reminder to follow-up. Urgent tests are high-lighted on the blood form and where a result is not back before 5 pm eg cardiac enzymes, the on call dr is advised of the patient — as Pathlab call the on call Dr with the results."

Second medical centre — PSA testing in 2014

30. In October 2014, Mr A moved to another region and registered with a new medical centre. On 9 February 2015, following further investigations, Mr A was diagnosed with prostate cancer with extensive widespread metastatic deposits.[4]

[4] Metastatic prostate cancer is an advanced form of cancer.

Return to the medical centre

31. In February 2016, Mr A moved back and re-registered with the first medical centre. Once again, he consulted with Dr B as his regular GP.

Further information

The company

32. The company told HDC that it agreed an error was made by Dr B in not repeating Mr A's PSA test. It confirmed that at the time of the incident, routine tests were not managed by the practice using the Medtech[5] recall function.

33. The company informed HDC that the recall system under the Test Results and Medical Report Management Policy permitted doctors to keep requests in their "task box" and generate forms. The practice also advised that this proved to be challenging at times because of the volume of laboratory forms/referral follow-ups.

34. The company told HDC that following this event it took steps to make sure that Medtech was used for all recall testing going forward. In March 2016 the Clinical Correspondence Management Policy replaced the Test Results and Medical Report Management Policy. The new policy made it possible for doctors to send a request to the nurse or medical centre assistant to add a recall request, and for the nursing team to manage that recall request.

Dr B

35. Dr B told HDC that she is very sorry that Mr A did not have his follow-up blood test as discussed in the consultation in August 2012. Further, she said:

> "I am really sorry that [Mr A] developed metastatic prostate cancer. … I personally have taken this very seriously and changed my practice accordingly. I now track all important tests by using the task manager in [Medtech]."

36. Dr B stated that she has apologised in person to Mr A on several occasions. She further told HDC that she "will now always send a task to the nurse to set up a recall for important tests". Dr B also stated that the practice now has regular test audits.

Referral Guidelines —DHB

37. The DHB has confirmed that the Referral Guidelines were the prostate cancer management and referral guidelines in operation in 2012.

38. With regard to "Elevated PSA", the Referral Guidelines state:

> "In a well informed patient, PSA testing should be performed from the age of 50, as long as life expectancy is > 12 years.
>
> If there is a positive family history, commence PSA testing from the age of 40
>
> All men need DRE (if PSA is normal — if abnormal we will do it at time of biopsy)

[5] A patient management system.

If PSA is raised — recheck in 6 weeks (approx 25% will be transiently elevated) — Check MSU[6] at time of 2nd PSA

Who to Refer?
— Elevated PSA at second check
— PSA rises by more than 1ng/ml in 1 year
— Abnormal [digital rectal examination]

…"

Responses to provisional opinion

39. In response to the "information gathered" section of my provisional opinion, Mr A's family told HDC: "… We are happy that such a thorough investigation was carried out but have nothing further to add."

40. Dr B informed HDC that she accepts the findings in relation to the care she provided to Mr A. She stated:

> "Both the practice and I find the investigation and the report useful. In retrospect, we recognise now that in 2012 our systems could have been better. I wish to assure the Deputy Commissioner and the family again that the systems at the practice for recall testing is much more robust and the risk of missing a similar test is minimised."

Relevant standards

41. The Medical Council of New Zealand's publication *Good Medical Practice — A guide for doctors (2008)* states:

"…

Acting with integrity:

Be honest and open when working with patients; act with integrity by:

- Acting without delay to prevent risk to patients

…

Remember that you are personally accountable for your professional practice — you must always be prepared to justify your decisions and actions.

…

Medical care
Good clinical care — a definition

[6] Mid-stream urine.

2. Good clinical care includes:

…

- Providing or arranging investigations or treatment when needed
- Taking suitable and prompt action when needed

…

Communication

…

Giving information to patients about their condition

13. Give patients all information they want or need to know about:

…

- Treatment options, including expected risks, side effects, costs and benefits.

…

Keeping up to date

73. Keep your knowledge and skills up to date throughout your working life:

- Familiarize yourself with relevant guidelines and developments that affect your work …"

Opinion: Dr B — breach

Patient management

42. Results of the PSA tests for Mr A received in June 2012 and August 2012 were elevated (8.9µg/L in June and 9.25µg/L in August).

43. After receiving the two elevated PSA results, Dr B arranged a consultation with Mr A to discuss them. After seeking collegial advice from Dr C, Dr B did not refer Mr A for urological review as she did not consider this an option due to her understanding of the referral guidelines in place at the time. She made a plan to retest his PSA level in six months' time. Dr B told HDC that "treatment would have been started when PSA reaches 75–100 or symptomatic disease as quoted by the local urologist".

44. Dr B told HDC that due to the time that has elapsed since the event, she is unable to state which referral guidelines she considered during the consultation with Mr A on 10 August 2012.

45. The DHB confirmed that the guidelines for urologist referral in operation during 2012 were Guidelines for Prostate Cancer Management.

46. My independent expert advisor, GP Dr Gerald Young, advised:

> "There was no clinical evidence to suggest that [Mr A's] life expectancy would be less than 12 years, therefore referral of [Mr A] for a specialist urological review with a second elevated PSA, based on the guidelines at the time would have been appropriate …
>
> The advice that [Dr B] received from her colleague [Dr C] that a referral would not be accepted, although was clinically appropriate, was erroneous based on the […] guidelines at the time, because she followed this collegial advice and did not refer [Mr A] this initiated the management pathway that occurred.
>
> Once this alternate pathway [for retesting in six months' time] was taken the onus was on [Dr B] and/or the medical clinic to provide the appropriate follow up PSA testing. A retest in 6 months as proposed, was clinically acceptable."

47. Dr Young clarified that Dr B did not depart from a reasonable standard of care by not referring Mr A for further urological review on 10 August 2012, and it was acceptable to continue to monitor the PSA.

48. I accept Dr Young's advice, and I am satisfied that, in the circumstances, it was reasonable for Dr B not to refer Mr A for urological review on 10 August 2012.

Failure to carry out follow-up testing

49. Although Dr B made a plan to check Mr A's PSA level in another six months' time and informed Mr A of this plan, she failed to take the necessary step to ensure that the test was carried out. Dr B did not send a task to the nurses' task box for a form to be generated by the nurse to be sent to Mr A to have a repeat blood test in six months' time, and so acted contrary to the policy.

50. After February 2013, when Mr A's follow-up blood test was due, he consulted Dr B for other matters on eight occasions, and Dr B ordered blood tests on at least three separate occasions between January 2013 and June 2014. However, Dr B did not order a further PSA test.

51. Dr Young advised me that once the decision was made to re-check Mr A's PSA in six months' time:

> "… the onus was on [Dr B] and/or the medical clinic to provide the appropriate follow up PSA testing … [Mr A] was seen at least eight times after the [six] month period when the follow up PSA blood test was due. Blood tests were requested on three of those occasions by [Dr B] but a PSA test was not tested. This omission of follow-up testing of the PSA was unacceptable when [Mr A] was advised that there would be follow-up testing and follow-up testing was indicated with an elevated PSA. Even though [Mr A] did not raise the issue of follow up testing himself the onus was on [Dr B] to have carried out the appropriate follow-up. Indeed, after the consultation of 10 [August 2012] [Mr A] was under the impression that based on his age nothing further could be done for him irrespective of his PSA level."

52. The Medical Council of New Zealand's publication *Good Medical Practice — A guide for doctors (2008)* states that doctors should provide or arrange investigations or treatment when needed and take suitable and prompt action when needed.

53. Dr B accepts the error on her part and has told HDC that she has apologised several times to Mr A in person. She stated: "I accept that I did not repeat the PSA test as planned and that [Mr A] went on to develop prostate cancer."

54. On receipt of the elevated test results, Dr B had the responsibility to ensure that appropriate management of that result was facilitated. Following the second elevated test result, Dr B did not take the necessary steps to retest Mr A's PSA level in six months' time as she had planned. Accordingly, I find that Dr B failed to meet her obligation to ensure that the result was managed appropriately, and did not provide services to Mr A with reasonable care and skill and, therefore, breached Right 4(1) of the Code.

Opinion: The company — adverse comment

55. In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any actions or omissions of its employees. A defence is available to the employing authority under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.

56. At the time of these events, Dr B was an employee of the company. Accordingly, the company is an employing authority for the purposes of the Act.

57. As set out above, I have found that Dr B breached Right 4(1) of the Code for failing to follow up the elevated PSA test results appropriately.

58. The company's Test Results and Medical Report Management Policy in place at the practice in 2012 states: "All incoming medical reports are seen and actioned by the appropriate member of the practice team who requested these or a designated deputy." The policy specifically required Dr B to send a task to the nurses' task box in order to set a repeat test for a time in the future, and for the nurse to create a form and to contact the patient.

59. I am satisfied that the company took reasonably practicable steps to prevent this particular error. Accordingly, I do not find the company vicariously liable for Dr B's breach of the Code.

60. However, while I consider that the Test Results and Medical Report Management Policy indicates that the company took reasonably practicable steps to prevent Dr B' error, I am of the view that there are some deficiencies within the policy.

61. The policy states:

> "When a repeat test is required e.g. slightly abnormal thyroid function tests, which would need repeating in 4 weeks time. A task is sent to the Nurses task box and a form

> is then generated for the patient. The nurse/doctors assistant contacts the patient and a record of this contact is made in the notes. In the event of not being able to contact the patient an explanation note is posted to the patient and the alert attached to their notes. In the case of serious results a recall note is sent to the Dr's task box to recheck the results have been repeated. If not a further contact is made to bring the patient back for a repeat test."

62. Dr B informed HDC that at the time of these events, routine tests were not managed by the practice using a recall function within Medtech.

63. My expert advisor, Dr Gerald Young, advised me that the Test Results and Medical Report Management Policy is deficient, as a "recall" is not set in the patient recall system to indicate when a repeat laboratory test is due — only a laboratory form is generated and sent to the patient. He stated:

> "This creates a number of potential gaps, it makes it hard to track if a patient has not done a follow-up test, if a recall is set then these can be checked to see if they have been completed or not. Without a recall set it makes it harder for another doctor in the practice to see that a follow [up] test was due but have not been done as occurred in [Mr A's] case as he had been seen a further nine times by doctors at the clinic from January 2013 to September 2014 without anyone noticing that an outstanding follow-up PSA test for a previously elevated PSA had not been done."

64. I note that the policy required Dr B to send a task to the nurse's task box, and that, had she done so, the nurse would have been aware of the need for Mr A to receive a repeat blood test in six months' time. However, I am of the opinion that an appropriate safeguard to identify such errors in the future would be the use of a recall function, whereby all subsequent general practitioners who review a patient would be aware of the need for a test to occur.

65. I am critical that the practice's systems, including the Test Results and Medical Report Management Policy, did not require follow-up tests to be set within the patient recall system so that all subsequent practitioners who reviewed a patient were alerted to a due date for a repeat laboratory test.

Recommendations

66. I recommend that the company notify HDC of the dates of its test result audits for 2017, and provide the results of the audit/s to HDC within three weeks of receiving this report.

67. In the provisional opinion, I recommended that Dr B provide a written apology for forwarding to Mr A's family. This recommendation has now been met.

Follow-up actions

68. 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.

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

70. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Health Quality & Safety Commission (HQSC) and at the request of the company, the region's Primary Health Organisation, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from general practitioner Dr Gerald Young.

Expert Opinion Report One:
"I have been asked to provide specific advice regarding the care provided to [Mr A] at [the medical centre].

In preparing the advice on this case to my knowledge I have no personal or professional conflicts of interest giving advice in this case.

References provided to complete the report:

- Letter of complaint from [Mr A]
- Response from [Dr C]
- Response from [Dr B]
- Response from [Dr F]
- Clinical notes from [the medical centre]

Other references used:

- htto://www.bpac.oruz/BT/2010/July/docs/best_test_jul2010_psa_screening__pagesl4-18.pdf
- https://prostate.org.nzildocuments/diagnosis-management-prostate-cancer-nz-men (3).pdf

I have been asked to comment on the following issues:

1. **The discussion that took place regarding [Mr A's] management options at the consultation of 10 August 2012. Please include comment on the reasonableness of [Dr C's] advice that referral was not appropriate given the clinical presentation.**

   The advice given to [Mr A] by [Dr C] and [Dr B] at the consultation of 10th Aug 2012 was reasonable.

   The reasons for this opinion follow:

   [Mr A] is a long term patient of the [the medical centre]. He had the following PSA test results recorded:

Sept 2008	10.42
Oct 2008	8.71
Nov 2008	5.6
Apr 2009	6.51
Aug 2009	4.77
Jun 2012	8.9
Aug 2012	9.25

At the consult of 10-Aug-2012 it was noted that [Mr A] has had 'no change in urinary flow over the last few years. No pain urinating.'

The rectal exam revealed an enlarged prostate, with a palpable sulcus and symmetrical. There was no mention on the records of any roughness or nodules palpable. (It was also noted that the prostate exam done by [Dr E] on 31 Dec 2014 recorded that the prostate was enlarged but 'non-craggy'. Even though [Mr A] has significant prostate cancer by December 2014 his prostate was not nodular or rough.)

[Dr B] discussed the findings with her colleague [Dr C].

[Mr A] was advised that the PSA should be re-checked in 6 months and that because of his age [79] that he would not be seen by a urologist until PSA was over 30.

[Mr A] had an asymptomatic elevation of his PSA, and there were no clinical findings on examination to suggest any prostatic disease. His records also document elevated PSAs in the past in Sept 2008 which reduced spontaneously on the next test on Oct 2008.

The general guidelines around this period would not recommend urology opinion until the PSA was over 10 and consideration for biopsy only if PSA was greater than at least 20 in a man over 75 years of age. Therefore, the advice to retest in 6 months was appropriate and in keeping with recommended practice. It would not have been appropriate to refer [Mr A] to a urologist at that stage with PSA at 9.25 without at least another follow-up test.

2. The adequacy and appropriateness of follow-up provided to [Mr A] in respect of his PSA levels.

As discussed in #1 above it was appropriate to recommend a further follow up test in 6 months to check on the PSA level. That the follow up test was not done is a moderate to severe departure from appropriate care.

[Mr A] was advised that there would be a follow up test of his elevated PSA in 6 months. He was seen eleven times by doctors at [the medical centre] and had five blood tests during this time. As a patient [Mr A] should be able to rely on his GP/Clinic to do the appropriate blood tests in a timely manner if he had been advised that a follow up elevated PSA would be done in 6 months especially as he had five blood tests done in this period. It would be reasonable for him to assume that at least once the PSA was done and as he had not heard to the contrary assume the PSA result had returned to normal, as happened in 2008. It would also be reasonable for [Mr A] to assume that at least annual PSA screening for prostate cancer was continuing with his history of elevated PSAs.

That the follow-up PSA was not done denied [Mr A] earlier management options for managing his prostate cancer. Earlier active management may have prevented or reduced his metastatic bony and respiratory symptoms.

The overall management of [Mr A] at [the medical centre].

Apart from the failure to do the follow-up PSA in a timely manner, the care provided by [the medical centre] was of the standard expected in general practice. The clinical records and other care provided were of an appropriate standard.

3. Whether the changes made to systems at [the medical centre] are reasonable.

The changes made to the ordering and follow-up of tests in the 'Clinical Correspondence Management Policy' are appropriate and acceptable."

Expert Opinion Report Two:

"I have been asked to provide further advice regarding the care provided to [Mr A] at [the medical centre] by [Dr B] and [the second medical centre] by [Dr E] between 2006 and 2014.

In preparing the advice on this case to my knowledge I have no personal or professional conflicts of interest giving advice in this case.

References provided to complete the report:

1. Letter of complaint dated [date]
2. Information received from [the second medical centre] by email dated 29 April 2016
3. Information received from [the medical centre] by email dated 25 May 2016
4. Further information received from [the medical centre] by email dated 13 July 2016
5. Further information received from [the medical centre] by email dated 21 September 2016
6. Letter dated 13 December 2016 from [Mr A]
7. Information received from [the PHO] by email dated 13 January 2017
8. Information received by email dated 21 December 2016 from [lawyer] on behalf of [Dr B]
9. Information received by email dated 20 March 2017 from [the company] (trading as [the medical centre])
10. Information received from [the DHB], by email dated 28 March 2017 containing the [the DHB provider of Urology services] priority scoring tool and referral guidelines used in 2008 and 2012 prior to MOH FCT guidelines and prior to the referral protocols being [uploaded].

Other references used:

- http://www.bpac.org.nz/BT/2010/July/docs/best_test_jul2010_psa_screening_pages14-18.pdf
- https://prostate.org.nz//documents/diagnosis-management-prostate-cancer-nz-men_(3).pdf

I have been asked to comment on the following issues:

1. With reference to relevant guidelines including [the DHB] guidelines, the adequacy and appropriateness of the care provided to [Mr A] by [Dr B]. In your

response please include comments on the frequency of PSA testing prior to (from 2008–2012) and during 2012.

[The DHB guidelines], which were not available to me when I initially reviewed this case in Sept 2016. The guidelines for 'Elevated PSA' state that if there is 'elevated PSA at the second check' then the patient should be referred. There was no age exclusion stated, only if life expectancy was less than 12 years. There was no clinical evidence to suggest that [Mr A's] life expectancy would be less than 12 years, therefore referral of [Mr A] for a specialist urological review with a second elevated PSA, based on the guidelines at the time would have been appropriate.

If [Dr B] had followed through on her initial intention to refer [Mr A] for urological review this would have been appropriate based on the guidelines for [the DHB] at that time. If the referral had been made then [Dr B] would have no case to answer.

The advice that [Dr B] received from her colleague [Dr C] that a referral would not be accepted, although was clinically appropriate, was erroneous based on [DHB] referral guidelines at the time, because she followed this collegial advice and did not refer [Mr A] this initiated the management pathway that occurred.

Once this alternate pathway was taken the onus was on [Dr B] and/or the medical clinic to provide the appropriate follow up PSA testing. A retest in 6 months as proposed, was clinically acceptable. [Mr A] was seen at least eight times after the 6 month period when the follow up PSA blood test was due. Blood tests were requested on three of those occasions by [Dr B] but a PSA test was not tested. This omission of follow-up testing of the PSA was unacceptable when [Mr A] was advised that there would be follow-up testing and follow-up testing was indicated with an elevated PSA. Even though [Mr A] did not raise the issue of follow up testing himself the onus was on [Dr B] to have carried out the appropriate follow-up. Indeed, after the consultation of 10-08-12 [Mr A] was under the impression that based on his age nothing further could be done for him irrespective of his PSA level.

It was noted that [Mr A] had PSA tests which were elevated in 2008 associated with a urinary tract infection, but settled back to normal levels on subsequent tests in both 2008 and 2009. There was no PSA testing done in 2010 and 2011 [and] it is unknown if [Mr A] had wanted to have ongoing prostate screening. I could not see a record of PSA screening having been discussed in the notes reviewed, so from the clinical records it appears [Mr A] was not having formal prostate cancer screening. If [Mr A] had indeed wanted routine prostate screening then annual PSA tests should have been done.

[Dr B] was influenced by the collegial advice offered by [Dr C] to not refer [Mr A] when she initially was contemplating a urology referral. That the advice given did not reflect the actual [DHB] guideline in place at the time was a result of the evolving development of clinical guidelines for prostate cancer screening, PSA testing and appropriate clinical management in this period.

Ideally [Mr A] could have been advised at the consultation of 10-08-2012 that his PSA was elevated and he could be referred for urological review if he wanted but that the current clinical view for a man of his age, would be to do regular follow up PSA tests

and if the PSA rises above 20 then referral for urology review would be indicated then, this would have allowed [Mr A] a choice in his management. That [Mr A] was not referred for urological review in Aug 2012 was clinically acceptable but the onus was that the follow up PSA test would be done.

That the follow-up PSA test was not done when on three occasions after the 6 month retest period, even though blood tests were ordered is a breach of the expected standard of care to a moderate degree.

2 With reference to relevant guidelines including [the DHB guidelines], the adequacy and appropriateness of the advice provided by [Dr C] to [Dr B] in relation to referring [Mr A] to a urological review.

[Dr C] stated in his letter to the HDC dated 16-05-16, that [Dr B] asked his 'opinion about whether she should send a urology referral in view of his PSA being 9'. [Dr C] '… told her that to the best of my knowledge, a referral for a non-symptomatic man, over 70 years old with a PSA lower than 20–30 would probably not be accepted provided the rectal exam did not reveal any findings suspicious for cancer'.

The advice given to [Dr B] by [Dr C] was not correct based on the actual [DHB guidelines] for that time.

However, it is noted from the email from [a] (urologist) to [Dr B] dated 9th May 2016, confirms that 'the current guidelines now list 20 as being the upper limit of normal PSA in men 76 years or greater'. I am unsure when [the DHB guidelines] were officially changed but it appears that there were already indications that changes were to be made in 2012 as demonstrated by [Dr C's] advice. [The urologist] confirmed that no active treatment would have been undertaken for [Mr A] until his '… PSA reached 75–100 or there was clinical evidence of metastatic or locally advanced (symptomatic) disease'.

The advice provided by [Dr C] to [Dr B] was not entirely accurate with respect to the actual [DHB guidelines] in 2012 but the intent of [Dr C's] advice was reasonable and appropriate based on the actual clinical practice at that time.

3 The adequacy and appropriateness of the care [Mr A] received between August 2012 and November 2014 from the following doctors at [the medical centre] in relation to the PSA testing:

a) [Dr C]

b) [Dr D]

c) [Dr F]

3(a) [Dr C]: the advice he gave on 10 Aug 2012 was collegial advice requested by [Dr B] therefore [Dr C] was not in a doctor–patient relationship with [Mr A].

[Dr C] consulted [Mr A] 21 Feb 2013 to suture a laceration on his right arm. There was no indication to have reviewed [Mr A's] PSA.

The care provided by [Dr C] to [Mr A] was adequate and appropriate during the period Aug 2012 to Nov 2014.

3(b) [Dr D]: consulted [Mr A] once on 29 Aug 2014, as a locum, for a respiratory infection. There was no clinical indication for [Dr D] to review [Mr A's] prostate status or management.

The care provided by [Dr D] to [Mr A] was adequate and appropriate during the period Aug 2012 to Nov 2014.

3(c) [Dr F]: consulted [Mr A] on 26 Sept 2014 for left sided hip pain which [Mr A] associated with moving and shifting boxes as he was in the process of moving. There was nothing in the history given or findings to suggest that the hip pain may have been associated with a prostate problem, namely metastatic bony disease of the prostate at that time. Analgesia was given with advice that if it did not settle he '… MUST see new dr for bloods/xrays'; this advice was entirely appropriate.

The care provided by [Dr F] to [Mr A] was adequate and appropriate during the period Aug 2012 to Nov 2014.

4 The adequacy and appropriateness of the test result management systems in place at [the medical centre] to monitor [Mr A's] PSA levels. Please include comments on the adequacy of the Test Results and Medical Report Management Policy.

There was no formal system in place to manage the follow-up testing as stated in [Dr B] letter to the HDC dated 6th July 2016 'in 2012 there was no strict recall system in place for routine blood tests (which was [Mr A's] PSA result). A recall for the PSA testing wasn't set.' In this letter, it was indicated there was a reliance on patients to remember when to get blood tests 'we realised that we can't only rely on our patients to remember when they should come in for a blood test and that we must also take responsibility for this.' This suggests that for at least some follow-up testing the clinic relied only on the patients to remember to get the required follow up tests. In [Mr A's] case he did have blood tests on three separate occasions after the 6 month interval, so as a patient it would not be unreasonable for him to assume that the PSA had indeed been done and that it had returned to normal or was still under the limit for referral as previously indicated to him.

This was an ad-hoc system for follow-up testing which is not acceptable and falls short of acceptable standards by a moderate degree. I don't think that [Mr A's] PSA could be classed as a 'routine blood test' as he had two consecutive elevated PSA tests, so it should have been managed as following up of an abnormal test.

The 'Test Results and Medical Report Management Policy' (date approved March 2012) was deficient in that a 'recall' is not set in the patient recall system to indicate when a repeat lab test is due, only a lab form is generated and sent to the patient. This creates a number of potential gaps, it makes it hard to track if a patient has not done a follow-up test, if a recall is set then these can be checked to see if they have been completed or not. Without a recall set it makes it harder for another doctor in the practice to see that a follow [up] test was due but have not been done as occurred in [Mr A's] case as he had been seen a further nine times by doctors at the clinic from January 2013 to September 2014 without anyone noticing that an outstanding follow-up PSA test for a previously elevated PSA had not been done.

That the patient recall system was not used for all abnormal follow-up tests was a significant contributing factor in the delay in diagnosis and treatment that occurred in [Mr A's] case. I note that this has been corrected in the new policy.

5 With reference to the management of [Mr A's] 19 December 2014 PSA result, please comment on the standard of care provided to [Mr A] by [the second medical centre] and [Dr E].

The standard of care provided by [the second medical centre] and [Dr E] was appropriate.

It is noted that a follow-up PSA test was done as part of the investigations for lower back pain and to follow up the abnormal PSA test from 2012. The very elevated PSA test result of 1070 (normal <6.5) was received on 19 Dec 2014, a repeat test was requested and an appointment made for a consultation with [Dr E] on 31 Dec 2014. Whilst generally patients with such abnormal tests would be seen sooner than 12 days post result, in this circumstance with Christmas just 6 days away and there being no need for any urgent intervention it was appropriate and indeed considerate to see [Mr A] and advise him of the elevated PSA and probable implications of this after the Christmas holiday period.

6 Additional Comments

I note that I made an error in attributing the pleural effusion to the metastatic prostate cancer. On reviewing the medical records, I note that this was caused by a separate disease and therefore the consequences of the delayed diagnosis of metastatic prostate cancer and treatment was confined to the bony pathology.

[Mr A] did suffer musculoskeletal pain when he was seen at [the medical centre] by [Dr F] on 26 Sept 2014. This pain persisted and was investigated by [Dr E] on 18 Dec 2014. The bone scan result of 09-02-2015 '… demonstrated extensive and widespread bone secondaries from the known CA prostate'. The metastatic secondaries were '… noted in the skull vault, several ribs anteriorly and posteriorly, sternum, scapulae, both sides of the pelvis, most of the thoracic and lumbar vertebrae and in the lesser trochanter of the left femur.

With such extensive bony metastasis that he only suffered left hip and lower back pain was fortunate. It was also fortunate for [Mr A] that his bony pain was brought under control quickly once he was started on hormonal treatment for his metastatic prostate cancer by the urologist.

The reason for the finding that there is a moderate departure from a reasonable standard of care is based on the evidence that there was a significant delay in the time that [Mr A's] diagnosis could have been made, had follow-up testing been done as indicated in a timely manner and appropriate treatment offered. That [Mr A] responded quickly and very well to the treatment offered does not mitigate that his diagnosis should have been made sooner and therefore appropriate treatment would have been started sooner and possibly he would have had less extensive bony metastasis. I accept the evidence that [Mr A] has responded well to the treatment given even with his extensive bony

metastasis but this does not make omitting to get the follow-up PSA tested, less of a departure from the expected standard of care.

I have changed my findings from a moderate to severe departure to a moderate departure as [the DHB] PSA referral guidelines at the time indicate that [Dr B's] initial intention to refer for a urological review would have been accepted. It was on discussion with a colleague that the alternate management was agreed. When a doctor seeks collegial advice, which is to be supported and encouraged, but the advice was not technically 100% correct, this does need to be considered in my findings. Also, the procedures in place at [the medical centre] for follow-up testing was a contributing factor to the follow-up test not being done.

This medical mishap was caused in part by not having a robust recall process at the time. There is nothing to indicate that there was a lack of clinical knowledge on the part of [Dr B] or any of the other providers that attended [Mr A].

The recall process at [the medical centre] has now been amended to correct this."

The following further advice was received from Dr Young on 11 December 2017:

"*Can you please clarify whether you consider [Dr B] departed from a reasonable standard of care by not referring [Mr A] for further urological review on 10 August 2012?*

[Dr B] did not depart from a reasonable standard of care by not referring [Mr A] for further urological review on 10th August 2012. It was acceptable to continue to monitor the PSA …

Taking into account the fact that [Dr B] did not set a recall in the system in place at the time, in your view, how did the system contribute to the intended resetting not taking place?

As I understood the system that was in place at the clinic at the time, there was one system for blood tests that needed repeating and other different system for those tests that were deemed 'abnormal' and needed further action now not just another follow-up test at a later date. This system then created a gap for tests that were not 'normal' but did not require immediate action but did require another follow-up test to monitor at a future date. This system treated [Mr A's] elevated PSA that required a follow-up test, to monitor for any further change, the same as any other routine test. Being treated the same as a routine test made overlooking the required future follow up easy to miss.

In light of this do you consider there was a departure?

Although the system was flawed there wasn't a departure from a reasonable standard of care by [Dr B] at this stage as the follow-up test had not been missed at this stage, as it was due to be done at a future date.

The recall system used was a departure from a reasonable standard expected of recall systems by a moderate degree.

If so to what degree (mild, moderate or severe)?

Could you please explain what you mean that [Mr A's] PSA test follow up should have been treated as a follow up for an abnormal test?

As discussed in the answer above, one way that may have worked, may have been to treat the elevated PSA as an 'abnormal test' in the clinic results follow-up system so that it could have been 'flagged' as requiring future follow-up. Without looking at their recall protocol that was in place at the time I don't know for sure that this was actually possible, as 'abnormal' tests were those requiring immediate actions."