General Practitioner, Dr A

Medical Centre

A Report by the

Health and Disability Commissioner

(Case 15HDC00677)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of Contents

Executive summary

1. This opinion concerns the care GP Dr A provided to Mr B between 2012 and 2014. In 2012 Mr B was 60 years old, and had been a patient of Dr A, at a medical centre, since 2002.

2. On 5 March 2012, Mr B presented to Dr A with reduced energy and breathlessness. Amongst other investigations, Dr A ordered blood tests and included a prostate-specific antigen (PSA) test. On 9 March 2012, Dr A received the PSA result, which was 8.3 µg/L, above the normal range, which is between 0.0–4.5 µg/L.

3. Dr A filed the elevated PSA result as "normal", and did not discuss the result with Mr B at his next consultation on 10 March 2012 or take any further follow-up action. On 28 July 2014, Mr B presented to Dr A with urinary complaints, and Dr A ordered a PSA test, which came back as 66 µg/L, which is significantly above the normal range. It was during or soon after the 28 July 2014 consultation that Dr A noticed the earlier elevated 2012 PSA result.

4. On 31 July 2014, Dr A informed Mr B of the 30 July 2014 PSA result, but did not disclose the missed 2012 PSA result at that time. Dr A made a referral to urologist Dr C, who confirmed that Mr B had a prostate tumour. Subsequently, oncologist Dr D confirmed that Mr B had aggressive prostate cancer that had spread to the lymph nodes in his pelvis.

5. Dr A informed Mr B of the missed 2012 PSA result after he returned from an overseas trip on 23 September 2014. Subsequently, with Mr B's consent, Dr A discussed the matter further with Mrs B on 3 October 2014.

Findings

6. Dr A failed to recognise an elevated 2012 PSA result and take appropriate follow-up action upon receipt of the result, a failure that resulted in Mr B missing an opportunity for early diagnosis of his prostate cancer. By failing to recognise and take appropriate action on the abnormal result, Dr A did not provide services to Mr B with reasonable care and skill, and so breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[1]

7. In July 2014, Dr A did not contact Mr B in a timely manner once realising that he had missed the 2012 PSA result. By failing to inform Mr B promptly about the missed PSA test result, Dr A breached Right 6(1) of the Code.[2]

8. Other comment is made about the consent Dr A obtained before ordering the 2012 PSA test.

9. The medical centre was found not to be in breach of the Code.

---

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

[2] Right 6(1) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive".

Complaint and investigation

10. The Commissioner received a complaint from Mr B about the services provided to him by general practitioner (GP) Dr A. The following issues were identified for investigation:

- *Whether Dr A provided an appropriate standard of care to Mr B between March 2012 and December 2014.*
- *Whether the medical centre provided an appropriate standard of care to Mr B between March 2012 and December 2014.*

11. An investigation was commenced on 21 August 2015.

12. The parties directly involved in the investigation were:

Dr A	Provider/General practitioner
Mr B	Consumer/Complainant
Mrs B	Consumer's wife
Medical centre	Provider

13. Information was reviewed from the above parties and also urologist Dr C and oncologist Dr D.

14. Independent expert advice was obtained from GP Dr David Maplesden **(Appendix A)**.

Information gathered during investigation

Background

15. Mr B was aged 60 years in 2012, and had been a registered patient of GP Dr A[3] since 2002.

2012 consultations and PSA test

16. On 5 March 2012, Mr B presented to Dr A with "reduced energy, breathless walking/cycling on slopes" and a minor cough. The clinical notes do not record any physical assessment findings but document that an ECG,[4] spirometry,[5] PSA test,[6] and

[3] Dr A is vocationally registered in general practice and is a Fellow of the Royal New Zealand College of General Practitioners.
[4] An electrocardiogram (ECG) is a test that checks for problems with the electrical activity of the heart.
[5] Spirometry is the measurement of the movement of air in and out of the lungs during various breathing manoeuvres.
[6] Prostate-specific antigen (PSA) is a protein produced by cells of the prostate gland. The PSA test measures the level of PSA in a man's blood.

other blood tests were ordered.[7] Dr A told HDC that Mr B did not mention any symptoms relating to prostate function, and that he included a PSA test when ordering other blood tests "simply because it was something I aimed to record every year or two and was approximately due".

17. Dr A cannot specifically recall discussing the PSA test or obtaining consent from Mr B at this consultation. However, Dr A told HDC that before Mr B's first PSA test, recorded on 30 March 2009, he discussed prostate screening with Mr B. Dr A said that they specifically discussed that "while it was somewhat contentious … on balance, I considered prostate cancer screening was a good practice". Dr A stated: "[Mr B] was happy to follow my guidance on the matter." Dr A also makes specific mention of this discussion in his referral letter dated 31 July 2014 to urologist Dr C.[8]

18. On 9 March 2012, the PSA results were reported by the laboratory and sent to Dr A, who reviewed them on 10 March 2012. The results showed that Mr B's PSA was 8.3 µg/L — above the normal range, which is between 0.0–4.5. The result was accompanied by the following comment from the laboratory:

> "PSA between upper reference range to 10 µg/L: approximately a third of cases have prostate cancer. Other causes include benign hyperplasia, prostatitis, prostate massage, prostatic needle biopsy, ejaculation, DRE, exercise and spontaneous variation."[9]

19. Dr A told HDC that his general practice when filing electronic test results is to log each result as either "normal" or "negative" before clicking the "file" button in his practice management system. Dr A confirmed that he logged the elevated 2012 PSA result as "normal", and then filed it along with Mr B's other test results. Dr A stated: "I am simply at a loss as to why I erroneously filed the result without further action and remain deeply disappointed over my omission."

20. Dr A further commented:

> "I am very much aware that a PSA of 8.3 µg/L is a significantly abnormal result. I overlooked this result and mistakenly filed it as normal whilst I was focusing on other symptomatic medical issues that were being investigated at this time."

21. On 10 March 2012, Dr A saw Mr B again, as his ECG had shown a first degree atrioventricular block[10] and a slow pulse rate. Mr B also complained of a shoulder ache, all of which Dr A told HDC made him consider cardiac disease. An urgent troponin test (for acute cardiac damage) was performed, and the result was negative.

[7] The other blood tests that were ordered included a complete blood count, lipid test, ferritin test and serum B_{12} and folate tests.
[8] More specifically, Dr A stated in his letter: "[T]he first PSA he [Mr B] had was in 2009, as below. The controversy around screening for prostate cancer ha[s] been discussed."
[9] "DRE" refers to digital rectal examination.
[10] An atrioventricular block is a type of heart block in which the conduction between the atria and ventricles of the heart is impaired.

Dr A stated that Mr B's spirometry was consistent with mild chronic obstructive pulmonary disease,[11] and a referral was made to a respiratory specialist.

22. Mr B's 9 March 2012 PSA result was not discussed, nor was a prostate examination conducted at this consultation, and Dr A stated that "one reason this [PSA result] was overlooked was undoubtedly the focus on other concerns around unrelated prostate issues".

2014 consultations and PSA tests

23. On 6 May 2014, the next relevant consultation,[12] Mr B is documented as having presented again to Dr A for a general check-up with "no specific concerns". Mr B's weight and blood pressure were recorded, and Dr A conducted a routine digital rectal examination (DRE) and documented Mr B's prostate as being "firm moderate sized smooth regular", which is a normal finding. Mr B's abdomen was also examined and was recorded as soft with no masses.

24. Dr A told HDC that at this consultation Mr B presented with no symptoms related to prostate function. Dr A does not recall whether he reviewed the 2012 PSA result, but expects that he would have taken action on the result had he noticed it.

25. Mr B initially told this Office that he did not have any recollection of his visit to Dr A in May 2014. However, in response to the "information gathered" section of my provisional report, Mr B told HDC that he visited Dr A on 6 May 2014 because he was experiencing mild pain in his groin and wanted it checked.

26. On 28 July 2014, Mr B saw Dr A with urinary complaints. Dr A documented: "[Mr B's urine] stream just seems slower and sometimes has to go again within 20mins of voiding." Dr A ordered a PSA test but did not conduct a DRE at this consultation. Dr A told HDC that it was either after this consultation or on 31 July 2014 that he first noticed the missed 2012 PSA result.

27. On 30 July 2014, Dr A received Mr B's PSA result, which was 66 µg/L — significantly above the normal range. The result was accompanied by the following comment from the laboratory:

> "PSA > 10 µg/L: prostate cancer more likely than benign hyperplasia. For prostatitis, suggest to repeat several weeks after resolution."[13]

28. On 31 July 2014, Dr A telephoned urologist Dr C to arrange for a specialist referral to assess Mr B's prostate. Prior to seeing Mr B, Dr C requested that Mr B's PSA be rechecked, that he have an anal swab to check for extended-spectrum beta lactamases

[11] Chronic obstructive pulmonary disease is a lung disease characterised by chronic obstruction of lung airflow that interferes with normal breathing and is not fully reversible.
[12] Between 11 March 2012 and 5 May 2014, Mr B is recorded as seeing Dr A twice, along with multiple other communications (text messages, emails or telephone calls) concerning testing, results and prescriptions. No prostate issues or PSA results are recorded during that time.
[13] Benign prostatic hyperplasia is a common, non-cancerous enlargement of the prostate gland. Prostatitis is swelling and inflammation of the prostate gland.

(ESBL),[14] and that Dr A issue a prescription for prophylactic ciprofloxacin,[15] in the event a biopsy was needed.

29. Dr A recorded that he also telephoned Mr B at this time and advised him that his 30 July 2014 PSA result was elevated, and that he was going to refer him to urologist Dr C. Dr A outlined the testing Dr C requested he undertake.[16]

30. Dr A also wrote a referral letter to Dr C, in which he stated:

> "He [Mr B] last came in for a general checkup in March 2012 as he reported generally reduced energy. After a set of blood tests he came back for review … PSA was elevated then and was not followed up."

31. On 6 August 2014, Mr B's PSA result is recorded as 78 µg/L — well above the normal range (0–4.5 µg/L). The laboratory analysis again stated: "[P]rostate cancer more likely than hyperplasia."

Follow-up urology and oncology care

32. On 8 August 2014, Mr B and his wife went to see Dr C. Mr B reported that he had noticed deterioration in his urinary flow six months previously. On examination, Dr C recorded that Mr B had a moderate volume prostate with a firm nodule at the left base, and informed Mr B that he had a poorly differentiated tumour in his prostate and bilateral internal iliac lymphadenopathy.[17]

33. Dr C telephoned Dr A and advised him that Mr B had a prostate tumour. Dr C recommended hormonal management for Mr B, and stated that he had checked this plan with oncologist Dr D. Dr C also cleared Mr B to travel, as he was about to take a month-long trip to Europe. Mr B told HDC that he received his first hormone treatment at the medical centre on the afternoon of 8 August 2014, and left to go on holiday that day.

34. Mr and Mrs B met with oncologist Dr D on 10 September 2014. Dr D explained to them that Mr B had aggressive prostate cancer, and confirmed that the cancer had spread to the lymph nodes in his pelvis. Dr D told Mr B that his chance of a cure was low, even with an aggressive approach of hormone treatment and radiation.

35. Mr B's prognosis is that his condition is terminal, and he is receiving ongoing oncology care.

---

[14] ESBL is an enzyme produced by some bacteria; the enzyme prevents certain antibiotics from working. Bacteria that are able to produce this enzyme are more resistant to many of the antibiotics prescribed to treat infections, which makes an infection caused by ESBL more difficult to treat. Most commonly, ESBL is associated with the bacteria *E. coli* and *Klebsiella*, both of which are normal inhabitants of the bowel.

[15] A prophylactic is a medication or a treatment designed and used to prevent a disease from occurring. Ciprofloxacin is an antibiotic that fights bacteria in the body.

[16] Dr A documented on 31 July 2014 that he telephoned Mr B, but no substantive details were recorded. Dr A subsequently told HDC the content of the conversation.

[17] Lymphadenopathy refers to the swelling of the lymph nodes or glands.

Dr A's contact with Mr B regarding the missed 2012 PSA result

36. Dr A told HDC that on 23 September 2014 he telephoned Mr B to explain that the March 2012 PSA result was abnormal and had not been followed up. Dr A said that he delayed telling Mr B about the 2012 PSA result until then, and stated: "I wanted to avoid causing him further upset as he was just about to leave for a holiday and my first priority had been to obtain a definitive diagnosis and commence treatment."

37. Mr B told HDC that whilst he did not wish to meet with Dr A to discuss the missed PSA result further, Mrs B did, and he consented to her contacting Dr A directly. Dr A received a telephone call from Mrs B on 29 September 2014, and they arranged to meet at the medical centre later that week.

38. On 3 October 2014, Dr A met Mrs B to discuss the 2012 missed result and Mr B's prostate cancer. Dr A told HDC that he explained to Mrs B that he filed the 9 March 2012 PSA result without taking any further follow-up action, and that he apologised for his error.

The medical centre and Dr A's process for checking test results

39. The medical centre uses a practice management system (PMS) that allows laboratory results to be sent to the provider inbox of the requesting doctor electronically. Dr A told HDC that his PMS inbox has between 20 and 60 items per day, with approximately half of these entries being letters from other practitioners including after-hours GPs, specialists, hospital discharges or clinic summaries, and half of which are laboratory or radiology results. All of these entries remain in the doctor's PMS inbox until they are filed.

40. With respect to Mr B's missed 2012 PSA result, Dr A told HDC that he erroneously recorded the result as "normal" in his PMS inbox. He further stated that he does not know why he filed the result incorrectly, and that usually he is very careful with the management of his patients' test results.

41. Dr A also told HDC that the medical centre is in the process of adding a secure internet portal that will allow registered patients to access their own results.

Further information

42. Dr A told this Office: "[A] significant laboratory result was overlooked by me in 2012, and with that the opportunity for early diagnosis of prostate cancer was lost." Dr A stated that he was "shocked and saddened when [he] learnt in 2014 that [Mr B] was diagnosed with high grade prostate cancer", and apologised for overlooking the result.

43. Dr A conducted an audit of PSA and DRE results of all of his male patients over the age of 45 years for the 2014 year, and confirmed that all patients with elevated results were receiving appropriate follow-up care.

Responses to the provisional report

44. The parties were given an opportunity to comment on the relevant sections of the provisional report. These responses have been incorporated into the report where appropriate. Further responses have been outlined below.

Mr B

45. Mr B commented that knowing his profile, age and medical history, Dr A should have been more diligent when checking his blood results in both 2012 and 2014. Mr B further stated that he should have been informed of the missed PSA test result as soon as Dr A discovered it, and considers that the time it took Dr A to inform him of the missed result was an error of judgement.

46. Mr B also said that he has had great difficulty in accepting that he has terminal cancer, and that his ongoing treatment has had a significant impact on him.

Dr A

47. Dr A stated: "I have no hesitation in apologising for the error I made in my care of [Mr B]. I deeply regret overlooking the PSA result in 2012." Dr A further commented: "[Mr B's] case and this investigation has been a salutary lesson for me and I can assure the HDC that I will do my utmost best to ensure the same errors in this case will not occur again the future."

48. Dr A told HDC that he has presented and discussed with his peer review group an anonymised precis of Mr B's case. Dr A further stated that he knows of no other occasion on which he has filed an abnormal result incorrectly, and that "sadly the missed result was very much a one-off human error".

49. Dr A accepted the recommendations of this report, and that he had breached Right 4(1) of the Code, but said he considered that the finding that he had breached Right 6(1) of the Code was "harsh in all the circumstances". Dr A acknowledged that the delay in informing Mr B of the 2012 PSA result may be seen as an unwise decision, but he genuinely believed he was acting in Mr B's best interests.

50. Dr A stressed that it was always his intention to advise Mr B about the 2012 PSA result when Mr B returned from his holiday. Dr A also stated that "the guidelines around informing patients of unintentional harm refer to delay being acceptable if it is in the patient's best interests". Dr A apologised "if [he] made an error of judgement", and said that "there was no intention to hide the truth".

Standards

51. The Medical Council of New Zealand's publication *Good Medical Practice* (2008) states:

> "2. Good clinical care includes:

- adequately assessing the patient's condition, taking account of the patient's history and his or her views and examining the patient as appropriate
- providing or arranging investigations or treatment when needed
- taking suitable and prompt action when needed
- referring the patient to another practitioner when this is in the patient's best interests."

52. The Medical Council of New Zealand's statement on "The maintenance and retention of patient records" (August 2008) states:

"*1. Maintaining patient records*

a) You [registered doctor] must keep clear and accurate patient records that report:

- relevant clinical findings
- decisions made
- information given to patients
- any drugs or other treatments prescribed

b) Make these records at the same time as the events you are recording or as soon as possible afterwards.

2. Practice systems

a) [The] Council recommends that every practitioner has access to systems for recall of patients who need regular checks or treatment.

b) Doctors should have systems in place to ensure that test results are acted upon in a timely manner, including notification of patient as appropriate."

Opinion: Dr A

Introduction

53. On 5 March 2012, Dr A ordered a PSA and other blood tests for Mr B. On 9 March 2012, Dr A received the PSA result, which was 8.3 µg/L — above the normal range, which is between 0.0–4.5 µg/L. Dr A filed the elevated PSA result as "normal", and did not discuss the result with Mr B until September 2014 or take any further follow-up action. This opinion considers the services Dr A provided to Mr B, including Dr A's actions once he became aware of the error.

Failure to recognise and follow up on 2012 PSA result — Breach

54. On 5 March 2012, Mr B presented to Dr A with "reduced energy, breathless walking/cycling on slopes". Dr A told HDC that based on Mr B's presentation, he decided to rule out ischaemic heart disease and chronic pulmonary disease, and ordered an ECG and other blood tests.

55. Mr B did not report any symptoms regarding his prostate function at this consultation, and Dr A stated that a PSA test was included along with other blood tests "simply because it was something [he] aimed to record every year or two and was approximately due".

56. On 9 March 2012, Mr B's PSA result was sent electronically by the laboratory to Dr A, and is recorded as being 8.3 µg/L, which is above the normal range (0.0–4.5). The result was accompanied by a statement from the laboratory — "PSA between upper reference range to 10 µg/L: approximately a third of cases have prostate cancer".

57. Dr A told HDC that he erroneously logged the result as "normal" and filed it electronically in his practice management system. Dr A took no further action and did not become aware of the 2012 result again until late July 2014.

58. Dr A stated that whilst in general he is "very much aware that a PSA of 8.3 µg/L is a significantly abnormal result", he overlooked the 2012 result and mistakenly filed it as normal because he was "focusing on other symptomatic medical issues that were being investigated at this time". I note that Dr A saw Mr B promptly on 10 March 2012 after reviewing his ECG results, which showed a first degree atrio-ventricular block and a slow pulse rate.

59. My expert advisor, GP Dr Maplesden, advised that "it was clinically inappropriate to file the 2012 result without further action and this must represent a moderate departure from expected standards of care".

60. Dr Maplesden also advised that following receipt of the 2012 PSA result, it would have been appropriate "to notify the patient of the result and its possible implications, repeat the [PSA] test and MSU and, if the result remained elevated and infection had been excluded, discuss with the patient the recommendation of referral for specialist review". I note that none of these follow-up actions occurred following receipt of the 2012 result, and the cause of Mr B's elevated PSA went undiagnosed until 2014.

61. The Medical Council of New Zealand's (the Council's) publication *Good Medical Practice* (2008) requires clinicians to take suitable and prompt action when needed, and to refer patients to another practitioner when it is in their best interests.[18] The Council's statement on "The maintenance and retention of patient records" (August 2008) further states that registered doctors "must keep accurate patient records" and have in place systems to "ensure that test results are acted upon in a timely manner, including notification of a patient as appropriate".

62. Recognising elevated results and taking appropriate follow-up action on abnormal test results is fundamental to accepted and basic medical practice in New Zealand. As I have stated previously, "doing the basics well matters", and doctors owe patients a duty of care when handling test results, including advising patients of, and following up on, their results.[19]

[18] Medical Council of New Zealand, *Good Medical Practice*, Wellington, 2013.
[19] See Opinion 13HDC00599, page 6, available at www.hdc.org.nz.

63. Accordingly, I consider that by failing to recognise the 2012 PSA result and take appropriate follow-up action upon receipt of the result, Dr A did not provide services to Mr B with reasonable care and skill, and so breached Right 4(1) of the Code.

Failure to inform Mr B of the 2012 PSA result — Breach

64. On 28 July 2014, Mr B presented to Dr A with urinary complaints. Dr A documented that Mr B's urinary stream was slow, and that he "sometimes ha[d] to go again within 20mins of voiding". Dr A conducted further investigations, including ordering a PSA test.

65. The PSA result received from the laboratory on 30 July 2014 was 66 µg/L, and was accompanied by the laboratory comment: "[P]rostate cancer more likely than benign hyperplasia." Upon reviewing this result on 31 July 2014, Dr A took immediate action by notifying Mr B of the result and referring him to urologist Dr C.

66. It was on or soon after 28 July 2014[20] that Dr A also noticed that he had missed the 2012 PSA result, but he waited until 23 September 2014 to inform Mr B. Dr A told HDC that the reason he did not notify Mr B of his error immediately was because he wanted to avoid causing Mr B further upset before he went on holiday overseas in August 2014. In response to my provisional decision, Dr A also stated that "guidelines around informing patients of unintentional harm refer to delay being acceptable if it is in the patient's best interests".

67. I acknowledge Dr A's submission and accept that Dr A informed Mr B of his diagnosis in a timely manner prior to his holiday. However, I consider that information about the missed 2012 PSA result was also information that a reasonable consumer in Mr B's circumstances would expect to receive in a timely manner, and that delaying the provision of that information was not appropriate.

68. In my opinion, a consumer should be informed about any adverse event in a timely manner, including where the consumer has suffered unintentional harm while receiving a healthcare service.[21] Accordingly, I remain critical of the time it took Dr A to notify Mr B that he had missed the 2012 PSA result.

69. Taking into account all the circumstances, I consider that Dr A should have made contact with Mr B in a timely manner once realising his error, and certainly before Mr B left for his overseas trip in August 2014. In my view, by failing to inform Mr B about the error promptly, Dr A breached Right 6(1) of the Code.

Other comment

Consent

70. Dr A regarded Mr B's consent for ongoing prostate screening in 2009 as consent to conduct an opportunistic PSA test on 9 March 2012. More specifically, Dr A told HDC that he discussed ongoing prostate cancer screening with Mr B in 2009, and that he considered it to be a good thing to do. Dr A stated: "[Mr B] was happy to follow

[20] Dr A told this Office that he first noticed the missed 2012 PSA result on either 28 July 2014 or on 31 July 2014.
[21] Health and Disability Commissioner, *Guidance on Open Disclosure Policies* (2009), available at: www.hdc.org.nz.

my guidance on the matter." I further note reference to this discussion in Dr A's referral letter to Dr C dated 31 July 2014.

71. With respect to the appropriateness of Dr A relying on Mr B's previous consent to ongoing screening, my independent expert advisor, GP Dr David Maplesden, advised that Dr A's actions were consistent with common and accepted practice.

72. I am satisfied that such consent occurred in light of Dr A's referral letter to Dr C, which specifically references the discussions Dr A had with Mr B regarding ongoing prostate screening in 2009. In light of the fact that Mr B did provide consent to ongoing prostate screening, I consider that appropriate consent was obtained for the 2012 PSA test.

73. However, I note that the disadvantage of relying on previous consent for regular screening is that patients such as Mr B will not have any reason to enquire after their results, as they are not aware that the tests have been taken. Had Dr A obtained contemporaneous consent for the 2012 PSA test, Mr B may have asked about the result, and a missed opportunity for earlier detection of his cancer may have been avoided. Furthermore, I am critical that the 2009 consent to ongoing prostate screening was not documented in the body of Mr B's clinical notes at the time the consent was given.

Consultation — 6 May 2014

74. On 6 May 2014, Mr B saw Dr A and is documented as having presented for a general check-up with "no specific concerns". Dr A told HDC that Mr B presented with no symptoms related to prostate function. Initially Mr B stated that he could not recall this appointment, but in response to the "information gathered" section of the provisional report he said that he visited Dr A because he was experiencing mild pain in his groin. In light of conflicting accounts I am unable to make a factual finding as to what was raised at the consultation.

Opinion: The medical centre — No Breach

75. Under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing agency may be held vicariously liable for any actions or omissions of its employees and/or agents who have been found to be in breach of the Code, whether or not the actions or omissions occurred with the employing authority's knowledge or approval. Pursuant to section 72(5) of the Act, it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the acts or omissions leading to an employee's breach of the Code. In addition to vicarious liability, the medical centre may also be held directly liable for the services it provides.

76. Dr Maplesden has advised that the medical centre "has recall processes in place that appear consistent with the current standard … however there remains a 'human' element that will affect the efficacy of even the best electronic recall process".

77. In light of Dr Maplesden's advice, I do not consider there to be any systematic deficiency in the management of prostate screening or the handling of laboratory results. Accordingly, I do not find that the medical centre is vicariously liable for Dr A's breach of the Code, or directly liable for any breach of the Code.

78. I note that the practice intends to introduce a secure electronic portal whereby registered patients can review their results remotely online. Whilst not obligatory, I consider the implementation of such a tool a positive and proactive measure that will certainly assist in mitigating human error.

Recommendations

79. In my provisional report I recommended that Dr A read and review HDC's publication *Guidance on Open Disclosure Policies* (2009) and MCNZ's statement on "Disclosure of harm following an adverse event" (2010). In response to the provisional report Dr A advised that he has now done this.

80. I recommend that Dr A also take the following actions:

a) Provide a written apology to Mr B for his breach of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mr B.

b) Undertake an audit of his clinical records to ensure that all patient test results he has received in the last six months have been followed up appropriately and communicated to patients. Dr A should provide evidence to this Office of this audit and its outcome within three months of the date of this report.

Follow-up actions

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

b) A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be placed on the Health and Disability Commissioner's 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 David Maplesden:

Expert Opinion Report One:

"1. Thank you for the request that I provide clinical advice in relation to the complaint from [Mr B] about the care provided to him by [Dr A] of [the medical centre]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors. I have reviewed the information on file: complaint from [Mr B]; response from [Dr A]; [medical centre] GP notes and various policy/process documents; clinical notes from oncologist [Dr D] and urologist [Dr C].

2. [Mr B] complains that [Dr A] failed to notify him in March 2012 that he had an abnormally elevated PSA result (8.3 µg/L — reference range for his age <4.5 µg/L) and that [Dr A] failed to appropriately follow up the elevated result. [Mr B] had no urinary symptoms at the time but the test was performed as part of screening for prostate cancer. When [Mr B] developed lower urinary tract symptoms (LUTS) in July 2014 the PSA was repeated and was markedly elevated at 66µg/L. [Mr B] underwent prostate biopsy and imaging in early August 2014 and was diagnosed with prostate cancer with local lymph node involvement but no distant metastases (Stage T3aN1M0 — Gleason 4+4) and he has required hormone therapy and radiotherapy. [Mr B] is concerned that an opportunity for earlier diagnosis and possible curative surgery for his cancer was lost because of [Dr A's] oversight in failing to action the March 2012 result.

3. [Dr A] has provided a detailed response which will not be reiterated here. He acknowledges his oversight with respect to his management of the PSA result in question: *I have reflected on this matter at length … My conclusion is that a single laboratory result was overlooked while unrelated symptomatic medical issues were being investigated. I am simply at a loss as to why I erroneously filed the result without further action and remain deeply disappointed over my omission as I regard my usual standard of test result management as very careful and vigilant …*

4. Brief notes review

(i) GP notes are consistent with the response. Clinical notes of 5 and 10 March 2012, when [Mr B] presented with possible cardiorespiratory symptoms, are somewhat deficient in that there is no record of any physical assessment findings (vital signs, lung auscultation). However, [Dr A] was conscientious in ordering blood tests, ECG and spirometry as further investigation of the symptoms, and appropriate further specialist referrals were made.

(ii) PSA result dated 9 March 2012 was 8.3 µg/L (reference range 0.0–4.5). The lab has identified the result as being elevated with an 'H' beside the result. There

is an additional (standard) pathologist comment: *PSA between upper reference range to 10µg/L: approximately a third of cases will have prostate cancer. Other causes include benign hyperplasia, prostatitis, prostate massage, prostatic needle biopsy, ejaculation, DRE, exercise and spontaneous variation.* While not evident on the documentation provided, [Dr A] has stated in his response that he annotated the result as normal and it was filed.

(iii) The next relevant consultation was 6 May 2014 when notes include: *Check up, sent by wife, no specific concerns …* a discussion on various lifestyle issues is recorded but there is no reference to LUTS. Cardiorespiratory and abdominal examination recorded. Digital rectal examination (DRE) was performed with comment: *firm moderate sized smooth regular prostate.* No blood tests were ordered. I note subsequent specialist report ([Dr C] — 9 August 2014) includes the comments: [Mr B] *has noticed a deterioration in his urinary flow over the last six months, getting up twice at night. He has urinary frequency during the day, but no urgency. Over the last month he has had a discomfort over the suprapubic region which is worse when he leans forward. On examination he has a moderate sized prostate with a firm nodule at the left base …* This implies [Mr B] may have had some LUTS at the time he saw [Dr A] in May 2014 but the symptoms were evidently not discussed at the time. I assume therefore that the reason [Dr A] performed a DRE/prostate examination on [Mr B] at this time was to screen [Mr B] for prostate cancer. I think a significant number of my peers would have ordered a PSA blood test at this time despite the apparently normal DRE (advising the test be done a couple of days after the DRE) although as discussed further below there is much controversy over what is 'best practice' in terms of screening asymptomatic men for prostate cancer such that I cannot say the failure to order a PSA at this point (leaving aside the issue of the previous elevated result) was a departure from accepted practice. However, it probably represents a lost opportunity for a slightly earlier diagnosis of [Mr B's] malignancy although I do not feel the three month delay until eventual diagnosis is likely to have altered [Mr B's] prognosis or eventual management.

(iv) On 28 July 2014 [Dr A] has recorded: *stream seems just slower and sometimes has to go within 20 minutes of voiding … check PSA and MSU.* Dipstick urinalysis was clear. PSA result 30 July 2014 was 66µg/L and [Dr A] made an immediate referral of [Mr B] to urologist [Dr C]. Further management was as noted above.

5. [Mr B] was asymptomatic and the elevated PSA result of 9 March 2012 required notification and specific management. A 2010 BPAC publication[1] included the following comments and recommendations:

(i) *PSA results between 4 and 10 µg/L are considered mildly to moderately elevated, while levels over 10 are considered high.*

[1] http://www.bpac.org.nz/BT/2010/July/docs/best_test_jul2010_psa_screening_pages14-18.pdf Accessed 27 July 2015

(ii) *The higher the PSA, the more likely the presence of prostate cancer. However, there is no PSA level that below which a man can be reassured he definitely does not have prostate cancer.*

(iii) *As there are a number of non-cancerous contributors to an increased PSA it is generally prudent to repeat any initial high result. Care should be taken when interpreting trends, particularly being careful not to over interpret small changes.*

(iv) *Effect of ejaculation and DRE have historically been thought to increase the PSA level temporarily. This effect is variable and in most patients insignificant (about 5% rise over several days for DRE). While PSA can usually be performed after DRE, it is probably better, if practical, to either collect the PSA sample beforehand or delay collection for up to a week.*

(v) *If there is concern at the current level of PSA, or an increase of the PSA level, referral to a specialist is recommended.*

I feel the expected management of [Mr B] following receipt of the PSA test result dated 9 March 2012 would have been to notify the patient of the result and its possible implications, repeat the test and MSU and, if the result remained elevated and infection had been excluded, discuss with the patient the recommendation of referral for specialist review (with or without preceding DRE).

6. Comments: With respect to the decision to undertake PSA screening for prostate cancer in asymptomatic men, the available evidence for such a practice, and whether or not DRE should be incorporated, is confusing and very much debated and there is no universally accepted 'best practice'. For instance, both the US Preventive Services Taskforce (in 2012)[2] and the Canadian Task Force on Preventive Health Care (in 2014[3] — and including males with LUTS) recommended against PSA screening for prostate cancer yet other local and international organisations and individual urologists advocate strongly for such screening. Therefore, whether or not [Mr B] should have had PSA screening in 2012 or thereafter is open to debate. However, the following issues I feel are more easily defined:

(i) No blood test should be undertaken without the informed consent of the patient. [Dr A] indicates in his response that the risks and benefits of PSA testing for prostate cancer screening had been previously discussed with [Mr B] and he understood such screening would be undertaken on the advice of [Dr A]. It is unclear whether [Mr B] was aware a PSA test had been requested amongst the bloods taken on 9 March 2012. While I think it was reasonable to order a PSA test given [Mr B] had apparently previously agreed to such screening, I would be mildly critical if he was not made aware the test was being repeated on 9 March

[2] http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/prostate-cancer-screening?ds=1&s=prostate Accessed 27 July 2015

[3] http://canadiantaskforce.ca/ctfphc-guidelines/2014-prostate-cancer/clinician-faq/ Accessed 27 July 2015

2012. Had he not been aware the PSA test was being undertaken there would be no indication for him to enquire after the result.

(ii) The patient has a right to be informed of the results of investigations and should be informed of any abnormal result including the significance of the result and management plan in relation to that result. It is apparent the abnormal PSA result in this case was not notified to [Mr B] nor any management plan put into place such as clinical review to check on LUTS/DRE and/or repeat PSA testing. [Dr A] has been unable to explain precisely why the result was filed without appropriate actioning other than that [Mr B's] unrelated but significant cardiorespiratory symptoms at the time may have been a distraction. It is not possible for me to determine unequivocally whether [Dr A] recognised the result as being significantly abnormal and filed it in error, or whether he erroneously felt it was an insignificant result that required no further action. He states he had annotated the result as 'normal' which might imply the latter, although he outlines a practice audit which indicates he was an 'above average' user of PSA screening for prostate cancer in which case I would have thought he would be very familiar with the appropriate management of the PSA results he was receiving. I think it was reasonable for [Mr B] to assume that absence of notification of his blood results meant the results were not concerning. Assuming [Dr A] had recognised [Mr B's] PSA result of 9 March 2012 as being abnormal, but inadvertently filed the result (human error), I would be moderately critical of his failure to notify [Mr B] of the result and to take appropriate further action on the result. If [Dr A] failed to recognise the potential significance of the elevated PSA result, having made a decision with [Mr B] to undertake screening for prostate cancer, and the result was deliberately filed because [Dr A] did not recognise further action was required, I would regard his management (including the failure to notify [Mr B] of the result) as being a severe departure from expected practice. However, [Dr A's] discussion in his response of his PSA audit results is somewhat reassuring that [Mr B's] case represents a management exception rather than a trend.

(iii) [Dr A's] management of [Mr B] following the consultation of 28 July 2014 and the detection of the very raised PSA result on 30 July 2014 was consistent with expected practice.

(iv) [Dr A's] management of [Mr B] on 6 May 2014 was probably acceptable if [Mr B] was not complaining of LUTS. If there was a complaint of LUTS at this point I would be at least mildly critical that further investigation by way of repeat PSA testing, and review of PSA results, was not undertaken in conjunction with the DRE.

7. Relevant practice policies have been reviewed and appear consistent with accepted practice. I agree with [Dr A] that the introduction of a Patient Portal may reduce the risk of such an error happening again and such Portals are slowly being adopted throughout the country."

Expert Opinion Report Two:

"I have reviewed the letter from [Dr A] dated 21 August 2015 in which he provided further information in response to specific questions posed to him by the Legal Investigator:

1. Whether [Mr B] was informed of, and consented to, the 9 March 2012 PSA test.

[Dr A] had previously had a detailed discussion with [Mr B] regarding the merits of prostate screening and it had been agreed [Mr B] would undergo regular PSA screening. The most recent test prior to the March 2012 test had been taken in 2009 so a repeat test was due. [Dr A] regarded [Mr B's] previous consent for this opportunistic screening as applying to the current situation and PSA was ordered as part of other blood tests being taken for an unrelated issue, but without specific discussion or consent. I think a significant number of my colleagues would regard consent to regular screening as applying to future tests in relation to that screening and therefore I feel [Dr A's] actions were consistent with common and accepted practice. However, as noted in my original advice the disadvantage of such an approach in this instance was that [Mr B] did not have any reason to enquire after his PSA result as he was not aware it had been taken.

2. Whether [Mr B] presented with LUTS or any other urinary symptoms on 6 May 2014. If [Mr B] did present with LUTS on 6 May 2014, please provide a response regarding why this presentation was not documented and further investigations conducted, including a PSA test.

[Dr A] states [Mr B] did not refer to any issue with LUTS at the consultation of 6 May 2014. The DRE was undertaken opportunistically as a screening test because [Mr B] had not had one done for some time. The DRE showed a normal prostate so no further tests were performed. [Mr B] would have been asked about LUTS as part of the 'system review' undertaken during the consultation. Earlier in his response [Dr A] stated that when screening asymptomatic men for prostate cancer he *aimed to record* [a PSA] *within every two years.* It is therefore somewhat puzzling that a PSA was not recorded on this occasion when it was over two years since the previous result and a DRE was being performed. Nevertheless, I accept [Dr A's] assertion regarding the absence of any admission by [Mr B] to having LUTS and, with reference to the discussion in my original advice regarding the controversies regarding prostate screening, it is not possible to say the failure to undertake a PSA on this occasion was departure from accepted practice.

3. A response detailing the steps you took to contact [Mr B] upon reviewing the 9 March 2012 PSA result in July 2014, including: (a) The precise date you noticed the PSA result in July 2014; (b) A timeline of the communication (attempted or otherwise) you had with [Mr B], or members of his family, between July 2014 and 3 October 2014 regarding the 2012 PSA result.

[Dr A] received the markedly elevated PSA result on 31 July 2014. He thinks it was at this stage he reviewed [Mr B's] Inbox and found the result from March 2012. There had been 32 Inbox results filed in the interim so the previous PSA

result was not immediately obvious and had to be specifically searched for. On 31 July 2014 [Dr A] notified [Mr B] of the latest result, and that referral to a urologist was required. The previous result was not discussed at this point as [Mr B] was shortly travelling overseas and [Dr A] states he did not want to cause the patient additional distress. However, both results were disclosed in the referral letter to the urologist. [Mr A] underwent urgent assessment by the urologist prior to departing overseas and [Dr A] facilitated this assessment on the direction of the urologist. The cancer was diagnosed and initially felt to be suitable for hormone therapy which was initiated prior to [Mr B's] departure. Following [Mr B's] return to New Zealand [Dr A] contacted him by phone on 23 September 2014 and disclosed the situation regarding his unintentional failure to act on the 2012 PSA result. Further discussions were later held with [Mr B's] wife, evidently with his consent. The Medical Council of New Zealand gives recommendations regarding open disclosure in its publication 'Disclosure of harm following an adverse event'[4] although the discussion refers to where a patient has been harmed as a direct result of receiving medical treatment in a clinical situation. Recommendations include: *It is important that you make a disclosure in a timely manner. Therefore it is appropriate to make the initial disclosure as soon as practical, with a more detailed discussion with the patient to follow once the team has had an opportunity to meet and assess the circumstances that led to the patient being harmed. This will also give time for the patient to think about the situation and provide an opportunity to ask for more information … While it may be more appropriate to disclose the harm in stages so the patient understands and processes the information without being overwhelmed, ongoing delay in giving full information is only acceptable if this is in the patient's best interests.* The HDC advice on open disclosure policies[5] includes the comment: *Disclosure should be made in a timely manner, usually within 24 hours of the event occurring, or of the harm or error being recognised.* While I understand [Dr A's] concern not to burden [Mr B] with additional stress when he had a likely diagnosis of prostate cancer and was just about to travel overseas, I feel it was an unwise decision to defer the open disclosure to [Mr B]. It was important the urologist had all relevant information regarding [Mr B's] previous PSA tests (which was provided by [Dr A]) and there was a risk this information would be presented to [Mr B] by the urologist which was not an appropriate method of disclosure under the circumstances. I recommend [Dr A] review the MCNZ and HDC statements on open disclosure.

4. On reviewing the additional response from [Dr A] and PSA audit provided previously, it is evident the oversight regarding the 2012 PSA result was the result of a 'one off' human error rather than any systematic deficiency in management of prostate screening or handling of laboratory results. The practice has recall processes in place that appear consistent with current standards. However, there remains a 'human' element that will affect the efficacy of even the best electronic recall process with a current weakness of many GP-based systems being if a result

[4] Available at: https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Disclosure-of-harm.pdf Accessed 30 September 2015

[5] Available at: http://www.hdc.org.nz/decisions--case-notes/open-disclosure Accessed 30 September 2015

is inadvertently filed as 'normal', and there is no reason to be expecting an abnormal result (as is the case of screening tests when the patient is asymptomatic), and the patient has been reassured that only abnormal results will be notified and does not enquire after the result (as is a common scenario), there is the potential for an abnormal screening result to 'slip through the net'. National screening programmes such as the Cervical Smear Programme do have additional safeguards to prevent such errors, but there is no national screening programme for prostate cancer and unlikely to be such a programme (on the basis of current evidence) in the near future. As noted in my original advice, the increasing use of a Patient Portal, which allows patients direct remote access to components of their clinical file including results, may mitigate the risk to some extent. Noting this was a 'one-off' human error it is difficult to quantify the departure from expected standards of care but the fact remains that it was clinically inappropriate to file the 2012 PSA result without further action and this must represent a moderate departure from expected standards of care under the circumstances."