Medical Centre

General Practitioner, Dr B

General Practitioner, Dr C

A Report by the

Health and Disability Commissioner

(Case 16HDC00592)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. At the time of these events Mr A was aged between 62 and 75 years, and regularly attended a medical centre. The practice was operated as a partnership for a number of years by various GPs within the practice. In July 2015 it had a change of ownership.

2. Between 2002 and 2013, Mr A had five prostate-specific antigen (PSA) tests — all of which were recorded as being within the normal range expected for Mr A's age at the time of testing. On 8 October 2014, Mr A presented to locum general practitioner (GP) Dr E, who conducted a digital rectal examination (DRE) and made a plan to order bloods including a PSA test.

3. On 15 October 2014, Mr A's PSA was 7.2µg/L (normal range 0.0–6.5). On 19 October 2014, Dr C reviewed the result and recorded in the medical notes: "[R]epeat PSA [in six months' time] probably a [benign prostatic hyperplasia]." There is no record that Dr C set a recall within the practice management system, and Mr A was never informed of the PSA result or Dr C's plan to re-test Mr A's PSA levels.

4. On 21 April 2015, Mr A was sent a letter by the medical centre's practice nurse inviting him to have blood tests to assess his cardiovascular risk. Enclosed within the letter was a laboratory order form from Dr B, which requested a number of blood tests including a PSA test. On 1 May 2015, Mr A presented to Dr B complaining of a nasal lesion and requesting a driver's license medical examination. Dr B told HDC that it was at this consultation that he ordered a PSA test for Mr A, but did not tell Mr A he was doing so due to time constraints. There is no record of Dr B ordering any blood tests on 1 May 2015.

5. On 4 May 2015, Mr A's PSA result was 10.5µg/L. Dr B told HDC that he considered this result to be "borderline", and that he did not inform Mr A of the result but decided to recall Mr A for further testing in three months' time. Dr B did not document that he reviewed the result or his plan for further PSA testing. An audit of the practice management system shows that Dr B did set a recall in the system for 5 August 2015. On 10 August 2015, Mr A was sent another letter by the practice nurse inviting him to have blood tests done to assess his cardiovascular risk profile. No reference was made to a PSA test. On 10 August 2015, a series of blood tests were ordered for Mr A but a PSA was not requested.

6. On 5 November 2015, Mr A presented to Dr C complaining of urinary related symptoms. Dr C conducted a DRE and found Mr A's prostate moderately enlarged and nodular, and made a plan to conduct a PSA and mid-stream urine test. On 9 November 2015, Mr A's PSA was 15.3µg/L. On 10 November 2015, Dr C referred Mr A to a urologist. It was subsequently confirmed that Mr A had prostate cancer.

Findings

7. Dr C breached Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code) by failing to inform Mr A of the 15 October 2014 test result, its implications, and the management plan to re-test his PSA levels in six months' time.[1]

8. Dr B breached Right 4(1) of the Code by failing to order further tests to rule out other causes for the elevated 4 May 2015 PSA test result, and by failing to document relevant clinical information including the reasons for ordering a PSA test, his assessment of the PSA result, and his plan to conduct further PSA testing in three months' time.[2] Dr B also breached Right 6(1) of the Code by failing to provide Mr A with information regarding the ordering of a PSA test, the 4 May 2015 PSA test result, the implication of the elevated result, and his plan for further testing in three months' time.

9. The medical centre owed a duty of care to Mr A when managing recalls for future blood tests. By failing to contact Mr A in August 2015 for further PSA testing, the medical centre breached Right 4(1) of the Code. Adverse comment was also made regarding the Test Result Policy current at the time of these events.

Recommendations

10. It is recommended that Dr C provide Mr A with an apology for his breach of the Code. It is also recommended that he undertake a random audit of his clinical records to demonstrate that he has communicated the results of tests to patients appropriately.

11. In his response to the provisional report, Dr B provided Mr A with an apology for his breach of the Code. It is recommended that Dr B undertake a random audit of his clinical records to demonstrate that he has assessed, recorded, and communicated the results of tests to patients appropriately. It is also recommended that Dr B arrange for further training regarding effective communication with patients, diagnosis and management of prostate cancer, and record-keeping and management of test results.

12. It is recommended that the Medical Council of New Zealand consider whether a review of Dr B's competence is warranted.

13. It is recommended that the medical centre provide Mr A with an apology for its breach of the Code. It is also recommended that it undertake an audit of the practice's clinical records and practice management system to ensure that all PSA test results received for a one-month period have been reviewed and annotated correctly, and recalls for further testing set. It is further recommended that all staff involved in the management of test results meet to discuss the findings of this report and the practice's new test results and medical record management procedure.

[1] Right 6(1) states that every consumer has the right to information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including the results of tests and an explanation of the options available.
[2] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

Complaint and investigation

14. The Commissioner received a complaint from Mr A about the services provided to him by the medical centre. The following issues were identified for investigation:

- *The appropriateness of the care provided to Mr A by the medical centre.*
- *The appropriateness of the care provided to Mr A by general practitioner Dr C at the medical centre.*
- *The appropriateness of the care provided to Mr A by general practitioner Dr B at the medical centre.*

15. An investigation was commenced on 14 September 2016.

16. The parties directly involved in the investigation were:

Mr A	Consumer/complainant
Dr B	General practitioner
Dr C	General practitioner
Medical centre	

Also mentioned in this report:

Dr E	General practitioner
Dr F	General practitioner
Dr G	General practitioner

17. Information was reviewed from:

Operations Manager, Medical Centre	
Dr D	Urologist
Insurance company	
Medical Council of New Zealand	

18. Expert advice was obtained from in-house advisor general practitioner Dr David Maplesden (**Appendix A**).

Information gathered during investigation

Background

19. At the time of these events, Mr A was aged between 62 and 75 years, and had regularly attended the medical centre since August 2000. The medical centre provides general medical and nursing services. In July 2015, it had a change of ownership.

20. Mr A had a regular doctor until 2013, following which Dr F[3] was Mr A's regular doctor until August 2014. Between August and December 2014, Mr A did not have a regular doctor. In December 2014, Dr B was Mr A's regular doctor.[4]

2002–2013 PSA testing

21. Between 2002 and 2013 Mr A had five prostate-specific antigen (PSA) tests.[5] All of the PSA test results were recorded as being within the normal range expected for Mr A's age at the time of testing.

2014 PSA testing

22. Following Dr F's departure from the medical centre in August 2014, Mr A did not have a regular doctor until Dr B was appointed as a long-term locum in December 2014 to provide cover. It was during this time (ie, August–December 2014) that Mr A was seen by locum general practitioner Dr E,[6] and his test results were reviewed by general practitioner Dr C.[7]

23. On 8 October 2014, Mr A presented to Dr E with "nil specific health concerns". Mr A reported that his brother had been diagnosed with diabetes and prostate[8] cancer, and requested that he be checked for the same. Dr E conducted a digital rectal examination (DRE) and noted that Mr A's prostate was "smooth clearly defined including sulcus [slightly] firm but not hard approx. egg sized [as a whole]". Her clinical impression was recorded as a "normal exam", and she made a plan to "do bloods" and documented that Mr A was "aware re PSA limitations". Mr A stated that at this consultation he was told by Dr E that his prostate was "fine".

24. On 15 October 2014, Mr A's PSA result was 7.2µg/L. The laboratory result recorded that the normal range was 0.0µg/L–6.5µg/L, and noted: "PSA between upper reference range to 10 µg/L: approximately a third of cases have prostate cancer." On 19 October 2014, Dr C reviewed Mr A's PSA result and recorded: "[R]epeat PSA [in six months' time] prob[ably] a [benign prostatic hyperplasia[9]]."

[3] Dr F is registered under a general scope of practice with the Medical Council of New Zealand.
[4] Dr B is registered under a general scope of practice with the Medical Council of New Zealand.
[5] 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. PSA testing occurred on 11 October 2002, 23 December 2005, 23 June 2010, 16 August 2012, and 13 August 2013.
[6] Dr E is vocationally registered under a "general practice" scope with the Medical Council of New Zealand.
[7] Dr C is vocationally registered under a "general practice" scope with the Medical Council of New Zealand.
[8] The prostate is a gland found only in men and is located below the bladder. Its function is to secrete a milky fluid which becomes part of the semen.
[9] Benign prostatic hyperplasia is an enlarged prostate gland and is common among men as they age. It is not cancerous but as the prostate gets bigger it may squeeze or partly block the urethra.

25. The medical centre stated with respect to the 15 October 2014 PSA test result:

> "Dr [C] received the results of the blood tests which showed a [PSA] of 7.2. [Dr C] believes that he would have forwarded the results to [Dr B], [Mr A's] regular doctor, as was standard practice within the clinic at the time. A recall was set for follow up blood tests to be completed in 6 months time. The notes do not record whether or not the patient was contacted."

26. Dr C clarified with HDC that upon reviewing the test result and considering Dr E's clinical note:

> "I felt a repeat test in six months was appropriate. I presumed that [Mr A] was aware that he had been having his prostate health screened at this time.
>
> As [Mr A] says he was not notified and a recall not sent, there appears to have been a breakdown in communication for which I apologise. [Dr B] was not in the practice at the time as he started in December 2014."

27. With respect to whether Dr C set a recall on the practice management system, the medical centre stated:

> "It is unclear as what action was taken, other than [Dr C's] documentation in the notes, and whether he set a recall. There was an auto-recall for [PSA] testing which he could have updated to [6 month] recall which is now inactive. The audit log for this recall is blank which seems to [be] an unexplained MedTech[10] issue, as other recalls show audit histories."

28. Mr A told HDC that the medical centre did not contact him regarding the 15 October 2014 PSA test result.

April 2015 cardiovascular risk assessment

29. On 21 April 2015, Mr A was sent a letter by the practice nurse inviting him to have blood tests done to assess his cardiovascular risk profile. No reference to PSA testing was mentioned in the letter. Enclosed within this letter was a laboratory order form also dated 21 April 2015, which was generated by Dr B and requested a number of blood tests including a PSA test.[11]

May 2015 consultation and PSA testing

30. On 1 May 2015, Mr A presented to Dr B complaining of a growth in his left nostril and requesting a driver's licence medical examination. Dr B made a referral to an ENT surgeon regarding the nasal lesion, and recorded that Mr A passed his medical examination for a driver's licence.

31. With respect to the 1 May 2015 consultation, Dr B told HDC that he familiarised himself with the consultation notes for the eight months prior to the consultation, and noted Dr E's findings on 8 October 2014. Dr B further explained:

[10] MedTech is a practice management computer system.
[11] The other tests Dr B requested were: ferritin, creatinine, uric acid, electrolytes, thyroid-stimulating hormone, HbA1 (glycated haemoglobin) and lipids non-fasting.

> "I reviewed the PSA blood test results of 15 October 2014 … which were slightly elevated at 7.2 µg/L. I did not discuss with [Mr A] the previous PSA result and its implications because I had assumed that [Dr C], who reviewed the results on 19 October 2014, had discussed the results with him and ordered a repeat PSA test in 6 months time ... At my consultation with [Mr A] on 1 May 2015, I ordered blood tests including PSA blood tests. Regrettably, due to time constraints, I did not discuss with [Mr A] that I was ordering a repeat PSA … as would be my routine practice. [Mr A] presented for a driver's license medical and for a growth on his nose also, which took up the entire consultation time. I therefore relied on the fact that [Dr E] had previously discussed the limitations of the PSA tests with him during his last consultation in October 2014."

32. There is no record in the clinical records that Dr B ordered blood tests for Mr A, including a PSA test, on 1 May 2015. It is, however, documented that Dr B ordered a series of blood tests, including a PSA test, on 21 April 2015 (as stated above).

33. On 4 May 2015, Mr A's PSA test result was 10.5µg/L. The laboratory results recorded the normal range as being 0.0µg/L–6.5µg/L and stated: "PSA > 10 µg/L: prostate cancer more likely than benign hyperplasia. For prostatitis,[12] suggest to repeat in several weeks after resolution." With respect to the 4 May 2015 PSA result, Dr B told HDC:

> "I received the results on 4 May 2015 and PSA levels were 10.5 µg/L. I considered these results to be borderline. I did not inform [Mr A] about these results. At the time, I was not aware of the [Ministry of Health] guideline regarding informing patients about borderline increases in blood test results and referring men aged between 71–75 to a urologist. I therefore was guided by the advice I have received in the past from the urology department [electronic referrals] which was to 'Please repeat PSA in 3 months, if over 20 or becoming symptomatic refer back to us'. I had received such advice on several occasions even when the PSA was 15 µg/L.
>
> Therefore I followed previous advice and ordered a follow up PSA test. In addition, because of the borderline result and the fact that [Mr A] did not have any signs or symptoms, I initiated another recall for a PSA check in 3 months. I am not aware if [Mr A] was recalled, and if not, why he was not. To my knowledge, the nurse at [the medical centre] usually checks the recalls. However the GPs did not have a dedicated nurse working for them."

34. Dr B did not document within Mr A's clinical notes that he reviewed the PSA result or set a recall. However, the medical centre was able to produce an audit report from its practice management system which showed that on 5 May 2015 Dr B had set a three-month recall for PSA testing, with a due date of 5 August 2015.

35. Mr A told HDC that he was not informed of the 4 May 2015 PSA test result.

[12] Prostatitis is swelling and inflammation of the prostate gland, a walnut-sized gland situated directly below the bladder in men.

August 2015 cardiovascular risk assessment and PSA recall

36. On 10 August 2015, Mr A was sent a letter by the practice nurse inviting him to have blood tests done to assess his cardiovascular risk profile. No reference was made to a PSA test. On 10 August 2015, a series of blood tests were ordered for Mr A but a PSA was not requested.[13]

37. With respect to why Mr A was not recalled for a PSA test in August 2015, the medical centre told HDC that in July 2015 the practice had an "acute" nursing staff shortage and that the nurse involved in issuing the cardiovascular blood test letter cannot remember whether she noticed a recall for the PSA blood test.

38. On 17 August 2015, general practitioner Dr G[14] reviewed the blood results and marked them as "all ok". On 24 August 2015, Mr A was contacted by a practice nurse at the medical centre and informed of the test results. Mr A stated that he was told that "all was OK" regarding the 17 August 2015 results.

November 2015 consultation, PSA testing and urology referral

39. On 5 November 2015, Mr A presented to Dr C complaining of urinary related symptoms. Dr C conducted a DRE and found that Mr A's prostate was moderately enlarged and nodular. He documented a plan to repeat a PSA test and referred Mr A to a urologist. A mid-stream urine test (MSU) was also ordered.[15]

40. Mr A told HDC that during this consultation he took the initiative and requested a PSA test "as a preliminary to my seeing the specialist, Dr D, at my request. This was for a urinary problem and at no time did I suspect cancer nor was it suggested by [Dr C]."

41. On 9 November 2015, Mr A's PSA test result was 15.3µg/L. The laboratory result specified a normal range of 0.0µg/L–6.5µg/L, and stated: "PSA > 10µg/L: prostate cancer more likely than bengin hyperplasia." The MSU result showed that there was no infection or pyuria.[16]

42. On 10 November 2015, Dr C referred Mr A to the public hospital for a urology appointment. On 17 November 2015, Mr A was informed that his urologist appointment was in three months' time. On 20 November 2015, Dr C referred Mr A to Dr D, stating that because of the waiting time under the public system Mr A wished to be seen privately.

Urology findings

43. On 16 December 2015, Mr A received a prostate biopsy. On 23 December 2015, Dr D recorded:

[13] The blood tests that were requested were recorded as follows: "full blood count, liver/enzymes — liver function, renal — creatinine, renal — electrolytes, renal — micro albumin (urine), glucose — AbA1, lipids — lipids non fasting."
[14] Dr G is a permanent member of the medical team at the practice.
[15] An MSU is used to test for urine infections.
[16] Pyuria is the presence of pus or white blood cells in urine.

> "Unfortunately 10 out of the 12 biopsies that were taken revealed short to significant sections of Gleason[17] 7 or 8 adenocarcinoma.[18] He has quite a large prostate and there is significant risk that he has locally advanced or metastatic disease. As such I have arranged for him to have a whole body bone scan and a pelvic MRI scan."

44. On 5 January 2016, Mr A underwent a bone scan, which found that there was "no evidence to suggest metastatic bone disease". On 8 January 2016, Mr A underwent an MRI, which found local extracapsular[19] spread of the cancer within the left pelvic lymphadenopathy[20] and a likely sacral metastasis.[21]

45. Mr A told HDC that subsequently he was informed by Dr D that his prognosis was "difficult" to determine, and further treatment "should be effective for at least 18 months and then there are other (unspecified) options".

Further information

Test Results & Medical Record Management Procedure

46. The medical centre provided the Test Results & Medical Record Management Procedure (Test Result Policy) that was current at the practice between 1 August 2014 and 1 August 2015. Relevant excerpts of the procedure are as follows:

> "Incoming reports from [the] laboratory, [the radiology service], hospital and some private specialists, are received electronically into the inbox of the provider who requested the report.
>
> …
>
> If the Health provider who requested the report is away, the report is viewed by a Locum provider, the health provider's Nurse or Doctor of the practice who is caring for the patients of the staff member who is absent.
>
> All incoming reports received in the Health provider's inbox [are] read and commented on, then filed into the patients file if no further action is required. If further follow up is required, the Health provider records this in the outcome section of the report indicating what action is required and then marked to the attention of appropriate staff member for follow up.
>
> All abnormal reports should be actioned by either the patient's health provider or the health provider who requested the reports. The patient is notified of the report, any further intervention needed and appropriate recall. Patient can be notified by

[17] The Gleason classification is used for adenocarcinoma and describes how aggressive a prostate cancer tumor is. The Gleason score range is between 6–10 and a higher score indicates a more aggressive tumor.
[18] Adenocarcinoma is a type of cancer that forms in mucus-secreting glands, including the prostate gland.
[19] Situated or occurring outside a capsule of a joint.
[20] Disease of the pelvic lymph nodes.
[21] Sacral refers to the sacrum. The sacrum is a triangular bone in the lower back formed from fused vertebrae and situated between the two hip bones of the pelvis. Metastasis is the development of secondary malignant growths at a distance from a primary site of cancer.

phone, letter, email, texting or faxing. Outcomes are recorded on the patient's file and appropriate recall completed.

All discussions with patients when contacted in regard to reports, should be documented, noting the date and who advised the patient."

Medical centre

47. With respect to its recall and inbox processes in place for reviewing and ordering further test results, the medical centre stated that it had "identified some weakness". It further stated that "on the basis of the documented information", Mr A was not made aware of his abnormal test results after they had been read and reviewed by Dr C and Dr B.

48. The medical centre told HDC that it has made the following changes to its practice:

"[T]he following changes have been made:

1. Nurses now use a collective email address as a default mail to send communications. All nurses are expected to view this email inbox every day, and it is checked at least weekly by the operations manager and clinical leader. The Practice has now launched [an online patient portal where patients can access their personal health information] and encourages patients to use this facility to access results promptly.

2. Over the last 3 months, the practice has vigorously attacked the recall list. It has now employed a [healthcare assistant] to provide additional support, to ensure the recall list is maintained and does not lag.

3. We continue to work with the nursing team, educating them as to the importance of recalls as part of patient care, upskilling them to use a consistent approach when completing recalls, and ensuring they check the patients recall list for other recalls due or overdue. Regular audits are carried out by the Clinical Leader, removing all filters to check that no recalls have been overlooked as the nurses use the Medtech's filtering ability to obtain their specific criteria lists to complete e.g. Smears.

If test results are ordered by a doctor who is not the patient's regular doctor, the expectation is that this doctor follows up and completes any immediate actions deemed necessary by the results. This applies to situations where the patient is seen as an 'acute' patient, or the patient's regular doctor is away from the clinic and a locum doctor has not been employed to cover their absence. This is [the] practice['s] policy and covered in [the] Test Results & Medical Record Management Procedure.

It is usual the patient's regular doctor be advised of any abnormal results that require continued care, recall and/or monitoring. This would happen either by task or discussion with the regular doctor on their return. Historically this has been a collegial arrangement, but on reflection and in discussion with our senior doctors, this protocol will be clarified and incorporated into the clinic procedure."

49. The medical centre further stated that a uniform protocol has now been established for the management of test results and "the expectations are now very clear and express that all abnormal results will be communicated to the patient, either by the doctor directly or practice nurse as a delegated duty". the medical centre also told HDC that it has used Mr A's example as a case study "to highlight to all clinical staff the potential implications of poor communication, and not proactively involving a patient in his/her ongoing care, and complete documentation".

50. On 23 June 2014, the medical centre achieved Cornerstone[22] accreditation with the Royal New Zealand College of General Practitioners (RNZCGP).[23] The medical centre stated that following a restructuring of its business in July 2015 (when the company took ownership of the practice), "[t]here is now a more team focused approach, and robust environment to support The Cornerstone quality assurance principles and processes. The new model is involving all staff in positive reflection and proactive engagement."

51. The medical centre told HDC: "[O]ur clinic is extremely sorry for the distress that has been caused to [Mr and Mrs A] which could have been lessened if there had been prompt and ongoing dialogue with [Mr A]."

Dr C

52. With respect to his management of test results and changes to practice, Dr C told HDC:

> "In the case of my own patients, I advise them to ring the clinic if they have not been informed within a suitable time after having had investigations. I now personally activate appropriate recalls in all patients as well as notifying the nurse and their doctor.
>
> I have read the policy brief on managing patient test results with the Royal [New Zealand] College of General Practitioners, Issue 6, April 2016, and attended a Mastering Your Risk Workshop with the Medical Protection Society. The practice as a whole has re-examined procedures and systems for dealing with patient test results."

Dr B

53. Upon reviewing general practitioner Dr David Maplesden's expert advice reports to HDC, Dr B accepted that he should have informed Mr A about his abnormal PSA results. He told HDC "by way of explanation" that PSA testing has limitations and "it is generally accepted that it is an imperfect screening tool". Dr B further stated:

> "Without presenting symptoms, I regretfully did not consider that [Mr A's] result was abnormal. But in having said this, I understand that informing a patient about borderline blood test results is of importance and communication of these is a key factor which needs to be reviewed and improved. I do accept that I should have

[22] The Cornerstone programme is run by RNZCGP and seeks to provide the means to assess the systems within a general practice against the national standard for New Zealand general practices as outlined in *Aiming for Excellence* (2011–2014).
[23] The medical centre is due for reaccreditation in 2018.

> ordered tests to exclude prostatitis/[urinary tract infection] as the cause of the raised PSA.
>
> …
>
> Unfortunately, as stated above, due to time constraints, I did not discuss the repeat PSA with [Mr A]. I relied on the discussion [Dr E] had previously with [Mr A]. I also wanted to discuss this with him after his next PSA test in a few months time, which would have confirmed a possible trend."

54. Dr B stated that he believed that "practice management deficiencies" had "a significant part to play" in Mr A's care, and that following this incident he set up a warning notification within his practice management system for scheduled tests or investigations that are overdue. With respect to other changes to his practice, Dr B stated: "[I]n the future I will not make any assumptions and always discuss previous abnormal (even borderline) test results with patients in order to ensure that they are fully informed."

55. Dr B told HDC that he has reviewed the guidelines produced by the Ministry of Health's Prostate Cancer Taskforce, including the algorithm for supporting men with prostate-related concerns. Dr B also told HDC that he has taken Mr A's complaint seriously and is "very sorry" that he missed the opportunity to discuss the elevated PSA results with Mr A.

Responses to provisional opinion

56. 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 A

57. Mr A stated that he has "difficulty believing" that a recall was entered into the practice management system following Dr C's review of his PSA test result on 19 October 2014, and considers that this was due to human error.

Dr B

58. Dr B stated that he accepts that he should have managed Mr A differently, "including ordering further testing, documenting the reason for the PSA test and discussing the test result with Mr A". He told HDC that he will "continue to make a conscious effort to discuss any previous borderline and abnormal test results with patients and not make any assumptions". Dr B stated that he intended to complete further training regarding effective communication with patients, record-keeping, and the management of prostate cancer in primary care.

Dr C

59. Dr C stated that he did not wish to comment on the provisional decision.

Medical centre

60. The directors of the medical centre stated that they did not wish to comment on the provisional decision.

Standards

61. The Medical Council of New Zealand's publication *Good Medical Practice* (2013) states:

> "*Providing good clinical care:*
>
> 2. When you assess, diagnose or treat patients you must provide a good standard of clinical care. This includes:
>
> - adequately assessing the patient's condition, taking account of the patient's history and his or her views, reading the patient's notes and examining the patient as appropriate
> - providing or arranging investigations or treatment when needed
> - taking suitable and prompt action when needed, and referring the patient to another practitioner or service when this is in the patient's best interests.
>
> …
>
> *Keeping records*
>
> 5. You must keep clear and accurate patient records that report:
>
> - relevant clinical information
> - options discussed
> - decisions made and the reasons for them
> - information given to patients
> - the proposed management plan
> - any drugs or other treatment prescribed.
>
> 6. Make these records at the same time as the events you are recording or as soon as possible afterwards.
>
> 7. Take all reasonable steps to ensure that records containing personal data about patients, colleagues or others are kept securely.
>
> *Administration Systems*
>
> 8. Your administrative systems must support the principles and standards contained within *Good Medical Practice*.
>
> …
>
> *Supplementary guidance — Referring patients*
>
> Referring involves transferring some or all of the responsibility for some aspects of the patient's care. Referring the patient is usually temporary and for a particular purpose, such as additional investigation, or treatment that is outside

your scope of practice. When you refer a patient, you should provide all relevant information about the patient's history and present condition.

You must appropriately document all referrals.

When you order a test and expect that the result may mean urgent care is needed, your referral must include one of the following:

- your out-of-hours contact details
- the contact details of the another health practitioner who will be providing after-hours cover in your absence.

You must also have a process for identifying and following up on overdue results.

You should ensure that the patient is aware of how information about them is being shared and who is responsible for providing treatment, undertaking an investigation and reporting results."

62. 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

63. Due to the passage of time, the investigation focused on the services provided from October 2014.

Opinion: Dr C — breach

64. On 8 October 2014, Mr A presented to locum general practitioner Dr E and reported that his brother had just been diagnosed with diabetes and prostate cancer, and requested that he be checked for the same. Dr E conducted a DRE and made a plan to order blood tests including a PSA test.

15 October 2014 PSA result

65. On 15 October 2014, Mr A's PSA result was 7.2µg/L. The laboratory result specified a normal range of 0.0–6.5µg/L and stated: "PSA between upper reference range to 10 µg/L: approximately a third of cases have prostate cancer." On 19 October 2014, general practitioner Dr C reviewed Mr A's PSA result and recorded within the clinical records: "[R]epeat PSA [in six months' time] prob[ably] a [benign prostatic hyperplasia]."

66. Mr A stated that he was not notified of the 15 October 2014 PSA result. Dr C told HDC that upon reviewing the test result and considering Dr E's clinical note:

> "I felt a repeat test in six months was appropriate. I presumed that [Mr A] was aware that he had been having his prostate health screened at this time.
>
> As [Mr A] says he was not notified and a recall not sent, there appears to have been a breakdown in communication for which I apologise."

67. Dr C stated that in the case of his own patients he advises them to ring the practice "if they have not been informed within a suitable time after having had investigations". He further stated that he now personally activates "appropriate recalls in all patients as well as notifying the nurse and their doctor".

68. The medical centre stated that other than Dr C's entry in the clinical notes documenting his plan to recall Mr A for further PSA testing, it is "unclear" whether he set a recall in the practice management system. The medical centre told HDC that "the audit log for this recall is blank which seems to be an unexplained MedTech [practice management computer system] issue".

69. My expert advisor, general practitioner Dr David Maplesden, advised that Dr C's plan to re-test Mr A's PSA levels in six months' time was clinically reasonable. I accept this advice. Dr Maplesden considered Dr C's failure to ensure that Mr A received notification of the abnormal October 2014 PSA test result, the implications of the result, or the intended follow-up (ie, re-testing in six months' time) to be a mild to moderate departure from expected standards regarding the patient's right to notification of results and management plan.

70. Dr Maplesden stated that the relatively minor nature of the abnormal PSA result (7.2µg/L — normal range 0.0–6.5µg/L), Dr C's role as an interim provider who never saw Mr A personally, the fact that Dr C was accustomed to asking his patients to contact the practice if they had not heard about their result "within a suitable" time period, and that his assessment of the PSA result was clinically appropriate, were mitigating factors when considering the level of the departure from accepted practice.

71. I note that the practice's Test Result Policy, current in October 2014, stated that abnormal results should be actioned by either the patient's health provider or the health provider who requested the reports. The medical centre told HDC that following Dr F's departure in August 2014, no permanent doctor was employed to take over the care of his patients, including Mr A. Dr E was a temporary locum when she consulted with Mr A on 8 October 2014. Dr C was a permanent member of the clinical staff at the practice, and he was the clinician who reviewed Mr A's results on 19 October 2014.

72. In light of these circumstances, including the fact that Dr E was a temporary locum, that Mr A had no regular doctor at the medical centre, the Test Result Policy, the fact that Dr C was a permanent member of the clinical staff, and that he reviewed the 15 October 2014 PSA result and made a plan to set a recall, I consider that Dr C was responsible for ensuring that Mr A was notified of the result.

Failure to inform Mr A of PSA test results — breach

73. I note that the Medical Council of New Zealand (MCNZ) statement on "The maintenance and retention of patient records" (August 2008) states that "doctors should have systems in place to ensure that test results are acted upon in a timely manner, including notification of patients as appropriate". I further note that MCNZ's publication *Good Medical Practice* (2013) states that doctors should ensure that "the patient is aware of how information about them is being shared and who is responsible for providing treatment, undertaking an investigation and reporting results".

74. The practice's Test Result Policy stated that where there was an abnormal result the patient in question was to be notified of the result, and any further intervention needed and "appropriate recall". Dr C did not follow the steps outlined in the policy, and I am critical that he failed to do so.

75. Effective communication between doctors and patients regarding relevant clinical information is fundamental accepted medical practice in New Zealand, and I am critical that Dr C failed to ensure that Mr A was appropriately informed of the 15 October 2015 test result, its implications, and his clinical plan for further PSA testing in six months' time. Provision of this information would have enabled Mr A to be a partner in his own treatment. As I have stated previously, doctors owe patients a duty of care when handling test results, and this includes advising patients of abnormal test results.[24]

76. Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code) states that every consumer has the right to information that a reasonable consumer in Mr A's circumstances would expect to receive, including the results of tests and an explanation of the options available.

77. Dr C assumed responsibility for the 15 October 2014 PSA test result when he reviewed the result and made a plan to re-test Mr A's PSA levels in six months' time. Information regarding this PSA test result and Dr C's management plan was

[24] Opinion 10HDC01419, page 9, available at www.hdc.org.nz.

information that Mr A was entitled to, but did not receive. Accordingly, by failing to inform Mr A of the test result, its implications, and the management plan to re-test PSA levels in six months' time, Dr C breached Right 6(1) of the Code.

Six-month recall for PSA testing — other comment

78. With respect to whether a recall for PSA testing in six months' time was set in the practice management system, I accept that it was Dr C's intention to do so, as evidenced by his clinical documentation. The medical centre stated that following an audit of its practice management system, it was unable to identify whether a recall was set as per Dr C's clinical plan. I note that on 21 April 2015 Mr A was sent a letter inviting him to have blood tests for a cardiovascular risk assessment. There is no specific mention of PSA testing in the letter. However, enclosed with the letter was a laboratory order form generated by Dr B, also dated 21 April 2015, which requested a number of blood tests including a PSA test. I note that this request for blood tests was made approximately six months following Dr C's plan on 19 October 2014.

79. In light of such information, I am unable to make a factual finding as to whether Dr C set a recall within the practice management system. However, I remind Dr C to take care to ensure that appropriate recalls have been set within the practice management system when making a plan to recall patients for future blood tests.

Opinion: Dr B — breach

80. On 21 April 2015, Mr A was sent a letter by the medical centre's practice nurse inviting him to have blood tests done to assess his cardiovascular risk profile. No reference to PSA testing was mentioned in the letter. Enclosed with the letter was a laboratory order form, also dated 21 April 2015, which was generated by Dr B and requested a number of blood tests including a PSA test.

81. On 1 May 2015, Mr A presented to Dr B complaining of a growth in his left nostril and requesting a driver's licence medical examination. Dr B made a referral to an ENT surgeon regarding the nasal lesion, and recorded that Mr A passed his medical examination for a driver's licence.

82. With respect to the 1 May 2015 consultation, Dr B told HDC that he familiarised himself with Mr A's consultation notes for the eight months prior to the consultation, and noted Dr E's findings on 8 October 2014. Dr B further explained:

> "I reviewed the PSA blood test results of 15 October 2014 … which were slightly elevated at 7.2 µg/L. I did not discuss with [Mr A] the previous PSA result and its implications because I had assumed that [Dr C], who reviewed the results on 19 October 2014 had discussed the results with him and ordered a repeat PSA test in 6 months time.
>
> At my consultation with [Mr A] on 1 May, I ordered blood tests including PSA blood tests. Regrettably, due to time constraints, I did not discuss with [Mr A]

> that I was ordering a repeat PSA … as would be my routine practice. [Mr A] presented for a driver's license medical and for a growth on his nose also, which took up the entire consultation time. I therefore relied on the fact that [Dr E] had previously discussed the limitations of the PSA tests with him during his last consultation in October 2014."

83. There is no record in the clinical notes that Dr B ordered blood tests for Mr A, including a PSA test, on 1 May 2015. It is, however, recorded that Dr B ordered a series of blood tests, including a PSA test, on 21 April 2015.

84. On 4 May 2015, Mr A's PSA test result was 10.5µg/L. The laboratory results recorded the normal range as being 0.0µg/L–6.5µg/L and stated: "PSA > 10 µg/L: prostate cancer more likely than benign hyperplasia. For prostatitis, suggest to repeat in several weeks after resolution." Dr B told HDC that he considered the result to be "borderline", and set a recall for a PSA check in three months' time. Dr B stated that he did not inform Mr A of the 4 May 2015 PSA test result, and accepted that he should have ordered tests to exclude prostatitis and/or a urinary tract infection as causes for the elevated result.

85. Dr B did not document within Mr A's clinical notes that he reviewed the PSA result or set a recall. However, the medical centre was able to produce an audit report from its practice management system, which showed that on 5 May 2015 Dr B had set a three-month recall for PSA testing, with a due date of 5 August 2015.

Clinical management and documentation — breach

86. I note that the laboratory comment that accompanied the 4 May 2015 PSA result stated: "[F]or prostatitis, suggest to repeat in several weeks after resolution." My expert advisor, Dr David Maplesden, stated that following a review of the 4 May 2015 PSA test, Dr B should have ordered further tests to rule out prostatitis, urinary tract infection, or other possible causes for the elevated result. Dr Maplesden advised that Dr B's failure to order further tests represented a mild to moderate departure from the expected standard of care.

87. I further note that the Medical Council of New Zealand (MCNZ) publication *Good Medical Practice* (2013) states that providing good clinical care includes "providing or arranging investigations or treatment when needed". *Good Medical Practice* also requires doctors to keep clear and accurate patient records that report relevant clinical information, options discussed, decisions made and the reasons for them, information given to patients, and the proposed management plan.

88. The medical centre's Test Results Policy current in May 2015 states that all incoming test results received must be "read and commented on", and that if the result requires further action the doctor must record "what action is required" and then mark it to the attention of the appropriate staff member for follow-up.

89. Guided by the expert advice obtained, I am critical that Dr B failed to order further testing to rule out prostatitis and a urinary tract infection. Doctors owe patients a duty of care, and this duty includes situations where doctors are reviewing test results and considering further investigations.

90. I am also critical that Dr B failed to document the reasons he ordered a PSA test for Mr A on 21 April 2015 and the fact that he had reviewed the 4 May 2015 PSA result and made a plan to set a recall for further PSA testing in three months' time. As I have stated in previous opinions, the importance of good record-keeping cannot be overstated.[25] It is the primary tool for continuity of care, and a tool for managing patients.

91. By failing to order further tests to rule out other causes for the elevated 4 May 2015 PSA test result, and by failing to document relevant clinical information including the reasons for ordering a PSA test, his assessment of the PSA result, and his plan to conduct further PSA testing in three months' time, I consider that Dr B breached Right 4(1) of the Code.

Failure to notify Mr A of PSA test result — breach

92. On 21 April 2015, Mr A was sent a letter inviting him to have blood tests to assess his cardiovascular risk. On the same day, Mr A had blood samples taken and Dr B ordered a series of blood tests to assess Mr A's cardiovascular risk, and included a PSA test. Dr B told HDC that he did not discuss with Mr A the fact that he was going to order a PSA test.

93. Dr B reviewed the 4 May 2015 PSA result, which was elevated at 10.5µg/L, and made a plan to conduct further PSA testing in three months' time. However, Dr B did not inform Mr A of this result or his management plan. Dr Maplesden advised that Dr B's failure to communicate both his intention to conduct a further PSA test and the elevated result of the test represented a departure from the expected standard of care.

94. I note that the practice's Test Result Policy current in April–May 2015 stated that where there was an abnormal result the patient in question was to be notified of the result, any further intervention needed, and "appropriate recall". I am critical that Dr B failed to follow this policy.

95. The MCNZ statement on "The maintenance and retention of patient records" (August 2008) states that "doctors should have systems in place to ensure that test results are acted upon in a timely manner, including notification of patients as appropriate". I further note that MCNZ's publication *Good Medical Practice* (2013) states that doctors should ensure that "the patient is aware of how information about them is being shared and who is responsible for providing treatment, undertaking an investigation and reporting results".

96. I consider effective communication between doctors and patients regarding relevant clinical information, including the general groupings of blood tests (eg, tests for cardiovascular risk, or tests for prostate-related issues), the results of tests, and management plans, to be fundamental to good practice in New Zealand.

97. In light of the time that has passed since Mr A started to receive PSA testing at the medical centre, and Mr A's lengthy history of PSA testing, I am unable to make a

[25] See, for example, Opinion 14HDC01100; Opinion 13HDC00482; Opinion 12HDC01483, available at www.hdc.org.nz.

finding on whether Mr A gave informed consent to have his PSA levels tested in May 2015. However, I am critical that Dr B failed to ensure that Mr A understood that the blood tests ordered on his behalf included a PSA test. Provision of this information would have enabled Mr A to be a partner in his own treatment. I also do not consider being short of time as an excuse for failing to provide salient clinical information to a patient.

98. I am also critical that Dr B failed to follow the practice's Test Results Policy and advise Mr A of the elevated PSA test result and his management plan. As I have stated previously, doctors owe patients a duty of care when handling patient test results, and this includes advising patients of abnormal test results.[26]

99. Right 6(1) of the Code states that every consumer has the right to information that a reasonable consumer in Mr A's circumstances would expect to receive, including an explanation of the options available and the results of tests.

100. In my view, Mr A had the right to receive information regarding the ordering of a PSA test, the 4 May 2015 test result, the implication of the elevated result, and Dr B's plan for further PSA testing in three months' time. I am critical that Dr B failed to provide this information, and consider that he breached Right 6(1) of the Code.

Opinion: Medical centre — breach

101. There was new ownership of the medical centre in July 2015.

The medical centre and 2015 care

102. As stated, Dr B ordered a PSA test for Mr A on 21 April 2015. Upon reviewing the 4 May 2015 PSA test result (10.5µg/L), Dr B made a plan to recall Mr A for further PSA testing in three months' time. Dr B told HDC:

> "I am not aware if [Mr A] was recalled, and if not, why he was not. To my knowledge, the nurse at [the medical centre] usually checks the recalls. However the GPs did not have a dedicated nurse working for them."

103. Dr B did not document within Mr A's clinical notes that he reviewed the PSA result or set a recall. However, the medical centre was able to produce an audit report from its practice management system which showed that on 5 May 2015 Dr B had set a three-month recall for PSA testing, with a due date of 5 August 2015.

104. On 10 August 2015, Mr A was sent a letter by the medical centre's practice nurse inviting him to have blood tests done to assess his cardiovascular risk profile. No reference was made to a PSA test. On the same day, a series of blood tests were

[26] Opinion 10HDC01419, page 9, available at www.hdc.org.nz.

ordered for Mr A but a PSA was not requested.[27] On 17 August 2015, general practitioner Dr G reviewed the blood results and marked them as "all ok".

105. On 24 August 2015, Mr A was contacted by a practice nurse at the medical centre and informed of the test results. Mr A stated that he was told that "all was OK" regarding the 17 August 2015 results.

106. With respect to why a PSA was not included within the blood tests for cardiovascular risk assessment on 10 August 2015, the medical centre told HDC that in July 2015 the practice had an "acute" nursing staff shortage and that the nurse involved in issuing the cardiovascular blood test letter cannot remember whether she noticed a recall for the PSA blood test.

107. My expert advisor, Dr David Maplesden, stated that if recalls for further PSA testing had been set correctly in October 2014 (by Dr C) and in August 2015 (by Dr B), he is moderately critical that the practice's processes enabled the recalls to be overlooked on two separate occasions.

108. As stated, I am unable to make a finding as to whether Dr C set a recall for PSA testing in October 2014. However, in light of the audit record of the medical centre's practice management system I accept that Dr B initiated a recall for further PSA testing in August 2015. I consider that once a recall was logged within the practice management system it was reasonable for Dr B to trust that the medical centre's recall system would ensure that Mr A was contacted at the appropriate time (in this case in August 2015). I am critical that the medical centre did not have a recall system in place that clinicians within the practice could rely upon.

109. Notwithstanding any staff shortages that the medical centre was experiencing, it owed a duty of care to Mr A when managing recalls for future blood tests, and I am critical that it failed to contact Mr A in August 2015 for further PSA testing. I consider this failure to be a systems issue and, accordingly, in my view the medical centre breached Right 4(1) of the Code.

Test Result Policy

110. I note that the medical centre achieved Cornerstone accreditation with the Royal New Zealand College of General Practitioners in June 2014. Dr Maplesden noted that the wording of the Test Result Policy (current between 1 August 2014 and 1 August 2015) lacked clarity regarding which doctor was responsible for actioning abnormal test results, and that this ambiguity may have contributed to test results not being "actioned as they should have".

111. I note that the medical centre has since amended its Test Result Policy, and Dr Maplesden has advised that "the practice's documented procedure for handling of test results appears robust and consistent with similar policies I have reviewed from other practices".

[27] The blood tests that were requested were recorded as follows: "full blood count, liver/enzymes — liver function, renal — creatinine, renal — electrolytes, renal — micro albumin (urine), glucose — AbA1, lipids — lipids non fasting."

112. I accept Dr Maplesden's advice and remind the medical centre that it is critically important that it ensure that its policies are clear and easily understood by employees — especially when the policy concerns the management of a patient's health, including test results.

Recommendations

113. I recommend that Dr C undertake the following actions:

a) Provide a written apology to Mr A 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 A.

b) Undertake a random audit of his clinical records for three months from the date of this report, to demonstrate that he has communicated the results of tests to patients appropriately. Dr C is to provide evidence of this audit within four months from the date of this report.

114. In my provisional report I recommended that Dr B provide a written apology to Mr A for his breach of the Code. In response, Dr B supplied an apology letter.

115. I recommend that Dr B also undertake the following actions:

a) Undertake a random audit of his clinical records for three months from the date of this report, to demonstrate that he has assessed, recorded, and communicated the results of tests to patients appropriately. Dr B is to provide evidence of the audit within four months from the date of this report.

b) Arrange for further training with the Medical Council of New Zealand regarding:

i. Effective communication with patients.
ii. Diagnosis and management of prostate cancer in New Zealand.
iii. Record-keeping and management of test results.

Dr B is to provide HDC with evidence of the training within four months from the date of this report.

116. I recommend that the Medical Council of New Zealand consider whether a review of Dr B's competence is warranted.

117. I recommend that the medical centre undertake the following actions:

a) Provide a written apology to Mr A for its 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 A.

b) Undertake an audit of the practice's clinical records and practice management system (MedTech) to ensure that all PSA test results received for a one-month period following the date of this report have been reviewed and annotated correctly, and recalls for further testing set in MedTech. The medical centre is to

provide evidence of the audit and its outcome to HDC within four months of the date of this report.

c) Meet with all staff involved in the management of test results to discuss the findings of this report, and the medical centre's new test results and medical record management procedure. The medical centre is to provide HDC with minutes of this meeting within four months of the date of this report.

Follow-up actions

118. 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 Royal New Zealand College of General Practitioners (RNZCGP), and the district health board, and they will be advised of Dr C's and Dr B's name. RNZCGP will also be informed of the medical centre's name.

119. 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 and Safety Commission.

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

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from general practitioner Dr David Maplesden:

Expert Opinion Report One:

"1. Thank you for providing this file for advice. To the best of my knowledge I have no conflict of interest in providing this advice. I have reviewed the available information: complaint from [Mr A]; response from [the medical centre] per [operations manager]; blood results from August 2013 to current; clinical notes from October 2014 to current.

2. [Mr A] complains that he had several blood tests ordered by doctors at [the medical centre] in 2014 and 2015 and at no stage was he aware PSA testing was being undertaken, and he was not notified of any results although there was an abnormal PSA pattern evident on sequential testing. [Mr A] states it was only when he developed urinary symptoms that he asked for a specialist review and was then diagnosed with advanced prostate cancer.

3. The [medical centre's] response notes [Mr A] had four PSA blood tests performed between 2000 and 2012 *and all received normal PSA levels.* In August 2013 [Mr A] was seen by [Dr F] and PSA was ordered with result of 6.3 µg/L (age-specific range at the time given as 0.0–6.5). [Dr F] evidently filed the result and reviewed [Mr A] on 16 September 2013 prior to overseas travel. There is no documentation to suggest the PSA result was discussed at this point.

4. On 8 October 2014 (recorded in the response as 2013) [Mr A] (now aged 74 years) saw [Dr E] (locum for [Dr C]) and discussed that his brother had been diagnosed with prostate cancer. Notes include: *Nil specific health concerns … prostate smooth, clearly defined including sulcus sl firm but not hard, approx. egg size in toto … he is happy to do bloods & aware re PSA limitations.* Bloods were done on 18 October 2014 and PSA obtained of 7.2 µg/L (range still given as 0.0–6.5). Standard pathologist comment accompanying the result was: *PSA between upper reference range to 10µg/L. Approximately a third of cases have prostate cancer. Other causes include benign hyperplasia, prostatitis, prostatic massage …* On 19 October 2014 [Dr C] has evidently filed the result and commented in the notes: *repeat PSA 6/12 Prob BPH.* The response includes: *[Dr C] believes he would have forwarded the results to [Dr B], [Mr A]'s regular doctor, as was standard practice in the clinic at that time. A recall was set for follow-up blood tests to be completed in 6 months' time. The notes do not record whether or not the patient was contacted.*

5. On 21 April 2015 [Mr A] was sent a letter inviting him to have blood tests done for a cardiovascular risk assessment (no reference to PSA blood test). [Mr A] attended [the medical centre] on 1 May 2015 and saw [Dr B]. He underwent a drivers' license medical examination and was referred to an ENT surgeon regarding a nasal lesion. Blood tests (including PSA) were ordered although there is no reference in the notes to discussion regarding the previous PSA result or any urinary symptoms. Blood tests were undertaken on 4 May 2015 and PSA result was 10.5 µg/L. The accompanying

pathologist comment was: *PSA > 10 µg/L: prostate cancer more likely than benign hyperplasia. For prostatitis, suggest to repeat several weeks after resolution.* The [medical centre] response includes: *[Dr B] set a recall for [Mr A] to have repeat blood tests completed in 3 months, but has stated that he did not contact the patient to advise him of the results.* There is no reference in the notes to the elevated PSA test or that a recall was set.

6. On 10 August 2015 [Mr A] was sent a letter inviting him to have bloods done for a cardiovascular risk assessment (unclear why these were requested so soon after the May bloods, which included lipid profile, renal function and HbA1c). PSA was not requested. The blood results were reviewed by [Dr G] (whose name was on the request form) and were unremarkable. This information was passed on to [Mr A] in a telephone call on 24 August 2015. The [medical centre] response includes: *No PSA test was included in these tests, as it was clear from the notes that a recall to test PSA had been planned for November 2015 by his usual GP.* I cannot see any clarity from the notes that a PSA recall was planned, and if it was planned in three months (as noted earlier in the response) it was overdue by the time the CVRA recall went out.

7. On 5 November 2015 [Mr A] attended [Dr C] at [the medical centre] complaining of *sl increase urinary freq, occ urgency … OE PR mod enlarged sl nodular … repeat PSA, refer Urology.* On 9 November 2015 [Mr A] had MSU taken (no infection or pyuria) and repeat PSA which was now 15.3 µg/L. He was referred to the DHB urology service on 11 November 2015 — initially through the public system then privately when he was initially assigned a three-month wait. Prostate biopsy performed on 16 December 2015 (urologist [Dr D]) showed invasive cancer, Gleason score 8. On 8 January 2016 MRI scan showed local extracapsular spread of the cancer with left pelvic lymphadenopathy and a likely sacral metastasis. However, bone scan on 5 January 2016 was not suspicious for metastatic disease.

8. Notes by [Dr B] dated 1 April 2016 include: *was referred by* [Dr C] *to Urologist, stated as non-urgent, waiting time 3 months. Patient decided to see Urologist privately, was seen immediately, biopsies showed Prostate Ca …* I am unable to find copies of the referral letters or urologist reports on file.

9. The [medical centre] response acknowledges that it appears there was a deficiency in communicating [Mr A]'s results to him and this involved [Drs F, C and B]. Since July 2015 *a uniform protocol has been established, and the expectations are now very clear and express that all abnormal results will be communicated to the patient, either by the doctor directly or practice nurse as a delegated duty.*

10. The RNZCGP Cornerstone accreditation document[1] outlines standards that must be achieved as a prerequisite to accreditation. I note [the medical centre] is Cornerstone accredited although I am not sure when accreditation occurred. Some of the standards relevant to this complaint are:

[1] Aiming for Excellence: RNZCGP Standard for New Zealand General Practice. 2011–2014 https://www.rnzcgp.org.nz/assets/documents/Standards--Policy/A4E2012revision4web.pdf Accessed 22 June 2016

(i) The practice has a documented policy that describes how laboratory results, imaging reports, investigations and clinical correspondence are tracked and managed. There is an agreed and consistent approach to the tracking of health information to manage and assist continuity of care.

(ii) All incoming test results or other investigations are sighted and actioned by the team member who requested them or by a designated deputy. Facilitation of patient results and investigations improves continuity of care and ensures a clear pathway to an outcome.

(iii) Patients are provided with information about the practice procedure for notification of test results. Patients must be notified about important test results and referrals. Patients have rights and responsibilities for their own health care and must be provided with information so that there is a shared understanding about the process.

(iv) The practice can demonstrate how they identify and track potentially significant investigations and urgent referrals. There is an agreed and consistent approach to the tracking of health information to manage and assist continuity of care. The HDC considers that the need for tracking is especially important where serious pathology is suspected.

(v) A record is kept of communications with patients informing them about test results. Documenting communications about test results is essential record keeping for continuity of care, and helps mitigate risk.

11. The Prostate Cancer Taskforce developed in 2012 (published by Ministry of Health in 2013) a set of recommendations for diagnosis and management of prostate cancer in New Zealand men[2]. Relevant extracts from this publication are reproduced in section 12 below. This advice was revised in 2015[3] and included a management algorithm (Appendix 1) which does not differ significantly from the advice contained in the 2013 publication, and which I have used as a standard for my comments regarding [Mr A]'s management. Importantly, the Code of Health and Disability Services Consumers' Rights has been in force since 1996 (with respect to comments regarding informed consent for PSA testing and information regarding test results).

12. Extracts from 'The Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce (2012)':

(i) Population screening for asymptomatic men with PSA testing is currently not recommended. However, men or their partners may present to a general practitioner with a request for prostate cancer screening (usually involving a PSA test), for information on prostate cancer or for a general practitioner's opinion on prostate cancer screening. Under these circumstances, Rule 6 of the Health and Disability Commissioner's code is applied to all clinicians. Namely the information that is

[2] Prostate Cancer Taskforce. 2012. Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce. Wellington: Ministry of Health.
[3] Prostate Cancer Working Group and Ministry of Health. 2015. Prostate Cancer Management and Referral Guidance. Wellington: Ministry of Health.

provided to men is sufficient for them to make an informed decision. In addition, the Medical Council of New Zealand states that patients must be given all the information they want or need to know including any expected risks and benefits. The National Screening Advisory Committee and National Health Committee advise that the complete screening pathway should be explained.

(ii) Screening for prostate cancer must be by both PSA and DRE testing. PSA testing alone is acceptable only where DRE is considered a barrier to testing …

(iii) All men presenting with lower urinary tract symptoms, and men with systemic features of malignancy, must have an appropriate examination and assessment, which includes checking for prostate cancer. This check will include a serum PSA and creatinine, other appropriate blood tests, urinalysis and a clinical examination, including digital rectal examination.

(iv) In the presence of a normal DRE, PSA values of <4.0 ng/mL do not generally merit specialist referral. A significant PSA rise in a man whose PSA has previously been low may warrant referral.

(v) Irrespective of the manner in which a man enters a diagnostic or screening pathway, his general practitioner is responsible for adequate tracking and follow-up. This responsibility ends only when care is transferred to another clinician such as a urologist.

(vi) The general practice in which the general practitioner works must have appropriate processes to ensure the tracking and follow-up occur. To this end, the practice needs to:

- have a clinical policy and protocol for delivering a prostate information service
- track PSA and other investigations
- track referrals to secondary care, ideally through an eReferrals process
- have practice-level clinical governance to oversee that the tracking is functioning correctly, such as through audit and data review.

(vii) General practitioners should refer patients to a urologist according to the following criteria:

men aged 50–70 years — when the PSA is elevated to ≥4.0 ng/mL
men aged 71–75 years — when the PSA is elevated to ≥10.0 ng/mL
men aged ≥76 years — when the PSA is elevated to ≥20 ng/mL
men with a palpable abnormality in the prostate on DRE
a significant PSA rise in a man whose PSA has previously been low may warrant referral.

(viii) If a man has one first-order relative (father or brother) with prostate cancer, then his risk of developing prostate cancer is at least doubled. If two or more first-order relatives are affected, the risk increases by 5–11 times.

13. Comments

(i) If [Mr A] is correct in his claim that he was never informed he was undergoing prostate cancer screening (at least before the consultation of 8 October 2014) this would imply the limitations and implications of such screening were never discussed, and he had not made an informed choice to have the PSA tests done. To proceed with testing in this situation (referring to the five tests done between 2000 and 2014) would be a moderate departure from expected standards — a mitigating factor being that if multiple providers were involved, I think it is reasonable to assume an informed choice to proceed with screening was made prior to the first test and discussion at the time would have included discussion that the test might be repeated at regular intervals. Notes prior to 2014 have not been provided. **The practice should be asked to provide a copy of the four PSA results between 2000 and 2012 and the clinical notes relevant to ordering of these tests. All clinical notes from the start of 2013 to October 2014 should also be obtained. The relevant providers (if they are available) should be asked to confirm whether [Mr A] was aware that PSA testing was being undertaken on these occasions, and to clarify what information [Mr A] was given regarding the benefits and shortcomings of prostate cancer screening using PSA.**

(ii) The consultation by locum [Dr E] on 8 October 2014 was consistent with expected standards and clearly documents that there was discussion regarding the limitations of PSA testing. The PSA level obtained at this time, together with the 'benign' clinical examination findings and absence of red flags or urinary symptoms, means there was no indication for referral and a reasonable strategy was to repeat the PSA and DRE in 12 months (see Appendix 1). The PSA at this point was outside the age specific 'normal' range but not within the range justifying referral taking into account the normal DRE findings. [Dr C] evidently set a recall for repeat PSA in six months although I cannot see [Mr A] was ever formally recalled for the test (or for the subsequent test due in either August or November 2015). Given the result was outside the normal range, even though referral was not indicated, I believe [Mr A] should have received notification of the result and had the implications explained to him (that it was likely he had benign prostatic hyperplasia but, in view of his family history, annual PSA and DRE was warranted). This did not occur. It is unclear whether this deficiency in management was due to practice processes (the doctor who ordered the test was a locum so did responsibility for notification fall to the patient's usual provider ([Dr B]) or to [Dr C] (on whose behalf [Dr E] ordered the blood test)? As [Dr C] appears to have taken responsibility for ordering follow-up of the test, I believe he should also have taken responsibility for ensuring [Mr A] was notified — forwarding of the result to [Dr B] (if that did occur) not being sufficient action alone without specific comment. I would expect a practice in 2014 to have had robust policies around notification of results. I would be moderately critical of the practice if it did not have such a policy in place at that time, and I would be moderately critical of [Dr C] if he did not follow the practice policy. If there was no robust policy in place, I remain mildly to moderately critical that [Dr C] did not take adequate steps to ensure

[Mr A] received notification of his result and discussion of its implications. **The practice should be asked to provide copies of its policies on notification and tracking of results, both historical (if available) and current. The practice should be asked to provide further details on the recalls set for [Mr A] in October 2014 and May 2015 (what software module was used) — preferably with some documentation to support their statement.**

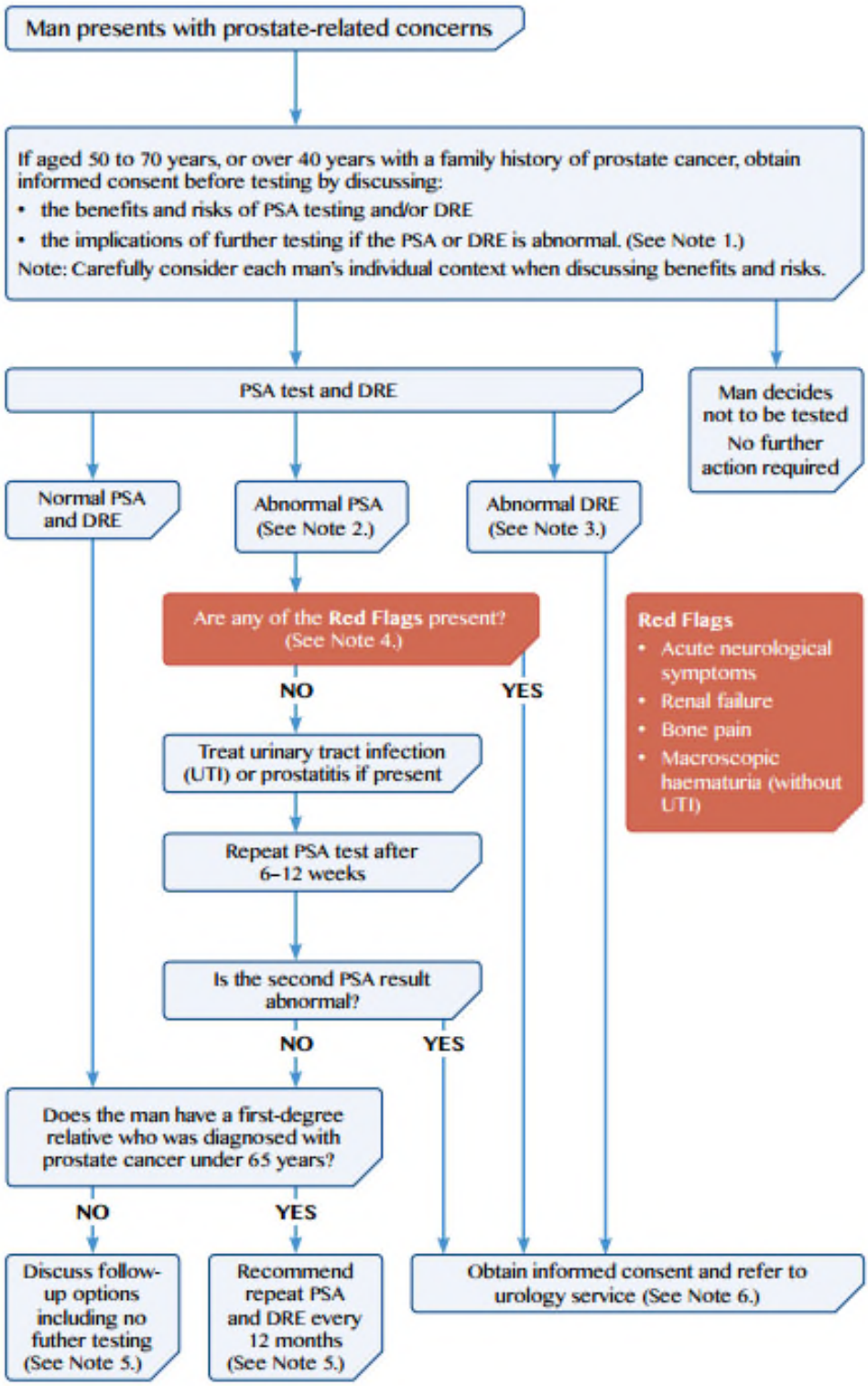
(iii) Regarding the consultation with [Dr B] on 1 May 2015, I would be moderately critical if the fact a PSA test was being requested, and the reason for this, were not discussed with [Mr A] at the time. I am not critical that a DRE was not performed assuming [Mr A] was not complaining of urinary symptoms. The result and the implications of the result should have been promptly notified to [Mr A] and I am moderately critical this did not occur. [Mr A] was by now 74 years old and guideline recommendations are that he should have been offered specialist referral at this point (see 12(vii) and Appendix 1). Some of my colleagues might have wanted to exclude an alternative cause for the rise in PSA, or a spurious rise) by repeating the PSA and a MSU within a few weeks prior to referral. The practice response suggests [Dr B] intended to repeat [Mr A]'s PSA by three months (or six months) and the three-month recall was probably not an unreasonable strategy taking into account the borderline elevation of PSA (for referral purposes), the relatively recent normal DRE, and the apparent lack of symptoms. However, I would be mildly critical if the intention was to wait six months to repeat the further investigations. In any event PSA was not done in August 2015 but a seemingly premature recall for cardiovascular bloods was undertaken instead. It does not appear [Mr A] was recalled for PSA at either three months or six months which might indicate a deficiency in the practice recall process. **I suggest the practice be asked to explain why a recall for cardiovascular bloods was sent to [Mr A] in August 2015 when he had had the same bloods done only three months previously (and they were not concerning). Was there an error in this recall ie should it have been for PSA screening rather than CVR screening. If so, how did the error occur and what steps have been put in place to prevent such an error in the future?**

(iv) [Mr A]'s management by [Dr C] on 5 November 2015 was consistent with expected standards (DRE, repeat PSA and MSU, urology referral) although **I require a copy of the urology referral letters and urologist consult reports to finalise my advice.** It is interesting to note that had the current guidelines been adhered to (see Appendix 1) [Mr A] would have been reviewed with DRE and PSA only one month earlier than he was (12 months from 8 October 2014) which would not have had any significant impact on his clinical course or outlook.

(v) Please confirm with the practice when it first achieved Cornerstone accreditation and when re-accreditation is due.

Appendix 1 [see following page]: From 'Prostate Cancer Working Group and Ministry of Health. 2015. Prostate Cancer Management and Referral Guidance. Wellington: Ministry of Health'."

Algorithm for supporting men with prostate-related concerns



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

Expert Opinion Report Two:

"I have reviewed the additional clinical information and responses provided by [the medical centre]. The following advice should be read in conjunction with my original advice dated 22 June 2016.

1. [Mr A] had four PSA tests performed prior to those reviewed in my original advice. All four were ordered by [a GP]: 11 October 2002 (1.6 µg/L), 23 December 2005 (2.7 µg/L), 23 June 2010 (3.2 µg/L) and 16 August 2012 (result not on file). It is not possible for me to determine from the available clinical documentation the extent to which PSA testing was discussed (if at all) at the consultations in October 2002 and December 2005. The consultation of 9 October 2002 refers to [Mr A]'s imminent travel and *Needs a well man check.* The consultation of 19 December 2005 contains no reference to well man check or similar. The consultation of 18 June 2010 refers to enquiry regarding prostate symptoms: *No hesitancy. Dribbling no change* and a DRE was performed (benign slightly enlarged gland) so it might be assumed there was discussion regarding PSA screening on this occasion. The consultation of 15 August 2012 contained no reference to PSA screening or urinary symptoms. With respect to comments in section 13(i) of my original advice, I think it is likely that there was some discussion of prostate issues and prostate screening in the consultation of 18 June 2010. I am unable to confirm the nature of any such discussion prior to the commencement of PSA screening in 2002 or the second test in 2005 but I would be mildly to moderately critical if the pros and cons of such screening (as was known at the time) were not discussed, and consent gained for regular screening, at the time screening was commenced. If such discussion had taken place, I would not be critical that this discussion was not repeated prior to each episode of testing, but the patient should have been made aware that a PSA test was being requested on the relevant occasions. I would be mildly critical if such information was not conveyed to the patient provided consent had been obtained for regular PSA testing, and the patient was aware of the agreed monitoring schedule, prior to initiation of screening.

2. The practice response has clarified to some extent the sequence of events of October 2014 (see section 4 in original advice). [Dr E] was a locum who ordered a PSA for [Mr A] in October 2014. [Dr F] had been [Mr A]'s regular doctor but he had left the practice in October 2014. [Dr B] did not start at the practice until December 2014. The PSA result was acknowledged as being received at the practice on 19 October 2014 (result 7.2 µg/L) and was reviewed by [Dr C]. [Dr C] advised that it was his usual practice to forward test results to the patient's usual GP (but there was no 'usual GP' currently at the practice) or to the practice nurse to set a recall. Unfortunately, there is no record in the recall audit log of a recall being set on this date (which could possibly be a PMS technical issue) although [Dr C] had documented an intention or instruction to recall [Mr A] in six months. Thus, the actual management of the result on this occasion remains unclear although it is apparent that [Mr A] was not notified of the result and there was no documented intention for him to be notified. With respect to the discussion in section 13 (ii) of my original advice, I remain moderately critical that [Dr C] did not ensure [Mr A] received notification of his abnormal result, the implications of the result and the intended follow-up, although the intended follow-up documented was reasonable from a clinical

perspective. The practice had a documented 'results management' policy in place at the time which states that the responsibility of ensuring a patient was made aware of an abnormal result was the responsibility of either the requesting provider or the patient's usual provider. Given the circumstances described, I think it was clearly the responsibility of [Dr C] to ensure the patient was notified and this did not occur. The reasons behind the failure to ensure a six-month recall was activated are less clear and I am unable to make any conclusions regarding this issue.

3. The provider response includes a screen dump of the recall and screening module 5 May 2015 indicating [Dr B] set a three-month recall for PSA screening for [Mr A], with a due date for the recall of 5 August 2015. Given the previous result which was elevated beyond the age-specific range for [Mr A] but was not sufficiently elevated to generate a referral in the absence of abnormal clinical prostate assessment or presence of lower urinary tract symptoms (LUTS) (see Appendix 1 and section 12(vii) in original advice), I believe the previous result and implications of that result should have been discussed with [Mr A] at the appointment of 1 May 2015 together with the management plan to be undertaken including initially a repeat PSA. Best practice would have been to question [Mr A] regarding presence of LUTS, and to acknowledge the increased risk of prostate cancer associated with his positive family history documented the previous October. [Dr B] did not inform [Mr A] of the PSA results received on 4 May 2015 (10.5 µg/L) which was not consistent with the practice results policy. He did not order tests to exclude prostatitis/UTI as a cause of the raised PSA (although there were evidently no symptoms to suggest these conditions) but he did set a recall for repeat PSA testing in three months which was consistent with the recommended guidelines. Under the circumstances, the failure by [Dr B] to follow his practice policy and ensure [Mr A] was made aware of his abnormal PSA result represents a moderate departure from expected practice. If, at the consultation of 1 May 2015, [Dr B] did not discuss with [Mr A] the fact a repeat PSA was being ordered and the reasons for this (specifically that the October 2014 result had been elevated beyond the age-specific reference range), I would also be moderately critical. I would expect that if [Mr A] had been made aware of his previous result and current testing on this occasion, and noting his concerns about prostate cancer given the positive family history, he might have been more proactive in seeking the result.

4. [Mr A] was not recalled for his repeat PSA test scheduled for early August 2015. The practice response explains why [Mr A] was recalled prematurely for cardiovascular risk bloods that month but there is no clear explanation as to why he was not recalled for the scheduled PSA test. It appears there was some deficiency in the practice management of recalls at the time and I feel this may have contributed to delays in [Mr A] obtaining definitive management for his condition (although given the overall time frame it is unlikely this delay will have affected his prognosis or eventual management). I am mildly to moderately critical that the practice evidently did not have processes in place at the time of the events in question that were sufficiently robust to prevent [Mr A]'s early August 2015 recall for PSA to be overlooked until at least November 2015. I note appropriate remedial actions have been taken since the complaint to ensure management of the PMS recall system is optimised.

5. I have reviewed the relevant specialist letters and confirm the referral letters sent by [Dr C] in November were of reasonable quality. I note [Mr A] had been reviewed by urologist [Dr D] on 9 September 2010 following a referral by [a GP] with testicular/groin pain. A DRE was performed as part of the specialist assessment and [Dr D] noted *a moderately enlarged smooth regular benign feeling prostate.* No cause for the groin pain was found and further investigation recommended only if the symptoms worsened. In the letter [to] [Dr D] from [Dr C] dated 20 November 2015 (following referral for elevated PSA) specialist comments include: *[Mr A] has had a rise in his PSA over the past few years. He has recently noticed symptoms of slightly increased freq, nocturia and urgency. His younger brother has prostate cancer. His prostate feels enlarged, sl firm and nodular …*

6. The practice gained Cornerstone accreditation in June 2014 and is due for reaccreditation in 2018. I have reviewed the test managment policies provided and note that while generally the current policy is robust and in line with similar policies I have reviewed from other practices, the responsibility for actioning results when the test has been ordered by other than the patient's usual provider may not be sufficiently explicit. The current wording is: *All abnormal reports should be actioned by either the patients health provider or the health provider who requested the reports.* As discussed in the body of the report, a lack of clarity over this issue may have been the reason on at least one occasion (October 2014) for the result not being actioned as it should have. I suggest the wording or process be reviewed to minimise the risk of one provider assuming the other has actioned a result. Assuming the result comes through to the doctor who has ordered the test, if that doctor is not the patient's usual provider but is expecting the usual provider to follow-up the result there needs to be a robust process for ensuring this intention is clear. The deficiencies identified in [Mr A]'s management might also provide a basis for general discussion within the practice of how results management can be optimised when there are multiple providers involved in management of the patient."

Expert Opinion Report Three:

"1. Advice requested

I would be grateful if you could review [Dr C]'s, [Dr B]'s and [the medical centre]'s responses to your advice reports and provide further expert advice. In particular please comment on the:

i. Appropriateness of the services [Dr C] provided to [Mr A].

ii. Appropriateness of the services [Dr B] provided to [Mr A].

iii. Appropriateness of the services [the medical centre] provided to [Mr A]. Please include specific comment regarding:

(i) the changes [the medical centre] has made to its practice.

(ii) the adequacy and appropriateness of [the medical centre]'s new Test Result procedure.

iv. Any other matter you consider relevant to comment on.

2. I have reviewed the documentation referred to above. This advice should be read in conjunction with the original advice provided on 22 June 2016 and 28 July 2016.

3. Appropriateness of the services [Dr C] provided to [Mr A]

[Dr C] apologises for not notifying [Mr A] of his mildly elevated PSA result of October 2014 and the fact that recall for repeat PSA in six months was being organised. [Dr C] states that it is his usual practice to inform his patients to ring the clinic for information regarding blood results if they have not been informed of the result *within a suitable time.* However, on this occasion the blood test had been ordered by a locum. [Dr C] states he assumed also that the locum had discussed with [Mr A] the fact that his PSA was being tested and how results would be managed. Under the circumstances, I think the failure by [Dr C] to ensure [Mr A] was notified of his mildly abnormal result, and that specific follow-up was clinically indicated and being arranged, represents a mild to moderate departure from expected standards regarding the patient's right to notification of results and management plan as discussed in section 2 of my supplementary advice dated 28 July 2016. In downgrading my previous view that this represented a moderate departure from expected standards or care I have considered the following mitigating factors: the relatively minor nature of the abnormality; [Dr C]'s role as an interim provider who never actually saw [Mr A] prior to November 2015 and who was accustomed to informing patients regarding expectation of results notification at the time the results were ordered; the fact that the intended/documented follow-up was clinically appropriate. However, I acknowledge [Mr A] was denied the opportunity to question the significance of his result and he was not made aware to expect a recall for PSA testing around April 2015 (and therefore was not prompted to question the delay in this recall). I am unable to establish whether [Dr C] made an oversight in relation to activating the appropriate recall system. The actual clinical care offered to [Mr A] by [Dr C] was otherwise consistent with expected standards.

4. Appropriateness of the services [Dr B] provided to [Mr A]

[Dr B] confirms the following: that on 1 May 2015 he did not notify [Mr A] that he was ordering a repeat PSA test; that he did not convey to [Mr A] the result of that test when it was received on 4 May 2015 or that a further blood test was required in three months and was being organised; that he failed to exclude prostatitis/UTI as a cause of [Mr A]'s elevated PSA. As per section 3 of my supplementary advice dated 28 July 2016, I remain of the view that there were deficiencies in [Dr B]'s communication with [Mr A] regarding his PSA testing and results, and deficiencies in some aspects of his clinical management of [Mr A] (excluding prostatitis and UTI as a cause of transient PSA elevation) when compared with relevant national guideline recommendations, with no obvious reason for him to have departed from these guidelines. I believe these deficiencies represent moderate departures from expected standards of communication and a mild to moderate departure from expected standards of clinical management.

5. [The medical centre's] response

(i) [The medical centre's] response indicates there was an acute nursing shortage around the time [Mr A]'s cardiovascular recall was undertaken in July 2015 and this

may have resulted in the PSA recall being overlooked while the cardiovascular recall was duplicated. However, it remains unclear why the PSA recall due in April 2015 ([Dr F]) was overlooked if it had actually been activated, or why the recall of August 2015 ([Dr B]) was overlooked if this too had been activated. If the recalls had been correctly activated by the doctors concerned, I would be moderately critical that [the medical centre] processes enabled the recall to be overlooked on two separate occasions. However, I am unable to confirm that this was the case.

(ii) I have reviewed the remedial measures taken by [the medical centre] since [Mr A]'s complaint and I think these are appropriate. The practice's documented procedure for handling of test results appears robust and consistent with similar policies I have reviewed from other practices.

(iii) I have no further comments or recommendations."