Medical Centre

Doctor, Dr B

Doctor, Dr C

General Practitioner, Dr D

A Report by the

Deputy Health and Disability Commissioner

(Case 19HDC01583)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the management of a man's prostate-specific antigen (PSA) levels from November 2016 to December 2018, and the inadequate communication of his test results. The report highlights the importance of keeping up to date with guidelines, following recommendations, and keeping clear and effective documentation.

2. Between November 2016 and December 2018, four test results showed that the man's PSA levels were abnormal; however, the tests were not repeated promptly or relayed to the man, and he was not referred to a urologist. Subsequently, the man was diagnosed with prostate cancer.

Findings

3. The Deputy Commissioner found that a locum doctor at a medical centre breached Right 4(1) of the Code for failing to document the man's family history of prostate cancer, failing to enquire about red flags for prostate cancer, incorrectly documenting "no red flags" in the man's medical records, and failing to repeat the man's PSA test in six to twelve weeks' time. The Deputy Commissioner also found that by not informing the man of an abnormal PSA test result, the locum doctor breached Right 6(1)(f) of the Code.

4. The Deputy Commissioner found that by twice failing to refer the man to urology services or to repeat the PSA test promptly, another doctor at the medical centre breached Right 4(1) of the Code. The Deputy Commissioner also found that by not informing the man of his abnormal PSA test results, the doctor breached Right 6(1)(f) of the Code.

5. The Deputy Commissioner found that by failing to refer the man to urology services or repeat the PSA test promptly, a general practitioner (GP) at the medical centre breached Right 4(1) of the Code. The Deputy Commissioner also commented on the GP's record-keeping.

6. The Deputy Commissioner made adverse comment about the medical centre.

Recommendations

7. The Deputy Commissioner recommended that the medical centre provide a written apology to the man addressing the changes it has made since these events; provide evidence of staff training on PSA management and prostate screening; provide a copy of the results of its audit on the management of elevated PSA results since 2016, and, if required, an action plan regarding any elevated results; consider whether a review of its test recall system or its orientation process for doctors is necessary; and consider incorporating the Prostate Cancer GP Tool decision support tool into its practice.

8. In response to the Deputy Commissioner's recommendation in the provisional opinion, the locum doctor and the second doctor provided HDC with formal apologies for forwarding to the man. The Deputy Commissioner recommended that the GP also provide a written apology. The Deputy Commissioner recommended that all three practitioners conduct an audit of their assessments of patients with abnormal PSA results over a three-month period,

and, where the audit does not show that appropriate steps were taken as mandated by the Prostate Cancer Management Guidance, to outline why, and the steps taken to remedy such issues.

Complaint and investigation

9. On 26 August 2019, the Health and Disability Commissioner (HDC) received a complaint from Mr A about the services provided by a medical centre. The following issues were identified for investigation:

- *Whether Dr C provided an appropriate standard of care to Mr A between May and December 2017.*
- *Whether the medical centre provided an appropriate standard of care to Mr A between May and December 2017.*
- *Whether Dr B provided an appropriate standard of care to Mr A in November 2016.*
- *Whether Dr D provided an appropriate standard of care to Mr A in May 2018.*

10. This report is the opinion of Deputy Commissioner Vanessa Caldwell, and is made in accordance with the power delegated to her by the Commissioner.

11. The parties directly involved in the investigation were:

Mr A	Consumer
Medical centre	Provider/general practice
Dr B	Provider/doctor
Dr C	Provider/doctor
Dr D	Provider/general practitioner (GP)

12. Also mentioned in this report:

Dr E	Medical Director
Dr F	GP

13. Independent clinical advice was obtained from GP Dr Garry Brown (Appendix A).

Information gathered during investigation

Background

14. This report concerns the management of Mr A's prostate-specific antigen (PSA)[1] levels from November 2016 to December 2018, and the lack of communication of the results to Mr A.

15. On 31 October 2016, Mr A, aged in his sixties at the time of events, registered with the medical centre.

16. Mr A has a family history of prostate cancer, and his father and paternal uncle both died of metastatic prostate cancer, both aged in their sixties. As such, Mr A's risk of developing prostate cancer was doubled.[2] He was very aware of his family history of prostate cancer, and told HDC that he mentioned this every time he dealt with a doctor regarding the topic, to ensure that they were aware that his risk profile was somewhat higher than normal.

30 November 2016

17. On 30 November 2016, Mr A attended his first appointment at the medical centre with Dr B, a locum doctor.[3] Dr B discussed Mr A's diabetes, cholesterol, diet, insulin commencement options, medication adjustments, and the re-prescribing of ten medications. At this appointment, Dr B did not document Mr A's family history of prostate cancer.[4]

18. Dr B told HDC that he is unsure whether Mr A mentioned his family history at this appointment, which is possibly why he did not record it. However, Dr B acknowledged that he overlooked the identification of Mr A's family history, and stated:

> "Unfortunately, this was not the main purpose of the consultation as I probably did not have time to enquire about prostate symptoms and signs and have not recorded any history pertaining to prostate disease."

19. The clinical notes document that Mr A requested a check of his prostate protein levels by way of a PSA test, which Dr B ordered. This was Mr A's first PSA test requested by the medical centre.

20. Mr A's PSA test result of 30 November 2016 (PSA1) was 5.18ng/ml.[5] The laboratory form containing the result made two separate recommendations regarding referral to a urologist. First, the form stated that Mr A's PSA levels were elevated and that accordingly a referral to

[1] PSA is a protein produced by normal, as well as malignant, cells of the prostate gland.
[2] A man is defined as having a family history of prostate cancer if he has at least one first-degree relative (father or brother) who was diagnosed with prostate cancer. Men with a family history of prostate cancer are twice as likely to develop the disease than men without a family history. See: https://www.health.govt.nz/publication/prostate-cancer-management-and-referral-guidance.
[3] Dr B worked as a locum doctor at the medical centre three days a week.
[4] Mr A told HDC that his family history was outlined in his notes from his previous general practice.
[5] For men aged 50–70 years, a normal PSA range is ≤4.0ng/ml. A PSA level of more than 4.0ng/ml is suggestive of prostate cancer. If a man's PSA level is between 4.0g/ml and 10.0ng/ml, there is a 40% chance of detecting prostate cancer on prostate biopsy.

a urologist was recommended. However, this recommendation was based on outdated guidance.[6]

21. Secondly, the form stated: "If this is a repeat raised value, or in the presence of abnormal DRE[7] or other red flag conditions refer to urologist."

22. Dr B did not refer Mr A to a urologist, and did not enquire into any of the "red flags" for prostate cancer, ie, neurological symptoms, bone pain, macroscopic haematuria, and renal failure. However, despite this, Dr B entered: "no red flags" into the inbox PSA result box. Dr B told HDC that he is deeply saddened that he documented "no red flags", and he can offer no reasonable rationale for having done so. He told HDC that the comment was not made with any malice or laziness, and he wishes he had not done so.

23. The laboratory form also provided a website link to the Prostate Cancer Working Group and the Ministry of Health 2015 *Prostate Cancer Management and Referral Guidance* (the Guidance). The Guidance outlines that for a man aged between 50 and 70 years (or over 40 years with a family history of prostate cancer), if the PSA test result is abnormal, the PSA test should be repeated after six to twelve weeks.[8]

24. However, Dr B set a six-month PSA recall instead of the required six- to twelve-week recall. In addition, although Dr B documented that he had asked Mr A to return for a GP review in one month's time, the review did not occur. In response to the provisional opinion, Mr A told HDC that he was not asked to return for a review in one month's time, and that had he been asked, he would have done so.

25. Finally, Dr B did not inform Mr A of his high PSA result. Dr B told HDC that he cannot remember the exact protocol for informing patients of abnormal test results, but he accepts that his failure to inform Mr A of the abnormal result was inappropriate and was his responsibility.

26. Dr B said that owing to a career break,[9] he may not have been familiar with the Guidance when he saw Mr A.

23 February 2017

27. Dr B left the medical centre on 15 February 2017 and, prior to leaving, he asked Dr D to arrange a repeat PSA test for Mr A in May 2017. Dr D told HDC that she clearly remembers that Dr B did not hand over Mr A to her in person, but that he sent her a task message asking her to arrange a repeat PSA, and did not mention any symptoms or red flags or family history.

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[6] Ministry of Health Prostate Cancer Taskforce 2012, *Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce*.

[7] Digital rectal examination.

[8] The Guidance explains that increased PSA levels can be transient, which is why men should always have a repeat PSA test after 6–12 weeks to confirm the result.

[9] Dr B returned to general practice in 2016 after several years, and was catching up on many guidelines relating to the common general practice conditions.

May 2017

28. On 11 May 2017, Mr A consulted a clinical pharmacist at the medical centre, and a second PSA test (PSA2) was ordered under Dr C's name.[10] Dr C was a permanent staff member at the medical centre, and the medical centre preferred tests to be ordered by permanent doctors rather than locum doctors. Mr A's family history of prostate cancer was not recorded.

29. The PSA2 result of 4.8ng/ml was received on 15 May 2017. Despite the result being higher than normal for Mr A's age, the laboratory form did not include a recommendation for referral or provide a website link to the Guidance.

30. According to the Guidance, if the second PSA test undertaken within six to twelve weeks is abnormal, the person should be referred to a urologist. However, the Guidance (which is in the form of a flowchart) does not outline whether this relates to the second ever abnormal PSA test a man has received, or whether it relates to the second PSA test, which should have been done six to twelve weeks after the first test. Accordingly, when following the flowchart, arguably it is unclear whether after six months have passed, the user should start at the beginning of the flowchart and treat the second PSA test as the first (which would necessitate a test six to twelve weeks later and no referral), or whether the test should be treated as if it had been taken six to twelve weeks after the first, which would necessitate a referral.[11]

31. Dr C reviewed Mr A's PSA2 result. However, inconsistent with both the above approaches, Dr C set the recall period at six months, and did not refer Mr A. Dr C told HDC that because he was unfamiliar with Mr A, he reviewed Mr A's medical records and took note of Dr B's comment "no red flags" from the November 2016 visit, and the drop in PSA level since the previous test. Dr C said that in light of this, he thought that a longer time between repeats was appropriate, particularly because often he had had referrals (to urology) declined. Dr C told HDC that with hindsight he accepts that he should have recalled Mr A to have a DRE and set the repeat PSA test for three months rather than six months.

32. Mr A told HDC that he was not consulted about this result. However, Dr C told HDC that although he did not inform Mr A of the result himself, he recorded his comments, which were passed to nursing staff, and he understood that nursing staff contacted Mr A on 15 May 2017. In response to the provisional opinion, Mr A said that if he had been provided with this result, he would have asked for it to be followed up, as he would have been worried.

33. It is documented: "PSA results were ok and dropping, repeat 6/12 [6 months] — informed."

[10] Dr C had worked at the medical centre since 2013. At the time of events, Dr C was not a vocationally registered GP.

[11] See https://www.health.govt.nz/system/files/documents/publications/prostate-cancer-management-referral-guidance_sept15-c.pdf at page 6.

December 2017

34. Mr A's third PSA test (PSA3) undertaken on 13 December 2017 showed that his PSA levels had risen to 5.5ng/ml. Despite the result being higher than normal for Mr A's age, the laboratory form did not include a recommendation for referral, or provide a website link to the Guidance.

35. On 14 December 2017, a practice nurse wrote to Mr A asking him to schedule an appointment at the medical centre as the results of his third PSA test had been received and required discussion. Mr A did not make an appointment; therefore, on 22 December 2017 the practice nurse wrote to Mr A asking him to attend for a prostate examination.

36. Mr A attended the medical centre and saw Dr C on 29 December 2017. Dr C obtained a family history of prostate cancer and conducted a DRE. He documented that Mr A's PSA levels were "slightly up again" and noted Mr A's family history of prostate cancer and that his father had passed away at 67 years of age and his paternal uncle at 65. Dr C documented that Mr A's prostate examination was normal and that his prostate was smooth and non-tender. Dr C noted: "[T]o be reviewed if symptoms deteriorate, condition worsens or if concerned."

37. Despite three tests having shown elevated PSA levels, Dr C again organised a recall of Mr A for a further PSA test for six months' time. Dr C told HDC that he should have organised the recall for six to twelve weeks, and he apologised for the error.

38. Dr C did not refer Mr A to a urologist. Dr C told HDC that this was because a number of his referrals had been rejected by the district health board (DHB), and he considered that he needed to make further enquiries and examinations of Mr A to see whether a referral to a urologist was needed. Also, he thought it prudent to obtain two consecutive PSA tests that showed an increasingly elevated PSA before making a referral.

16 May 2018

39. On 16 May 2018, the practice nurse recalled Mr A for a fourth PSA test (PSA4), ordered under Dr D's name.

40. Dr D told HDC that it is unclear to her why a blood test was ordered under her name when previously Mr A had been seen by Dr C, and it meant that she was dealing with the blood results of an unfamiliar patient at a time when the patient management system had recently changed. The medical centre told HDC that the practice nurse ordered the test under Dr D's name in accordance with its policy that nurses generate laboratory form recalls under the name of a salaried doctor, which in this instance was Dr D.

41. As PSA4 was ordered under Dr D's name, she was responsible for reviewing the results, which she did on 17 May 2018. The result showed that Mr A's PSA had risen slightly to 5.7ng/ml.

42. The laboratory form stated that Mr A's PSA levels exceeded the recommended level for referral to urology. As noted above, this recommendation was based on outdated

guidelines. However, despite this being the fourth abnormal PSA result, no such referral occurred.

43. Dr D told HDC that when she reviewed Mr A's notes, she noted that on 27 March 2018 Mr A had seen a pharmacist prescriber[12] who had documented that his symptoms were unchanged.[13] She also considered Dr C's notes from 29 December 2017 that the examination findings in December 2017 were largely unremarkable and that he had made a plan to repeat Mr A's PSA in six months' time. Dr D said that she did not think that any additional action was required because she was reassured by the stability of Mr A's PSA results and symptoms. Dr D told HDC that regrettably, her colleague's note falsely reassured her, and her decision-making for Mr A was clouded by the fact that she had not seen him herself.

44. Dr D documented in Mr A's medical records: "Biochem; Tumour markers (stable)."[14] The nurse documented that Mr A was informed. Dr D told HDC that she sent a message to the nurses asking them to inform Mr A of the result, and she believes she also wrote, "Review if concerns. Please inform the patient," but this was amended by the nurse to say "patient informed".

45. In response to the provisional opinion, Mr A told HDC that he is certain that he was not told that there was anything exceptional in relation to these results, and that if he had been informed, he would have asked for a urology referral. A PSA recall was set for six months' time, again contrary to the Guidance.

46. Dr D told HDC that in hindsight she should have been more cautious and asked Mr A to come in for a face-to-face appointment in order to examine him and refer him to the urology team for a prostate biopsy and further management.

Subsequent events

47. Mr A's fifth PSA test on 3 December 2018 (PSA5) showed that his PSA level had risen to 6.32ng/ml. On 7 December 2018, a semi-urgent urologist referral was sent to the public hospital.

48. On 8 May 2019, a biopsy of Mr A's prostate showed prostate cancer measuring 0.8mm.

Doctor shortage

49. From 2015 to 2018, a number of long-standing doctors retired from the medical centre, and the vacancies were filled intermittently with short-term locum doctors. Dr D told HDC that as a result of this, patients frequently saw different doctors, which disrupted continuity of care. In response to the provisional opinion, Dr D told HDC that the medical centre was a busy clinic that was constantly short staffed, and the doctors were regularly asked to see

[12] A specialist pharmacist working in a multi-disciplinary clinical health team and trained to prescribe medication.
[13] The clinical notes of 27 March 2017 state: "Seen by GP in December for [prostate examination] as PSA slightly elevated. No further concerns."
[14] PSA is the most important tumour marker.

patients other than those already on their list, and this meant they had to rely on nurses to complete certain tasks such as ringing patients with abnormal blood results.

50. The medical centre told HDC that the increasing difficulty in recruiting doctors and nurse practitioners meant that sometimes the medical centre had fewer clinicians than required to manage its registered patients. The medical centre stated that it attempted to have specific salaried doctors covering specific lists of patients, but it balanced this with sharing the workload and its obligation to provide clinicians with restful breaks from work.

Blood test recalls and test result management

51. At the time of events, the blood test recall process at the medical centre was managed by the nurses. Laboratory forms were generated by nurses based on instructions left by the doctors (locum, temporary, or retired). The nurses also contacted patients if they did not respond to a recall. Recalls were generated under the name of a salaried doctor in the practice, not necessarily under that doctor's directive. The medical centre stated that it encouraged all doctors to ask their colleagues for assistance and advice regarding results if they had been involved with the care of the patient in some form previously.

52. In response to the provisional opinion, the medical centre stated that where a clinician is away, it is important that test results continue to be processed to avoid delay and to prevent clinicians returning to work with an overwhelming amount of test results and paperwork, in addition to their full workload.

53. Dr D told HDC that patients also had consultations with nurses, pharmacists, and doctors for various issues, and the entire team was involved in the patient's holistic care. Dr D said that as a result, frequently they relied on other team members' documentation in order to manage patients with whom they were unfamiliar. In response to the provisional opinion, Mr A commented that this approach did not work for him.

PSA policy

54. The medical centre had a policy regarding management of test results, but did not have a policy or procedure for the management of abnormal PSA results.

55. In response to the provisional opinion, the medical centre explained that a PSA policy to guide clinicians is not required where an approved Ministry of Health guideline on PSA testing is readily accessible. The medical centre considers that it is reasonable to expect clinicians to remain up to date with guidelines, and provided a letter from the Royal New Zealand College of General Practitioners (the College) to support this view. The College explained that its requirement is that a Centre must have a document that provides general guidance on how to manage laboratory test results, but there is no suggestion that these should be specific to particular test results, and the guidance does not suggest that the Ministry of Health guidance on PSA testing should be part of the medical centre's document. The College stated that such guidance would have to be incorporated into the medical centre's practice management system (PMS), and such systems are not designed to allow for that. Additionally, the College stated that a guideline for every type of result would be very difficult to manage.

56. The medical centre had a policy regarding management of test results. In response to the provisional opinion, Mr A pointed out that for him the medical centre's policy on the management of test results failed.

Clinical guidance

57. The medical centre told HDC that prior to November 2019, clinicians used Map of Medicine,[15] which they believe linked to the Guidance published in 2012[16] and the Guidance that was linked on the laboratory forms (published in 2015). In response to the provisional opinion, the medical centre told HDC that all clinicians were encouraged to use these guides, and there were direct links to the guidance within the PMS to facilitate access. The medical centre said that it had no knowledge or awareness that clinical staff had any issues with the resources, and no difficulties were brought to its attention, and, had they been, the medical centre would have considered remedies.

58. The medical centre told HDC that importing the MOH guidance into a policy would not have prompted the clinicians to act differently, and that the guidance was actively drawn to Dr B's and Dr D's attention in the laboratory form, yet the decisions on recalls were based on each clinician's independent rationale.

Communication of test results

59. The medical centre's Test Results & Medical Report Management Policy (see Appendix C) outlines that a nurse contacts patients about abnormal results (or normal results in some circumstances) and associated instructions from the clinician.

60. In response to the provisional opinion, the medical centre told HDC that it had an appropriate structure in place to promote communication of test results. The medical centre explained that staff were inducted to the Test Result Policy on commencing employment, and that the expectations under it were clear. Consistent with that Policy, Dr C and Dr D asked the nurses to communicate the test results to Mr A. The medical centre stated that if effective communication with Mr A did not occur, it was not the responsibility of the medical centre, and it was not the systems in place that inhibited communication, as the systems set a clear structure to achieve communication provided it was complied with.

61. Dr D told HDC that the comments section in the results box can be altered easily, and it is not saved automatically in the PMS. Dr D explained that when she passes a result to other members of staff, they can alter the comments.

Locum orientation and staff induction

62. Dr E, the Medical Director, told HDC that as part of Dr B's orientation, they carried out extensive investigations within the medical centre to establish whether Dr B had been made aware of the test results policy, which states that where test results are abnormal but not acute, instructions on what needs to be done should be placed in the nurse provider inbox

[15] An online clinical knowledge resource that provides healthcare professionals with specialist knowledge at the point of care.

[16] Ministry of Health Prostate Cancer Taskforce 2012, *Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce*.

(see Appendix C). Unfortunately, however, the medical centre was unable to find detailed orientation documents from the time when Dr B was orientated. Dr E told HDC that it has been long-term practice across all its sites that in the first few days of employment of any new employee, they are orientated to all policies and protocols, with a particular focus on the ones most relevant to their role.

63. In response to the provisional opinion, the medical centre told HDC that it ensures that it is a requirement of appointment that clinicians agree to comply with professional and regulatory obligations, which include an obligation to maintain detailed and accurate records to guide subsequent care.

Cornerstone accreditation

64. In response to the provisional opinion, the medical centre told HDC that as part of the Cornerstone Accreditation,[17] clinicians undertake a self-audit of their notes and report back to highlight systemic issues with the medical centre and individual issues. The medical centre stated that when it was reviewed, there was no suggestion that a PSA policy was required.

Further information

Mr A

65. Mr A told HDC that on each visit he made sure that he repeated his serious family history related to prostate cancer, as he wanted to make sure that the medical centre knew his concerns. He said that the reason for his complaint is that he was ignored.

Dr B

66. Dr B told HDC that he is "apologetic to Mr A" and he empathises with the frustration Mr A had with the process of visiting the doctor, doing the right things, and feeling he was failed.

67. Dr B said that he has reflected on the failures mentioned, and has a more sharpened view of prostate screening, history, and examination, and of writing concise notes to reflect this. Dr B told HDC that he will not make the same mistakes again, and he has become even more mindful when discussing prostate disease with patients, given this investigation. Dr B said that he wished and prayed for Mr A to do well with his condition.

Dr C

68. Dr C told HDC that he was very sorry to hear that Mr A's prostate cancer was not diagnosed sooner.

69. Dr C said that he wants to assure HDC that he is aware of the information about prostate cancer and PSA testing for all New Zealand men between the ages of 50–70 years, and knows that men with a family history of prostate cancer should be offered an annual DRE and PSA testing from the age of 40 years. He stated that he offers this to all his patients who fit into this category. Dr C also told HDC that in all cases, referral to secondary care should be done

[17] A combined quality improvement and quality assurance process that allows a GP practice to measure itself against a defined set of standards.

when there are abnormal DRE findings, the presence of any red flags, or two persistently elevated PSA results (dependent on age).

Dr D

70. Dr D told HDC that she would like to apologise to Mr A for the distress he has experienced. Dr D stated:

> "I wish to assure him that all clinicians involved in his care, me including, had his best interest at the forefront of our minds and tried to manage him to the best of our abilities. It is disheartening to hear that he has developed prostate cancer. I hope that his treatment is successful and that his recovery is complete.
>
> …
>
> It is my regret that [Mr A's] diagnosis was delayed. I would once again like to convey my apologies to him and [assure] him that his complaint has been taken on board and has changed my current clinical practice and will certainly inform my future clinical practice."

The medical centre

71. In its response letter, the medical centre conveyed its apology to Mr A for the deficiencies in the care provided to him regarding the management of his PSA levels.

72. Dr E told HDC that the medical centre acknowledges that risk monitoring and risk management are the responsibility of the medical centre (meaning the medical centre is accountable for continuously improving the quality of its services and safeguarding high standards of care). Dr E acknowledged that there were deficiencies in its system, which are being addressed.

73. However, Dr E stated that what cannot be overlooked is that this would have been a difficult process to have recognised at the time, as no problems or alerts were raised or identified, and an error in documentation from one clinician has produced a "snowball" effect in future clinician management. Dr E said that it is not accepted that responsibility for clinical decision-making lay with the practice. She told HDC that ultimately this responsibility rests with the individual practitioner who is exercising professional judgement, and not with the practice in which the practitioner works.

Responses to provisional opinion

74. The medical centre was given an opportunity to respond to the provisional opinion. Where relevant, its response has been incorporated into this report. The medical centre stated that throughout the period relevant to the complaint, the medical centre, appreciating the risks staff resourcing posed to continuity of care, had appropriate systems in place to guide and support staff to limit any detrimental effects. While the clinicians had independent professional obligations to document the consultations with Mr A appropriately, the medical centre reinforced the obligations through its contracts, policies, education, and training.

75. The medical centre said that beyond that it had very little ability to identify omissions in the notes where the information transcribed was received in private medical consultations to which the medical centre was not party. The medical centre stated that at a systems level, it is unrealistic and unworkable to suggest that the medical centre should direct that all negative findings within a consultation be recorded, or that failure to record family history — or other (non-defined) aspects of the patient's health — necessitates further contact and the arranging of a follow-up appointment. The medical centre asserted that ultimately, the details a clinician records is an independent judgement call. The medical centre stated that it was open to the clinicians who reviewed Mr A's results to request an in-person review with him, if they felt that was clinically indicated or they required further detail on his history or symptoms.

76. Dr B, Dr D, and Dr C were given an opportunity to respond to the relevant sections of the provisional opinion, and their responses have been incorporated into this report where relevant.

77. Dr C stated:

> "I regret the delay in referral to specialist urology care and for the suboptimal communication and shared decision making with [Mr A] regarding his health … I wish him the best with his ongoing treatment."

78. Dr D conveyed her apologies to Mr A and stated that his complaint has been taken on board and has changed her clinical practice, and will inform her future clinical practice. In addition, Dr D told HDC:

> "As clinicians we all did the best that we could in order to provide patients the medical care and attention they needed. I am deeply regretful that [Mr A's] diagnosis was delayed."

79. Mr A was provided with an opportunity to respond to the "information gathered" section of the provisional opinion, and his response has been incorporated into this report where necessary. Mr A told HDC that he hopes that the doctors and staff involved have become more aware of the failures and how they occurred, so that they can mitigate the chances of this occurring for any other patient. Mr A said that he feels that the medical centre has not taken any responsibility for its part in the failings.

Opinion: Introduction

80. The Prostate Cancer Management Guidance outlines the following:

- If a patient's first PSA result is abnormal (above 4.0ng/ml for Mr A's age at the time), the PSA test should be repeated after six to twelve weeks.
- If the second PSA test undertaken within six to twelve weeks is abnormal, the person should be referred to urology.

81. However, the Guidance (which is in the form of a flowchart) does not outline whether this relates to the second ever abnormal PSA test a man has received, or whether it relates to the second PSA test that should have been done six to twelve weeks after the first test. Accordingly, when following the flowchart, arguably it is unclear whether after six months has passed, the user should start at the beginning of the flowchart and treat the second PSA test as the first (which would necessitate a test six to twelve weeks later and no referral), or whether it should be treated as if it had been taken six to twelve weeks after the first, which would necessitate a referral.[18]

82. Between November 2016 and December 2018, Mr A's PSA levels were abnormal and there were numerous missed opportunities for earlier investigations into this, which may have led to an earlier diagnosis of his prostate cancer. Mr A told HDC that every time he discussed prostate protein level tests with a doctor, he mentioned his family history of prostate cancer, as he wanted to make sure they knew his concerns; however, he said that he was ignored.

83. I consider that the failures in this case are a result of individual clinical decision-making by multiple doctors, as well as an inadequate system that did not support its staff fully, for which the medical centre had responsibility. In order to assist my assessment of this matter, I sought independent clinical advice from GP Dr Gary Brown, and I refer to this advice in my discussions below.

Opinion: Dr B — breach

Documenting family history

84. Mr A's first appointment at the medical centre was on 30 November 2016 with Dr B. Mr A requested a check of his prostate protein levels by way of a PSA test, and this was done. As noted above, Mr A told HDC that each time PSA was mentioned, he told the doctor about his serious family history of prostate cancer.

85. Despite Mr A's request to check his PSA levels, Dr B did not record Mr A's family history of prostate cancer. Dr B told HDC that prostate cancer was not the main purpose of this consultation, and the identification of Mr A's family history was overlooked, and the entire discussion about prostate disease was not raised as it was likely that time had run out.

86. My clinical adviser, Dr Brown, advised that he would regard this as a mild departure in the context of an otherwise well managed and complex consultation with a new patient. I agree with this advice. However, this was the first opportunity for Mr A's family history to be recorded and, in my view, it is likely that had this been done, it may have resulted in other

[18] See: https://www.health.govt.nz/system/files/documents/publications/prostate-cancer-management-referral-guidance_sept15-c.pdf at page 6.

doctors making further enquiries or taking a more assertive approach with Mr A's treatment (for example, referring Mr A to urology).

Enquiring into "red flags"

87. Despite Mr A requesting a PSA test, Dr B did not enquire as to whether Mr A had any other "red flags[19]" for prostate cancer. Again, Dr Brown advised that this was a mild departure from the standard of care in the context of an otherwise well managed and complex consultation with a new patient. Dr Brown explained that Dr B asked Mr A to return in a month's time, and this would have provided an opportunity to discuss the PSA results.

88. I consider that Dr B should have enquired about red flags for prostate cancer when Mr A asked for a PSA test. Whilst we do not know whether Mr A had any red flags, had any been elicited, this may have changed Dr B's management of the abnormal test results. However, I also acknowledge that this was Mr A's first appointment with Dr B, and during the appointment many topics were covered (diabetes, hypertension, cardiovascular risk, and medication), making it a busy and complex one.

Documentation of "no red flags"

89. On receipt of the test results, Dr B entered into Mr A's notes, "no red flags", despite not having made any enquiries into this. Dr B told HDC that he can offer no reasonable rationale for having done so, and apologised for his error.

90. Dr Brown advised that recording "no red flags" when in fact no enquiries had been made was a moderate departure from a reasonable standard of practice. He highlighted that the incorrect note of "no red flags" generated unintended consequences for Mr A. This note adversely altered Dr C's subsequent clinical decisions, and subsequently Dr D relied in part on the written records of Dr C. Dr Brown stated that all doctors rely on the accuracy and integrity of the written record, and Dr B's note of "no red flags" was materially misleading.

91. I accept Dr Brown's advice regarding Dr B's incorrect documentation of "no red flags". Doctors review one another's notes regularly, and accurate notes are essential to good continuity of care. This error contributed to subsequent unfortunate events that may have affected the timeliness of Mr A's prostate cancer diagnosis.

Referrals and further tests

92. Mr A's PSA1 test result was 5.18ng/ml. This was Mr A's first abnormal PSA result at the medical centre.

93. The PSA1 laboratory form highlighted that Mr A's PSA levels were elevated and should trigger a referral to a urologist[20] (although that advice is no longer current). The laboratory

[19] Neurological symptoms, bone pain, macroscopic haematuria, and renal failure.

[20] This referred to the 2012 guidance, which recommended that when the PSA was elevated to ≥4.0ng/ml, GPs should refer men aged 50–70 years to a urologist. This guidance was superseded by the Prostate Cancer Working Group and Ministry of Health 2015 *Prostate Cancer Management and Referral Guidance*, which did not include this recommendation.

form also provided a website link to the Ministry of Health's Guidance, which states that if the level is abnormal, a repeat PSA test should be done in six to twelve weeks' time.

94. Dr B did not repeat the PSA test in six to twelve weeks' time. Three months after the appointment, on 23 February 2017, Dr B asked nursing staff to set a recall test for a further three months' time, and Mr A's PSA2 test took place on 11 May 2017.

95. Dr Brown advised that as this was the first elevated test result above 4.0ng/ml with a relatively short delay in repeat testing, Dr B's failure to arrange for a timelier repeat PSA was a mild departure from accepted standards. Dr Brown explained that standard practice was to schedule a repeat PSA test within six to twelve weeks (eg, on or around 22 February 2017) and, if this test result came back abnormal, the appropriate course of action was to offer a DRE and information, and provide the option to consent for routine urology referral for biopsy.

96. Dr Brown also stated that Dr B's initial failure to manage the first PSA result is particularly perplexing, given that the laboratory flagged the result of 30 November 2016 as abnormal and above the threshold for referral, and provided a direct link to the appropriate nationally agreed clinical guidance.

97. I accept Dr Brown's advice. The clinical management for situations such as Mr A's was laid out clearly in the Guidance. I acknowledge that Dr B was returning to practice after several years, and was "catching up on many guidelines relating to the common General Practice conditions"; however, it was his responsibility to ensure that he was up to date with relevant guidance. In this case, the form containing the test results specifically provided a website link to the Guidance. There can be no suggestion that Dr B was unaware that there were guidelines that could have assisted him.

98. Furthermore, even if Dr B was not up to date with the Guidance and did not consider that he should read it, the prompt in the laboratory form to refer Mr A to urology (even though out of date at the time) should have alerted him that further action was required, and prompted him to view the website to ascertain what action was required. If Dr B had viewed the Guidance, he would have learned that the appropriate action was to retest Mr A's PSA levels in six to twelve weeks' time.

Communication of test result

99. Dr B ordered the PSA1 test and, as such, he retained the responsibility for communicating the result to Mr A. Mr A was not informed of his PSA1 test result. The medical centre's "Test Results & Medical Report Management Policy" (see Appendix C) states that if results are abnormal but not acute, instructions of what needs to be done are to be placed in the nurse provider inbox.

100. Dr Brown advised that the failure to communicate the test result to Mr A is a mild/moderate departure.

101. Dr Brown noted that there is no written record of how the PSA result would be communicated to Mr A. Dr Brown highlighted that it is prudent practice to make it clear how

results will be communicated, particularly to a new patient who is attending the practice for the first time.

102. I agree with this assessment. Given Mr A's significant family history of prostate cancer, an abnormal PSA result was information that Mr A would reasonably expect to receive in his circumstances. The failure to communicate the result to Mr A meant that he was unable to advocate for his own health at an early stage.

Conclusion

103. I acknowledge that at the time of Mr A's appointment, Dr B had returned to general practice after an extended break, and that this was Mr A's first appointment at a new GP practice and he presented with several complex medical issues.[21] I am not critical of Dr B for omitting to refer Mr A to a urologist on this occasion (even though the laboratory form recommended this action) because the laboratory form was referring to outdated guidelines.

104. Whilst I acknowledge the above, in summary I am critical that Dr B:

- Failed to document Mr A's family history of prostate cancer;
- Failed to enquire about red flags for prostate cancer;
- Incorrectly documented "no red flags" in Mr A's medical records; and
- Failed to repeat Mr A's PSA test in six to twelve weeks' time.

105. Taking into account these deficiencies cumulatively, in my opinion Dr B did not provide services to Mr A with reasonable care and skill. Accordingly, I find that Dr B breached Right 4(1)[22] of the Code of Health and Disability Services Consumers' Rights (the Code).

106. In addition, Dr B failed to inform Mr A of his abnormal PSA test result, which was information that Mr A would reasonably expect to receive, denying Mr A the opportunity to participate in his own care. As such, I also find that Dr B breached Right 6(1)(f)[23] of the Code.

Opinion: Dr C — breach

Referral to urology and test recall

107. On 11 May 2017, Mr A saw a clinical pharmacist, and the PSA2 test was ordered under Dr C's name (as per the medical centre's process). Dr C did not see Mr A on this date but he received and reviewed the PSA2 result on 15 May 2017.

[21] Including diabetes, hypertension, cardiovascular risk, and medication.
[22] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[23] Right 6(1)(f) states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including the results of tests."

108. The PSA2 result showed that Mr A's PSA levels had dropped slightly from 5.18ng/ml to 4.8ng/ml. This was Mr A's second abnormal PSA result. The laboratory form did not include a recommendation for referral or provide a website link to the Guidance.

109. The Guidance outlines that after the second abnormal PSA test result (above 4.0ng/ml for Mr A's age at the time) a referral to urology should be made. However, the Guidance does not outline whether this relates to any second abnormal PSA test result a man receives in his life, or whether it relates to the second PSA test that should have been done six to twelve weeks after the first test. Accordingly, when following this Guidance, it is unclear whether after twelve weeks have passed and there is a second abnormal PSA result, the clinician should start at the beginning of the flowchart and treat the second PSA test as the first (which would necessitate a test 6–12 weeks later and no referral), or whether it should be treated as the second PSA test, which would necessitate a referral.[24]

110. Dr C documented in Mr A's notes that the "PSA results were ok and dropping". Dr C told HDC that when he reviewed Mr A's medical records, he took into account Dr B's note of "no red flags" dated 30 November 2017 and, in light of this, he thought that a longer time between repeats was appropriate, and noted that he had had referrals (to urology) declined. Dr C told HDC that with hindsight he accepts that he should have recalled Mr A to have a DRE and set the repeat PSA test for three months rather than six months.

111. Dr Brown stated that when reading Dr B's notes of 30 November 2017, Dr C had the opportunity to observe that there was no discussion about prostate symptoms or the presence or absence of red flags. Dr Brown highlighted that the inconsistency between the note "no red flags" and no documentation of a discussion may have given other practitioners pause for reflection, but he noted that Dr C was reasonably entitled to accept that what his colleague had written in the notes was an accurate record of events.

112. Dr Brown advised that given the reduced and very mildly abnormal PSA result, Dr C's decision to repeat the test in six months' time and not refer to a urologist on this occasion are mild departures from the accepted standard of care.

113. I accept this advice. This was Mr A's second abnormal test result. As outlined above, the correct action after PSA1 was for a retest to be done six to twelve weeks later. The Guidance does not anticipate what should occur where the second test has not been repeated after six to twelve weeks, as was the case here. One reading of the Guidance suggests that the correct action was for Dr C to refer Mr A to a urologist as per the Guidance. I am of the opinion that a decision to re-test after six to twelve weeks and make a referral to urology, or at least document the rationale for not doing so, would have been appropriate.

114. I note Dr C's explanation that previously he had had referrals to urology declined, and that the laboratory form did not include a recommendation for referral or provide a website link

[24] See: https://www.health.govt.nz/system/files/documents/publications/prostate-cancer-management-referral-guidance_sept15-c.pdf at page 6.

to the Guidance. However, I am of the opinion that Dr C should at least have documented his reasoning for deviating from national guidance.

29 December 2017

115. Mr A's PSA3 test took place on 13 December 2017, and his PSA levels had risen from 4.8ng/ml to 5.5ng/ml. The laboratory form did not include a recommendation for referral or provide a website link to the Guidance. This was Mr A's third abnormal PSA result.

116. On 29 December 2017, Mr A attended an appointment with Dr C. Dr C obtained a history of prostate cancer and conducted a DRE, but did not refer Mr A to a urologist. Dr C told HDC that he did not refer Mr A to a urologist on this occasion because a number of his previous referrals had been rejected by the DHB, and he thought it prudent to obtain two consecutive tests that showed an increasingly elevated PSA before doing so.

117. Dr Brown advised that Dr C's history taking, including obtaining a family history of prostate cancer, enquiring about lower urinary tract symptoms, and making records of a good standard, were all appropriate. However, Dr Brown stated:

> "[Dr C] now had three important clinical facts available to him. Firstly, that [Mr A] had a risk for prostate cancer double that of someone with no such family history. Secondly, that [Mr A] had a persistently abnormal PSA result on three occasions over the past year. Thirdly, that [Mr A] had no lower urinary tract symptoms and a normal prostate exam."

118. Dr Brown stated that despite this, Dr C appeared completely unaware of the Guidance and the steps he should take in the presence of two or more abnormal PSA results. Dr Brown considered this to be a departure from the accepted standard of practice.

119. However, Dr Brown stated that the extent of this departure can be viewed in two ways. If Dr C's earlier error of 11 May 2017 (resulting from a lack of awareness of the guidelines) is regarded as a mild departure, then arguably it would be unfair to regard another error with the same root cause as being of greater significance. The alternative view is that the increased number of abnormal tests, and now known elevated family history risk, should have triggered closer consideration of the clinical situation.

120. Dr Brown concluded that in the presence of three abnormal tests and a known family history of increased risk, the combined failure of not referring Mr A to a urologist and not acting to consult further was a moderate departure from the accepted standard of care. Dr Brown advised that if Dr C had made a urology referral, then the burden of managing Mr A's risk and clinical uncertainty would have fallen to the District Health Board urology service. Dr Brown explained that a telephone call to a urology registrar about possible referral would also have been an appropriate option.

121. I agree with Dr Brown's advice, and do not think that any lack of clarity in the Guidance (discussed above at paragraph 113) can mitigate this. It was not appropriate for Dr C's past experience with referrals to have guided his clinical decision-making with respect to Mr A.

If Dr C had referred Mr A to a urologist on 29 December 2017, it is possible that Mr A's prostate cancer may have been diagnosed at this stage.

122. In conclusion, Dr C was responsible for the management of Mr A's PSA results on two separate occasions. On each occasion, Mr A's PSA result was abnormal, and required a referral to urology. On both these occasions, Dr C omitted to refer Mr A to urology services, and instead set the PSA recall for six months. These failures contributed to delays in Mr A receiving specialist care and allowing for the early detection of his prostate cancer. It follows that I find that Dr C breached Right 4(1) of the Code.

Communication of test result

11 May 2017

123. Dr C documented in Mr A's medical records that Mr A had been informed of the abnormal PSA test result from 11 May 2017. However, Dr C did not inform Mr A himself, and told HDC that he recorded his comments, which were passed to nursing staff, and he understood that nursing staff contacted Mr A on 15 May 2017. However, there is no documented evidence of any delegation of this task from Dr C to the nurse, and no documentation from nursing staff that this was carried out. Mr A told HDC that he was not informed of the results of this elevated PSA test.

124. As Mr A was very aware of his family medical history, I consider that if he had been informed of the elevated PSA result, it is likely that he would have taken further action on the result. Given this, and that there is no documentation from the nurses that they informed Mr A of the result in accordance with Dr C's instructions, I am satisfied that it is more likely than not that Mr A was not informed of this result.

125. Dr Brown advised that Dr C retained responsibility for informing Mr A of the test result, and it was appropriate that the result and its significance was communicated to Mr A. Dr Brown considers that Dr C appears not to have reflected on the fact that his decision on 11 May 2017 — to set a recall for six months' time (instead of making a referral to urology) — was made entirely without discussion with Mr A. Dr Brown advised that a more comprehensive written note of how or what was communicated to Mr A would have been preferable.

126. Dr Brown stated:

> "[M]ost colleagues would expect that any decision to depart from the nationally agreed guidelines would be supported by full and adequate documentation of his clinical reasoning; and documentation that he had sought and gained [Mr A's] consent in an informed discussion about such matters."

127. I accept this advice. From the evidence available it is unclear whether Dr C clearly delegated to a nurse the responsibility of informing Mr A of the abnormal result. I remind Dr C of the importance of keeping clear and accurate patient records and, in this case, the importance of documenting the instruction to the nurse.

29 December 2017

128. There is no documentation of any discussion Dr C had with Mr A about his PSA3 test result. Mr A told HDC that he received no communication regarding the result of the PSA3 test. Dr C has not provided any explanation regarding why he did not inform Mr A of the PSA3 test result.

129. Dr Brown highlighted that in hindsight it is likely that Mr A had prostate cancer in 2017, and that Mr A was "reasonably entitled to be informed and involved in any discussion about options for further investigation that could materially affect his future health". Dr Brown explained that significant decisions were made for Mr A, rather than with or by Mr A.

130. I agree with Dr Brown. On two occasions, Dr C did not communicate abnormal PSA results to Mr A. Given Mr A's significant family history of prostate cancer, an abnormal PSA result was information that Mr A would reasonably expect to receive in his circumstances. Accordingly, I find that Dr C breached Right 6(1)(f) of the Code.

Opinion: Dr D

Referral to urology and test recall — breach

131. On 16 May 2018, the practice nurse arranged Mr A's PSA4 test under Dr D's name. Dr D did not see Mr A on this date but reviewed the results of the test on 17 May 2018.

132. The PSA4 result showed that Mr A's PSA levels had risen from 5.5ng/ml to 5.7ng/ml. This was Mr A's fourth abnormal PSA level result. The laboratory form noted: "The elevated PSA exceeds the recommended level for referral under MOH guidelines."[25]

133. Dr D documented in Mr A's medical records: "Biochem; Tumour markers (stable)."[26] The nurse documented that Mr A was informed.

134. Dr D told HDC that when deciding what action to take, she considered that the pharmacist prescriber had documented on 27 March 2018 that Mr A's symptoms were unchanged, and she considered that Dr C's examination findings in December 2017 were largely unremarkable. As such, she did not make a referral to urology for Mr A.

135. As noted above, the Guidance outlines that after the first abnormal PSA result, a retest should occur after six to twelve weeks. After the second abnormal PSA test result, a referral to urology should be made. The Guidance does not anticipate what should occur where the test has not been repeated after six to twelve weeks, as was the case here.

[25] This referred to the 2012 guidance, which recommended that when the PSA was elevated to ≥4.0ng/ml, GPs should refer men aged 50–70 years to a urologist. This guidance was superseded by the Prostate Cancer Working Group and Ministry of Health 2015 *Prostate Cancer Management and Referral Guidance*, which did not include this recommendation.

[26] PSA is the most important tumour marker.

136. However, Dr Brown highlighted that if Dr D had been aware of the Guidance, she would have been expected to bring Mr A back promptly for further assessment. Dr Brown advised that not doing this was a mild departure from accepted standards.

137. Dr Brown acknowledged that Dr D had had no previous contact with Mr A, and that essentially the results were unchanged from those that informed Dr C's earlier decisions. However, Dr Brown noted that this was Mr A's fourth abnormal elevated PSA test, and that the laboratory form contained a clear prompt that further action was required. As such, he considered that Dr D's failure to refer Mr A to a urologist was a moderate departure from the accepted standard.

138. I agree with Dr Brown. Despite any lack of clarity in the Guidance, and what had been documented by her colleagues, this was the fourth consecutive abnormal PSA test result. Dr D was aware of Mr A's family history, and the laboratory form stated clearly that Mr A's result exceeded the recommended level for referral to urology under MOH guidelines. This should have alerted Dr D to the need for a referral to urology, but instead Dr D set a PSA recall for six months' time. Accordingly, I find that Dr D breached Right 4(1) of the Code.

Communication — other comment

139. It is documented in the notes that Mr A was "informed" after Dr D received his PSA4 result. Mr A told HDC that he is certain that he was not told that there was anything exceptional in relation to the PSA4 result, and that if he had been told, he would have asked for a urology referral.

140. In response to the provisional opinion, Dr D told HDC that the nurse has the ability to change the notes on the PMS, and she believes she documented, "stable. Review if concerns. Please inform patient," and that the nurse acted on this instruction, and added "patient informed" to the notes.

141. I have considered the following: the limited documentation that states "patient informed", Mr A's statement that he was not told that there was anything exceptional in relation to the PSA4 result, and the fact that Dr D considered that the result did not require further action. While I acknowledge that the nurse may have spoken to Mr A at Dr D's instruction, I consider it more likely than not that, at this point, Mr A was told that he was stable (as per Dr D's note) and was not told that his result was abnormal.

142. Dr Brown stated that the adequacy of communication regarding the PSA result of 16 May 2018 was partly reasonable given the information available at the time — an essentially stable PSA result, and the recent clinical report of no concerns. Dr Brown advised that Dr D's failure to inform Mr A of the information contained in the laboratory result (that the elevated PSA exceeded the recommended level for referral to urology) was a mild departure from accepted standards.

143. While Dr D delegated the responsibility of informing Mr A of the PSA result to a nurse, her documentation makes it unclear whether she asked the nurse to inform Mr A of the actual test result and the information contained in the laboratory result, or just that Mr A's result

was "stable". Either way, Mr A was not informed of his abnormal result from May 2018. I remind Dr D of the importance of keeping clear and accurate patient records and, in this case, the importance of documenting clear instructions to the nurse.

Opinion: Medical centre — adverse comment

Introduction

144. The medical centre had experienced difficulties with staff shortages and had implemented various procedures to assist, including nurse-led recalls and communication of test results. Despite implementing these procedures, Mr A was not informed of his abnormal PSA results. While there is individual accountability for this, I consider that the medical centre also holds responsibility for deficiencies at an organisational level for the reasons outlined below.

Continuity of care

145. From November 2016 to December 2018, Mr A saw three different doctors, as well as a nurse practitioner and a clinical pharmacist at the medical centre.

146. At the medical centre, blood tests and recalls were requested by the nurses, in the name of a permanent salaried doctor, rather than in the name of a locum, and the nurses contacted patients if they did not respond. The medical centre told HDC that these processes were in place because of difficulties recruiting doctors and nurse practitioners, and at times there were fewer clinicians than required to manage registered patients.

147. The medical centre also told HDC that it attempted to have specific salaried doctors covering specific patient lists, but it balanced this with the equal distribution of the workload.

148. This system of clinicians reviewing test results for patients they had not met meant that Mr A had PSA tests ordered by clinicians who had not reviewed him in person and had not had an opportunity to take a full history. For example:

- In May 2017, Dr C reviewed Mr A's test result and decided the course of action to take. He had not seen Mr A and had to rely on previous documentation written by Dr B, and did not have the opportunity to take a full history or ask any questions.
- In May 2018, Dr D reviewed Mr A's fourth PSA test result and decided the course of action to take, again without having the opportunity to have a consultation with Mr A, and relying on Dr C's previous assessment.

149. In response to the provisional opinion, the medical centre told HDC that it appreciates the benefits of continuity of care for patients, and that such continuity would have been achieved by Mr A seeing the same doctor on each occasion, but the unfortunate reality is that it was not possible.

150. Dr Brown made the same observation, and stated:

> "Overall, there was little continuity of care available to [Mr A], and this created a degree of clinical risk for [Mr A], and also for the various clinicians undertaking their best efforts to provide care in a complex and challenging environment. This risk was not fully appreciated, and was not effectively communicated to [Mr A], who was blind to the majority of clinical decisions made on his behalf."

151. It is apparent that the medical centre realised that continuity of care was a problem, and proactively attempted to minimise the potential risk associated with this by assigning locum or nurse-ordered tests to a salaried doctor, and by the nurse-led recall process. The nurse-led test recall process was carried out very efficiently. However, there is an element of risk when test results are reviewed by clinicians who have not had a consultation with the patient, as they have not had an opportunity to take a history and ask questions, and this creates a risk of over-reliance on the original documentation. However, it is reasonable for the medical centre to expect doctors to keep accurate notes and have a working knowledge of the appropriate management of PSA results.

152. With medical practices focusing less on individual doctor consultations and more frequently involving a multidisciplinary team, practices must ensure that robust systems exist to address the issues that can arise when no single clinician takes overall responsibility for the patient, and the need to ensure continuity of care. This includes a thorough orientation to the practice's PMS, and ensuring that doctors access the relevant clinical HealthPathways for guidance on local recommendations.

Communication of test results

153. Between November 2016 and May 2018, Mr A had four PSA tests that all returned abnormal results. Mr A told HDC that he was not informed that his PSA results were abnormal. Both Mr A's father and uncle passed away from prostate cancer, and Mr A was very aware of the risk that this posed for his health. Mr A told HDC that he mentioned this every time he dealt with a doctor regarding the topic, to ensure that they were aware that his risk profile was somewhat higher than normal.

154. The medical centre's Test Results & Medical Report Management Policy (see Appendix C) outlines that a nurse contacts patients about abnormal results (or normal results in some circumstances) and associated instructions from the clinician. The medical centre has asserted that it has an appropriate structure in place to promote communication of test results, and that if effective communication to Mr A did not take place, the responsibility for that failure does not fall on the medical centre. The medical centre did not provide HDC with any evidence that the nurses had informed Mr A that his results were abnormal.

155. Whilst I acknowledge that there was a policy in place, and that some responsibility should (and has) been attributed to the clinicians involved for the lack of communication, in my view this does not mean that the medical centre is absolved of all responsibility. The fact that Mr A was not informed of his tests results four times by three different doctors suggests

a pattern of poor communication practices at the medical centre, for which the medical centre is partly responsible at an organisational level.

Lack of adherence to Ministry of Health Guidelines

156. Between 30 November 2016 and 16 May 2018, Mr A had four PSA tests that showed abnormal PSA levels, and further action should have been taken as per the Guidance. However, on each occasion, inappropriate action was taken, either by way of six-monthly repeat tests instead of the recommended six to twelve weeks, or referrals to urology not being done when indicated. Appropriate action was not taken until the fifth PSA test, when Mr A's result was 6.32ng/ml.

157. At the time of events, the medical centre did not have a policy regarding how to manage PSA results that guided when to obtain a repeat PSA test or when to refer to urology. The medical centre told HDC that prior to November 2019, clinicians used Map of Medicine,[27] which it believes linked to the 2012 guidelines[28] and the Guidance. The medical centre told HDC that from November 2019 its clinicians had access to HealthPathways,[29] and clinicians were strongly encouraged to use this.

158. Dr Brown advised that he is firmly of the view that had an adequate policy been in place to manage elevated PSA levels, any knowledge deficit on the part of any individual practitioner would have been detected and corrected at a much earlier time, and would have avoided the repetition of previous errors, namely repeatedly setting six-monthly recalls for abnormal PSA results. Dr Brown stated that the fact that there was no internal practice policy or guidance on the appropriate management of abnormal PSA testing, and without this key knowledge, the omissions by individual practitioners were needlessly open to repetition.

159. In response to the provisional opinion, the medical centre stated that not having a PSA policy did not constitute a breach of the Code, and that the national guidelines were available for use, and that the medical centre expected clinicians to follow that guidance. The medical centre also provided a letter from the College, which is outlined at paragraph 55. The letter states that there is no requirement for practices to have policies for every type of test result, or to "import" national guidance into its PMS.

160. I have taken into account the comments from the medical centre and the College, and Dr Brown's advice. On balance, I am not critical of the medical centre for not having a specific PSA policy. I also acknowledge that it is a doctor's responsibility to be up to date with relevant Ministry of Health guidance. In my opinion, it was reasonable for the medical centre to expect its clinicians to be up to date with the national guidance on how to manage abnormal PSA results. However, the fact that the guidance was not followed four times by

[27] An online clinical knowledge resource that provides healthcare professionals with specialist knowledge at the point of care.
[28] Ministry of Health Prostate Cancer Taskforce 2012 *Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce*.
[29] An online manual used by clinicians to help make assessment, management, and specialist request decisions for over 550 conditions.

three different doctors suggests a pattern of poor adherence to guidance at the medical centre, for which the medical centre is partly responsible at an organisational level.

Conclusion

161. On behalf of the medical centre, Dr E submitted that it does not accept that responsibility for clinical decision-making lay with the practice. Dr E told HDC that ultimately this responsibility rests with the individual practitioner exercising their professional judgement, and not the practice where the practitioner works.

162. While there is certainly individual accountability and clear standards that place obligations on individual providers (discussed in more detail above), it is the responsibility of the medical centre to have in place robust systems to ensure continuity of care for patients, and ensure it fosters good communication practices.

163. I acknowledge that the medical centre has worked hard to envisage problems that could occur because of issues with retaining staff, and has devised systems to try to mitigate this. Whilst the efforts by the medical centre were admirable, in my opinion there is an element of risk when a doctor reviews test results of a patient whom they have not seen or had an opportunity to ask questions, and when the expectation on the doctor is that the nurse communicates results to patients. I remind the medical centre of the risks this poses, and I have addressed this in my recommendations.

Changes made since events

Medical centre

164. The medical centre told HDC that since these events, it has undertaken, or is undertaking, the following:

a) It has developed, distributed to, and trained all 15 sites on a protocol for the collective management of abnormal PSA results, which takes into account the "Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce"; and the "Prostate Cancer Management Guidance",[30] and recommends the use of HealthPathways and the KUPE tool.[31]

b) It is making recommendations to the Health Network[32] that this protocol be included in a future communication to the network.

c) It is undertaking a full audit across all 15 of its sites regarding the management of elevated PSA results since 2016, to ensure that patients have been managed correctly under the 2015 Ministry of Health guidelines.

[30] The Ministry of Health 2015 Prostate Cancer Management and Referral Guidance.
[31] A support tool to assist in deciding whether a man requires a prostate cancer check.
[32] The Health Network supports the day-to-day activities for the medical centre.

d) It has provided further guidance, protocols, and training about the collective management of abnormal PSA results to clinicians at all 15 sites.

e) It has developed quality management systems to take information from various systems and processes across the organisation and review issues/complaints regularly.

f) It has upskilled staff regarding PSA management and prostate screening.

165. The medical centre told HDC that it has identified that its orientation process is too generic, and it is undertaking considerable work to ensure that the process is updated to include role- and site-specific information.

Dr B

166. Dr B told HDC that he now undertakes the following:

a) He routinely follows the guidance on PSA testing and manages PSA testing more thoroughly.
b) He asks for a more detailed history, and regularly performs DRE in combination with testing, in particular if the patient has not had a DRE in the past but has had PSA testing and is over 40 years old.
c) He uses the prostate awareness week to prompt discussion about prostate disease.

167. Dr B has provided HDC with a written apology to Mr A.

Dr C

168. Dr C told HDC that he now undertakes the following:

a) If a patient's PSA is elevated and the patient's DRE and urine test[33] are normal, he prescribes a course of antibiotics and repeats a PSA test two weeks later.

b) He refers to a urologist if the second test result is elevated.

c) He documents all examinations and any negative findings fully.

d) He has lowered his threshold for urological referral.

169. In response to the provisional report, Dr C told HDC the following:

a) A protocol for PSA screening and management was reviewed and discussed at his GP meeting in April 2021 and was implemented.

b) An individual audit of all of his patients with abnormal PSA results was completed in August 2021, and the audit showed that all 43 patients were treated according to the PSA protocols and the guidelines.

c) The audit was discussed at a GP meeting in August 2021 and the following suggestions were made:

- To standardise DRE notes.

[33] Mid-stream urine test.

- To make reference to the PSA thresholds for individual patients, for easy identification for other doctors.

Dr D

170. Dr D told HDC that she now undertakes the following:

a) She enquires about family history, lower urinary tract symptoms, red flags of prostate cancer (urological symptoms, bone pain, macroscopic haematuria,[34] and renal failure).

b) She uses the KUPE tool to aid the decision-making process for patients.

c) She pays close attention to PSA results and repeats elevated PSA tests in asymptomatic patients within six to twelve weeks, and refers persistently elevated results to urology.

d) She has reflected on the Ministry of Health guidance and made it part of her continued professional development.

e) She has completed the bpac[NZ35] learning module on "Prostate cancer testing decision support tool for patients and their families" and the bpac[nz] learning module on "Testing for Prostate Cancer: helping patients to decide".

Recommendations

171. I note the changes made by the medical centre since these events. In addition, I recommend that the medical centre:

a) Provide a written apology to Mr A addressing the changes it has made to ensure that the issues outlined in this report do not happen to another patient in the future, within one month of the date of this report.

b) Provide evidence of staff training on PSA management and prostate screening, within three months of the date of this report.

c) Provide a copy of the results of its audit (referred to at paragraph 164(c)) and, if required, an action plan regarding any elevated PSA results since 2016, within three months of the date of this report.

d) Consider a review of the test recall system or the orientation process to ensure that doctors have the opportunity to consult with a patient prior to deciding the next steps, and are made aware of this option in their orientation.

e) Consider incorporating the Prostate Cancer GP Tool decision support tool[36] (available nationally since April 2018) into its practice.

[34] Blood in the urine.
[35] Best Practice Advocacy Centre NZ (which delivers education and continuing professional development programmes to medical professionals).
[36] https://kupe.net.nz/en/about-prostate-cancer.

f) Consider adapting its communication policy to ensure that nurses do not amend doctors' instructions regarding communication to patients.

172. I recommend that Dr B conduct an audit of his assessments of patients with abnormal PSA results (in accordance with the Prostate Cancer Management Guidance) over a three-month period, and report back to HDC on whether the audit showed that appropriate steps were taken as mandated by the Prostate Cancer Management Guidance, within four months of the date of this report. Where the audit does not show 100% compliance, Dr B's report should outline why, and the steps taken to remedy such issues.

173. I recommend that Dr C:

a) Conduct an audit of his assessments of patients with abnormal PSA results (in accordance with Prostate Cancer Management Guidance) over a three-month period, and report back to HDC on whether the audit showed that appropriate steps were taken as mandated by the Prostate Cancer Management Guidance, within four months of the date of this report. Where the audit does not show 100% compliance, Dr C's report should outline why, and the steps taken to remedy such issues.

174. I recommend that Dr D:

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

b) Conduct an audit of her assessments of patients with abnormal PSA results (in accordance with the Prostate Cancer Management Guidance) over a three-month period, and report back to HDC on whether the audit showed that appropriate steps were taken as mandated by the Prostate Cancer Management Guidance, within four months of the date of this report. Where the audit does not show 100% compliance, Dr D's report should outline why, and the steps taken to remedy such issues.

Follow-up actions

175. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the DHB.

176. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's, Dr C's, and Dr D's names.

177. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Royal College of General Practitioners, and it will be advised of Dr D's name.

178. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Cancer Control Agency, the Ministry of Health, and the Prostate Cancer Foundation of New Zealand, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following independent clinical advice was obtained from Dr Garry Brown, GP:

"Independent Advice to the Commissioner

24 August 2020

Complaint: **[Mr A]/[the medical centre]**

HDC Reference: **C19HDC01583**

Statement:

This statement is to confirm that I have read, understood, agreed to and followed the Guidelines for Independent Advisors to the Health and Disability Commissioner.

I have no known conflict of interest with any of the individuals or parties involved in the investigation.

Personal Qualifications:

I am a vocationally registered Fellow of the Royal NZ College of General Practitioners; and hold a Postgraduate Diploma in Obstetrics and a Postgraduate Diploma in Business Administration.

I am a currently practising GP and have worked in general practice since 1987. I have served as a Fellowship Censor, RNZCGP since 2006.

Documents provided:

1. Letter of complaint dated 26 August 2019
2. [The medical centre's] response dated 7 October 2019
3. Clinical records from [the medical centre]
4. Further information from [the medical centre] dated 6 January 2020
5. Further information from [the medical centre] dated 12 August 2020

Instructions from the Commissioner:

Please advise whether you consider the care provided met accepted standards in all the circumstances and explain your rationale.

In particular, please comment on:

1. The management of [Mr A's] prostate cancer screening and PSA results.

Please advise:

a. What is the standard of care/accepted practice?

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

c. How would it be viewed by your peers?

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

If you note that there are different versions of events in the information provided, please provide your advice in the alternative. For example, whether the care was appropriate based on scenario (a), and whether it was appropriate based on scenario (b).

Management of Prostate Cancer in NZ:

Prostate cancer is a significant burden to men's health and is now one of the most important issues facing New Zealand men.

The lack of a reliable way of detecting prostate cancer early has created many challenges. The commonly used prostate specific antigen (PSA) blood test detects both cancer and non-cancerous conditions. As well, some prostate cancers are slow growing and may not affect a man's quality of life or cause early death.

In response to a Health Select Committee recommendation, The Prostate Cancer Taskforce (the Taskforce), a group of clinical experts was established in 2012 to agree recommendations for the Prostate Cancer Awareness and Quality Improvement Programme.

This resulted in the 2012 publication of Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce.[1]

This document included specific guidance to primary care. Recommendations 15, 16 and 20 are particularly relevant in the context of this complaint.

Recommendation 15:

Primary health care should provide high-quality, culturally appropriate information on prostate cancer and PSA testing to men aged 50 to 70 years.

All men who are concerned about prostate cancer or are requesting a PSA test must be presented with high-quality, culturally appropriate information.

Recommendation 16:

Systems must be introduced to general practices to facilitate the informed consent process.

[1] Prostate Cancer Taskforce. 2012. *Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce*. Wellington: Ministry of Health.

Recommendation 20:

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.

In 2015 the Ministry of Health published updated Prostate Cancer Management and Referral Guidance[2] due to concerns that New Zealand men were receiving conflicting advice about prostate cancer testing.

This guidance was formally endorsed by a number of organisations including the Royal New Zealand College of General Practitioners, the Prostate Cancer Foundation of New Zealand, the Urological Society of Australia and New Zealand and the New Zealand Society of Pathologists.

In April 2018 the Ministry of Health rolled out Kupe — a consumer information website specifically about prostate cancer detection and treatment.[3]

Best Practice Advocacy Centre (BPAC) simultaneously published a prostate cancer decision support tool for general practice incorporating the use of Kupe.[4]

Family History of prostate cancer:

Specific mention is made in the 2015 Guidance under section 1.2 regarding men with a family history of prostate cancer. Men with a family history of prostate cancer are twice as likely to develop the disease than men without a family history.[5]

Under section 5.1 guidance was provided on follow-up options for men with a family history of prostate cancer, noting:

[2] Prostate Cancer Working Group and Ministry of Health. 2015. Prostate Cancer Management and Referral Guidance

[3] https://kupe.net.nz/en

[4] https://bpac.org.nz/2018/prostate-decision-support.aspx#fig1

[5] A man is defined as having a family history of prostate cancer if he has at least one first-degree relative (father or brother) who was diagnosed with prostate cancer. Men with a family history of prostate cancer are twice as likely to develop the disease than men without a family history. If a man has two or more first-degree relatives who were diagnosed with prostate cancer under the age of 65 years, then his risk increases by 5–11 times (Steinberg et al 1990).

> 'Although there is no strong evidence to support how often to test men with a family history of prostate cancer, best practice suggests that these men should be offered a PSA test and DRE every 12 months from the age of 40–70 years.'

Interpretation of PSA test results:

The 2015 Guidance noted that generally the higher a man's PSA level, the more likely it is that he has prostate cancer. However, some men will have prostate cancer even in the absence of a raised PSA.

If a man's PSA level is between 4.0 µg/L and 10.0 µg/L, there is a 40 percent chance of detecting prostate cancer on prostate biopsy (Leinert et al 2009).

The Guidance specifically recommended that in circumstances where PSA was 4.0 µg/L and 10.0 µg/L, men should always have a repeat PSA test after 6–12 weeks:

> 'Increased PSA levels can be transient, which is why men should always have a repeat PSA test after 6–12 weeks to confirm the result. The exceptions to this are if a man has a raised PSA level and an abnormal DRE or if a man has a raised PSA level and one of the red flags shown in the algorithm on page 3 (see Note 4 for more information on the red flags).'

In circumstances where PSA was clearly abnormal, the criteria for referral to a urology or radiation oncology service are set out in Table 3, including: Routine referral *(should be seen within 6–8 weeks)*	PSA is between 4 and 10 µg/L AND macroscopic haematuria is present (in the absence of infection) PSA is < 10 µg/L AND prostate feels hard and/or irregular on DRE Two clearly abnormal PSA results 6–12 weeks apart *(see Table 1 on page 8 for definitions of a clearly abnormal PSA)*

The 2015 Guidance also directed that District Health Boards and Primary Health Organisations are responsible for integrating this guidance into their clinical pathways for prostate cancer in a way that reflects the particular needs of their patients and communities.

The recommendations set out in Table 3 above have been directly incorporated into the [region's] Community Health Pathways which state that:

> 'Elevated PSA on 2 or more tests to less than 100 micrograms/L, request non-acute urology assessment for prostate biopsy (within 8 weeks).'

Review of clinical notes

The response to HDC from [the medical centre] of 7 October 2019 sets out a reasonable summary of the clinical notes between 30 November 2016 and 23 August 2019.

[Mr A] appears to have a range of other significant health issues including insulin dependent Type 2 diabetes mellitus, hypertension, hyperlipidemia, GERD, and glaucoma.

Relevant comment related to key entries is highlighted as below.

30 November 2016:

The initial GP assessment focused on a number of medical issues, [Mr A's] request for a PSA test was actioned, but there is no recording of any family history of prostate cancer.

The PSA result obtained was 5.18 ng/ml (H). The [DHB] laboratory form noted that:

> 'The elevated PSA exceeds the recommended level for referral (under MOH guidelines. If this is a repeat raised value or in the presence of abnormal DRE or other 'red flag' conditions refer to a urologist. For further information refer to the prostate cancer management referral guidance, Sept 2015 document in: http://tinyurl.com/PCA-MOH'

The Inbox comment on the PSA result from [Dr B] stated 'Biochem: Tumour markers — 5.13 no red flags rpt (repeat) 6/12'.

It is not apparent how [Dr B] determined there were no red flags present, given that the clinical records show no entry related to the red flags (as set out in Table 2 of the 2015 Guidance).

A 6-month PSA recall was set.

11 May 2017:

[Dr C] undertook a review of diabetes management and noted [Mr A] had recurrent symptoms of complete visual loss lasting 30 minutes.

[Mr A] was reminded that his PSA and diabetes blood tests were due, and a lab form provided.

There is no clinical record of any enquiry regarding family history of prostate cancer, red flag symptoms or lower urinary tract symptoms (LUTS).

The PSA result of that date was 4.8 ng/ml (H). This result was filed into the Inbox with [Dr C's] comment 'Biochem; Tumour markers — psa 4.8 ok dropping, repeat 6/12 — informed.

There is no clinical record provided documenting the way in which [Mr A] was informed of the result, whether by telephone, text message or letter. It is unclear what information was provided to [Mr A] about the interpretation of this test result.

It is also noted that [the DHB] Lab result did not include the clinical interpretation and reference to MOH guidance as previously provided in the result of 30 November 2016.

December 2017:

[Mr A] had been recalled for his 6-monthly PSA test by the practice on 16 November 2017. He underwent PSA blood testing on 13 December. The result was 5.5 ng/ml (H).

This resulted in the practice nurse sending [Mr A] a proforma recall letter on 14 December 2017 asking him to see his doctor to discuss the test result at his earliest convenience. A further letter was sent by the practice nurse on 22 December 2017 asking [Mr A] to attend for a prostate examination.

29 December 2017:

[Dr C] saw [Mr A] for a digital rectal examination (DRE) as 'PSA level slightly up again'.

[Dr C] enquired as to risk factors for prostate cancer including family history, and also for lower urinary tract symptoms (LUTS). He recorded that [Mr A's] father had died aged 67 from prostate cancer and his father's brother had died at aged 65 from prostate cancer.

DRE was unremarkable. [Mr A] was advised to have a further 6-month PSA test, and to seek 'review if symptoms deteriorate, condition worsens or if concerned.'

There is no record of any discussion of increased risk for prostate cancer due to strong family history, or options regarding urology referral or consideration of prostate biopsy.

It is again noted that [the DHB] Lab result did not include the clinical interpretation and reference to MOH guidance as previously provided in the result of 30 November 2016.

27 March 2018:

Seen by [the] Clinical Pharmacist, for repeat prescription. Noted 'Seen by GP in December for DRE as PSA slightly elevated. No further concerns. Prescription generated.'

16 May 2018:

Recalled by practice nurse for repeat PSA test, result 5.7 ng/mL (High). Laboratory form notes 'The elevated PSA exceeds the recommended level for referral under the MOH guidelines'.

This result was filed into the Inbox with [Dr C's] comment 'Biochem; Tumour markers (stable)'. Nurse Inbox comment notes 'Stable. Review if concerns. Pt informed.'

3 December 2018:

Recalled for repeat PSA, result 6.32 ng/mL (High). This result was filed into the Inbox with nurse comment 'Biochem; Tumour markers (PSA 6.32 continues to rise. TCI for DRE has appt booked 7/12).'

7 December 2018:

Seen by [Dr F]. No clinical notes entry except urology referral.

Referral letter sent to Urology the next day 8 December 2018 noting rising PSA, strong family history prostate cancer. PR findings 'a little firmer in the upper region of the right lateral lobe'.

Referral sent with Urgency — semi urgent. Assessment: High Risk of Prostate Cancer.

Subsequent events:

PSA continued to rise slowly, repeat test 7.53 12 February 2019. [Mr A] went on to have investigation by the urology team.

First specialist appointment was on 26 February 2019. No abnormal findings on DRE. TRUS biopsy was recommended.

Initial TRUS biopsies 8 May 2019 indicated low grade prostate cancer (Gleason 3 +3).

However subsequent MRI 23 May 2019 showed a large nodule at the right base, suspicious for high grade disease.

Repeat targeted biopsy 1 July 2019 confirmed the presence of high-grade prostate cancer Gleason 3+4 = 7.

No further information on staging and management on file. [Mr A] lodged a formal complaint with [the medical centre] 23 August 2019.

Advice and Reasoning:

1) What is the standard of care/accepted practice?

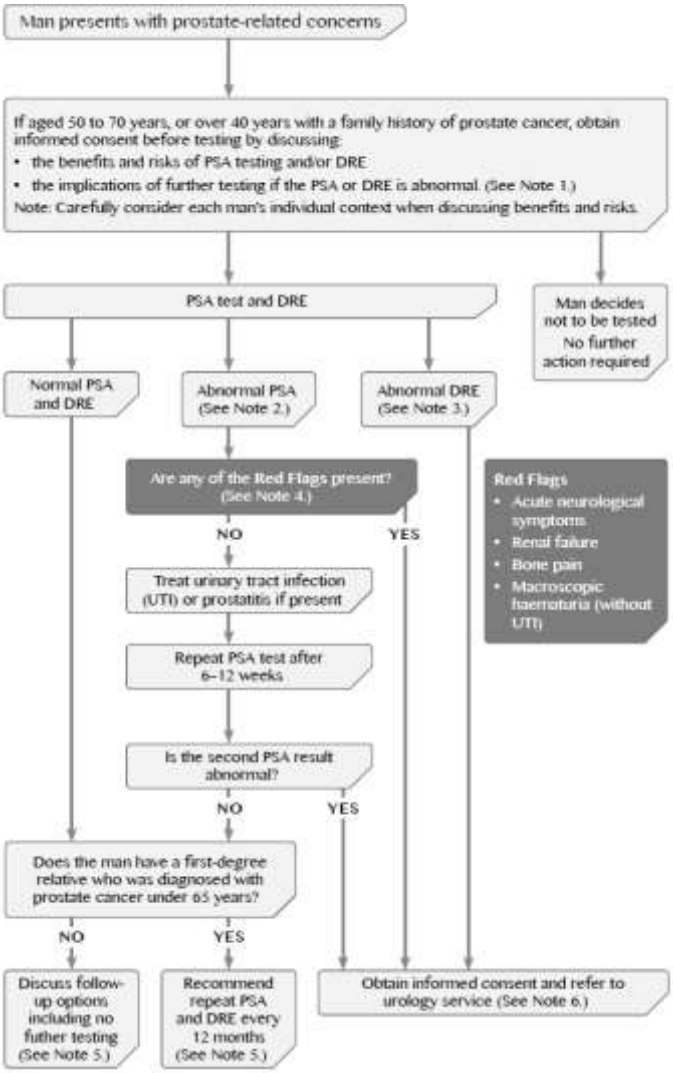
The 2015 Prostate Cancer Management and Referral Guidance makes clear the standard of care when PSA screening is undertaken for concerned individuals.

[Mr A] was concerned and had good reason for concern — given the family history of his father, and his father's brother dying in their sixties from metastatic prostate cancer.

The presence of his father's aggressive prostate cancer at a relatively young age doubled [Mr A's] risk of developing prostate cancer. When [Mr A] had his initial PSA test on 30 November 2016, the result of 5.18 ng/mL was clearly abnormal e.g. >4.0 ng/mL.

The laboratory result form clearly indicated that the elevated PSA exceeded the recommended level for urology referral (under MOH guidelines). A website link to these MOH guidelines was also provided on the result form.

The management algorithm clearly laid out on page 3 of the 2015 Guidance (as shown below) indicates that a repeat PSA test should been performed within 6–12 weeks.



If the second result is also abnormal, then informed consent should have been sought for consideration of a routine urology referral for prostate biopsy.

This is also clearly explained in the text of the Guidance under section 2.2, and further stated in Table 3.

The same management information is also laid out in [the region's] Health Pathway section on Prostate Cancer Diagnosis under Management Item 5:

> *'If DRE is suspicious of malignancy,* ***or elevated PSA on 2 or more tests to less than 100 micrograms/L, request non-acute urology assessment for prostate biopsy (within 8 weeks).'*** (emphasis added).

Therefore, in optimal circumstances, [Dr B] should have advised [Mr A] to have a repeat PSA no later than 12 weeks after his first test e.g. on or around **22 February 2017**.

At that point, had the test been abnormal (as was highly likely given he never returned a test result <4.0) [Mr A] should then have been offered DRE, and offered information and the option to consent for routine urology referral for biopsy.

[Mr A] states in his complaint that '*every time I deal with a doctor regarding this topic, I mention my family history to ensure they are aware that my risk profile is somewhat higher than normal.'*

Had [Dr B] recorded [Mr A's] family history, he should also have been aware of [Mr A's] increased risk.

This is the earliest point of a departure from a reasonable standard of care. There were multiple subsequent occasions when further opportunities for appropriate management were overlooked.

In the absence of earlier repeat testing, the second elevated PSA result of 4.8 ng/mL on **11 May 2017** should also have triggered an informed discussion and the option to consent for routine urology referral for biopsy.

The third abnormal PSA result of 5.5 ng/mL obtained on 13 December 2017 appropriately triggered a recall letter and invitation for DRE. Despite the very limited information in the proforma recall letter, [Mr A] attended for review with [Dr C] on 27 December 2017.

At this time [Dr C] documented [Mr A's] family history. He appropriately enquired as to the presence of lower urinary tract symptoms (none noted), and performed a DRE, which was normal. This normal finding was unsurprising given that the prostate cancer was located at the base of the prostate (adjacent to the base of the bladder). There is no record of checking for relevant red flags (neurological symptoms, bone pain, macroscopic haematuria, renal failure).

[Dr C] now had three important clinical facts available to him. Firstly, that [Mr A] had a risk for prostate cancer double that of someone with no such family history. Secondly that [Mr A] had a persistently abnormal PSA result on three occasions over the past year. Thirdly that [Mr A] had no LUTS and a normal DRE.

The accepted standard of care at this time **27 December 2017**, as outlined in the 2015 Guidance and [the] Health Pathways, was to seek informed consent for urological referral and biopsy.

Instead, a further six-month PSA recall was set. This subsequent result of **17 May 2018** was again abnormal at 5.7 ng/mL; and should also have resulted in seeking [Mr A's] informed consent for urological referral and biopsy.

It appears [Dr C] repeated the earlier oversights of her colleagues, and simply requested a further six-month recall.

Finally, the increasingly abnormal PSA test result of 3 December 2018 of 6.32 ng/mL resulted in [Dr F] promptly reviewing [Mr A] and referring him for urology assessment on a semi-urgent basis with high suspicion of cancer.

This, according to the 2015 Guidance, should have resulted in [Mr A] receiving a first specialist appointment (FSA) within 6–8 weeks. The interval between referral on 8 December 2018 and FSA on 26 February was marginally outside the Faster Cancer Pathway target of 62 days but is of no evident clinical significance in my opinion. If this delay is considered relevant, expert urologist opinion should be obtained.

2) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

[The medical centre's] letter of 12 August 2020 states that '*There is no standard internal policy or process related to prostate screening as there is no nationally agreed screening process standard.'*

This is factually incorrect. The 2012 publication *Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce* sets out a series of recommendations that are specifically relevant to this complaint; in particular recommendations 15, 16 and 20.

The 2015 Prostate Cancer Management and Referral Guidance has been endorsed by RNZCGP and other specialist urology and pathology organizations, adopted by DHBs and Primary Health Organisations nationwide, and incorporated into Health Pathways for some years.

As set out in detail above, this document provides specific, clear and detailed guidance on the appropriate management of persistently abnormal PSA results in a man who has specific concerns given his family history; and who has requested and engaged with an individual screening program in view of his elevated risk for prostate cancer.

This guidance has been enhanced with a BPAC decision support tool published in April 2018.

In a further statement [the medical centre] state[s]: '*Each individual is looked at and screened or not depending on numerous factors e.g. age, family history, whether they have symptoms or not, patient wishes (following recommendations of the health pathways).*' [The medical centre] confirm[s] that they have access to the … Health Pathways and hold Foundation and Cornerstone Bronze Accreditation.

Despite having access to [the] Health Pathways, [the medical centre] appears to have been unaware of the specific pathway that should have been actioned in the case of [Mr A] (informed consent for urology referral after two consecutive abnormal PSA results in the absence of red flags or abnormal DRE).

Furthermore, in my opinion there has been a collective failure of clinical governance by [the medical centre], in not meeting the expected standards in relation to patient safety and clinical effectiveness set out in Indicator 9 of the RNZCGP Foundation Standard.[6]

These factors have combined in a manner that could be viewed as materially impacting on a number of [Mr A's] rights under the HDC Code; including but not limited to an appropriate standard of care, effective communication, the right to be fully informed, and the right to make an informed choice or decision.

The opportunity to facilitate early referral and detection of [Mr A's] high-grade prostate cancer should have been available on or around 22 February 2017.

Multiple further opportunities were also missed. An assumption is that this possibly resulted from a misapprehension that the absence of red flags or LUTS reasonably precluded the possibility of prostate cancer.

In fact, the baseline risk for any man under 70 with a PSA > 4.0 ng/mL was in the order of 40%; and [Mr A] had double the risk of a man without a family history of prostate cancer.

As stated in the 2015 Guidance '*generally the higher a man's PSA level, the more likely it is that he has prostate cancer. However,* ***some men will have prostate cancer even in the absence of a raised PSA****'* (emphasis added).

This is essentially the scenario that occurred for [Mr A], he has a large high grade tumour despite having only a slow rising and moderately elevated PSA. The 2015 Guidance algorithm is designed to facilitate detect of such circumstances.

Overall [Mr A] has every reason to be disappointed with the standard of care he has received, and as he notes this is '*doubly disappointing*' in view of his stated efforts to inform the attending practitioners of his significant and highly relevant family history.

In this particular case [Mr A] does not appear to have ever reported any red flag symptoms.

The absence of consistent formal documentation of negative findings for red flag symptoms is disappointing, and while of no material impact in the case of [Mr A], this may indicate a potential systemic issue placing other male patients at increased risk of incomplete assessment for prostate cancer risk.

[6] https://www.rnzcgp.org.nz/Quality/Indicators/Indicator_9_Clinical_governance.aspx

Some aspects of care have been commendable, the nurse led recall system has worked well, [Mr A] has appropriately been offered DRE on two occasions with appropriate consent, each time this examination was normal.

It is also important to note that [Mr A] has a number of significant medical issues, and the first consultation with such a patient, new to the practice, is complex and covered a number of concerns in a limited amount of time.

However, the delay in recording [Mr A's] significant family history, and the apparent lack of awareness of the potential significance of persistently abnormal PSA results has led to repeated missed opportunities to recognise and appropriately act on the evidence available.

The initial failure in managing the first PSA result by [Dr B] is particularly perplexing, given that the laboratory flagged the result of 30 November 2016 as abnormal; as being above the threshold for referral, and provided a direct link to the appropriate nationally agreed clinical guidance:

> *'The elevated PSA exceeds the recommended level for referral (under MOH guidelines). If this is a repeat raised value or in the presence of abnormal DRE or other "red flag" conditions refer to a urologist. For further information refer to the prostate cancer management referral guidance, Sept 2015 document in: http://tinyurl.com/PCA-MOH'.*

[Dr C] had a significant opportunity to intervene appropriately on 27 December 2017, but despite the evidence available to him at that time, does not appear to have been aware of the appropriate action that was required.

In fairness to [Dr C], the PSA result forms of 11 May 2017 and 13 December 2017 contain no additional information or guidance whatsoever, and I would view this departure from a standard of care as somewhat less than the initial departure by [Dr B] who had the benefit of explicit guidance on the laboratory result form of 30 November 2016.

The inconsistency in laboratory reporting has not enhanced [Mr A's] overall care and is addressed further below.

Overall I would view this departure from the standard of care that [Mr A] should have received between 2016 and 2018 as moderately serious — given the multiple points of failure, the serious nature of the underlying health condition, and the length of time taken to finally recognise the implications of the abnormal results.

Against this view is the fact that there was no internal practice policy or guidance on the appropriate management of abnormal PSA testing, and the apparent belief that there is no relevant national standard or guidance. Without this key knowledge, the omissions by individual practitioners were needlessly open to repetition.

Once the significance of the persistently elevated and slowly rising PSA was recognised by [Dr F] in December 2018, the subsequent primary care management has been entirely satisfactory.

3) How would it be viewed by your peers?

In my opinion, and having informally consulted colleagues working across several practices, I believe my peers would also see the collective departures from an appropriate standard of care as significant.

4) Recommendations for improvement that may help to prevent a similar occurrence in future.

[The medical centre]:

a) That [the medical centre] undertake a critical incident analysis — if they have not already done so.

b) That [the medical centre] develop an internal policy for collective management of abnormal PSA results that accords fully with 2015 Prostate Cancer Management and Referral Guidance, and [the] Health Pathway on Prostate Cancer Diagnosis. This would also be informed by consideration of the Reflection points contained in the BPAC National Report: Testing for prostate cancer in primary care.[7]

c) That [the medical centre] consider undertaking a full audit of all elevated PSA results since 2016 in order to ensure that the relevant patients have been safely and adequately managed in accordance with the algorithm outlined on page 3 of the 2015 Prostate Cancer Management and Referral Guidance.

d) That [the medical centre] consider incorporating the Prostate Cancer GP Tool decision support tool[8] which has been available nationally since April 2018. If relevant, Kupe is available as an integrated module in Medtech practice management systems.[9]

If this report contains errors of fact, I would be pleased to provide any necessary corrections.

Yours sincerely

Dr Garry Brown
ED, BHB, MBChB, Dip Obst, PG Dip Bus Admin, FRNZCGP"

[7] https://bpac.org.nz/report/2020/psa.aspx
[8] https://kupe.net.nz/en/about-prostate-cancer
[9] https://bpac.org.nz/2018/prostate-decision-support.aspx#fig1

The following further advice was obtained from Dr Brown dated 15 October 2020:

> "Thank you for your further enquiries. I have reviewed the complaint, the clinical records, and conferred with senior colleagues. My responses are as below.
>
> **[Dr B]:**
>
> [Mr A] has stated 'Every time I deal with a doctor regarding this topic I mention my family history to ensure they are aware that my risk profile is somewhat higher than normal'.
>
> On 30/11/2016 [Mr A] had a new patient first appointment at [the medical centre] with [Dr B]. The GP notes are generally of an excellent standard and cover a number of separate topics including 'request PSA on bloods'; review of poor diabetic control with discussion of possibly starting insulin treatment; high cholesterol; diet; adjustment to medications; re-prescribing of 10 medications. There are a number of complex issues that appear to have been managed skillfully.
>
> However [Dr B] has not recorded any discussion of prostate cancer family history, and in the presence of [Mr A's] above statement, and in the absence of notes to state otherwise it must be assumed that this was overlooked. I would regard this as a mild departure in the context of an otherwise well managed and complex consultation with a new patient.
>
> Equally, regarding the failure to enquire about red flags for prostate cancer I would regard as a mild departure in the context of an otherwise well managed complex consultation with a new patient. My reasoning is that the pending test with abnormal result could not be known at this time, and that PSA in this context was a screening test, not a diagnostic test.
>
> [Dr B] also asked [Mr A] to return for GP review in one month, and this would have provided an opportunity to further discuss the PSA and diabetes test results. I can see no record of any such follow up visit.
>
> There is also no written record of how the PSA result would be communicated to [Mr A]. This may have been discussed, and there may be a practice policy regarding informing patients of their test results — but it is prudent practice to make clear how the result will be communicated, particularly to a new patient attending the practice for the first time.
>
> [Dr B] ordered the PSA test and retains the responsibility for communicating the test result to [Mr A]. The outcome of [Mr A] not being informed of the abnormal result is inappropriate.
>
> Taking all of these factors into consideration I would regard the failure to communicate the result as a mild/moderate departure. I have sought anonymised opinion on this

topic from two vocationally registered senior GP colleagues, one of whom felt it was a mild departure, and the other that it was a moderate departure.

It appears that communication from [Dr B] to nursing staff about setting a recall test did not occur until 23/02/2017, some 3 months later. At this time a repeat test was requested in 3 months time — May 2017. I cannot identify any reason for this long delay in follow up/communication — [Dr B's] brief note states 'I had this on my task list'. This is not an appropriate standard of timeliness, and allowing for the Christmas/New Year period and any leave taken, I would regard this as a mild departure.

The decision to retest the elevated PSA result in six months is clearly that of [Dr B]. The decision to deviate from the guidelines (repeat in 6–12 weeks) could potentially have been justified had any reasoning for doing so been documented, but there is no such record. Had [Dr B] taken the time to check the guidelines advice referred to in the initial laboratory result (weblink), he would have realised that it was more appropriate to repeat the test in February — not in a further three months' time.

However this departure from the guideline resulted in a delay for repeat testing of only 12 weeks, which has limited clinical significance in this context. Given that this was the first test elevated above 4.0 with a relatively short delay in repeat testing I would regard this as a mild departure.

[Dr C]:

11/05/2017 — [Mr A] had a somewhat complex consultation with … (a pharmacist?) covering a number of topics around close control of diabetes testing and diet. Further advice on diabetes management was sought from Dr …

It would appear on a review of the notes that [Dr C] did not have direct contact with [Mr A], but did order the repeat diabetes and PSA blood tests. My apologies for not recognising this in my earlier report.

Observing the reduced PSA result [Dr C] has noted 'PSA 4.8 ok dropping, repeat 6/12 — informed'. The modest reduction in PSA to only just above the upper limit of the normal range (4.0) has reasonably been interpreted as 'ok'. I would not disagree with that view in the context of interpreting a single result.

It seems to me that [Dr C] was unaware of the guidelines and while ignorance is not a defence, given the reduced and very mildly abnormal PSA result I would regard his decision to repeat the test in 6 months as only a mild departure. The failure to refer to a urologist equally reflects a lack of knowledge of the guidelines. I would also regard this as a mild departure at this point in time.

[Dr C] retains responsibility for informing [Mr A] of the test results. Obviously it is appropriate that the result and its significance is communicated to [Mr A].

The written notes clearly state — 'informed' but give no further detail. [Mr A] states he was not informed. Given the contemporaneous written record I cannot see a clear case

of failure to communicate the PSA result of the 11/05/2017. I will leave any further decision in that regard to you.

A more comprehensive written note record of how/what was communicated by way of 'informing' [Mr A] would have been preferable, but at most this would be a very mild departure, and some colleagues would not agree that this is a departure.

29/12/2017 — this is a more significant event, and must be viewed in context.

The first step was the routine recall of [Mr A] by the nurse for the follow up PSA. This was done on 13/12/2017, and had significantly increased to 5.5. The practice appropriately recalled [Mr A] for further assessment and prostate examination (DRE).

I would also note that in his complaint [Mr A] states he was not informed of the result of the test 13/12/2017. He was however recalled in writing for the appropriate DRE assessment, and must have been informed of the test result on 29/12/2017, he has not stated otherwise in his complaint. I do not see a departure in that regard.

On 29/12/2017 [Dr C] saw [Mr A], and obtained a detailed family history of prostate cancer, and carefully enquired about lower urinary tract symptoms (LUTS). This may well have included a question about blood in the urine (macroscopic haematuria).

There are no other records of enquiry about symptoms of metastatic prostate cancer e.g. neurological symptoms, bone pain, renal failure.

Given the absence of abnormal findings on DRE, and negative symptoms on LUTS enquiry on reflection I do not regard this lack of extended enquiry as a significant departure — particularly because [Mr A] did not (to the best of my knowledge) have metastatic prostate cancer.

The written records are of a good standard, [Dr C] has performed a DRE and recorded his normal findings. In hindsight (the registrar examination and MRI imaging) there were no abnormalities of the lower prostate that could have been detected by DRE. I cannot fault any of the above aspects.

The overall significance of the departure to refer is that despite an otherwise mostly excellent process, [Dr C] appears completely unaware of the guidelines and the steps he should take in the presence of two or more (now three) abnormal PSA test results.

The extent of this departure can be viewed in two ways. If his earlier error of 11/05/2017 (resulting from lack of awareness of the guidelines) is regarded as a mild departure, then it would arguably be unfair to regard another error with the same root cause as being of greater significance.

The alternate view is that the increased number of abnormal tests, and now known elevated family history risk, should have triggered closer consideration of the clinical situation.

Possible actions available to [Dr C] at that time would include seeking advice from a practice colleague, or consulting the urology registrar available on call. These omissions could be seen as a moderate departure.

Again these two differing views were presented to two senior colleagues, and resulted in some animated debate. The normal DRE (likely correct) and normal LUTS (also correct) have been weighed against the now known higher risk family history. The outcome also indicates a lack of perception of the relevance of the abnormal family history, and [Mr A's] at least doubled personal risk for prostate cancer.

The combined failure, of not knowing to refer and not acting to consult further in the presence of three abnormal tests and a known family history of increased risk, is on balance a moderate departure.

[Dr D]:

On 27 March 2018 [Mr A] was seen by [the] Clinical Pharmacist, for repeat prescription. He noted 'Seen by GP in December for DRE as PSA slightly elevated. No further concerns. Prescription generated.'

On 16 May 2018 [Mr A] was recalled by a practice nurse for a repeat PSA test ordered under the name of [Dr D], who had not previously been involved in [Mr A's] care.

The result was 5.7 ng/mL (High). Laboratory result form notes 'The elevated PSA exceeds the recommended level for referral under the MOH guidelines'.

This result was filed into the Inbox with [Dr D's] comment 'Biochem; Tumour markers (stable)'. Nurse Inbox comment notes 'Stable. Review if concerns. Pt informed.'

These notes indicate that [Mr A] was likely informed of the test result, and that it was stable and largely unchanged from the previous test of 5.5. The slight variance (5.7 v 5.5) is within the laboratory error of measurement (+/- 5%) and is not clinically significant.

The clinical records indicate that two months earlier (late March) there was an indication from [Mr A] implying unchanged symptoms.

The previous abnormal PSA results were available to [Dr D], together with [Dr C's] notes of the examination and assessment of 29/12/2017. [Dr D's] decisions and actions may have provided her with false reassurance.

Had [Dr D] personally been aware of the guidelines she would have been expected to bring [Mr A] back promptly for further assessment (as [Dr F] did in response to the further abnormal test). [Dr D] did not do so. As outlined above in comments regarding [Dr C], this can be viewed as either a mild or moderate departure.

Given that [Dr D] had no previous contact with [Mr A], and that the results were essentially unchanged from those informing [Dr C's] earlier decisions, the failure to refer supports a mild departure.

However, the absence of [Dr D's] further enquiry or response to the clear prompt in the test result (the elevated PSA exceeds the recommended level for referral under the MOH guidelines), and that this PSA is now the fourth instance of an abnormally elevated result, supports that this is a moderate departure with regard to failure to refer or enquire further.

The adequacy of communication regarding the PSA results of 16/05/2018 is partly reasonable given the information available at that time — an essentially stable PSA result, and the recent clinical report of no new concerns.

However the failure to inform [Mr A] of the information contained in the laboratory result (the elevated PSA exceeds the recommended level for referral under the MOH guidelines) is not reasonable, and represents a moderate departure in communication.

My comments above highlight deficiencies in gathering the available clinical information, and then appropriately interpreting and acting further on the current abnormal PSA result.

Clinical documentation when filing laboratory results is typically brief, and the accuracy and adequacy of [Dr D's] written records has not detracted further from the standard of care provided to [Mr A].

Further comment:

I have undertaken my best efforts to provide a fair and balanced view of the actions of each individual provider given the knowledge that was available to them at the time of each encounter, and without the benefit of hindsight and the now evident diagnosis of prostate cancer.

I can appreciate that from [Mr A's] perspective the overall standard of care he has received is deeply disappointing.

Although I understand the HDC is obliged to consider the actions of individual practitioners, I would again refer you to my previous report describing the systemic failures at [the medical centre] with regard to policy, and practice wide management of abnormal PSA results.

Had an adequate policy been in place, I am firmly of the view that any knowledge deficit on the part of any individual practitioner could have been detected and corrected at a much earlier time. This would also likely have avoided the repetition of previous errors, namely repeatedly setting recalls in 6 months for abnormal PSA results. Having such a policy would likely have led to appropriately earlier urology referral for [Mr A], and to earlier detection of his prostate cancer.

Please let me know if I can be of further assistance.

Nga mihi,

Dr Garry Brown FRNZCGP"

The following further advice was obtained from Dr Brown dated 5 January 2021:

"**Statement:**

This statement is to confirm that I have read, understood, agreed to and followed the Guidelines for Independent Advisors to the Health and Disability Commissioner.

I have no known conflict of interest with any of the individuals or parties involving in the investigation.

Personal Qualifications:

I am a vocationally registered Fellow of the Royal NZ College of General Practitioners; and hold a Postgraduate Diploma in Obstetrics and a Postgraduate Diploma in Business Administration.

I am a currently a practising GP and have worked in general practice since 1987. I have served as a Fellowship Censor, RNZCGP since 2006.

Documents provided:

[Dr C's] response
[Dr B's] response
[Dr D's] response
[Medical centre] response including:
- [Medical centre] Event Reporting, Recording, and Corrective Action Process 2020
- [Medical centre] Quality and Risk Management system 2020
- [Medical centre] Consumer (Patients) Code of Rights Policy
- [Medical centre] Clinical Correspondence Protocol 2020
- [Medical centre] Code of Rights Policy 2015–2017
- [Medical centre] peer group summaries
- [Medical centre] test results and medical report management 2016
- [Medical centre] Code of rights Training attendance record
- Catch All form.
- Notes from Peer Group in September 2015

Instructions from the Commissioner:

Please read all of the responses provided and provide your comments on the responses in particular whether the additional information changes any of the criticisms in your previous reports. If you would like to change your opinion please explain the reasons why.

In addition to looking at each of the individual doctors please also comment on whether the additional information changes any of the criticisms in your previous reports.

[Dr B's] response:

30 November 2016

Not recording the conversation about family history = mild departure

Failure to enquire about red flags = mild departure

> 'I am not sure if the patient mentioned his family history which is possibly why it was not recorded. In essence, I am confirming Dr Brown's supposition that the identification of a family history was overlooked, and in fact the entire discussion about prostate disease was not raised as likely time had run out. In retrospect I probably should have made another appointment for the patient.'

Not informing [Mr A] of the abnormal result = mild/moderate departure.

> 'I agree with Dr Brown that my failure to inform [Mr A] was inappropriate. I cannot remember the exact protocol for informing patients of abnormal test results but accept it is my responsibility.'

Repeat test in 6 months = mild departure.

> 'I was catching up on many BPAC guidelines relating to the common General Practice conditions. I may not have been familiar with the Prostate Management guidelines when I saw this patient.'

Comment:

[Dr B's] report of his return to general practice in 2016 after [a long] hiatus gives context to the difficult situation he faced, in gaining familiarity with all the new or changed guidelines that were published during this period. Changes to prostate cancer screening management would have been but one of a number of such altered clinical guidance across a wide range of important medical fields.

Time management in a first consultation with a patient new to a practice is always challenging. The patient's agenda (in this case several substantial clinical issues) must be prioritized against the health screening processes that are a core part of general practice care. In this case [Dr B] has openly reflected that 'discussion about prostate disease was not raised as likely time had run out'.

[Dr B] has appropriately acknowledged the departures identified, particularly in regard to the responsibility to adequately ensure [Mr A] was informed of the test results.

It would be reassuring to understand that [Dr B] has taken the opportunity to address any gaps in his recollection of 'the exact protocol for informing patients of abnormal test results'.

The provided copy of [the medical centre's] test result policy shows it was first approved on 30 June 2016. In optimal circumstances this should have been available to [Dr B] in his orientation into [the medical centre], even more so if this was his first workplace on returning to clinical practice after [a] hiatus.

[Dr B's] overall response is considered and refreshingly open, containing careful reflection on the comments offered. He has demonstrated an insightful approach to ongoing learning and professional development. His personal response to [Mr A] appears sincere and deeply felt.

There is however one further matter of concern that now arises, and that is the comment entered by [Dr B] attached to the Inbox PSA result recorded on 30 November 2016 at 5:50 pm.

This record states 'Biochem: Tumour markers — 5.13 no red flags repeat 6/12'.

As [Dr B] has now confirmed that 'discussion about prostate disease was not raised', this clearly contradicts the written record of 'no red flags' — unless [Dr B] is mistaken in his recall of the consultation, and did in fact have some discussion with [Mr A] about prostate disease.

The comment 'no red flags' appears to have been misleading and is without apparent factual foundation.

As is evident from his response to HDC, [Dr C] appears to have placed significant weight on the written record of 'no red flags' when formulating his plan to manage the subsequent mildly abnormal PSA test of 11 May 2017.

For [Dr B] to run out of time to address all aspects in a new patient consultation is understandable, particularly if he has recently returned to practice. There are also human factors at play, as the comment was entered at 5:50 pm, presumably at the end of a full day of work.

However, [Dr B] will be disappointed to reflect that recording unsupported significant negative findings has generated significant and unintended consequences for both [Mr A] and [Dr C], adversely altering [Dr C's] subsequent clinical decisions to the further detriment of [Mr A].

In turn, [Dr D] has relied in part on the written records of [Dr C] when making her subsequent decisions of May 2018. No urology referral was made at this date.

Inaccurate written records cannot reflect well on our professional and personal integrity. I would expect that [Dr B] may wish to make further comment in response.

[Dr C's] response:

11 May 2017

Decision to repeat the test in 6 months = mild departure

Failure to refer to a urologist = mild departure.

29 December 2017

Increased number of abnormal tests (3), known elevated history risk and not seeking advice from a colleague or consulting urology registrar = moderate departure

Comment:

[Dr C] outlines his qualifications and training, and that he has successfully been awarded RNZCGP Fellowship on the basis of a recent in practice assessment.

[Dr C] has highlighted that he only saw [Mr A] face to face on the one occasion, at a time when the practice faced a significant GP shortage. He appropriately expresses his sorrow that [Mr A] has developed prostate cancer.

[Dr C] explains that the ordering of relevant diabetes and PSA tests on 11 May 2017 was made in his name, following a review with the clinical pharmacist … This was stated as in accordance with practice policy (that locum GPs do not order recall or screening blood tests).

[Dr C] appropriately acknowledges that the responsibility was his for reviewing the results of this test. In considering the test result of 11 May 2017 [Dr C] states he reviewed the patient notes, saw the previous test result (of 30 November 2016), and that there were 'no red flags recorded on his previous visit.'

I am uncertain if [Dr C] has been made aware of [Dr B's] response to HDC, but this clearly states 'discussion about prostate disease was not raised as likely time had run out'.

Therefore, [Dr C] appears to have been materially misled by [Dr B's] previous comment 'no red flags'.

In reading [Dr B's] notes of 30 November 2016, [Dr C] had the opportunity to observe that there is absolutely no record of any discussion about prostate symptoms or the presence or absence of red flags.

This inconsistency may have given other practitioners pause for reflection, but [Dr C] is reasonably entitled to accept that what his colleague has written in the notes is an accurate record of events.

Regrettably, we now know that there was no factual basis for the written record of 'no red flags'.

[Dr C] has stated he is aware of the relevant information about prostate cancer screening in men.

I am not completely certain if [Dr C] means he is currently aware of the relevant information; or that in fact he was aware of the relevant information in 2017 — at the time of his decision making with regard to [Mr A].

My previous assumption was that in 2017 [Dr C] was probably unaware of the relevant guidelines, as the most logical explanation for why he did not follow the guidelines.

If I interpret [Dr C's] current response 'As I mentioned, I am aware of the processes for referring elevated PSA results' to mean he was aware of the relevant guidelines in 2017 — then most colleagues would expect that any decision to depart from the nationally agreed guidelines would be supported by full and adequate documentation of his clinical reasoning; and documentation that he had sought and gained [Mr A's] consent in an informed discussion about such matters.

[Dr C] does accept that he has departed from the 2015 Guidance by setting a six-month recall, and acknowledges that 'with hindsight I accept that I should have recalled [Mr A] to have a DRE and set the repeat PSA test for 3 months rather than 6 months.'

This hindsight acceptance does not fully reconcile with the stated awareness of the processes for referring elevated PSA results.

Certainly [Dr C] has reason to be disappointed that his reliance on his colleague's inaccurate written record of 'no red flags' (attached to the previous PSA Inbox result of 30 November 2016) was misplaced.

However [Dr C] does not appear to have reflected on the fact that his decision of 11 May 2017, whether correct or otherwise, was made entirely without any discussion with [Mr A].

[Dr C] does not acknowledge that the second abnormal PSA result could have triggered consideration of referral to urology at that time. He does however discuss this in relation to the consultation of 29 December 2017, noting that he had previously experienced rejection of referrals 'by [the DHB] if there are drops in the elevated PSA and there are no other red flags or an abnormal DRE.'

He therefore states he considered it 'prudent to obtain two tests in a row which showed an increasingly elevated PSA. I should have put this recall at 6–12 weeks though, rather than 6 months. I apologise for this error in setting the recall.'

The repetition of the mistake in setting the recall for six months, rather than 6–12 weeks, again detracts from [Dr C's] strongly stated awareness of the referral guidelines.

I accept that declined referrals from DHB services are a frustrating fact of GP life, reflecting an overburdened and under resourced health system.

However, after examining [Mr A], if [Dr C] had made a urology referral, then from a GP perspective his care would have been above reproach.

The burden of managing the risk and clinical uncertainty in [Mr A's] case would have fallen to the DHB urology service. As previously noted, a telephone discussion with the urology registrar about possible referral would have also been an appropriate option.

It is positive to read that [Dr C] has reflected on and changed his practice and management of elevated PSA results; and that he has also reflected on his standard of record keeping and sought to make improvements where necessary.

[Dr C] has described discussion with [Mr A] on 29 December that 'because of his family history [Mr A] should have annual DREs and PSA tests …'

However, there is no documentation or subsequent description of any discussion with [Mr A] around difficulties in making referrals to [the DHB]; of other treatment paths available for [Mr A] to consider (e.g. earlier repeat testing, second opinion, self-funded referral or MRI imaging); or that [Mr A] consented to the decision made on his behalf.

[Mr A] knew that his father had died prematurely of prostate cancer. [Dr C's] knowledge of the 2015 guidelines should have made him aware that this family history gave [Mr A] at least a doubled risk for prostate cancer at an earlier age. Having this fact available makes the subsequent decision to postpone further action for six months even more puzzling.

We now know in hindsight that [Mr A] likely had prostate cancer in 2017, and that the test of December 2017 was his third mildly abnormal PSA result. [Mr A] was reasonably entitled to be informed and involved in any discussion about options for further investigation that could materially affect his future health.

I am not certain that this point has been fully appreciated by [Dr C], who has concentrated his response on his medical decision-making considerations without really addressing the issue that significant decisions were made for [Mr A], rather than with or by [Mr A].

In the interests of balance, I would also support [Dr C's] inference that I do consider many aspects of the consultation of 27 December 2017 to be accurate and of an appropriate clinical standard, including his physical examination findings.

Furthermore, I commend [Dr C's] dedication and valued professional contribution to the local practice population, as I understand he is the only GP involved in this complaint still working at [the medical centre].

[Dr D's] response:

16 May 2018

Failure to refer to a urologist = mild departure.

Absence of further enquiry or response to the clear prompt in the test result, 4th elevated PSA result = moderate departure.

Failure to inform [Mr A] of the result = moderate departure.

Comment:

[Dr D] has provided a detailed two-page response. Her distress, and empathy for [Mr A's] situation is evident, even though she has not personally met [Mr A]. [Dr D] provides further context to the 'systems factors' at work during the period 2015–2018; with the retirement of senior colleagues, the turnover of locum GP staff, and the considerable disruption involved in switching practice management systems in April 2018. This would have had a real impact on accurate and timely day to day workflow for all practitioners during that period.

In addition [Dr D] has clarified that the relevant PSA test was generated by a nurse under the name of any salaried GP (a practice wide process), not at [Dr D's] personal directive.

[Dr D] gives a clear account of the process she undertook in managing the PSA test result generated under her name, and I would agree that the notes and actions of her colleagues could easily have provided false reassurance.

While agreeing with the risks for false reassurance, [Dr D's] conclusion that no additional action was required remains invalid, and does not reconcile with full awareness of the relevant guidelines at that time. This is disappointing, in that [Dr D] has completed her [overseas] based GP training in 2014, and was on the cusp of successfully attaining her vocational registration as a GP in New Zealand ([2016]).

It is reassuring to read of the changes in [Dr D's] practice and management of prostate cancer screening in men, and that this has been informed by a detailed re-examination of the relevant guidelines and closer vigilance in regard to elevated PSA test results. This has been incorporated into her ongoing professional development. [Dr D] has also reflected that an opportunity was overlooked to offer [Mr A] a face-to-face appointment and discussion of the persistently elevated PSA results.

These learnings have been adequately addressed.

Wirth regard to communication, I accept that [Dr D] had asked the nurses to inform [Mr A] of the result, which was reasonable in the context of her conclusion that [Mr A's] symptoms and results were stable.

Given the context that [Dr D] did not see [Mr A], and the multiple system factors at play in April 2018 detracting from provision of continuity of care, I would revise my previous opinion to state that the failure to inform [Mr A] of the result was a mild departure.

I would commend [Dr D's] professional and empathetic response. The departures identified would appear unlikely to re-occur in the future.

Other matters:

[Dr B] was acting as a locum doctor when seeing [Mr A]. It has been stated that practice policy was that locum GPs should not order laboratory tests. Both [Dr C] and [Dr D] state they are not [Mr A's] usual doctor; with [Dr C] only seeing [Mr A] on a single occasion,

and [Dr D] not at all. In between times [Mr A] has had visits with two different clinical pharmacists, who cannot order funded laboratory tests. The PSA and other test recall process was run (very efficiently) by the practice nursing team.

I acknowledge the turnover of senior GPs, major changes to practice management systems, and the GP shortage often filled with locums. Yet it is not at all clear where the clinical responsibility sits within [the medical centre] for ensuring that the results of [Mr A's] PSA recall process were managed in an accurate and timely way.

It is clear that this did not occur in [Mr A's] case for a number of reasons; with multiple smaller errors, inaccuracies and omissions contributing to a significant delay before making appropriate referral for urology investigation.

Given his [long] hiatus from clinical practice it is not surprising [Dr B] may not have been fully familiar with the 2012 and 2015 guidelines. The fact that time was not available to discuss PSA testing at the new patient appointment is also not entirely surprising, given the otherwise thorough processes demonstrated by [Dr B] in addressing several important and complex medical issues.

However, in recording 'no red flags' against the first PSA screening result false reassurance has been generated, and a series of unintended adverse consequences has resulted.

[Dr C] has relied on the 'no red flags' in formulating his own management plans of 2017. These plans departed from accepted best practice guidelines.

In 2018 [Dr D] has concluded no additional action was required; by partly relying on [Dr C's] unremarkable examination findings (which were accurate), and also in relying on and replicating [Dr C's] plan to repeat [Mr A's] PSA in 6 months (which was not consistent with best practice advice).

Overall, there was little continuity of care available to [Mr A], and this created a degree of clinical risk for [Mr A], and also for the various clinicians undertaking their best efforts to provide care in a complex and challenging environment. This risk was not fully appreciated, and was not effectively communicated to [Mr A], who was blind to the majority of clinical decisions made on his behalf.

Risk monitoring and risk management are properly the domain of clinical governance at a practice owner level.

[Dr E], Clinical Director of [the medical centre], has provided a detailed and considered response to my comments in this regard.

[Dr E] has provided context setting out challenges facing all practices within the group in accessing relevant best practice pathway guidance when using the Map of Medicine — and that the much more user-friendly Health Pathways system has only been

available for the past 18 months (e.g. prior to the timeline of the majority of consultations under consideration in this complaint).

[Dr E] further confirms that there was a change in practice management systems in April 2018. Having personally experienced three such system changes I cannot overstate the significance and initial adverse impact of this process on daily clinical workflow.

[Dr E] further outlines that due to technical IT issues with PMS integration with the BPAC prostate cancer screening tool — apparently as the vendor (Indici) state they do not have an application processing interface (API) to support integration with the BPAC screening tool. The absence of an effective integration in regard to PSA cancer screening and test management detracts from the ability of practitioners to provide optimal patient care.

I would note that Indici have reportedly achieved considerable market share in the general practice PMS vendor space, and that the BPAC integration issues described by [Dr E] will also be affecting practices in many other regions.

Although [Dr E] has described a practical local workaround by recommending that all [medical centre] clinicians use the Kupe website, HDC may wish to consider making further enquiries with both BPAC and Indici, as it would appear that other PMS vendors have successfully overcome this technical challenge.

I fully accept [Dr E's] point that [the medical centre] has not yet had the opportunity to be assessed against the current Foundation Indicator 9 standard introduced in mid 2020, and I apologise for my error in this regard. While [Dr E] is factually correct, it is also very clear that the underlying principle around opportunities for improvements in clinical governance has been fully accepted and addressed.

[Dr E] has outlined in detail that multiple steps have been taken to address specific issues raised. I would agree with her comment that the recall process at [the medical centre] appears excellent, and that individual clinicians have veered away from the standard guidelines for when this recall should have been undertaken. While each clinician must bear some individual accountability, they cannot be held responsible for the 'sum of the parts' that have directly impacted on [Mr A].

[Dr E] comments that [Dr B] made some decisions in managing recalls that are not within the current standard of practice regarding recalls.

I would draw [Dr E's] attention to my comments above regarding the importance of orientation to [the medical centre's] test result policy (approved 30 June 2016) as part of [Dr B's] overall orientation to [the medical centre] — particularly if this was his first workplace on returning to clinical practice after [a long] hiatus.

Please be clear that I have no knowledge of any detail around the orientation process for [Dr B] at [the medical centre], but simply offer this observation as a quality assurance

suggestion in light of [Dr B's] own statement that he 'did not recall the exact protocol for informing patients of abnormal test results'.

[Dr E] has discussed previous limits in formal incident/complaint reporting processes at [the medical centre], and has provided confirmation of a revised and standardised process across [the medical centre], and various steps to implement that process.

With regard to improving management of abnormal PSA test results [Dr E] confirms [the medical centre] agrees with the suggested need to develop a policy and protocol for the collective management of all abnormal PSA results obtained through screening and recall processes.

Implementation is planned across all … sites alongside an education session opportunity for all clinical staff members regarding PSA testing and screening for prostate cancer. Also, in a positive light, this protocol will be recommended across the [medical centre's] health network (PHO).

I am sure HDC would be interested to view a copy of this protocol in due course.

Coupled with this new practice protocol there is planning for a prostate cancer information and education programme, aimed at relevant male patients across the … practices.

I would commend the various steps set out by [Dr E] on behalf of [the medical centre] as a professional, thorough, and comprehensive approach to both improving systems and processes, and to supporting patient and provider education on prostate cancer.

There is also a clear expression of intent to monitor and evaluate these changes for their clinical effectiveness and impact on patient care. Furthermore there is a programme of work in place for improvement to clinical governance and quality management.

I would also hope that [Mr A], informed by his November meeting with [Dr E] and [the medical centre], is encouraged by these changes aiming to ensure that no other male patient goes through his experience.

Finally I would wholeheartedly agree with [Dr E] that it is important that there is feedback provided to [the medical laboratory] regarding standardised reporting of abnormal PSA results and having a link to the relevant guidelines for management — this no doubt would have helped to reduce some of the delays that have happened in this case where several of the results did not have the clinical interpretation and reference to the MOH guidelines link in them (as they did in the first result).

Any such feedback is not criticism, but reflects the fact that laboratory providers are health practitioners who play a vital role in patient care, and that there is an opportunity to further enhance patient care and reduce unwanted opportunities for human error.

If this report contains errors of fact, I would be pleased to provide any necessary corrections.

Yours sincerely

Dr Garry Brown
ED, BHB, MBChB, Dip Obst, PG Dip Bus Admin, FRNZCGP"

The following further advice was obtained from Dr Brown dated 10 March 2021:

"Thank you for your email, and for forwarding [Dr B's] further response of 28th Jan 2021.

[Dr B] has clarified that the written entry annotating the initial PSA result with 'no red flags' was not based in fact, and did not reflect any discussion or enquiry with [Mr A].

The action of recording significant negative findings in such circumstances is a departure from a reasonable standard of practice, and in my opinion would be at least a moderate departure.

The unintended consequences of this action have been significant, and have likely influenced the subsequent actions of [Dr C] and [Dr D], at least in part.

[Dr B] cannot have known that these future events would occur, and he cannot be responsible for the actions of his colleagues, but the above departure has contributed significantly to the overall adverse outcome for [Mr A].

Some colleagues may see the actions of [Dr B] as a moderate to severe departure, given that we all rely on the accuracy and integrity of the written record. [Dr B] himself openly acknowledges that 'making this comment without a factual basis, is poor note taking and would reflect badly upon myself and the wider profession'.

My reasons for viewing the departure as moderate reflect some potential mitigating factors.

These centre around the fact that [Dr B] had just returned to general practice, after a very long hiatus of [several] years.

There were many new changes and systems to contend with, and [Mr A] presented new to the practice with several important medical issues to be addressed (diabetes, hypertension, cardiovascular risk, medication). All of these were managed appropriately.

[Dr B] admits running out of time in the consultation, and has made his decision to (inaccurately) annotate the PSA result at 5:50 pm, at the end of what would have likely been a challenging day.

> Furthermore [Dr B] is open and professional in his responses, and has clearly reflected on these events and engaged in discussion with a peer supervisor.
>
> I hope that these comments are of assistance to yourself and the Commissioner.
>
> Kind regards
>
> Garry Brown
> ED, BHB, MBChB, Dip Obst, PG Dip Bus Admin, FRNZCGP"

The following further advice was obtained from Dr Brown dated 6 July 2021:

> "The 2012 Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce was effectively superseded by the 2015 Ministry of Health updated Prostate Cancer Management and Referral Guidance.
>
> The 2015 guidance was formally endorsed by a number of organisations including the Royal New Zealand College of General Practitioners, the Prostate Cancer Foundation of New Zealand, the Urological Society of Australia and New Zealand and the New Zealand Society of Pathologists. The 2012 Recommendations had not been so endorsed.
>
> My advice is that the 2015 Prostate Cancer Management and Referral Guidance is the appropriate standard to reference, and that at the time of [Dr B's] first consultation with [Mr A] on 30/11/2016 the 2012 Recommendations were no longer valid or in use.
>
> Ngā mihi
>
> Garry Brown"

The following further advice was obtained from Dr Brown dated 9 July 2021:

> "I can see why the laboratory form is confusing. In my opinion the lab form result refers (unhelpfully) to both the 2012 Taskforce recommendations and the 2015 Prostate Cancer Referral and Management Guidance. If you follow the web link cited on the result form http://tinyurl.com/PCA-MOH it does open the September 2015 guidelines.
>
> I cannot speak for the laboratory in question, but it seems to me that they have simply added references to the Sept 2015 guidelines after the existing text on their PSA result forms — which likely previously contained the first paragraph referring to the 2012 Recommendations from the Prostate Cancer Taskforce.
>
> This does create some potential confusion, but I stand by my earlier advice, that the correct actions for [Dr B] to consider at the time he ordered the PSA test was appropriately set out in the Sept 2015 guidelines, and had he simply followed the link contained on the lab form, this information would have been readily available to him.

I don't believe [Dr B] can be criticised in 2016 for not referring [Mr A] on receipt of the initial PSA result, which was historic advice based on outdated Taskforce recommendations.

I do hope this is helpful, and please don't hesitate to follow up with any questions you may have.

Kind regards

Garry"

Appendix C: Relevant policies

The medical centre's "Test Results & Medical Report Management Policy" dated 30 June 2016 stated:

"**Follow up of abnormal/normal results**

If urgent and immediate action is required it is up to the GP to notify the GP Nurse/phone nurse of this and the actions required. If abnormal but not acute, instructions of what needs to be done is placed in nurse provider inbox. The nurse decides (unless specified by the requestor) whether to phone or send a letter to the patient. The result remains in the inbox until such time as complete instructions have been fulfilled. If a letter is sent to the patient then the results remain in the inbox until the patient has fulfilled instructions.

If a patient is contacted over the telephone to discuss either a normal or abnormal/ urgent result, the nurse indicates in the inbox that the patient has been contacted and instructions given. The audit section of the result will record the date, time and by whom has done this.

Should a patient not respond to a recall, a second point of contact is made, usually a different method than the first and notes entered in the daily record about no-response so that the next person who deals with this patient can action the instructions. All attempts of contact should be documented in the notes with date, time and by whom.

…

Patient notification

The system for notification of results is explained to patients by the Requestor at the time of the consultation. The most appropriate method of notification required is discussed with the patient. Expected timeframes are outlined.

Patients are advised they will be contacted if the result is abnormal.

If a result is normal and/or no further action if required, the patient will not be generally contacted. However, if it is a circumstance where a normal result is significant enough for the patient to be contacted, the Requestor will contact them or forward it to the nurses (as above) to notify the patient.

…

Patients are advised that if they want to know the outcome of their test they can ring and leave a message to the Nurses answer phone and will be followed up in a timely manner.

There is notification of our process for giving out test results in the patient hand out (given to new patients). It is also written on the bottom of the laboratory form and notices placed throughout surgery.

…

Tracking test results and medical records

Any test that the provider (including cervical smears) deems important will have a patient task set on them or be active on Alert System via Medtech to notify the provider if the test result has not been returned. We also encourage patients to follow up on urgent results.

…

General test management issues

Any new staff or locums will be made aware of the test management policy (in orientation folder) by the clinical manager."

Appendix D: Relevant standards

The Ministry of Health Prostate Cancer Taskforce (2012) *Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce* states:

> "**Recommendation 15:**
>
> Primary health care should provide high-quality, culturally appropriate information on prostate cancer and PSA testing to men aged 50 to 70 years.
>
> All men who are concerned about prostate cancer or are requesting a PSA test must be presented with high-quality, culturally appropriate information.
>
> **Recommendation 20:**
>
> 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."

The Ministry of Health *Prostate Cancer Management and Referral Guidance* (2015) states:

> "1.2. Family history
>
> A man is defined as having a family history of prostate cancer if he has at least one first-degree relative (father or brother) who was diagnosed with prostate cancer. Men with a family history of prostate cancer are twice as likely to develop the disease than men without a family history. If a man has two or more first-degree relatives who were diagnosed with prostate cancer under the age of 65 years, then his risk increases by 5–11 times (Steinberg et al 1990).
>
> Note 2: Prostate specific antigen (PSA) testing
>
> 2.2. The relationship between age, PSA level and prostate cancer.
>
> Generally the higher a man's PSA level, the more likely it is that he has prostate cancer (Heidenreich 2008). However, some men will have prostate cancer even in the absence of a raised PSA (Thompson et al 2004).
>
> …
>
> Increased PSA levels can be transient, which is why men should always have a repeat PSA test after 6–12 weeks to confirm the result.

…

If a man's PSA level is between 4.0 µg/L and 10.0 µg/L, there is a 40 percent chance of detecting prostate cancer on prostate biopsy (Leinert et al 2009).

…

Table 1: Definitions for an abnormal PSA level, by age

Age group	Abnormal PSA level (µg/L)
Men aged ≤ 70 years	≥ 4.0
Men aged 71–75 years	≥ 10.0
Men aged ≥ 76 years	≥ 20.0

…

Table 3: Criteria for referral to a urology or radiation oncology service

Type of referral	Criteria
Routine referral (should be seen within 6–8 weeks)	• PSA is between 4 and 10 µg/L AND macroscopic haematuria is present (in the absence of infection) • PSA is < 10 µg/L AND prostate feels hard and/or irregular on DRE • Two clearly abnormal PSA results 6–12 weeks apart (see Table 1 on page 8 for definitions of a clearly abnormal PSA)

Note 5: Follow-up options after a normal PSA and DRE

5.1. Follow-up options for men with a family history of prostate cancer

As noted in section 1.2 a man is defined as having a family history of prostate cancer if he has at least one first-degree relative (father or brother) who was diagnosed with prostate cancer. Although there is no strong evidence to support how often to test men with a family history of prostate cancer, best practice suggests that these men should be offered a PSA test and DRE every 12 months from the age of 40–70 years.

…

> Integrating this guidance into routine clinical practice
>
> District health boards and primary health organisations are responsible for integrating this guidance into their clinical pathways for prostate cancer in a way that reflects the particular needs of their patients and communities."

The region's Community Health Pathways state:

> "Elevated PSA on 2 or more tests to less than 100micrograms/L, request non-acute urology assessment for prostate biopsy (within 8 weeks)."