HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Inadequate monitoring and interpretation of PSA results led to delayed diagnosis of recurrent prostate cancer

(Case 23HDC00728)

Contents

Introduction

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

2. The report discusses the care provided to Mr A by general practitioner (GP) Dr B at a medical centre. Mr A raised concerns about the inadequate monitoring of his prostate-specific antigen (PSA)[1] levels, leading to a delayed diagnosis of recurrent prostate cancer. I am very sorry to hear of Mr A's diagnosis, and I extend my sincere sympathies to Mr A and his whānau during this difficult time.

3. The following issues were identified for investigation:

- *Whether [Dr B] provided [Mr A] with an appropriate standard of care from January 2013 to October 2022 (inclusive).*

[1] A protein produced by normal and malignant cells of the prostate gland. Prostate cancer, as well as other conditions, can cause PSA levels in the blood to increase.

- *Whether [the medical centre] provided [Mr A] with an appropriate standard of care from January 2013 to October 2022 (inclusive).*

4. The parties directly involved in the investigation were:

Mr A	Complainant
Dr B	Provider/GP
Medical centre	Group provider

5. Further information was received from urologist Dr C.

6. To assist my consideration of the care provided, in-house clinical advice was obtained from Dr David Maplesden, a vocationally registered GP (Appendix A).

Information gathered during investigation

Background

7. Mr A had seen Dr B for GP care for approximately 20 years, although Dr B noted that Mr A presented infrequently during this period due to being in generally good health.

8. PSA testing arranged by Dr B in 2012 showed that Mr A had a raised PSA level of 9.4µg/L.[2] Mr A saw urologist Dr D for further investigations, and in August 2012 he was diagnosed with prostate cancer.

9. Dr D advised Mr A that a radical prostatectomy[3] would be the most appropriate treatment option. Accordingly, Mr A was referred to Dr C, a urologist, who was experienced in performing this type of surgery. The radical prostatectomy was completed on 10 October 2012. Treatment was considered to be successful, and Mr A's PSA level was not detectable in testing completed on 14 January 2013.

10. On 28 January 2013 Dr C saw Mr A for his three-month post-surgical appointment. In a clinic letter to Dr B dated the same day as the appointment, Dr C advised:

> '[Mr A] should continue with six monthly PSA checks and if the level ever becomes detectable (greater than 0.05ng/mL)[4] then I would like to see him again. At this stage I have not made any further appointments for him.'

Further urology follow-up and care

11. Further PSA testing was ordered by Dr C in July 2013 and January 2014. Mr A's PSA levels remained undetectable.

[2] The commonly accepted normal PSA range for men without a history of prostate cancer is 0.00 to 3.99µg/L.
[3] Surgical procedure to remove the entire prostate gland.
[4] The unit of measure of 'ng/mL' is equivalent and interchangeable with 'µg/L', which is used throughout this report.

12. Dr C saw Mr A on 10 August 2013 and 1 February 2014 for further post-surgical follow-up, including discussion of erectile dysfunction and an incidental right-sided hydrocele.[5] Surgery was planned to repair the hydrocele, but Mr A decided not to go ahead with it at that time.

13. In 2016 Mr A's hydrocele was causing him more discomfort. He saw Dr C on 24 November 2016 and surgery for repair was discussed. Surgery was completed on 16 February 2017.

14. Dr C told HDC:

> '[I saw Mr A] on several occasions after the three month [post-surgical] appointment. These additional appointments were to discuss his erectile dysfunction and hydrocele. On these occasions I ensured that he had an up-to-date PSA [test] and that it was undetectable.'

15. Dr C acknowledged that he continued to see Mr A following the three-month post-surgical appointment of 28 January 2013. However, Dr C told HDC that he considered he had formally transferred responsibility for Mr A's ongoing PSA surveillance to Dr B in his letter dated 28 January 2013. Dr C said: 'I advised Dr B in my letter that I was not planning to see Mr A again and that he required a PSA check six monthly going forward.'

16. Dr C's clinic letters to Dr B from 1 February 2014 onwards do not make reference to Mr A's PSA levels.

GP surveillance and management of PSA following Mr A's radical prostatectomy[6]

17. On 29 January 2013 Dr B completed the following note:

> '[L]etter from [Dr C] noting undetectable PSA. (letter includes that should continue six monthly PSA checks and if level ever becomes detectable (greater than 0.05ng/ml) then would like to see him again).'

18. It appears that Dr B did not set up a recall or alert for regular PSA testing for Mr A at that time.

19. Mr A told HDC that the medical centre 'would text [him] annually to tell [him] to go and get a blood test'. He said that he was unaware of Dr C's instructions for six-monthly PSA testing, and did not make contact with the medical centre to request testing.

20. Dr B told HDC:

> '[Mr A] underwent a regular blood test to check his PSA levels. This took place annually following his discharge in 2018 from the care of the Urologist.
>
> …

[5] Collection of fluid around the testicle causing swelling.
[6] A full table of Mr A's PSA testing dates and results is set out as an appendix to Dr Maplesden's clinical advice, and this information is also outlined at paragraphs 23 to 29.

> [Mr A] would contact the medical practice once per year to seek blood test forms to enable him to have his PSA and lipids checked. This was led by [Mr A], and, we assumed, his urologist.'

21. In a later response to HDC, Dr B stated:

> '[T]here was a recall for annual PSA & lipid bloods inserted 3/6/14 by nurse …; updated 8/3/18 by nurse …. This meant that [Mr A] was sent a blood test [form] and advised to do the blood test so his PSA levels could be checked.'

22. Dr B told HDC that the medical centre's recall system between January 2014 and March 2018 'was not working at optimal performance'. This was due to organisational changes, including the amalgamation of three medical practices, high staff turnover, and software system changes. Dr B stated: 'These significant concurrent changes created substantial challenges in maintaining continuity of established systems, including the PSA recall programme.'

23. Following Mr A's radical prostatectomy, Dr C ordered PSA tests on 14 January 2013, 18 July 2013, and 13 January 2014. None of these tests returned a detectable PSA result.

24. It appears that no PSA testing was requested for Mr A in 2015.

25. On 19 July 2016 Mr A completed a PSA test requested by Dr B. The result was <0.03µg/L.

26. No PSA testing was completed in 2017.

27. Dr B ordered PSA testing for Mr A from 2018 onwards and the results are as follows:

- 8 March 2018: 0.08µg/L;
- 4 September 2019: 0.10µg/L;
- 18 September 2020: 0.18µg/L; and
- 4 October 2021: 2.74µg/L.

28. From 2018 onwards, Mr A's PSA levels exceeded 0.05µg/L, and therefore met Dr C's recommendation for re-referral. No action was taken by Dr B or the medical centre upon receipt of these results.

29. PSA testing ordered by Dr B and completed on 21 October 2022 showed a result of 67µg/L. At this point Dr B noted that Mr A's PSA level was 'out of the normal range and significantly higher than the previous recorded result'. Dr B notified Mr A and saw him on 28 October 2022 to discuss the result. Subsequently Mr A was referred for further investigations and it was found that he had recurrent prostate cancer with widespread skeletal metastases.

30. It appears that the PSA tests ordered by Dr B from 2016 onwards did not request that the result be copied to Dr C.

31. Dr B told HDC that he was aware of Dr C's instructions to test Mr A's PSA level every six months, and to make a referral if levels became detectable (greater than 0.05µg/L). Dr B noted:

> 'The blood tests took place annually, not on a six-monthly basis, and the level was recorded as being higher than the limit ascribed by the urologist. We did not draw this to the urologist's attention having assumed he was well equipped to review these results and take the appropriate steps.'

32. The medical centre also stated that Mr A could access his PSA test results by contacting the practice or accessing his clinical records. Dr B told HDC that Mr A was registered on the patient portal system on 1 June 2018, from which point he was able to access his test results.

33. In contrast to Dr B's earlier statements in which he advised that he was aware of Dr C's instructions for PSA surveillance, he provided the following statement in a later response:

> '[Mr A] was advised to go back and see [Dr C] if the PSA was ever detectable again. [Mr A] never mentioned this to me. He never informed me that he was supposed to go back and see the urologist if ever his PSA was detectable again or that he was meant to do a blood test every six months. It is surprising that [Mr A] did not mention these aspects to me given the level of attention he pays to his healthcare, he is considered to be very health literate.'

34. Dr B also told HDC that Mr A was aware of what would be considered an abnormal PSA result in his circumstances.

35. Mr A stated that it was his understanding that the medical centre would monitor his PSA levels through regular blood tests, and he 'believed the [PSA] results would be assessed [by the medical centre] and [he] would be advised if there were any problems'.

36. Dr B told HDC that no action was taken on the PSA results received before 21 October 2022 because they all fell within the normal range of 0.00–3.99µg/L and accordingly were marked as 'normal' by the reporting pathologist. According to Dr B, it is the medical centre's protocol to take further steps, including to inform the patient, only if results are marked as 'abnormal'.

37. The PSA request forms generated by the medical centre do not contain any clinical details, meaning that the reporting pathologist was not aware of Mr A's history of prostate cancer or Dr C's instructions.

38. Dr B told HDC that every week he receives between 400 to 600 documents that require his review. As the sole working director at the medical practice, he is also required to review documents on behalf of other doctors when they are on leave. Dr B told HDC:

> 'With a view to achieving some efficiency, blood test results that fall within the prescribed normal range (as prescribed by the Prostate Cancer Foundation and Cancer Council Australia guidelines and the European Society for Medical Oncology Guidelines

> 2020), as recorded by the Pathologist, have minimal attention given to them. It is only when the Pathologist reports the results as being abnormal that we consider a treatment plan for the patient, including the steps to communicate these abnormal results.'

39. Dr B and the medical centre provided the lower North Island HealthPathways[7] guidance on prostate cancer screening. Relevant excerpts from the section titled 'Prostate Cancer Follow-up Post-treatment' include:

> 'Check prostate specific antigen (PSA) every 6 to 12 months for the first 5 years [following prostate cancer treatment].'
>
> 'Manage PSA progression. Request non-acute urology assessment if the patient: is post-radical prostatectomy with 2 consecutive PSA values > 0.2 ng/mL, taken 3 months apart.'

40. Dr B told HDC that he has reflected on his actions, and '[he] believe[s] [he] managed Mr A's medical situation appropriately and in a way that best looked after him'. However, in a later response Dr B acknowledged that there was an oversight when reviewing Mr A's PSA results. Dr B and the medical centre have made several changes since these events to prevent a similar situation from happening again. These changes are set out later in this report.

Relevant standards

Best Practice Advocacy Centre (bpac^{nz})[8] — following up prostate cancer in primary care

41. The bpac^{nz} guideline dated October 2012 provides the following recommendation on frequency of PSA testing for men in Mr A's circumstances:

> 'Men who have undergone radical prostatectomy or radiotherapy should have their PSA level checked: Six weeks after treatment (unless adjuvant hormonal treatment is being given). At least every six months for the first two years. Then annually.'

Responses to provisional opinion

Mr A

42. Mr A was given the opportunity to respond to the 'Information gathered during investigation' section of the provisional opinion. Mr A told HDC that he is reassured that Dr B and the medical centre will check blood test results more thoroughly in future, which will benefit others.

Dr B

43. Dr B was given the opportunity to respond to the provisional opinion. He advised that he had nothing further to add.

[7] Regionally specific guidelines used by clinicians to assist with assessment, management, and referral to specialist services for over 600 health conditions.
[8] An independent organisation that advocates for best practice in healthcare treatments and investigations.

The medical centre

44. The medical centre was given the opportunity to respond to the provisional opinion. The medical centre confirmed that it had no further comment.

Opinion: Introductory comment

45. Again, I extend my deepest sympathies to Mr A for his diagnosis, and I acknowledge the ongoing distress he and his whānau would be experiencing as a result. I appreciate that Mr A's desired outcome is for Dr B and the medical centre to improve practices when reviewing blood test results so that this situation is not repeated. I commend Mr A for his wish to improve services and help others by making this complaint.

46. As healthcare providers, Dr B and the medical centre are responsible for providing services in accordance with the Code of Health and Disability Services Consumers' Rights (the Code).[9] They had a duty to deliver services to Mr A with reasonable care and skill. This includes the responsibilities of the individual doctor, and the wider organisational duty to ensure that reasonable care is provided, and that there are appropriate systems and resources in place to achieve this.

47. In October 2012 Mr A received radical prostatectomy surgery to treat his prostate cancer. Following surgery, Mr A's urologist, Dr C, instructed Dr B to undertake six-monthly PSA testing, and to re-refer Mr A should his PSA levels ever become detectable again (greater than 0.05µg/L). Despite this advice, Dr B and the medical centre did not adhere to the recommended surveillance schedule, and did not re-refer Mr A for urology review once his PSA levels became detectable.

48. In forming my opinion on the care provided by Dr B and the medical centre, I have considered responses from all relevant parties and the advice of my in-house clinical advisor, GP Dr David Maplesden, whose advice is incorporated below.

Opinion: Dr B — breach

Recall for PSA testing

49. Upon receipt of Dr C's letter dated 28 January 2013, Dr B made a note in Mr A's clinical file. The note, dated 29 January 2013, acknowledges Dr C's instructions to undertake six-monthly PSA surveillance, and to re-refer Mr A if his PSA levels became detectable again. However, a recall for PSA testing was not set up until 3 June 2014, and it was set for annual rather than six-monthly testing.

50. Dr Maplesden advised that accepted practice in this circumstance would have been for Dr B to set up a six-monthly recall at the time of receipt of Dr C's letter. However, it would also have been acceptable to set up a recall according to the bpac^{nz} guidelines set out above. That is, at least every six months for the first two years following treatment, and then

[9] The Code can be found on HDC's website at: https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/.

annually. Dr Maplesden noted that it would be common and expected practice for the GP to take on the role of surveillance in such circumstances.

51. Dr Maplesden was mildly critical of the fact that a recall for PSA testing was not set up until June 2014, and that it was set for annual recall, meaning that Mr A did not complete all six-monthly screenings for the two-year period post-surgery, as recommended by Dr C and the relevant bpac^{nz} guidelines. I accept this criticism.

52. Dr Maplesden identified that Dr C's letter could have been clearer in communicating that the responsibility was being passed to Dr B for the ongoing surveillance of Mr A's PSA levels. Dr Maplesden also noted that Dr C continued to follow up with Mr A, including ordering PSA tests, after the letter of 28 January 2013. It is considered that these were mitigating factors with respect to the delay in setting up a formal recall for PSA testing. I agree that Dr C's actions may have contributed to some confusion about which party held the responsibility for Mr A's ongoing PSA surveillance.

53. While I accept this as a mitigating factor, I note that usually it is the GP's responsibility to carry out ongoing surveillance in such cases. I also consider that if Dr B was at all uncertain about the meaning of Dr C's letter, he could have clarified this with him at the time. I am therefore critical of Dr B's failure to organise appropriate PSA surveillance for Mr A at the time of receipt of Dr C's letter.

Management of PSA results

54. Dr B told HDC that it is his practice to rely on the 'normal range' (0.00 to 3.99µg/L) stated by the reporting pathologist when reviewing test results. The PSA request forms completed by Dr B do not provide any clinical context, so the reporting pathologists would not have been aware of Mr A's history of prostate cancer. Therefore, the 'normal range' reported by the pathologist on Mr A's PSA test results was not relevant to him, considering his history of prostate cancer and Dr C's advice. As noted in Dr C's letter of 28 January 2013, Mr A was to be re-referred should his PSA levels become detectable (greater than 0.05µg/L) again.

55. Dr Maplesden advised:

> '[I]t is accepted practice that laboratory results are reviewed within the appropriate clinical context rather than being reviewed in isolation as referred to by [Dr B] … I believe accepted practice is that, on receipt of a PSA reading outside the range appropriate for the clinical context (in this case > .05 µg/L), the GP reviewing the result would seek urology advice as recommended in the relevant letter from [Dr C], or at least repeat the result at a short interval to confirm its accuracy and seek advice if it remained detectable.'

56. Mr A's four PSA results received and reviewed by Dr B from 2018 to 2021 were all greater than 0.05µg/L, and therefore in the detectable range and clinically significant. As Dr B told HDC, these results were marked by the pathologist as being within the 'normal range', so he took no further action.

57. Dr Maplesden considered Dr B's apparent failure to consider the relevant clinical context when reviewing Mr A's PSA results to be an unsafe practice, and at least a moderate departure from accepted practice. I accept this advice and am critical of Dr B's inappropriate practice when reviewing results, which meant that Mr A's PSA results were not reviewed with consideration of the appropriate clinical context.

58. Dr Maplesden cited the relevant bpac[nz] guidelines, which discuss the significance of PSA velocity[10] and doubling time in indicating further investigation:

> 'PSA doubling time has been shown to be a strong predictor of clinical progression and cancer mortality. A man with a PSA level that has doubled slowly, e.g. over 12 months, is more likely to have local recurrence and a less aggressive tumour than a man with a PSA doubling time of less than six months.'

59. Mr A's PSA level became detectable in the result of 8 March 2018. The rate of increase was slow over the following two years but increased significantly between 18 September 2020 and 4 October 2021 (an increase of approximately 15 times from 0.18µg/L to 2.74µg/L).

60. Dr B told HDC that he noted Mr A's PSA results were 'higher than the limit ascribed by the urologist'. However, he did not draw this to Dr C's attention because he assumed that the urologist would review the results and take appropriate steps. It is unclear which result(s) Dr B was referring to. Nonetheless, I consider that it was not reasonable for Dr B to have assumed that Dr C was responsible for the ongoing monitoring and review of Mr A's PSA results. This responsibility was transferred to Dr B in Dr C's letter dated 28 January 2013, and it is standard practice for the GP to undertake this duty. In addition, Dr C was not copied into the PSA testing ordered by Dr B, so was not able to review the results.

61. Dr Maplesden was critical of the 'failure by Dr B to recognize the significance of [Mr A's] detectable then rising PSA from March 2018, and certainly from October 2021, and to act on the results in an accepted fashion (notify the patient [and] seek urology advice)'. Dr Maplesden considered this to be a moderate departure from accepted practice. I accept this advice and am critical of Dr B's failure to interpret and act on Mr A's detectable and then rising PSA levels appropriately.

62. Dr B told HDC that he considered Mr A to be health literate, and that he was able to access his own results from 2018 onwards using the health portal. Dr Maplesden advised:

> '[S]uch access [to test results on the patient portal] I believe enhances shared care and decision-making but does not remove the responsibility from the clinician requesting a blood test to recognize, notify and appropriately manage an abnormal result.'

63. I agree. While it is beneficial for patients to have a thorough understanding of their health care, I consider that it was not reasonable for Dr B to have assumed that Mr A would identify and proactively raise concerns about his abnormal PSA results. Despite Mr A's ability to

[10] 'Velocity' refers to the rate or speed at which test values change over time.

access test results and his perceived health literacy, it remained Dr B's responsibility to ensure that PSA results were reviewed and managed appropriately.

64. I acknowledge Dr B's concerns regarding his workload, and the amount of correspondence requiring his review each week. While I accept that this is a factor that may have contributed to the departures identified above, I remain critical of Dr B's practice when reviewing test results, and his failure to recognise and act on Mr A's concerning test results between 2018 and 2021. I will discuss the issue of management of high volumes of incoming correspondence in further detail below.

Conclusion

65. Dr B had a responsibility to provide Mr A health services with reasonable care and skill. In three instances, I consider that Dr B did not meet this obligation:

a) Dr B failed to organise timely and appropriate recall for Mr A's ongoing PSA surveillance.

b) He did not undertake safe and accepted practice by reviewing test results within the relevant clinical context.

c) He failed to recognise and act on Mr A's clinically significant PSA test results appropriately from 2018 to 2021.

66. Therefore, I find that Dr B did not provide services to Mr A with reasonable care and skill, and that Dr B breached Right 4(1)[11] of the Code.

Opinion: [The medical centre] — breach

Recall for PSA testing

67. It is concerning that Mr A did not receive PSA testing in 2015 and 2017, despite an annual recall being set by the medical centre staff in 2014. Dr Maplesden advised that it would be expected practice for PSA testing to occur approximately annually from the time the recall was set up.

68. Dr Maplesden was at least moderately critical if PSA testing was not completed in 2015 and 2017 owing to the medical centre failing to contact Mr A. Dr Maplesden said that he would be mildly to moderately critical if recalls were sent, but a failure by Mr A to respond to the recalls was not followed up and documented.

69. In the absence of any evidence to suggest that the medical centre contacted Mr A regarding PSA testing in 2015 and 2017, I consider it is more likely than not that the medical centre failed to contact Mr A regarding PSA testing in those years. I therefore accept Dr Maplesden's advice that this was a moderate departure from appropriate standards, and I am critical that the medical centre failed to carry out surveillance of Mr A's PSA levels adequately.

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

70. I acknowledge that in 2014 the medical centre was undergoing significant organisational changes. However, such changes must be managed to ensure that patient safety is not compromised. I therefore remain critical of this aspect of the medical centre's care of Mr A.

71. In light of this criticism, I am concerned that the medical centre may not have appropriate protocols in place for the sending and following up of recalls for important testing.

Management of PSA results

72. Dr B told HDC that it is only when test results are marked as abnormal by the reporting pathologist that 'we'[12] take action.

73. As I have discussed above, Mr A's PSA request forms did not provide relevant clinical details about his medical history. Therefore, the reporting pathologists would not have been aware of Mr A's history of prostate cancer and that the 'normal range' was not applicable to his case.

74. I note that Dr B is one of the directors at the medical centre, and that he is the only practising director. Taking into consideration Dr B's position and seniority within the medical centre, it would be reasonable to infer that his practices would reflect the organisation's expectations of the protocols to be followed by doctors at the medical centre.

75. It is concerning that it appears to be the medical centre's protocol to rely solely on the pathologist's reporting of whether a result is normal or abnormal, without considering the patient's relevant clinical context. As discussed above, Dr Maplesden considered this to be an unsafe practice and is moderately critical of this aspect of Mr A's care. I agree and am critical of the medical centre's practice for managing laboratory results.

76. Dr B told HDC that he has a high workload and is required to review 400 to 600 documents per week. Dr B's workload increased when other doctors at the practice took leave, as he was required to review correspondence on their behalf. Dr B said that to improve efficiency, results marked as normal 'have minimal attention given to them'.

77. I consider that Dr B's high workload and the pressure on him to cover the responsibilities of his colleagues are likely to have contributed to the unsafe practice of reviewing test results without consideration of the patient's relevant clinical context.

78. It appears that the medical centre did not have appropriate systems and resources available to review high volumes of correspondence in a safe manner, and I consider that this contributed to Mr A's abnormal PSA results not being recognised and managed appropriately.

Conclusion

79. I consider that the medical centre's recall system was deficient in that it failed to follow up and request PSA testing for Mr A in 2015 and 2017. I am also critical of the medical centre's

[12] I have interpreted 'we' as referring to Dr B's fellow GPs at the medical centre, and the organisation as a whole.

protocol for the review of test results, the failure to interpret results appropriately, and the systems in place to support staff to review high volumes of correspondence safely.

80. Therefore, I find that the medical centre did not provide services to Mr A with reasonable care and skill, and that the medical practice breached Right 4(1) of the Code.

Opinion: Dr C — other comment

81. Dr C is not subject to this complaint, and I am not critical of his actions. However, I would like to draw one matter to his attention, which he may wish to reflect on.

82. As identified in Dr Maplesden's advice, Dr C's communication and actions may have contributed to confusion regarding who was responsible for the ongoing surveillance of Mr A's PSA levels. Dr C may wish to consider whether his letter to Dr B dated 28 January 2013 could have been more explicit in explaining that Dr B would now be responsible for ongoing surveillance of Mr A's PSA levels. Dr C may also wish to reflect on how his actions in ordering further PSA testing following this letter may have further contributed to confusion around surveillance responsibilities.

Changes made since events

83. Dr B told HDC that he and the medical centre have taken several actions to avoid a recurrence of this situation. These are:

a) A review and/or implementation of the medical centre's policies/protocols on the following:

   i. recall system;

   ii. requests for laboratory testing; and

   iii. review and management of laboratory results.

b) A 'retired GP' has been contracted to assist with the review and management of laboratory results. 'She is now making certain all abnormal results are attended to either by me or my nurse in an appropriate time frame. The doctor is making certain that all results are checked in [their] clinical context.'

c) Dr B is undergoing ongoing medical education with a 'focus on the administrative aspect of being a director and doctor at the practice. This is to include a course on balancing the workload to ensure that patients receive the best care possible.'

d) Regular audit of results management processes.

e) Regular peer review and training sessions for the medical centre's clinical staff.

f) Discussion of this complaint with Dr B's peers.

Recommendations

Dr B

84. I note the changes made by Dr B since these events. In addition, I recommend that Dr B:

a) Provide a formal written apology to Mr A for the deficiencies 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 a random selection of 10 specialist letters and confirm that any specialist instructions and follow-up from the letters were actioned. The results of this audit should be sent to HDC within three months of the date of this report.

c) Review his practice regarding his interpretation of laboratory results, in particular to ensure that results are considered within the relevant clinical context, and that specialist advice is considered appropriately. A written reflection in relation to this point is to be sent to HDC within three weeks of the date of this report.

d) Reflect on how in future he will recognise situations where his workload is reaching a point where it may affect his ability to practise safely. This reflection should include how he could proactively seek support from his colleagues to manage such situations appropriately should they occur again in future. A written reflection in relation to this point is to be sent to HDC within three weeks of the date of this report.

85. In response to my provisional decision, Dr B provided an apology letter for forwarding to Mr A. I therefore consider the relevant recommendation complete.

The medical centre

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

a) Provide a formal written apology to Mr A for the deficiencies 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) Establish a process for surveillance and recall for ongoing laboratory testing. This process should set out the responsibilities of staff to set and action recalls for testing, as well as recording in the clinical documentation when reminders are sent, any further reminders, and if the patient does not respond. This can be included in an already established process or in a newly created process. A copy should be sent to HDC within three months of the date of this report.

c) Establish a process to ensure that laboratory test results are reviewed appropriately, taking into account the clinical information entered on laboratory request forms, and the need to consider the relevant clinical context in the consideration of results. This can be included in an already established process or in a newly created process. A copy should be sent to HDC within three months of the date of this report.

d) Conduct an audit of 50 patients undergoing ongoing surveillance to ensure that recalls have been actioned, followed up, and documented appropriately for the past year. The results of this audit should be sent to HDC within three months of the date of this report.

Follow-up actions

87. A copy of this report with details identifying the parties removed, except the clinical advisor on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.

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

Appendix A: In-house clinical advice to Commissioner

The following in-house advice was obtained from GP Dr David Maplesden:

'**FROM** : David Maplesden

CONSUMER : [Mr A]

PROVIDER : [Dr B]

FILE NUMBER : C23HDC00728

DATE : 29 August 2024; **Addenda 19 November 2024 (sections 8 & 10)**

---

1. My name is David Maplesden. I am a graduate of Auckland University Medical School and I am a vocationally registered general practitioner holding a current APC. My qualifications are: MB ChB 1983, Dip Obs 1984, Certif Hyperbaric Med 1995, FRNZCGP (Dist) 2003. Thank you for the request that I provide clinical advice in relation to the complaint from [Mr A] about the care provided to him by [Dr B]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors.

2. I have reviewed the following information:

- Complaint from [Mr A]
- Response and clinical notes from urologist [Dr C]
- Response from [Dr B]
- Clinical notes [the medical centre]

3. [Mr A] (B:1959) had a radical prostatectomy in 2012 following a diagnosis of prostate cancer (urologist [Dr C]). His PSA was monitored regularly thereafter to enable early detection and management of any recurrence of the cancer. [Mr A] complains that he was not notified when his PSA became detectable in 2020 with subsequent increase in 2021. Following a further marked increase in 2022 he was finally notified and referred to a urologist. He was found to have widespread skeletal metastases and has been commenced on androgen deprivation therapy (ADT). [Mr A] is concerned at the delay in detecting and therefore treating his cancer recurrence.

4. [Mr A] was in good health with no history of lower urinary tract symptoms (LUTS) when he was found to have an elevated PSA on routine screening in June 2012 (PSA 9.4 ug/L — age specific reference range <3.5). He was referred by his GP [Dr B] to urologist [Dr D] who performed prostate biopsy on 27 July 2012 with results, and subsequent staging investigations, indicating a high-risk cancer (Gleason 4+4=8, ISUP Grade 4, clinical stage T2b). [Dr D] referred [Mr A] to [Dr C] for surgery (radical prostatectomy performed on 10 October 2012). [Dr C] reviewed [Mr A] for his first post-op visit on 21 October 2012 then a telephone consult on 24 November 2012 to discuss histology results (clear surgical margins). Repeat PSA on 14 January 2013 ordered by [Dr C] was undetectable (defined as <0.05 ug/L). Three-month post-op review was undertaken by

[Dr C] on 28 January 2013. [Mr A] had recovered well from his surgery and recent PSA result was discussed. [Dr C's] report to [Dr B] concluded:

His PSA is undetectable which he was relieved to hear. Final histopathology showed Gleason 8 adenocarcinoma with extracapsular extension. All surgical margins were negative and lymph nodes negative. This result in combination with the undetectable PSA is very encouraging.

[Mr A] should continue with six monthly PSA checks and if the level ever becomes detectable (greater than 0.05ng/mL) then I would like to see him again. At this stage I have not made any further appointments for him.

In his response [Dr C] states, in answer to the question whether there was a formal transfer of responsibility to GP [Dr B] for appropriate PSA monitoring of [Mr A] following his radical prostatectomy: *Yes, at the three month post-operative appointment I advised [Dr B] in my letter that I was not planning to see [Mr A] again and that he required a PSA check six monthly going forward. All outlined in the GP letter from Jan 28, 2013.*

5. [Dr C] did continue to review [Mr A] and to order PSA tests (see Appendix 1). PSA on 18 July 2013 (copies to [Dr B] and [Dr D]) remained undetectable and clinic report dated 10 August 2013 begins: [*Mr A] attended my … clinic today in follow up of his radical prostatectomy performed on October 2012 for prostate cancer …* The recent PSA result was discussed together with [Mr A's] uncomplicated recovery other than some issues with erectile dysfunction (expected) which were improving with treatment. The report concluded: *I plan to meet up with him again in six months' time.* A further PSA ordered by [Dr C] (no CC) remained undetectable (13 January 2014) and report to the GP dated 1 February 2014 begins again *[Mr A] attended my office today in follow up of his radical prostatectomy performed for high risk prostate cancer in 2012.* There were no ongoing issues noted related to the surgery (recent PSA not referred to) but [Mr A] had an incidental right hydrocele which he initially requested be repaired and the report concluded: *We discussed the procedure of hydrocele repair and I will write when this has been performed.* In his response, [Dr C] states: *At subsequent appointments from 2012–2014 (for hydrocele, erectile issues etc) I made sure that PSA's were being regularly checked and that they were satisfactory.* [Mr A] later declined the planned hydrocele surgery and [Dr C] did not review him again until November 2016 when [Mr A] presented requesting repair of the hydrocele which had become increasingly bothersome. The final report from [Dr C] is an operation note (repair of hydrocele) dated 16 February 2017 with follow-up to be per telephone. [Dr C] did not request any PSA tests after January 2014 and there is no reference in the November 2016 and February 2017 reports to PSA readings, these reports being clearly focused on [Mr A's] hydrocele.

6. [Dr B] includes the following points in his response:

(i) On 16 October 2012 [Dr B] entered a classification of *Open prostatectomy for adenocarcinoma gleason 8.*

(ii) [Dr B] completed a note dated 29 January 2013: *letter from [Dr C] … noting undetectable PSA. (letter includes that should continue six monthly PSA checks and if level ever becomes detectable (greater than 0.05ng/ml) then would like to see him again).* [Dr B] states: *[Mr A] had his prostatectomy in October 2012. He was under the care of the Urologist, undergoing regular follow up appointments, until 16 February 2017.*

(iii) A recall for annual PSA and lipids was inserted by a practice nurse on 3 June 2014 and updated on 8 March 2018 by another nurse (modification not specified). [Dr B] states: *This meant that [Mr A] was sent a blood test and advised to do the blood test so his PSA levels could be checked.* In an earlier response, [Dr B] stated: *[Mr A] would contact the medical practice once per year to seek blood test forms to enable him to have his PSA and lipids checked. This was led by [Mr A], and, we assumed, his urologist. It was made slightly difficult as [Mr A] would not book appointments with myself or another doctor. He requested the blood test forms come from one of the nurses. He was able to access his results either by contacting the practice or by accessing his electronic patient records* [portal available from 1 June 2018]. It is unclear if [Mr A] was actively recalled on an annual basis or whether he initiated the recalls.

(iv) [Dr B] states: *In a letter received not long after the prostatectomy the urologist advised [Mr A] to undergo six monthly monitoring of his PSA level and to notify him if the level went above 0.05. The blood test results were provided to the urologist until [Mr A] was discharged from his care. The blood tests took place annually, not on a six-monthly basis, and the level was recorded as being higher than the limit ascribed by the urologist. We did not draw this to the urologist's attention having assumed he was well equipped to review these results and take the appropriate steps … The blood tests took place annually and not a six-monthly basis, a detail that was never queried by the urologist or [Mr A], and the level was recorded as being higher than the limit ascribed by the urologist, again, this was not queried by the urologist or [Mr A].*

(v) [Dr B] notes [the medical centre's] protocol is to inform patients of any abnormal blood test results only. With respect to reviewing of results, [Dr B] notes the pressures of dealing with clinical correspondence including laboratory results. He states: *With a view to achieving some efficiency, blood test results that fall within the prescribed normal range (as prescribed by the Prostate Cancer Foundation and Cancer Council Australia guidelines and the European Society for Medical Oncology Guidelines 2020), as recorded by the Pathologist, have minimal attention given to them. It is only when the Pathologist reports the results as being abnormal that we consider a treatment plan for the patient, including the steps to communicate these abnormal results … The computer system is unable to alert us as to any readings on blood test results. However, the lab, when it provides us with the results, identifies the normal range for each result next to what the patient's result was. This allows us to ensure, when reviewing blood test results in isolation as they come in, we know whether to be concerned or not. [Mr A's] PSA results were within the normal range until 2022.* I have reviewed the PSA request forms for [Mr A] generated at [the medical centre] and these do not contain

any clinical details meaning the pathologist was not aware of [Mr A's] prostate cancer history.

(vii) [Dr B] comments: *[Mr A] was seen after his prostatectomy by the Urologist and told that his PSA reading was undetectable at that time. He was advised to go back and see him if the PSA was ever detectable again. [Mr A] never mentioned this to me. He never informed me that he was supposed to go back and see the urologist if ever his PSA was detectable again or that he was meant to do a blood test every six months. It is surprising that [Mr A] did not mention these aspects to me given the level of attention he pays to his healthcare, he is considered to be very health literate.*

7. [Mr A] was an infrequent attender at [the medical centre] as he kept generally very good health. It does not appear he reported at any stage any symptoms that might have raised suspicion of prostate cancer recurrence. PSA surveillance was undertaken as described above and summarized in Appendix 1. It is apparent the significance of [Mr A's] PSA becoming detectable from March 2018, and slowly rising thereafter until the more rapid rise between the 2020 and 2021 results and marked rise by 2022, was not recognized by [Dr B]. I note the PSA remained within the age specific reference range for a man without a history of prostate cancer treatment until 2022 but this range was not applicable to [Mr A] because of his past history. On receipt of the markedly elevated PSA result dated 21 October 2022, [Dr B] arranged urgent urologist review, which was appropriate management, albeit significantly belated.

8. Surveillance of patients with prostate cancer either as a "watch and wait" strategy or following treatment is summarised in a 2012 BPAC article[1]. Surveillance for men such as [Mr A] is described as: *Men who have undergone radical prostatectomy or radiotherapy should have their PSA level checked: Six weeks after treatment (unless adjuvant hormonal treatment is being given). At least every six months for the first two years. Then annually.* As such, the recommendation provided by [Dr C] to [Dr B] in the letter dated 28 January 2013 was quite cautious although may have been so because of the high-risk nature of his cancer. I believe accepted practice would be, that on receipt of [Dr C's] report outlining monitoring recommendations, a record is made in the clinical file of the recommendations (which was apparently done) and a recall set up as per the recommendations. Had a recall been set up consistent with the cited BPAC recommendations rather than [Dr C's] recommendations, I would not be critical given this would be consistent with local guidance. However, it appears there was no recall set up until June 2014. I have not been provided with any PSA results for the years 2015, 2016 and 2017. I have assumed PSA was tested annually over this period and results were all < .05 ug/L. Confirmation and a copy of these results should be sought from [Dr B].

[1] https://bpac.org.nz/BT/2012/October/prostate.aspx Accessed 27 August 2024

Addendum 19 November 2024: [The medical centre] has provided results dated 19 July 2016 which include a PSA < .03. There were no additional results provided so it appears there was no PSA testing undertaken in 2015 and 2017.

9. I believe the surveillance recommendations by [Dr C] might have been more explicit making it clear the expectation was that [Dr B] would organize ongoing surveillance, but I believe it was common and expected practice for the GP to take on this role. The fact [Dr C] continued regular follow-up of [Mr A], including ordering of PSA tests, for a year following the "discharge from care" letter confused the surveillance picture somewhat and I note the clinic letters implied care over this time was for follow-up of the prostate surgery. [Dr C] might reflect on the potential for confusion of responsibility for PSA surveillance over this period and I would regard the situation as a mitigating factor with respect to the apparent delay in [the medical centre] setting up a formal recall for PSA surveillance. I note also there is no record of copying of the January 2014 result to [Dr B]. I believe the clinic letters from [Dr C] in 2016 and 2017 clearly indicate the reason for contact with [Mr A] at this time was in relation to hydrocele management rather than PSA surveillance. Taking these factors into account, I am mildly critical that a recall was not set up until June 2014 and was set up for annual recall meaning [Mr A] did not complete six-monthly screening for the first two years following his treatment. I believe it was reasonable of [Dr B] to assume [Dr C] had discussed surveillance with [Mr A] but I do not believe it was reasonable to assume [Mr A] was aware of the technical aspects of detectable versus non-detectable PSA levels. There is no reference to [Dr C] being copied in to the PSA results requested by [the medical centre] staff so it is difficult to see how [Dr B] apparently remained under the impression that [Dr C] retained responsibility for acting on these results from 2014 onwards.

10. [Dr B] has provided conflicting accounts of whether the PSA requests were initiated by [Mr A] or by [the medical centre] staff per the recall system. Either way, I would expect there to have been approximately annual PSA testing performed from the time the recall was set up, noting best practice was for six-monthly PSAs until October 2014. If approximately annual testing of PSA was performed between January 2014 and March 2018, and all results were < .05 ug/L, I would be mildly critical that there was no recall for the test recommended for mid-October 2014 but would regard management over this period as otherwise being consistent with accepted practice. If there were no PSA tests performed between January 2014 and March 2018, I would be at least moderately critical if this was the result of no recalls being sent, and mildly to moderately critical if recalls were sent but a failure by [Mr A] to respond to the recalls (if that was the case) was not followed up and documented.

Addendum 19 November 2024: It appears there was no PSA testing performed in 2015 or 2017. I would be at least moderately critical if this was the result of no recalls being sent when due in those years, and mildly to moderately critical if recalls were sent but a failure by [Mr A] to respond to the recalls (if that was the case) was not followed up and documented.

11. I believe it is accepted practice that laboratory results are reviewed within the appropriate clinical context rather being reviewed in isolation as referred to by [Dr B] (see section 6(v)). As this case so clearly illustrates, there are dangers inherent in not considering the clinical context. In this case the primary purpose of the PSA was to monitor whether it became detectable, suggestive of biochemical recurrence of [Mr A's] cancer if it did. Velocity of PSA increase even if it remains within the reference range can also be of significance for some patients. I believe accepted practice is that, on receipt of a PSA reading outside the range appropriate for the clinical context (in this case > .05 ug/L), the GP reviewing the result would seek urology advice as recommended in the relevant letter from [Dr C], or at least repeat the result at a short interval to confirm its accuracy and seek advice if it remained detectable. It may well be that [Dr C], if contacted, might have advised ongoing monitoring initially. The cited BPAC reference notes velocity and the PSA doubling time are used to guide further investigation and treatment during monitoring. *PSA doubling time has been shown to be a strong predictor of clinical progression and cancer mortality. A man with a PSA level that has doubled slowly, e.g. over 12 months, is more likely to have local recurrence and a less aggressive tumour than a man with a PSA doubling time of less than six months.* [Mr A's] PSA was detectable in the result dated 8 March 2018 and velocity of increase was slow over the next two years but increased significantly after September 2020 with a 15-fold increase between that result and the result of October 2021 and exponential rise thereafter.

12. I believe review of laboratory results without considering the relevant clinical context, if that is what has occurred, to be an unsafe practice and at least a moderate departure from accepted practice. I believe the failure by [Dr B] to recognize the significance of [Mr A's] detectable then rising PSA from March 2018, and certainly from October 2021, and to act on the results in an accepted fashion (notify the patient, seek urology advice), to be a moderate departure from accepted practice. I acknowledge the complexity and administrative burden of inbox management, perhaps exacerbated in this case by the Covid pandemic with respect to 2020 and 2021 results, but the practice has a responsibility to ensure there are robust processes in place that facilitate safe and efficient management of clinical correspondence. This is increasingly important as alternative or complementary inbox management processes are implemented (eg use of other practice team members, off-site clinicians, AI) to try and relieve the burden on the primary provider. I note some laboratories now attach a generic comment on all PSA results that the cited reference range does not apply if the patient has a history of prostate cancer. Whether or not this will reduce errors such as those evident in this case remains to be seen. I note also that [Mr A] apparently had access to his results from June 2018 per the patient portal and such access I believe enhances shared care and decision-making but does not remove the responsibility from the clinician requesting a blood test to recognize, notify and appropriately manage an abnormal result. However, if the patient is appropriately informed (and it is not clear in this case that [Mr A] was ever aware of the precise figures that constituted an abnormal result for him) use of the patient portal may act as an additional layer of safety to avoid "missing" of clinically significant results.

13. I recommend [Dr B] and [the medical centre] closely review their current practice and processes regarding management of clinical results, recognizing the need to consider the clinical context of results and in particular, PSA results. Following such review, I recommend [Dr B] and [the medical centre] provide to the decision-maker the practice policy on management of lab results and clinical correspondence incorporating any amendments or additions arising from the review and addressing some of the deficiencies identified in this case: sub-optimal recall practice, inadequate clinical information on lab request forms, failure to consider relevant clinical context when reviewing results.'

Appendix 1. PSA results

Date	PSA (ug/L)	Ordered by[2]	Copy to	Comment
6/2012	9.4	…	-	First PSA, referred following
14/1/13	< .05	…	-	First post-op PSA
18/7/13	< .05	…	…	
13/1/14	< .05	…	-	
2015				No testing
19/7/16	< .03	…	-	
2017				No testing
8/3/18	0.08	…	-	First level exceeding the recommendation
4/9/19	0.10	…	-	Patient GP listed as …
18/9/20	0.18	…	-	Patient GP listed as …
4/10/21	2.74	…	-	Patient GP listed as …
21/10/22	67	…	…	Referral made to a urology service by …

[2] … — [Dr B]; … — [Dr D]; … — [Dr C]