Health and Disability Commissioner
*Te Toihau Hauora, Hauātanga*

# A Decision by the Deputy Health and Disability Commissioner

# (Case 22HDC00652)



## Introduction

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

2. The report discusses the management of Mr A's prostate-specific antigen (PSA)[1] levels by a medical centre between 2019 and 2021.

3. In 2016 Mr A was diagnosed with prostate adenocarcinoma,[2] and in 2017 he underwent a radical prostatectomy[3] to remove the cancer. In 2019, his urologist provided instructions to Mr A's medical centre to check his PSA levels every six months and to complete an

[1] PSA is a protein in the blood that is produced by normal, as well as malignant, cells of the prostate gland.
[2] Cancer of the prostate.
[3] A surgical procedure to remove the prostate and surrounding tissue.

immediate referral back to urology if PSA levels became detectable. Over the next three years, five test results showed that Mr A's PSA levels were abnormal. However, the test results were not relayed to Mr A accurately, and he was not referred to a urologist. Shortly thereafter, Mr A was diagnosed with metastatic cancer,[4] and he passed away.

4. I take this opportunity to provide my sincere condolences to Mr A's wife and her whānau for the passing of Mr A.

5. The following issue was identified for investigation:

- *Whether the medical centre company provided Mr A with an appropriate standard of care from 2019–2021 (inclusive).*

6. The parties directly involved in the investigation were:

| | |
|---|---|
| Mr A | Consumer |
| Ms B | Complainant |
| Medical centre | |

7. Further information was received from:

| | |
|---|---|
| Te Whatu Ora[5] | District healthcare provider |
| Dr C | Consultant urologist |
| Dr D | General practitioner (GP)/Clinical Director |
| Dr E | GP |
| NP F | Nurse practitioner (NP) |

8. Also mentioned in the report:

| | |
|---|---|
| Dr G | Urologist |
| Dr H | Locum GP |

9. In-house clinical advice was obtained from GP Dr David Maplesden (Appendix A).

## Background

### Introduction

10. In New Zealand, prostate cancer is the third leading cause of cancer death in men.[6] With routine PSA testing, many men benefit from timely diagnosis and treatment.

[4] Cancer that has spread to different parts of the body.
[5] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force and resulted in all district health boards being disestablished. Their functions and liabilities were merged into Te Whatu Ora|Health New Zealand.
[6] https://bpac.org.nz/report/2020/psa.aspx

**Timeline of events**

11. Mr A, aged in his sixties at the time of events, had a history of prostate cancer. In 2016, a biopsy[7] of Mr A's prostate revealed prostate adenocarcinoma, and in 2017 a urologist, Dr C, performed a radical prostatectomy and a pelvic node dissection[8] at Te Whatu Ora. Mr A was followed up by the urology service until 2019 (Month1[9]), with regular PSA levels over this period being undetectable.

12. In Month1, Mr A's care was handed back to the medical centre for further regular surveillance of his PSA levels. The urology letter (written by Dr C) dated 21 Month1 provided details of Mr A's prostatectomy and instructions for checking his PSA levels 'every six months for the next two years and then annually thereafter'. If PSA levels were detectable, Mr A was to be referred to urology immediately, so that radiotherapy[10] could be considered.

13. The letter from Dr C was addressed to Dr D at the medical centre and was received on 8 Month2. However, the medical centre told HDC that Dr E had always been Mr A's registered GP whilst enrolled there.

14. The medical centre's 'Inbox Management Policy' states:

> 'Rather than being allocated into the named provider's Medtech[11] inboxes discharge summaries and radiology results are randomly allocated across all [medical centre company] inboxes.'

15. Regular PSA tests for Mr A were completed between Month1 and Month35. A recall was set for six-monthly PSA testing, with reminder texts being sent to Mr A. However, it appears that no patient alert[12] was set up.

16. PSA first became detectable (0.10µg/mL) on 18 Month8 following a routine test ordered by Dr E. The lowest reportable total PSA value is 0.05µg/mL. Dr E reviewed the PSA result and annotated it as 'ok', despite PSA being detectable. On 23 Month8, Mr A presented to the clinic for unrelated reasons, and on 19 Month10 he presented for a routine review. However, it appears that no urology referral was completed in 2019.

17. Clinical notes show that another PSA test was ordered by Te Whatu Ora urologist Dr G, with the results dated 12 Month13. However, Te Whatu Ora told HDC that the test was requested by a urology nurse, with the results copied to Dr E and Dr G, as the medical lead of the Urology Department at Te Whatu Ora at the time (which is standard practice). Te Whatu Ora said that the results were not reviewed by Dr G, as he was not involved in Mr A's care.

[7] A procedure to remove a piece of tissue or a sample of cells from the body for testing in a laboratory.
[8] Surgery to remove lymph nodes from the pelvis.
[9] Relevant months are referred to as Months 1–35 to protect privacy.
[10] Treatment to destroy cancer cells.
[11] Medtech is practice management software used by medical centres to streamline clinical records, patient scheduling, and billing.
[12] An alert warns the clinician to significant clinical information, without having to read the entire file.

The PSA level — now higher than the Month8 result — was reviewed by Dr E and annotated as '0.21' with no additional comments on the acceptability of the results.

18. On 5 Month14, Mr A telephoned the medical centre to obtain his PSA test results. Clinical notes state: '[A]dvised as per inbox.' However, the clinical notes of a further telephone consultation on 10 Month14 state: '[H]ad blood test (PSA and creatinine) on 12 [Month13] ordered by urology — not in our inbox. Called Medlab to have results sen[t] to [GP].' On 11 Month16, a nurse practitioner telephoned Mr A and 'discussed bloods taken in [Month13]'. The content of the discussion was not documented on any of these occasions.

19. On 7 Month20, Mr A's PSA levels were reviewed again and demonstrated an ongoing increase (0.60µg/mL) but again the result was annotated as 'ok' by NP F. Mr A telephoned the medical centre on 7 Month23 and a practice nurse advised Mr A of his results and documented: '[A]dvised as per inbox — happy with that.'

20. On 10 Month26, Mr A's PSA level was annotated as '1.7' by Dr E — an ongoing increase. On 18 Month29, Mr A's PSA result was annotated as '2.8 ok' by NP F. Evidently a text message was sent to Mr A on 24 Month29 advising him that his 'blood tests [were] all OK'.

21. On 8 Month35, nursing staff viewed Mr A's PSA level, which was now elevated at 5.7µg/mL, and marked this for review on 10 Month35. The laboratory test results form also indicated that this PSA level exceeded the recommended level for referral. The medical centre told HDC that '[Mr A] presented to the practice before these [results] were reviewed or actioned by [Dr E]'.

22. Mr A was seen by Dr H at the medical centre on 17 Month35, for a two-week history of persistent nausea. On examination, upper abdominal tenderness and bloating were noted. A foot pain issue was also addressed, together with discussion of Mr A's recent blood test results, including his PSA levels. Dr H recognised the deviation from Dr C's instructions on 21 Month1 and completed an urgent urology referral, noting:

> 'I was alarmed to see a PSA of 5.7 and looked back through his notes. There was a plan from Urology that he should be referred back if the PSA became detectable. This occurred in [Month8] and has never been acted upon. In the meantime the PSA has been steadily climbing. Notwithstanding that he does not appear to have had any real worsening of urinary symptoms.'

23. Dr H informed Mr A of the error and apologised for the oversight. Blood tests, an abdominal ultrasound scan, and a faecal specimen were planned.

24. An ultrasound was undertaken on 22 Month35 and showed multiple liver lesions consistent with metastatic disease. A further CT scan on 31 Month35 showed a pancreatic mass[13] and liver metastases, together with separate evidence of likely recurrent prostate cancer in the left pelvic sidewall lymph nodes. The urology service deferred any further prostate

[13] Most cases of pancreatic cancer are inoperable and advanced at the time of diagnosis, with less than 20% amenable to surgery, a five-year survival rate of 5–15%, and an overall survival rate of 6%.

intervention, with priority being management of the newly diagnosed pancreatic cancer. However, sadly, Mr A passed away from his illness.

**Further information**

25. Dr E, NP F, and medical centre Clinical Director, Dr D, expressed their sincere apologies to Mr A's wife. They advised that they were not alerted to the letter written by Dr C, and therefore this 'was a genuine oversight'.

26. The medical centre told HDC that the reviewing of any results is done by the team collectively, due to the small size of the medical centre and many staff working part time. However, the medical centre also said that test results always return to the ordering clinician, and 'PSA results needed to be monitored by and remain the responsibility of the GP or [nurse practitioner]'.

27. The medical centre told HDC that the failure to action Mr A's PSA results appropriately was raised as an incident of concern to the medical centre company. The results and outcome of this review are outlined in the 'Changes made' section below.

**Responses to provisional opinion**

*Ms B and Mr A's wife*

28. Ms B and Mr A's wife were given an opportunity to respond to the provisional opinion. They stated:

> 'We are very grateful for all the hard work you have all put into this investigation. We feel there is nothing more [t]hat can be done and the investigation has been reasonably thorough. We would just like to express the need for ongoing monitoring in terms of the practice management. I guess both being in the medical profession we have seen things lapse and fall back to unacceptable practice and do not want to see it happen again to another family.'

*Medical centre*

29. The medical centre was given an opportunity to respond to the provisional opinion. It stated that it had no further comments to make and accepted the recommendations made by the Deputy Commissioner.

30. As recommended by the Deputy Commissioner in her provisional opinion, the medical centre provided a formal written apology to Mr A's wife and her whānau for the breaches of the Code of Health and Disability Services Consumers' Rights (the Code) identified, addressing the changes it has made.

## Opinion: Introduction

31. On behalf of Mr A's family, Ms B complained about the management of her brother-in-law by the medical centre, prior to his passing. Ms B told HDC that Mr A's family is 'beyond devastated and extremely distressed' by the missed results, which may or may not have produced a more favourable outcome. In particular, they are concerned that Mr A's

'average' PSA levels should not have been overlooked in the context of his medical history, and therefore the PSA results were not managed appropriately.

32. I have undertaken a thorough assessment of the information gathered, including clinical advice from my in-house clinical advisor, Dr David Maplesden.

33. I consider that the failures in this case were the result of inadequate systems, for which the medical centre company had responsibility, as well as the result of individual providers' deficiencies in care.

## Opinion: Medical centre company — breach

34. This opinion considers the care provided to Mr A by the medical centre from Month1 to Month35 (inclusive). I acknowledge the distressing impact of this on Mr A and his family and again I express my sincere condolences to Mr A's family for their loss.

35. As a healthcare provider, the medical centre has an organisational responsibility to provide services in accordance with the Code. As a result of my assessment, I have identified deficiencies in the standard of care and communication provided to Mr A by the medical centre.

36. Between Month8 and Month35, multiple clinicians reviewed Mr A's PSA results. In addition, Mr A was reviewed periodically on other occasions for repeats of his usual medications and other unrelated matters. The medical centre confirmed that Dr C's letter was received on 8 Month2 and faxed into the practice management system on 11 Month2. However, clinicians overlooked Dr C's letter and stated that this was a genuine oversight.

37. The medical centre told HDC that Mr A's results from Month8 to Month29 were in the 'normal' range for someone of Mr A's age[14] who is asymptomatic, and therefore the results were signed off as 'ok' by the reviewing clinicians. The medical centre stated that as Mr A had not presented to the practice with any symptoms related to his urology history, and his PSA results were 'normal', a further urology referral was not considered over this period.

38. My in-house clinical advisor, Dr Maplesden, said that Mr A's PSA was being managed in the context of no previous history of prostate cancer, with recognition of an abnormality only when the level climbed outside the age-specific reference range in Month35.

39. Dr Maplesden advised that 'in signing and filing a test result, there is an expectation this action has been taken with an awareness of the clinical context in which the test was ordered'. Therefore, Dr Maplesden considers that the failure by the clinicians to adhere to the urologist's recommendations with respect to the management of Mr A's PSA results was a moderate to severe departure from accepted practice.

[14] For men aged 50–70 years, a normal PSA range is ≤4.0μg/ml. A PSA level of more than 4.0μg/ml is suggestive of prostate cancer.

40. I accept this advice. Whilst I acknowledge that overlooking Dr C's letter was a genuine error, I cannot accept that several clinicians were reviewing Mr A's PSA results without fully understanding Mr A's clinical history. In my view, this persistent practice contributes to a culture of acceptance for reviewing clinical tests without sufficient knowledge of the patient's clinical history. There were several opportunities for clinicians to review Mr A's clinical notes, and it must be acknowledged that had an earlier urology referral been made, it is possible (but not inevitable) that Mr A's pancreatic tumour may have been detected at an earlier stage.

41. I acknowledge that the medical centre is a busy practice in a rural area, where there is a shortage of primary care workers, and that on a practical level, clinicians may not have capacity to review clinical notes on every occasion. However, this is precisely why medical centres need to ensure that there are effective systems to minimise the risk of error and omissions by individual practitioners. In this case, effective risk mitigation would have included an effective recall system and the placement of a clinical alert within the practice management software, which would have alerted clinicians to Mr A's history of prostate cancer. However, this was not the case.

42. On many occasions, Mr A proactively enquired about his test results, only to be falsely reassured that his results were 'ok' because individual providers had referred to the clinician's incorrect filing comments. In my view, these were missed opportunities for providers to partner with Mr A effectively and support him in taking an active role in his care. In this case, providers could have explained the PSA surveillance regimen to Mr A from the outset, including what constituted a reassuring or non-reassuring result, and could have provided access to the results once these had been filed via the patient portal. This would have been an additional strategy in preventing medical errors.

43. In summary, I have found the medical centre company in breach of Right 4(1)[15] of the Code for the following reasons:

- The failure to read and adhere to the urologist's recommendations, including the failure to refer Mr A to a urologist following detectable PSA levels.
- The failure to interpret Mr A's rising PSA results in the context of his past clinical history.
- The failure to have effective administrative systems that supported coordinated care and communication amongst individual providers.

44. I have also found the medical centre company in breach of Right 6(1)[16] of the Code for the failure to communicate with Mr A accurately in relation to his PSA results.

45. The medical centre company has accepted my proposal to find it in breach of Rights 4(1) and 6(1) of the Code. Accordingly, I have concluded my investigation into the care provided to Mr A by the medical centre company.

[15] The right to have services provided with reasonable care and skill.
[16] The right to be fully informed.

## Opinion: Dr E — adverse comment

46. Dr E had been Mr A's registered GP at the medical centre since mid-2018. Dr E had a responsibility to provide services to Mr A in accordance with the Code.

47. From Month1 to Month35, Dr E ordered Mr A's PSA tests on three occasions. In Month8 Dr E recorded Mr A's PSA result as being 'ok', and on 12 Month13 he recorded it as '0.21', without further indication of the acceptability of the result. Dr E told HDC that as Mr A's primary GP, recalled blood tests and specialist letters were received into his inbox within the practice management system and would be read either by himself or a nurse before being actioned and filed. He said that usually he would read blood test results himself.

48. Dr E acknowledged that at the time of reviewing these results he was not fully familiar with Mr A's previous history of prostate cancer, and he told HDC that he had met Mr A only once. I recognise that this may have limited Dr E's opportunities to review Mr A's clinical notes sufficiently and familiarise himself with Mr A's history of prostate cancer. However, as advised by Dr Maplesden, when filing and reviewing a clinical test result, it is expected that the reviewing clinician is aware of the patient's clinical history, and I note that Dr C's urology letter in Month1 provided details of Mr A's prostate cancer.

49. I am concerned that Dr E did not review Mr A's previous clinical history, given Dr E's subsequent documentation that the test results were 'ok'. I remind Dr E of the importance of this when interpreting test results. Patient records are an important source of information about their care, and filing a test result in the absence of reviewing the clinical history has the potential to introduce medical errors.

50. In my view, Dr E, as Mr A's primary GP, was responsible for the inaccurate interpretation of Mr A's PSA results, as well as the subsequent inaccurate documentation. However, Dr E's care was compromised by the lack of robust systems at the medical centre. In addition, no clinical alert was placed on the practice management system to alert Dr E to Mr A's prostatectomy, which contributed to the mismanagement of Mr A's PSA levels. In this instance, Dr E most likely relied on the absence of a clinical alert when managing Mr A's PSA levels. The medical centre also told HDC that staff worked collectively to manage incoming test results, and the clinical records show that other clinicians also reviewed Mr A's test results. Dr Maplesden advised that this is a common practice in rural areas, in the context of ongoing workforce shortages. As such, although Dr E was Mr A's primary GP, I do not consider Dr E to be solely accountable for the failings in Mr A's care.

51. Dr E apologised to Mr A's family and accepted that the care he provided to Mr A was deficient. In response to this incident, Dr E told HDC:

> '[Mr A's] case has been a salutary lesson for me. I ensure any blood tests such as PSA tests are fully checked against past clinical history and trends of previous tests, and to familiarise myself further with the history and need for further treatment relevant to each test. I am mindful of being careful to double check the history of any patient having a PSA reading, as well as other similar biochemical markers, such as TSH and thyroglobulin, the suppression of which may be used to monitor patients with a history

> of thyroid cancer. Furthermore, I am careful to document thresholds for re-referral to secondary services when commenting on these tests. I have also inserted clinical alerts on the patient management systems for these patients, where a blood test reading within the normal range for most patients would need to be acted upon differently.'

52. I acknowledge the learnings Dr E has taken from this case and I am satisfied that he has improved his practice.

## Opinion: NP F — adverse comment

53. Although NP F was not Mr A's primary healthcare provider while she was employed by the medical centre company, the clinical notes show that she reviewed Mr A's PSA test results on two occasions and filed them as 'ok'. As a healthcare provider, NP F had a responsibility to provide services to Mr A in accordance with the Code.

54. NP F acknowledged that she had 'erroneously identified Mr A's PSA result as within normal limits and therefore identified this result as being ok'. She accepted that in the context of Mr A's previous prostatectomy, his rising PSA levels should have been flagged and a referral sent back to urology.

55. I reiterate Dr Maplesden's advice that in reviewing test results there is an expectation that the previous clinical history has been reviewed. I am concerned that this did not occur given NP F's acknowledgement that she had overlooked Dr C's letter. Again, I consider that NP F's care was compromised by the lack of robust systems at the medical centre. However, I remind NP F of the importance of reviewing previous clinical information when filing test results.

56. NP F accepted the errors on her part and told HDC:

> '[Dr D], as clinical lead, discussed what happened with me, how this had occurred and how to manage PSA results going forward. In addition, [Mr A's] case was discussed with all GPs and [nurse practitioners] at our monthly peer review meeting to highlight the risk and we agreed to change the process going forward to ensure no PSA results were filed until classifications and clinical notes including Urology letters were reviewed. As a result of [Mr A's] case, I have undertaken self-directed learning regarding screening and management of diseases of the prostate, including prostate cancer and the use of PSA as part of a complete investigation via Best Practice and Health Pathways. I have also consulted best practice and health pathways about managing PSA results.'

57. I acknowledge the learnings NP F has taken from this case and I am satisfied that she has changed her practice.

## Changes made since events

58. This incident was reviewed by the medical centre and discussed at the clinical governance meeting. The medical centre told HDC that as a result of this incident it made the following changes:

a) It made an amendment to its 'inbox management policy' to ensure that a system alert is set up immediately upon receiving instructions whereby a deviation from 'normal' values is required. This is to ensure that when reviewing test results, irrespective of the clinician, important instructions are not missed. This policy will be circulated to the wider team once finalised by the clinical governance group.

b) It established a 'double recall' system on every post-prostatectomy patient, where an initial recall is sent to the consumer reminding them to complete their PSA test, and, after two weeks, another recall is sent to the reviewing clinician specifically to look in the clinical notes, bearing in mind that the patient has had a prostatectomy. Staff have also received additional reminders about the recall processes.

c) It developed an 'inbox pilot' whereby a registered nurse and a GP/nurse practitioner work together to monitor incoming documentation, correspondence, and results sent to the provider inbox. The pilot will allow for robust monitoring of important information, ensuring that this can be actioned appropriately in a busy and changing environment.

d) It held a discussion with its local laboratory potentially to change the 'normal' ranges for PSA levels for post-prostatectomy cases.

e) It updated its 'Management of Clinical Correspondence and Test Results Policy' and its 'Referral and Referral Tracking Policy'.

59. In addition, in response to HDC's proposed recommendations, the medical centre said that it would undertake the following changes:

a) Migration from Medtech to Medtech Evolution for its practice management software, which would allow for a greater level of system audit information, such as user access data.

b) Integration of the Manage my Health portal[17] with its practice management software, to facilitate effective communication with its consumers, as suggested by HDC's clinical advisor.

## Recommendations

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

a) Confirm that a patient portal has been implemented into its practice as an additional strategy to communicate test results to patients, and report back to HDC following the implementation within three months of the date of this report.

b) Confirm that all post-prostatectomy patients in its practice have had a double recall system established in its practice management system to facilitate timely clinician review of test results and interventions.

[17] A patient portal.

c) Confirm the implementation of the proposed inbox management process and confirm that the process has been communicated to staff at the medical centre, within three months of the date of this report.

d) Conduct an audit of a random selection of specialist letters and confirm that any specialist instructions and follow-up from the letters were actioned, within three months of the date of this report.

e) Provide HDC with an update on the discussions held with the local laboratory for changing the PSA reference ranges for post-prostatectomy cases, within three months of the date of this report.

61. I recommend that Dr E provide an apology letter to Mr A's wife and her whānau 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's wife and her whānau.

62. I recommend that NP F provide an apology letter to Mr A's wife 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's wife and her whānau.

## Follow-up actions

63. A copy of this report with details identifying the parties removed, except the clinical advisor on this case, will be sent to Te Aho o Te Kahu|the Cancer Control Agency, Te Tāhū Hauora|the Health Quality & Safety Commission, Te Kāhui Mate Pukupuku Repe Tātea o Aotearoa|the Prostate Cancer Foundation of New Zealand, and the Primary Health Organisation (PHO) for the region, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

64. A copy of this report with details identifying the parties removed, except the clinical advisor on this case, will be provided to Te Whatu Ora|Health New Zealand for the PSA reference ranges for post-prostatectomy patients to be considered at the National Pathology and Laboratory Round Table.

## Appendix A: In-house clinical advice to Commissioner

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

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

2. I have reviewed the following information:

- Complaint from [Ms B] on behalf of the whānau of [Mr A] (dec)
- Response from manager [medical centre company]
- GP notes [medical centre]
- Clinical notes [public hospital]

3. The complaint notes [Mr A] had prostate cancer treated in 2017 (urologist [Dr C]) and was discharged to his GP for regular surveillance of PSA levels. The instruction provided to the GP was that if PSA was detected at any stage [Mr A] should be referred back to the urologist for consideration of radiotherapy. [Ms B] states [Mr A's] PSA first became detectable in [Month8] and slowly rose thereafter but [Mr A] was not notified of the increasing levels and no referral made to the urology service. In [Month35] [Mr A] presented to a locum GP with abdominal pain. The locum noted the PSA pattern and referred [Mr A] for abdominal ultrasound (revealed liver with metastases) and to the urology service. Subsequent CT scan revealed pancreatic cancer and sadly [Mr A] died as a consequence of this on [date]. Whānau are concerned that [Mr A's] PSA results were not managed appropriately and this failure may have denied [Mr A] the chance of diagnosis of his pancreatic cancer at an earlier stage.

4. [Mr A] was diagnosed with prostate cancer in 2016 having been referred initially in [2016] (GP registrar) with mild lower urinary tract symptoms (LUTS), mildly elevated PSA and normal digital rectal examination (DRE). Repeat PSA in [2016] remained mildly elevated and [Mr A] was eventually seen by the DHB urology service. Biopsy revealed prostate adenocarcinoma and [Mr A] underwent non-nerve sparing radical prostatectomy and pelvic node dissection [in 2017] ([Dr C]). He was followed up by the urology service until [Month1] with regular PSA levels over this period being undetectable. Urology clinic report ([Dr C]) dated 21 [Month1] and addressed to [Dr D] includes: *I have said to [Mr A] that now we are two years out from his radical prostatectomy with an undetectable PSA, I would ask you to continue the follow up. He did have some extra-prostatic extension of tumour with a 0.2 mm positive margin, so I would be grateful if you* ***could check his PSA every six months for the next two years and then annually thereafter. If his PSA ever became detectable could you please refer him back immediately so that radiotherapy can be considered*** [my emphasis]. *[Mr A]*

*knows he can be in touch at any point should he be having troubles with his flow in which case I would see him back to look at a second dilatation.*

5. GP notes have been reviewed from [Month1]. Amongst the recorded disease classifications are: *Prostatectomy NEC — radical prostatectomy + bilat lymph node dissection [2017] and Malig neop prostate — prostate adenocarcinoma — under Urology — [Dr C].* I do not see any patient alert documented in relation to the PSA instructions provided by [Dr C] but there was evidently a recall set for six-monthly PSA testing with [Mr A] being sent reminder texts at appropriate intervals to ensure test was taken. Results are summarised below.

| Date | PSA Result | Requester | Comment |
|---|---|---|---|
| 19 Month1 | <0.05 µg/mL | […] | Undetectable PSA. Ordered by urologist |
| 18 [Month8] | 0.10 µg/mL | [Dr E] | Significant increase in PSA — now detectable |
| 12 [Month13] | 0.21 µg/mL | [Dr G] | Ongoing increase in PSA ordered by urologist |
| 7 [Month20] | 0.60 µg/mL | [NP F] | Ongoing increase, elevated GGT also noted |
| 10 [Month26] | 1.7 µg/mL | [Dr E] | Ongoing increase |
| 28 [Month29] | 2.8 µg/mL | [NP F] | Ongoing increase in PSA and GGT |
| 8 [Month25] | 5.7 µg/mL | [Dr E] | Followed up by [Dr H] |

6. [Mr A] was reviewed periodically for repeat of his usual medications for hypertension and hyperlipidemia. I note he had a history of abdominal surgery for … in addition to his prostate surgery. He was an ex-smoker. Alcohol intake is recorded on 27 [Month4] as being within recommended limits. The PSA result of 18 [Month8] has been annotated *ok* by provider identified as [x] (assumed to be [Dr E]). [Mr A] was seen on 23 [Month8] in relation to hand symptoms and again on 19 [Month10] for routine review. There is no record of LUTS symptoms being presented in 2019. PSA result dated 12 [Month13] has been annotated *0.21* by [x/Dr E] although the circumstances of receipt of the results are somewhat unclear. The test was ordered by DHB urologist [Dr G] and GP notes dated 10 [Month14] include: *p/c from pt — had blood test (PSA and creatinine) on 12 [Month13] ordered by urology — not in our inbox. Called [laboratory] to have results sent to [Dr E] …* However, GP notes dated 5 [Month14] included: [Patient] *rang for results, advised as per inbox.* Phone consultation notes dated 11 [Month16] [nurse

practitioner] for repeat of usual medications includes: *Discussed bloods taken in [Month13].* The precise nature of the discussion is not documented.

Comment: PSA result dated 18 [Month8] should have resulted in a referral back to the urology service as requested by [Dr C]. I note the test dated 12 [Month13] was ordered by DHB urologist [Dr G] and the reason for this is unclear. **The DHB should be asked to confirm why the test was ordered by [Dr G] (evidently with no cc to the GP) and how [Dr G] managed the test (when was it viewed, what actions were taken).** This test was another missed opportunity (possibly by both the DHB and the DHB urology service) to recognise the PSA indicated likely cancer recurrence and the need to consider salvage radiotherapy as a management option.

7. On 7 [Month20] [Mr A] was seen by [NP F] in relation to a rash and knee pain. Routine bloods were ordered and PSA result from that date is annotated *ok* and filed by [z] who I have assumed is [NP F]. I note an isolated elevation of GGT was also evident at this time (most commonly alcohol related but I note previous reference to intake within acceptable limits). It is not clear what information was provided to [Mr A] regarding these results although on 7 [Month23] there is a nursing note: *wanting blood results — advised as per inbox — happy with that.* There were further consultations in 2020 regarding rash (biopsied and thought to be medication related) and foot pain. [Mr A] was recalled for routine blood tests in [Month26] and PSA has been annotated *1.7* by [x/Dr E]. On 8 [Month29] there was a telephone consultation with [Mr A] (Dr …) in relation to postural dizziness. [Month20] blood test results were evidently reviewed with comment that repeat tests were due and *creat gfr 71, same time lytes other ok, has recall in place for [Month32].*

Comment: It appears the recall in place followed [Dr C's] recommendation of six-monthly PSA for two years then annual PSA but the recommendation of referral if there was detectable PSA was overlooked.

8. Blood tests were repeated in [Month29], in part for investigation of [Mr A's] dizziness symptom. PSA result was annotated *2.8 ok* and filed by [z/NP F]. There was again an isolated elevation of GGT with an increase from the previous result (197 U/L — reference range 10–50). A text message was evidently sent to [Mr A] on 24 [Month29] advising him his results were acceptable. [Mr A] was recalled for blood tests in [Month35] (unclear if this is related to the scheduled [Month32] recall). PSA result was annotated *5/7, needs review please* and filed by [x/Dr E].

Comment: It appears [Mr A's] PSA was being managed in the context of no previous history of prostate cancer with recognition of an abnormality only when the level climbed outside the age-specific reference range.

9. On 17 [Month35] [Mr A] was reviewed at [the medical centre] by [Dr H]. The main symptom presented was two weeks of persistent nausea with upper abdominal tenderness and bloating noting on examination. A foot pain issue was also addressed together with discussion of recent blood test results, including PSA. Abdominal

ultrasound was ordered, and [Dr H] made an urgent referral to the urology service dated 17 [Month35]+ which included: *Please see this [man in his sixties] previously treated for prostate cancer, with some urgency. I met him today when he presented to me regarding a concern that is very likely unrelated, and reported to me that he had some lab results to review. I am copying the note below from the consultation nonetheless. I was alarmed to see a PSA of 5.7 and looked back through his notes. There was a plan from Urology that he should be referred back if the PSA became detectable. This occurred in [Month8] and has never been acted upon. In the meantime the PSA has been steadily climbing. Notwithstanding that he does not appear to have had any real worsening of urinary symptoms*.

10. Urology clinic report dated 22 [Month35] ([Dr C]) includes: *I received a letter from your locum outlining the fact that [Mr A's] PSA has unfortunately been detectable since [Month8]. The most recent reading is 5.7 on the 8th [Month35] this year.* Staging CT scan was organised with radiotherapy advised if this showed disease localised to the prostate bed. The ultrasound ordered by [Dr H] was undertaken on 22 [Month35] and showed multiple liver lesions consistent with metastatic disease, not evident on the staging CT performed in 2016 prior to [Mr A's] prostate surgery. Updated CT scan dated 31 [Month35] showed a pancreatic mass (likely pancreatic cancer) and liver metastases together with separate evidence of likely recurrent prostate cancer recurrence in left pelvic sidewall lymph nodes. The urology service deferred any further prostate intervention with priority being management of the newly diagnosed pancreatic cancer. I am unable to determine from the available information how the pancreatic cancer was managed but note a majority of cases of pancreatic cancer are inoperable and advanced at the time of diagnosis (less than 20% amenable to surgery which might alter prognosis) with a five-year survival rate of 5–15% and overall survival rate of 6%[1]. This is related mainly to the occult nature of the disease with initial symptoms being non-specific and often mild until the disease is well advanced.

11. The [medical centre company's] response acknowledges there was a significant oversight in the management of [Mr A's] PSA result. [Mr A's] registered GP was [Dr E] and [Dr E] and [NP F] signed off PSA results over the period in question. Multiple team members other than the registered GP may be involved with patient management including ordering tests per the patient recall system with the result coming back for review to the clinician ordering the test. It appears these clinicians were either not aware of or did not recall the context of the PSA testing and need for referral if PSA became detectable. Consequently, the results were managed using the normal reference range for comparison and were therefore deemed "OK" until they fell outside this range. The response notes the practice policy of not routinely informing a patient of normal results (which is common practice) although I note on most occasions [Mr A] enquired after his results and on one occasion was sent a text reassuring him the results were acceptable. I am not sure whether the significantly elevated GGT was a longstanding issue but I believe this result also required acknowledgement and

[1] Puckett Y, Garfield K. Pancreatic Cancer. [Updated 2022 Jan 21]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK518996/

discussion with [Mr A], mainly to determine whether excessive alcohol intake was a likely cause and to offer counselling if this was confirmed. An isolated GGT elevation seldom reflects significant liver disease and does not usually require additional investigation or follow-up if other liver function tests are normal (as they were in this case)[2].

12. [The medical centre company] has reviewed this incident at a clinical management level and have attempted to increase the robustness of their results and clinical correspondence management process. This includes adding an alert whenever a result is likely to require specific consideration (eg usual reference range not applicable) and considering a double recall system for patients undergoing post-treatment surveillance for recurrence of prostate cancer (recall for tests itself then reminder two weeks later to ensure test has been done and reviewed). There are also discussions being held with the local laboratory service to determine whether a different reference range or comment could be attached to PSA results for patients undergoing post-treatment surveillance. I have reviewed the policy documents provided by [the medical centre company] (Inbox Management, Referrals and Referral Tracking, Recalls, Management of Clinical Correspondence and Test Results) and these appear fit for purpose and consistent with similar policies I have reviewed from other medical centres.

13. The failure by [the medical centre company] clinicians to adhere to the urologist recommendations with respect to management of [Mr A's] PSA results must be regarded as a moderate to severe departure from accepted practice. Mitigating factors include the observation an effective recall system was in place to ensure the tests were performed (had the urologist surveillance recommendations been overlooked entirely this would be a severe departure from accepted practice), there was a classification of [Mr A's] prostate cancer and radical prostatectomy history, and the general standard of clinical documentation and care (in relation to [Mr A's] other chronic and acute conditions) appears very reasonable. In signing and filing a test result, there is an expectation this action has been taken with an awareness of the clinical context in which the test has been ordered. However, at a practical level this concept can be difficult to maintain particularly when staff may be charged with reviewing multiple results for multiple patients with whom they are not familiar but there is no time capacity to review the clinical notes of each patient prior to signing off apparently normal results. As the primary care workforce crisis accelerates, particularly in rural areas, it will be increasingly common for multiple members of a clinical team, including transient locums, to be involved with reviewing and management of results for unfamiliar patients and it is vital there are processes in place to minimise the risk of error and patient harm. The PMS has the capability to show patient alerts and I believe use of this resource, and/or an appropriate comment in the patient classifications, might have been considered with respect to monitoring of [Mr A's] PSA from the outset. However, "alert fatigue"[3] whereby repeated presentation of multiple alerts has a diminishing effect in terms of maintaining clinician awareness, is a recognised concept

[2] Community HealthPathways. Section "Abnormal Liver Tests" Accessed 19 September 2022
[3] https://psnet.ahrq.gov/primer/alert-fatigue Accessed 19 September 2022

and limits the ongoing effectiveness of this strategy. Most PMSs enable an automatic "Task" to be set for review of test results when a request form is generated but this can result in an overwhelming task list for many clinicians who subsequently disable the function and rely on setting a personal task reminder on a case by case basis. The Recall module could be used as discussed by [the medical centre company] to ensure tests are performed and results reviewed and this might be a more reliable strategy than the routine use of the Task Manager module.

14. Perhaps one of the most important and overlooked strategies is to facilitate an effective partnership with the patient in terms of managing their clinical information including results. Using [Mr A's] case as an example, this would involve explaining to him from the outset the PSA surveillance regime including what constitutes a reassuring or non-reassuring result and to provide access to his results (numerical value rather than comment) once filed, preferably via a patient portal or otherwise via telephone or text i.e. giving him the information and tools to take an active role in his surveillance. As at Month23 over 25% of patients nationally had access to a patient portal[4] and this is likely to have increased since that time as a consequence of face to face access issues secondary to the Covid pandemic. [The medical centre company] might give consideration to use of a patient portal as an additional results management strategy.

15. I believe the management of [Mr A's] gastrointestinal symptoms, which led to diagnosis of his pancreatic cancer, was conscientious and appropriate. The symptom history was around two weeks and abdominal ultrasound was ordered promptly and showed metastatic disease of the liver which was then revealed to be related to a pancreatic tumour. As discussed previously, such late diagnosis is characteristic of this disease. However, it must be acknowledged that had an earlier referral been made in regard to [Mr A's] elevated PSA, and a CT scan performed as part of pre-radiotherapy planning, it is possible (but not inevitable) that the pancreatic tumour may have been detected opportunistically at a somewhat earlier stage.'

[4] https://www.health.govt.nz/system/files/documents/pages/patient_portal_report_-_1st_oct_to_31st_dec_2020.pdf Accessed 19 September 2022