Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Health and Disability Commissioner

(Case 22HDC03116)

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Introduction

1. This report discusses the care provided to Mr A by a urologist, Dr B, in 2022. The report concerns issues of informed consent and the decision to proceed with a radical prostatectomy[1] with lymph node dissection[2] as a form of treatment.

2. The following issue was identified for investigation:

- *Whether Dr B provided Mr A with an appropriate standard of care in 2022.*

3. The parties directly involved in the investigation were:

Mr A	Consumer
Dr B	Urologist/provider

4. Further information was received from:

Radiology service	
Dr C	Radiation oncologist
Mr D	Support person of Mr A
Mr E	Further support person of Mr A
ACC	

[1] A surgical procedure in which the prostate gland is removed through an incision in the abdomen.
[2] Surgical removal of the lymph nodes with a sample of tissue taken to be checked for signs of cancer.

5. Independent clinical advice was obtained from a urologist, Dr Jonathan Masters (Appendix A).

Information gathered during investigation

Background

6. Mr A, aged in his sixties at the time of events, had a 10-year history of gradually increasing, moderate lower urinary tract symptoms and a relatively poor urinary flow rate.[3] Dr B first met Mr A on 31 March 2022, after he was referred by his general practitioner (GP) for an elevation in his prostate-specific antigen (PSA) levels.[4] During this initial consultation, Dr B recommended repeating the PSA test and undertaking an MRI[5] prior to considering whether a biopsy[6] of the prostate should be taken.

7. On 6 April 2022, Mr A's PSA levels had decreased to 5.8 but remained elevated. Accordingly, Dr B's secretary contacted Mr A on 19 April 2022 to book an appointment with Dr B and to have an MRI completed. This was undertaken on 11 May 2022 and showed two lesions[7] within Mr A's prostate. Dr B told HDC that there was no evidence of cancer spread through the wall of the prostate at this stage.[8]

8. On 19 May 2022, Dr B discussed the findings of the MRI scan with Mr A by telephone. Dr B told HDC that he explained that the presence of the lesions, although small, required further investigation. Dr B recommended a prostate biopsy, which was performed on 1 June 2022.

9. On 21 June 2022, Mr A was informed that the biopsy indicated high-grade prostate cancer.[9] Dr B told HDC that he explained to Mr A that although his PSA was relatively low, and the MRI did not show any direct growth of the lesion or spread outside the prostate, the grade meant that he fell into the high-risk grouping for prostate cancer. Dr B's clinical letter from

[3] Mr A's flow rate was Qmax 5.1mL/s on a 146mL void. Average urinary flow rate for a man over the age of 50 is 8.9mL/s.

[4] PSA is a protein produced in the prostate gland. A higher-than-normal level of PSA in the blood may indicate benign prostate hyperplasia, infection or inflammation of the prostate, or prostate cancer. The normal range is between 1.0 and 1.5ng/mL. For men in their sixties, a PSA level greater than 4.0ng/mL is considered abnormal. Mr A's result at this stage was 6.1ng/mL.

[5] Magnetic resonance imaging — a non-invasive procedure that produces detailed images of the internal structures of the body.

[6] The extraction of sample cells or tissues for examination to determine the presence or extent of a disease.

[7] One lesion was a 9mm 'Prostate imaging-reporting and data system' (PIRADs) 4 lesion, and one was a 7mm PIRADs 3 lesion. Each lesion is assigned a score from 1 to 5 indicating the likelihood of clinically significant cancer, with 1 being the lowest likelihood, and 5 being the highest.

[8] This was because there was no lymphadenopathy (swelling of the lymph nodes) or bony lesions seen within the pelvis. Lymphadenopathy can be secondary to bacterial, viral, or fungal infections, autoimmune diseases, and malignancy.

[9] ISUP (International Society of Urological Pathology) is a grading system for prostate cancer. Mr A's prostate cancer was considered ISUP grade 5, which is the highest ISUP grade for prostate cancer.

this appointment documented that a PSMA PET CT scan[10] was requested 'for staging purposes'.

10. Dr B stated that at this appointment he discussed both radiotherapy and surgery as treatment options and outlined the common side effects of the treatments. Dr B's clinical letter from this appointment records: '[Mr A] would be a candidate for either surgery or radiation. He is considering surgery at this point.'

11. Dr B provided Mr A with the New Zealand Cancer Society's booklet on prostate cancer[11] (the prostate cancer booklet), which details the diagnostic process and treatment options. Dr B asked Mr A to write down any questions he had for the next appointment and directed him to useful links on his website. The prostate cancer booklet (approximately 80 pages long) describes cancer and the understanding of prostate cancer, diagnosing of prostate cancer, making treatment decisions, treating prostate cancer, and living well with prostate cancer. The booklet suggests websites and books and includes a glossary of key terms and support services information.

12. In response to the provisional report, Mr A told HDC that 'while [the prostate cancer booklet] talks about side effects it has no mention of the likelihood of those side effects, or whether they were more or less likely with surgery than radiation, or if they were cumulative if [he] had to have both forms of treatment'.

13. Dr B told HDC that the prostate cancer booklet specifically details the role of radiotherapy in prostate cancer treatment, the availability of radiotherapy in New Zealand, and the right to consultation with a radiation oncologist. Dr B stated that he did not refer Mr A to a radiation oncologist as Mr A had 'expressed his preference for surgery for the treatment of his prostate cancer'.

14. A PSMA PET CT scan was performed on 5 July 2022.[12] The scan report stated: '[Impression:] PSMA avid disease involving the prostate gland and pelvic lymph nodes … A few areas of mild PSMA avidity within the ribs without CT correlate; indeterminate in this context.' Dr B told HDC that he considered 'the 3–6mm lymph nodes identified [in the report] as an inconclusive finding'.

15. On 6 July 2022, Dr B met with Mr A and Mr A's support person, Mr D, to discuss the findings. Dr B's recollection is that he explained the findings and noted that the lymph nodes did not meet the size criteria to conclude that the cancer had spread[13] on CT imaging and had not been visibly abnormal on the previous MRI. Dr B said that they also 'spent some time during the consultation focusing on the rib lesion' as this required a lengthy explanation.

[10] PSMA stands for 'prostate-specific membrane antigen'. A PSMA PET CT scan is used to detect prostate cancer in the body, with the scan result referring to 'PSMA avidity'.
[11] https://www.cancer.org.nz/assets/Downloads/Booklet-a-guide-for-people-with-prostate-cancer.pdf
[12] The clinical notes for the PSMA PET CT scan indicated: 'PSA 6. ISUP 5. ?metastasis.'
[13] Dr B told HDC that on conventional imaging (CT scan or MRI), 1cm is used as the size criterion for metastasis.

16. In contrast, Mr A told HDC that on review of his scan, '[Dr B] told [him] that no spread had been detected, other than a marking on the ribs which he believed to be harmless'.

17. Mr D told HDC that Dr B discussed the scan results and said that the cancer had not broken through the wall (of the prostate) which was a 'good sign'. Further, Mr D stated that they were informed by Dr B that the lymph nodes in the region would be biopsied to see whether the cancer had left the prostate.

18. Mr D also told HDC that Dr B discussed two markers on Mr A's rib area and described them as an 'anomaly and not cancer'. Mr D said that while he cannot remember every word from this appointment, he had the 'clearest understanding that cancer hadn't left [the] prostate except for the marking on the ribs'.

19. Dr B's clinic letter, dated 6 July 2022, recorded no specific discussion about pelvic lymph nodes and documented only: '[Mr A's] PSMA scan has come back showing an indeterminant area in the ribs which has no CT correlate.'

20. Dr B told HDC that although his belief at the time was that he had informed Mr A about the findings of the PSMA PET CT scan adequately, he now accepts that he did not. Dr B stated:

> 'Reviewing my notes, I have not documented any discussion around pelvic lymph nodes however I have specifically recorded that lymphadenectomy would be required … Although this is my recollection, if both [Mr A] does not recall it and his friend did not write it down I concede that I have clearly failed to communicate this effectively. It is possible that I spent too much time talking about the rib lesion and not enough time addressing the findings in the pelvis.'

21. Dr B accepts that the documentation of this discussion was inadequate.

22. Dr B told HDC that during this consultation with Mr A, he advised that radiation and surgery were options available to him, and that when proceeding with the option of surgery, pelvic lymph node dissection (lymphadenectomy) would be required. Dr B said that he answered all Mr A's questions, and, given Mr A's concern about the risk of progression of the cancer, he offered him the option of short-term hormonal therapy until a date for his surgery had been scheduled. Dr B told HDC: 'I felt that [Mr A], who is relatively young and in good health should not be excluded from treatment options.'

23. The clinic letter documented:

> '[Mr A's] options are surgery or radiation and he has chosen robotic prostatectomy which would include pelvic lymph node dissection [lymphadenectomy]. He is very keen on a nerve sparing approach.'

24. Mr D confirmed that radiation and surgery were discussed but said that the focus of the discussion was on surgery.

25. Mr A told HDC that although the options of radiation and surgery were presented to him, he understood that 'surgery was the right route' and, when he queried this with Dr B, he agreed. Mr A said that it was his understanding that surgery was 'more beneficial than radiation', which was the basis for the treatment route he chose.

26. Mr D told HDC that the focus of the appointment was around removing the prostate but there was some discussion on sensitive side effects.

27. There is no documentation of side effects having been discussed with Mr A at this appointment. However, a stamp included on the preoperative consent form signed on 6 July 2022 by Dr B, and on 7 July 2022 by Mr A, listed sensitive side effects. The consent form also included the following statement:

> 'I confirm I have received a satisfactory explanation of reasons for, risks and likely outcomes of the procedure/operation/treatment, and the possibility and nature of further related treatment including returning to theatre, should any complications arise.'

28. Mr A stated that '[he] was aware of side effects and that they could be bad' and that there was a risk of sensitive side effects. Mr A told HDC that he 'was not told that having both surgery and radiation had a cumulative effect on the risk of [specific sensitive] problems'. He also said that he was not told that the 'risk of [sensitive] side effects was worse with surgery than with radiation'.

29. Mr A said that based on the information he received from Dr B, as well as other information he was presented with, his impression was that both surgery and radiation carried similar side effects and risks, but with the benefit of hindsight, he 'does not think this is the case now'.

30. Mr A told HDC that based on the information provided by Dr B, he 'decided to go ahead with the operation'. Mr D told HDC that Mr A took the option of surgery as this was his 'best chance' to remove the prostate and therefore remove the cancer.

31. Mr A's surgery was scheduled for 4 August 2022. Dr B told HDC that on that day he met with Mr A and, before entering the operating theatre, he asked Mr A whether he had any questions. Dr B stated: '[Mr A] understood that I would include lymphadenectomy as part of the operation and the risks of the surgery.'

32. Mr A underwent a radical prostatectomy with lymph node dissection. Dr B described the operation as 'uneventful'.

Post-surgery

33. Following the surgery, Mr A's cancer was confirmed to be grade 5[14] that had extended through the prostate capsule into the layer of fat surrounding the prostate.[15] Two of the lymph nodes that were dissected during surgery came back positive for metastatic[16] disease. Dr B discussed these results with Mr A on 16 August 2022 and informed him that the chance of other metastatic disease was high. Dr B advised that Mr A's PSA levels would be monitored but that further treatment could be necessary in the future.

34. Mr A was seen by Dr B on 27 September 2022, at which time his elevated PSA levels[17] were discussed and a PSA test was repeated.[18] Accordingly, a repeat PSMA PET CT scan was arranged and undertaken on 3 November 2022.

35. Mr A and another support person, Mr E, attended an appointment with Dr B on 8 November 2022. Mr E told HDC that 'post operative matters' were discussed during this appointment. He noted that 'Dr B talked about … the results of the latest scan and … he mentioned [Mr A's] cancer had spread to some lymph nodes outside of the prostate'. Mr E told HDC that Mr A asked Dr B about the results and whether he had detected these earlier, to which Dr B responded that 'he hadn't detected … cancer in the lymph nodes in any of the previous scans, so he was very clear about that, that he had not detected it previously and this was new'. Following receipt of these results, Dr B recommended a referral to a radiation oncologist to consider whether pelvic radiotherapy would be an option for management of the lesions.

36. Mr A was referred to Dr C, a radiation oncologist, for further treatment. During his first appointment on 17 November 2022, Dr C noted that the spread of cancer to the lymph nodes in Mr A's pelvis had been revealed in the preoperative PSMA PET CT scan in July 2022. Mr A told HDC that he 'was surprised when [Dr C] noted that a spread to several regional lymph nodes had been revealed by the pre-op … scan' as this was the first time he was made aware of this. During this appointment, Mr D was present as a support person. He told HDC that when Dr C was going over Mr A's notes and mentioned that the cancer had spread to the lymph nodes, he and Mr A said: 'What? I beg your pardon, can you please repeat that?' Mr D said that this 'was a bombshell' as they were completely unaware of any regional cancer spread in the pelvic lymph nodes.

37. Mr A told HDC: 'I was not told that the surgery would not be curative as the cancer had spread outside and therefore that I would subsequently require radiation.'

[14] ISUP 5 grade.
[15] The cancer also had a positive margin recorded. A margin is described as positive or involved when the pathologist finds cancer cells at the edge of the tissue, suggesting that all the cancer has not been removed.
[16] The spread of cancer cells from the place where they first formed to another part of the body.
[17] Recorded as 0.7.
[18] Recorded as 0.8.

38. At the end of this appointment, Dr C recommended radiation[19] and androgen deprivation therapy (ADT)[20] as treatment for Mr A. Mr A told HDC:

> 'At this point I began to question what the point of the original surgery was? I would obviously never have undertaken surgery had I known I would have to undertake radiation treatment and ADT after the operation.'

39. On 21 November 2022, Mr A emailed Dr B detailing the conversation had with Dr C. Mr A told Dr B that he had been unaware of the preoperative PSMA PET CT scan results and asked Dr B to explain the rationale for the surgery. Mr A wrote:

> 'I was surprised to discover during the consultation with [Dr C] that this metastatic spread was first detected in the PET scan that I had on July the 5th, a month before my prostatectomy. During our consultation on July the 6th, you indicated that the scan was clear (apart from a shading on the ribs which was discounted) and that surgery was a reasonable way to go.'

40. Dr B replied by email, reiterating his interpretation of the PSMA PET scan results as showing a 'number of non specific findings'. He explained:

> 'There were also a number of small lymph nodes in the pelvis which showed some PSMA pick up. These lymph nodes were not large enough to fit the CT definition of metastasis (i.e. they were less than one cm) but they did show some PSMA activity suggesting that they might represent early disease spread. This was the reason for removing the lymph nodes during the surgery — firstly to determine the nature of the nodes and secondly in the hopes of a curative outcome if that proved to be the case.'

41. Dr B said that the rationale for surgery was his 'impression that [Mr A's] scan did not conclusively show disease spread but high risk that this might be the case'. Dr B telephoned Mr A the following day (22 November 2022). Dr B's telephone note records that he apologised that he had not communicated the scan results 'to the point where [Mr A] understood them'.

Information provided by ACC

42. Following Mr A's prostate cancer diagnosis, a treatment injury claim was lodged with ACC for 'unnecessary radical prostatectomy and lymph node dissection'. ACC accepted the treatment injury claim and, as part of its assessment, ACC sought external advice from a radiation oncologist. A copy of this report was provided to HDC by ACC.

43. ACC's external advisor's treatment injury advice states that the standard of care in New Zealand for a patient such as Mr A would be radical radiotherapy plus bilateral lymph node irradiation and an 18-month period of ADT. ACC's external advisor advised ACC that Mr A received an unnecessary radical prostatectomy and lymph node dissection as Dr B had not

[19] Cancer treatment that uses radiation to kill or control the growth of cancerous cells.
[20] ADT uses medication to reduce testosterone levels and treat prostate cancer.

appreciated that the results of the preoperative PSMA PET CT scan had 'clearly showed he had [an] inoperable disease'.

Further information

Mr A

44. Mr A told HDC that the care he received from Dr B has impacted him significantly. Mr A stated that had he been made aware of the spread of his cancer during the preoperative appointment with Dr B in July 2022, he 'would obviously never have undertaken surgery'.

Dr B

45. Dr B told HDC that his rationale for surgery as a treatment option was his impression at the time that 'the scan [had] overcalled the extent of [Mr A's] disease because of the findings on conventional imagining and the low PSA value'.

46. Dr B accepts that Mr A's preoperative PSMA PET CT scan results were not communicated to him fully and that, in retrospect, the PSMA PET CT scan results were a more accurate representation of the extent of Mr A's prostate cancer than the conventional imaging.

47. Dr B told HDC that a PSMA PET CT scan is a relatively new form of investigation for prostate cancer and currently is not readily available throughout New Zealand. Dr B stated:

> 'Although the scan is now considered more accurate than conventional imaging, the current European guidelines specifically comment that "no outcome data exist[s] to inform subsequent management". At the current stage, sufficient studies have not been completed to show that changing management on the basis of PSMA PET CT scan findings that contradict conventional imaging findings makes a difference to the outcome for patients treated for prostate cancer.'

48. Dr B told HDC:

> 'I fully appreciate the amount of distress that [Mr A] has experienced as a consequence of his surgical treatment of prostate cancer and am deeply sorry for having contributed to that. I do not accept that I was unconcerned by his troubles. At each step of his journey I have tried to perform his treatment as expeditiously as possible and minimise the problems that he has had.'

Responses to provisional opinion

Mr A

49. Mr A was given an opportunity to respond to the 'information gathered' section of the provisional report.

50. Mr A told HDC that while he appreciates '[Dr B's] acceptance of the error of his ways and his promise to change in future', this does not correct the damage that has already been done to him. Mr A stated that he continues to be affected by the events that occurred, and he is still living with prostate cancer and is having to pay a significant amount for further targeted radiation treatment.

Dr B

Dr B was given the opportunity to respond to the provisional opinion, and his comments have been incorporated into the report where relevant and appropriate.

Opinion: Dr B

Introduction

51. At the outset, I offer my condolences to Mr A for his diagnosis and acknowledge his ongoing distress. I wish him all the best for his future treatment.

52. I also acknowledge Dr B's engagement throughout HDC's investigation process and commend him for reflecting on his practice and making changes moving forward (as outlined in the 'changes made' section below).

53. As a healthcare provider, Dr B has a responsibility to provide his patients with healthcare services in accordance with the Code of Health and Disability Services Consumers' Rights (the Code). I have carefully considered all the information gathered on this case, including responses received from Dr B, and I set out my decision and the reasons for it below. I sought independent clinical advice from a urologist, Dr Jonathan Masters, and I have incorporated this in relevant areas of my opinion.

54. Overall, I consider that Dr B breached Rights 4(2),[21] 6(2),[22] and 7(1)[23] of the Code.

Informed consent — breach

55. Following Mr A's diagnosis of prostate cancer, he was offered two primary treatment options — radiation or surgery (a radical prostatectomy with lymph node dissection). Mr A is concerned that he opted for surgery as a treatment option on the understanding that his prostate cancer had not spread to the surrounding lymph nodes. Mr A's key concerns are that he did not receive a full explanation of his preoperative scan result and that he did not understand the rationale for surgery.

56. Informed consent lies at the heart of the Code. Pursuant to Right 6(2) of the Code, before a consumer can make a choice or give consent, they have the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive to make an informed choice or give informed consent. Furthermore, Right 7(1) of the Code states that every consumer has the right to receive services only if that consumer makes an informed choice and gives informed consent. The responsibility for ensuring that the

[21] Right 4(2) states: 'Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.'

[22] Right 6(2) states: 'Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.'

[23] Right 7(1) states: 'Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.'

consumer has been provided with sufficient information to make an informed choice and give informed consent lies with the clinician who is to undertake that treatment.

57. In my view, a reasonable consumer in Mr A's circumstances would have expected to receive a full explanation of their preoperative scan result, options for treatment, and the associated risks, side effects, and benefits of those treatment options, including the rationale for surgery as the preferred treatment option.

Preoperative scan result (PSMA PET CT)

58. Mr A's PSMA PET CT scan report of July 2022 noted: 'PSMA avid disease involving the prostate gland and pelvic lymph nodes … A few areas of mild PSMA avidity within the ribs without CT correlate; indeterminate in this context.' Mr A complained that during the consultation on 6 July 2022, Dr B did not communicate this result adequately, and, as a result, Mr A did not understand that his cancer had spread to his pelvic lymph nodes and the implications of this. Mr A's support person, Mr D, who attended this appointment, recalled that Dr B discussed the scan results and that the cancer had not broken through the wall (of the prostate), which was a 'good sign'.

59. Dr B's recollection is that he explained the findings of the PSMA PET scan and that the pelvic lymph nodes did not meet the size criteria for metastases, and he gave a detailed explanation about the rib lesion identified.

60. Dr B's clinic letter documented: '[Mr A's] PSMA scan has come back showing an indeterminant area in the ribs which has no CT correlate.' The letter contained no specific mention of a discussion about pelvic lymph node involvement.

61. Dr B accepts that his communication with Mr A about his PSMA PET CT scan result was inadequate at the 6 July consultation, and subsequently Dr B apologised to Mr A. On 22 November 2022, Dr B explained in an email to Mr A that his impression was that the scan 'did not conclusively show disease spread [to the pelvic lymph nodes] but high risk that this might be the case'. I consider that this explanation was not given to Mr A on 6 July 2022, and that overall, Mr A was not adequately informed of all relevant information about his PSMA PET CT scan result, in particular the involvement of the pelvic lymph nodes.

Treatment options

62. In relation to the different treatment options, it is documented that surgery and radiotherapy were discussed as options on 21 June 2022 and 6 July 2022. Mr D confirmed that these options were discussed on 6 July. I accept that both treatment options were discussed with Mr A.

63. Dr Masters (my clinical advisor) advised that in addition to these options, '[a]s per the Prostate cancer quality performance Indicator Action plan (4) it is anticipated that the majority of patients should be offered the chance to see a radiation oncologist prior to treatment'. He stated: 'In this case I think it would have been helpful particularly in the light of the PSMA PET CT result pre op.'

64. Dr B told HDC that he did not discuss the opportunity to be referred to a radiation oncologist prior to treatment because this information was contained in the prostate cancer booklet provided to Mr A, and Mr A had expressed a preference for surgery. I do not accept this as an adequate explanation. I also do not accept that it was sufficient to assume that Mr A was aware of his option of a referral to a radiation oncologist because it was contained in the prostate cancer booklet. This option should have been communicated to Mr A when the treatment options were discussed, and I am critical that it was not.

Risks, side effects, and benefits

65. The clinical records (other than the surgical consent form) contain no documentation about any discussion of the risks, side effects and benefits of surgery and radiotherapy. Dr B told HDC that he discussed the common side effects of both radiotherapy and surgery at the 21 June 2022 appointment, and the treatment options were discussed again on 6 July 2022. Mr A confirmed that the risks and side effects were discussed preoperatively, including sensitive side effects.

66. As detailed in paragraph 27, a list of possible risks and side effects was stamped on the preoperative consent form, indicating that there had been a discussion about this. On 7 July 2022 Mr A signed the consent form, which stated:

> 'I confirm that I have received a satisfactory explanation of the reasons for, risks and likely outcomes of the procedure/operation/treatment, and the possibility and nature of further treatment including a return to theatre, should any complications arise.'

67. The common side effects were also detailed in the prostate cancer booklet.

68. Mr A told HDC that he opted for surgery based on the treatment options presented to him, the information communicated regarding his scan results, and the information he received from Dr B about the potential side effects. Mr A said that he did not understand that surgery was not curative or that the risk of certain sensitive side effects was greater with surgery, and that had he been informed, he would not have proceeded with this choice. I am concerned that Mr A was not provided with sufficient information about the benefits (as opposed to risks) of surgery for his condition.

Conclusion

69. A reasonable consumer in Mr A's circumstances would expect to receive a full explanation of their PSMA PET CT scan result, all options for treatment, and the associated risks, benefits, and side effects of those treatment options, including the rationale for surgery. As discussed above, I accept that there was a discussion about treatment options and the risks and side effects of surgery, but I am critical that the discussion did not mention all possible side effects. I am also critical that Dr B did not provide Mr A with an appropriate explanation of his PSMA PET CT scan result in that Mr A did not understand that his pelvic lymph nodes were involved, and he did not have the opportunity for a radiation oncology review or a clear explanation of the benefits of radiation or surgery. As a result, Mr A did not receive all the relevant information prior to electing to proceed with surgery.

70. Accordingly, I find that Dr B did not provide Mr A with the information that a reasonable consumer in his circumstances would expect to receive. Therefore, I find that Dr B breached Right 6(2) of the Code. It follows that as Mr A did not make an informed choice, he did not give informed consent to the procedure, and I find that Dr B also breached Right 7(1) of the Code.

Documentation — breach

71. According to the Medical Council of New Zealand's standards of managing patient records,[24] '[p]atient records reflect a doctor's reasoning and are an important source of information about a patient's care'. This standard states that a patient's medical records should include (but is not limited to) information given to and options discussed with patients, decisions made and the reasons for them, consent given, and requests or concerns discussed during the consultation.

72. The contemporaneous clinical records from Dr B's consultations with Mr A on 21 June and 6 July 2022 contain no discussion about the PSMA PET CT scan result, including the involvement of the pelvic lymph nodes and what this meant. Dr B accepts that his documentation of this discussion was inadequate. Furthermore, it is noted in the clinical records from the consultation on 6 July 2022 that discussion was had regarding the option of surgery or radiation, but there is no detail about exactly what was discussed with Mr A. The clinical records for these consultations also contain no mention of a discussion with Mr A about the potential risks, side effects, and benefits of the treatment options, or that the proposed course of treatment was surgery.

73. My independent clinical advisor, Dr Masters, considers that overall Dr B's documentation of the consultation that led to the decision to proceed with a radical prostatectomy was of a very poor standard. Dr Masters advised that in these circumstances, there should have been better documentation about what was discussed with Mr A, and this should have specifically included the presence of pelvic lymph nodes, the implications of the avidity of the nodes, and the treatment options. I accept Dr Masters' advice and consider that Dr B's documentation deviated from the accepted standards.

74. I am critical that Dr B did not document his discussions with Mr A adequately. Given Mr A's diagnosis and prognosis, I would have expected Dr B to have taken appropriate steps to ensure that his discussions with Mr A, including the information provided to him, were documented adequately and accurately reflected what was discussed. Accordingly, I find that Dr B breached Right 4(2) of the Code (the right to have services provided that comply with relevant professional standards).

Consideration of multidisciplinary meeting (MDM) — educational comment

75. Dr Masters said that in the absence of advice from a radiation oncologist, this case should have been discussed in an MDM with both radiologists and the radiation oncologist involved in Mr A's care to confirm and interpret the PSMA PET CT scan findings. Dr Masters advised

[24] Medical Council of New Zealand, 'Managing patient records' (December 2020): https://www.mcnz.org.nz/assets/standards/0c24a75f7b/Maintenance-patient-records.pdf

that the outcome of this meeting should have been discussed with Mr A prior to proceeding with surgery as a treatment option, to ensure that he was provided with adequate information to make an informed decision about his treatment.

76. Dr Masters stated that if Dr B was doubtful about whether the cancer had spread to Mr A's lymph nodes in the pelvis, an MDM would have provided an opportunity to ask for a review of the films from the PSMA PET CT scans. I accept Dr Masters' comments and have recommended that Dr B reflect on this aspect of his care.

Appropriateness of surgery — no breach

77. Mr A is concerned that he underwent surgery unnecessarily. I acknowledge that ACC accepted a treatment injury claim and that its external advisor agreed that Mr A received unnecessary surgery. I acknowledge the ACC advisor's view, but I have come to a different conclusion. The ACC advice was obtained for a different purpose — to ascertain whether a treatment injury occurred — and the advice was sought from a radiation oncologist, which is not Dr B's specialty. I obtained independent advice from Dr Masters, a urology peer of Dr B, to establish the appropriate standard of care relevant to his scope of practice, based on what was known to Dr B at the time. I have also had the benefit of further information and responses from Dr B, which were not available to the ACC advisor.

78. Dr B told HDC that after informing Mr A of his prostate cancer diagnosis, he considered both radiotherapy and surgery as treatment options. As outlined above, Mr A chose to proceed with surgery, which was undertaken on 4 August 2022.

79. Dr B's rationale for surgery was that scans have a level of uncertainty, and his impression at the time was that 'the scan ha[d] overcalled the extent of [Mr A's] disease because of the findings on conventional imaging and the low PSA value'. It is also noted that Mr A had a 'relatively poor [urinary] flow rate' when he was first referred by his GP to Dr B. Dr B told HDC that '[he] felt that [Mr A], who is relatively young and in good health should not be excluded from treatment options'.

80. Dr Masters advised that Mr A's surgery was not unnecessary, and that Mr A will likely have gained a survival benefit from the treatment. Dr Masters said that the chance of curing Mr A's prostate cancer with surgery alone was very slim when taking into account the preoperative PSMA PET CT scan result and the high grade of cancer Mr A was diagnosed with.

81. Dr Masters advised that an important factor in Mr A's case when determining whether surgery or radiotherapy was the more appropriate treatment option was to give adequate consideration to Mr A's urinary flow rate.

82. Dr Masters stated:

> '[R]adical prostatectomy and lymph node dissection is the most appropriate treatment option for tackling the primary [cancer] given the poor flow (which would likely be worse with radiotherapy and better with surgery). [Dr B] is also correct in the interpretation of the current expert advice in the urology press namely that surgery

> should not be dismissed as a treatment option even if the PSMA PET CT scan is consistent with local lymph node involvement provided that the MRI/CT scans are within normal limits with regards lymph node size. Whilst I suspect this expert advice might change as urologists and radiologists get better at interpreting PSMA PET CT scans it is the current standard.
>
> …
>
> The best means of resolving the symptoms and treating the prostate cancer was surgery and not radiotherapy.'

83. Regarding Dr B's decision not to consult with a radiation oncologist prior to proceeding with surgery, Dr Masters advised that 'it is not uncommon for patients to proceed with surgery without a discussion with a radiation oncologist in New Zealand'. Having considered all the information available, I conclude that the decision to offer surgery to Mr A as a potential treatment option was appropriate in the circumstances.

Changes made since events

84. Dr B told HDC that he has reflected on this case, and it has led him to change his views on management in this type of situation, and the way he will practise in the future should a similar situation arise. He considers that this was an isolated incident in his practice in the setting of a relatively new technology, which is still evolving.

85. Dr B stated that in his future practice he will advocate for radiotherapy and hormone treatment as the recommended course of action unless future definitive outcome data directs differently. He said that this will be the case for all men with any loco-regional prostate cancer identified by PSMA PET CT scans.

86. Dr B said that now he routinely provides all new patients with written information that hard copies of clinical notes and test results can be requested, whereas previously he relied on the patient requesting this independently.

87. Dr B also stated that he will 'endeavour to more extensively document particularly the options available for treatment, potential side effects of treatment and findings from investigations'.

88. In response to the provisional report, Dr B told HDC:

> 'My routine practice has always been to offer to provide a referral to a Radiation Oncologist should the patient wish to consider this form of treatment for their prostate cancer. In future I will instead recommend to the patient that he be referred to a Radiation Oncologist before deciding on a course of treatment. Should he decline this I will, of course, respect his wishes.'

89. In response to the recommendations made in my provisional opinion, Dr B:

a) Provided a written apology to Mr A for the breaches of the Code found in this investigation;

b) Undertook further HDC online education/training on documentation, communication, and informed consent; and

c) Informed HDC that he regularly attends MDMs and he will continue to use MDMs in the future.

Recommendations

90. In light of the changes made above, I consider that no further recommendations are necessary.

Follow-up actions

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

92. A copy of this report with details identifying the parties removed, except the advisor on this case, will be sent to Te Aho o Te Kahu|Cancer Control Agency and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following independent clinical advice was obtained from urologist Dr Jonathan Masters:

'**Complaint:** **[Mr A]**

Our ref: **C22HDC03116**

Independent advisor: **Dr Jonathan Masters**

I have been asked to provide clinical advice to HDC on case number C22HDC03116. I have read and agree to follow HDC's Guidelines for Independent Advisors.

I am not aware of any personal or professional conflicts of interest with any of the parties involved in this complaint.

I am aware that my report should use simple and clear language and explain complex or technical medical terms.

Qualifications, training and experience relevant to the area of expertise involved:	My name is Jonathan Grenville Masters, Medical Council Number 26350. I have worked as a consultant … since 2000. My particular areas of interest are prostate and bladder cancer and their treatment. My qualifications are BA BMBCh MD FRCS(Urol) FRACS. I have no conflicts of interest in this case.
Documents provided by HDC:	1. Letter of complaint dated 9 December 2022. 2. [Dr B's] response sent to HDC on 1 February 2023. 3. Clinical records from [Dr B]. 4. Clinical records from [the radiology service]. 5. Clinical records from [Dr C] (Consultant Radiation Oncologist).
Referral instructions from HDC:	Please comment on the care provided by [Dr B] in respect to the following: • Whether [Mr A] received unnecessary radical prostatectomy and lymph node dissection surgery; • Whether it was evident from the initial PSMA PET CT scan that [Mr A's] cancer had spread; • Whether [Dr B's] interpretation of [Mr A's] pre-operative test results was appropriate, including PSA results, MRI scans, biopsy results and PSMA PET CT scan; • Whether [Dr B's] communication with [Mr A] in regards to his test results and treatment options was adequate; • Whether [Dr B] should have referred [Mr A] to a radiation oncologist pre-operatively;

	• Whether the side effects of [Mr A's] surgery […][25] are side effects one would expect following this type of surgery; • Please comment on the overall reasonableness of care provided to [Mr A]; • The adequacy of [Dr B's] documentation; and • Any other matters that you consider warrant comment.

Factual summary of clinical care provided:

Brief summary of clinical events:	**The complaint: That an unnecessary operation was performed that was not curative and has resulted in some long term consequences as treatment for prostate cancer. That alternative treatment approaches were not clearly discussed.** [Mr A] and [Dr B] met first on 31.3.22. He had a 10 year history of gradually increasing moderate lower urinary tract symptoms (IPSS 14/2) and a relatively poor flow rate (Qmax 5.1mL/s on a 146mL void). This had not been troublesome enough to him to seek treatment previously. The PSA at referral was 6.1. It was recommended that the PSA should be repeated and MRI imaging performed before consideration of a prostate biopsy. The MRI of 11/5/22 showed PIRADS 4 lesion (40% chance of high grade cancer approx.) and it was recommenced a prostate biopsy should be performed. This was done as a transperineal biopsy under general anaesthetic 1/6/2022. Results showed a high grade (ISUP Grade 5) prostate cancer. The histology and treatment options were discussed at the follow up consultation on 21/6/2022. A PSMA PET CT scan was recommended and this was performed 5/7/2022 and patient seen again 6/7/2022 and on the basis of this scan a radical prostatectomy with lymph node dissection was recommended and performed as a robot assisted procedure on 4/8/2022. Histology was discussed on 16/8/2022 and this showed lymph node metastases and extraprostatic spread with a positive surgical margin. The post operative PSA never became undetectable and so a repeat PSMA PET CT was organized which confirmed persistent PSMA positive nodes in the pelvis. [Mr A] appears to have made a reasonable recovery post operatively but was referred to [Dr C] (radiation oncologist) for consideration of pelvic irradiation where he was informed the pre operative PSMA PET CT had shown uptake in the pelvic lymph nodes which suddenly appeared to be new information to [Mr A]. This has resulted in

[25] Removed for privacy reasons.

	him complaining that he underwent an unnecessary operation that was never going to be curative.

Question 1: Whether [Mr A] received unnecessary radical prostatectomy and lymph node dissection surgery.	
Sources of information reviewed other than the documents provided by HDC:	1) TOMOGRAPHY.ORG | VOLUME 4 NUMBER 4 | DECEMBER 2018 2) **World Journal of Urology (2023) 41:2033–2041**
Advisor's opinion:	This is a surprisingly difficult question to answer. I believe [Mr A's] understanding and [Dr B's] hope was that this surgery should be curative. (All the cancer removed and no further treatment necessary.) In reality the chances of this being achieved were very slim given the pre operative PSMA PET CT scan result and also the high grade of the cancer. In my opinion [Mr A] will require ongoing multi modal therapy to keep his prostate cancer under control and that should include definitive local treatment (2) and also systemic treatment. The PSMA PET CT scan remains a relatively new technology and there are issues around interpretation (1) however the report for the first PSMA PET CT scan whilst it is equivocal around the rib lesion it is not equivocal about the lymph nodes. From the correspondence available to me the lymph nodes have not been adequately discussed pre operatively. However I believe that [Mr A] will likely gain a survival benefit from treatment of his primary cancer (by radical prostatectomy in this case) (2) and therefore I do not believe it was an unnecessary radical prostatectomy. The alternative approach to definitive local treatment would have been radiotherapy to the prostate and lymph nodes but [Mr A] had a very poor urinary flow and it is unlikely with a maximum flow rate of 5ml/sec that a radiation oncologist would irradiate the prostate without first having the outflow obstruction treated with surgery. This would increase the complication rate of radiotherapy and so once more in this case definitive local treatment is probably better achieved with surgery than radiotherapy.
What was the standard of care/accepted practice at the	Yes

time of events? Please refer to relevant standards/ material.	
Was there a departure from the standard of care or accepted practice? • No departure; • Mild departure; • Moderate departure; or • Severe departure.	I believe the treatment would fall within the accepted standard of care in New Zealand.
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	This is a complex case and it would have been helpful for this case to be discussed at a multi disciplinary meeting and for the outcome of that meeting to be recorded in the correspondence.
Please outline any factors that may limit your assessment of the events.	
Recommendations for improvement that may help to prevent a similar occurrence in future.	Please see below. I think the documentation of alternatives and side effects of treatment options are very limited in this case.

Question 2: Whether it was evident from the initial PSMA PET CT scan that [Mr A's] cancer had spread.	
Advisor's opinion:	In my opinion based on the report but not directly reviewing the films it is clear there were PSMA PET avid nodes in the pelvis and I would regard this as being consistent with there being spread of the prostate cancer to the pelvic lymph nodes. If [Dr B] was doubtful about the nodes or the report he should have asked for a review of the films and this would have best been done in a multi disciplinary meeting.
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/ material.	The main issue here is the brevity of the letter of 6th July which is the documented record of the consultation. There is simply no written record with regards the lymph nodes in the pelvis or the implication of the avidity of the nodes likely representing prostate cancer involvement of those nodes. It is clear from [Mr A's] response that he did not understand the implications of the report.

Was there a departure from the standard of care or accepted practice? • No departure; • Mild departure; • Moderate departure; or • Severe departure.	Mild departure
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	I have discussed node avidity and node size with [a radiologist] and it is his expert opinion that the size of the node is not important. An avid node is consistent with prostate cancer spread to that node regardless of size.
Please outline any factors that may limit your assessment of the events.	
Recommendations for improvement that may help to prevent a similar occurrence in future.	That [Dr B] discuss these cases in a multi disciplinary meeting and/or get an expert radiological opinion. Also that this discussion should be recorded in the notes.

Question 3: Whether [Dr B's] interpretation of [Mr A's] pre-operative test results was appropriate, including PSA results, MRI scans, biopsy results and PSMA PET CT scan.	
List any sources of information reviewed other than the documents provided by HDC:	3) European Journal of Nuclear Medicine and Molecular Imaging (2023) 50:2572–2575
Advisor's opinion:	In my opinion the timeline and interpretation of the PSA results, MRI, flow test and biopsy results are of a high standard of care. I believe the interpretation of the PSMA PET CT scan "low level suspicious lymph nodes" is wrong. It would seem to me that these avid nodes were highly suspicious and deserved to be mentioned in the documented discussion.
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/ material.	If there was any doubt in [Dr B's] mind he should have discussed the case with a radiologist. However the latest consensus statement includes the statement "Treatment should not be changed based on PSMA PET/CT findings, in view of current available data" .This statement is made because whilst it is recognised that a PSMA PET CT actually has very good specificity and sensitivity there is a risk that patients would be denied treatment that they would otherwise benefit from and this would be true in [Mr A's] case.

Was there a departure from the standard of care or accepted practice? • No departure; • Mild departure; • Moderate departure; or • Severe departure.	Mild departure. Here the problem is not so much the decision to treat the prostate cancer with a radical prostatectomy but the lack of clear documentation around the PSMA PET CT report and discussion of alternatives.
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	
Please outline any factors that may limit your assessment of the events.	I have not seen the scans just the report.
Recommendations for improvement that may help to prevent a similar occurrence in future.	That the PSMA PET CT findings be discussed preferably in a multi disciplinary meeting and that this be clearly recorded.

Question 4: Whether [Dr B's] communication with [Mr A] in regards to his test results and treatment options was adequate.	
List any sources of information reviewed other than the documents provided by HDC:	
Advisor's opinion:	There would not have been a complaint lodged if the communication particularly around the implications of the lymph nodes being positive on the pre op PSMA PET CT had been adequate. It is clear from [Mr A's] response to his consultation with [Dr C] that this result was only now registering with him. This is recognised by [Dr B] in his response and is something for which he has apologised.
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/ material.	No
Was there a departure from the standard of care or accepted practice? • No departure;	Mild departure

• Mild departure; • Moderate departure; or • Severe departure.	
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	
Please outline any factors that may limit your assessment of the events.	
Recommendations for improvement that may help to prevent a similar occurrence in future.	I note the changes [Dr B] plans to make to his practice with regards discussing scans that are complex with a radiologist. I think he would do well to discuss these cases in an MDM and convey the results of that discussion to the patient. I believe that as a matter of routine the patient should have a copy of all correspondence and have access to the results of investigations. I am not clear whether this is [Dr B's] practice.

Question 5: Whether [Dr B] should have referred [Mr A] to a radiation oncologist pre-operatively.	
List any sources of information reviewed other than the documents provided by HDC:	4) The Prostate Cancer Quality Performance Indicator Action Plan December 2021
Advisor's opinion:	In both the letters of 21 June and 6th July radiotherapy as a treatment option is mentioned by [Dr B] however there is no documented discussion with regards to the risks and benefits as an alternative to surgery and I do not believe that [Mr A] was offered the opportunity to see a radiation oncologist. As per the Prostate cancer quality performance Indicator Action plan (4) it is anticipated that the majority of patients should be offered the chance to see a radiation oncologist prior to treatment. In this case I think it would have been helpful particularly in the light of the PSMA PET CT result pre op. A reasonable alternative would have been a discussion at an MDM where the radiation oncologists and radiologists were part of the discussion.

What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/ material.	It is not uncommon for patients to proceed with surgery without a discussion with a radiation oncologist in New Zealand and it would certainly appear that if surgery was a reasonable option this was [Mr A's] preference and so I think that the management here still falls into an acceptable range of practice within New Zealand currently.
Was there a departure from the standard of care or accepted practice? • No departure; • Mild departure; • Moderate departure; or • Severe departure.	No departure
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	
Please outline any factors that may limit your assessment of the events.	
Recommendations for improvement that may help to prevent a similar occurrence in future.	

Question 6: 6. Whether the side effects of [Mr A's] surgery […][26] **are side effects one would expect following this type of surgery.**	
List any sources of information reviewed other than the documents provided by HDC:	
Advisor's opinion:	[…][27]
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/material.	Yes

[26] Removed for privacy reasons.
[27] Removed for privacy reasons.

Was there a departure from the standard of care or accepted practice? • No departure; • Mild departure; • Moderate departure; or • Severe departure.	No departure
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	I believe that the standard of care is acceptable. Once more the correspondence is brief. Whilst access to literature and websites may have been available to [Mr A] some record of the possible consequences of surgery should have been made.
Please outline any factors that may limit your assessment of the events.	
Recommendations for improvement that may help to prevent a similar occurrence in future.	I think there should be a more complete record of the discussions that have taken place.

Question 7: Please comment on the overall reasonableness of care provided to [Mr A].	
List any sources of information reviewed other than the documents provided by HDC:	
Advisor's opinion:	[Mr A] is unlucky enough to have a high grade (ISUP Grade 5) prostate cancer that even at initial presentation was almost certainly metastatic to his regional lymph nodes. [Dr B's] assessment and investigation and timeliness of investigation was of high quality. I believe that the surgery he offered was a reasonable option in this setting. I believe the quality of the surgery and the post operative care were also at a very good standard. However it was unlikely to be the only treatment needed to control this particular cancer. A more realistic and better documented discussion was required and this could have included an MDM discussion or referral to a radiation oncologist. Whilst [Dr B] may have felt he had provided adequate information within the consultations and with provision of recommendations to various websites, the recorded notes are not of a high quality. When comparing the letter of [Dr B] from 6th July 2022

	with that of [Dr C] from 7th November 2022 the differences in the quality of information provided are stark.
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/ material.	Yes
Was there a departure from the standard of care or accepted practice? • No departure; • Mild departure; • Moderate departure; or • Severe departure.	Mild departure around the quality of the records provided pre operatively.
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	
Please outline any factors that may limit your assessment of the events.	
Recommendations for improvement that may help to prevent a similar occurrence in future.	

Question 8: The adequacy of [Dr B's] documentation.	
List any sources of information reviewed other than the documents provided by HDC:	5) Informed Consent: Helping patients make informed decisions about their care June 2021 https://www.mcnz.org.nz/
Advisor's opinion:	Once more this is a complicated case of prostate cancer to deal with both from a patient's perspective and from a clinician's perspective. I would regard the decision to offer surgery as a reasonable decision and I think the outcomes of that surgery are well within the normal range for this type of high grade prostate cancer. Generally the letters, which I presume went to both the GP and patient, are quite short. I am particularly critical of the letter of 6th July 2022. For a start there is a typo line 2 where I suspect the word

	"not" is missed out and so whilst the letter reads as though he should have no further treatment it then goes on to talk about radiation or surgery. There is no discussion of the PSMA PET CT avid lymph nodes. There is no discussion of the advantages and disadvantages of the treatment options. There is no discussion that additional treatment is likely to be needed. This may have occurred in the consultation but it needs to be documented. It is not clear from the letters provided that [Mr A] was genuinely in a position to give fully informed consent (5).
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/ material.	No
Was there a departure from the standard of care or accepted practice? • No departure; • Mild departure; • Moderate departure; or • Severe departure.	Mild departure
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	
Please outline any factors that may limit your assessment of the events.	
Recommendations for improvement that may help to prevent a similar occurrence in future.	This case would have best been managed through an MDM. The letters to the GP (and patient) as a summary of a consultation need to include much more information to make it clear that the advantages and disadvantages of treatment have been discussed and that alternative treatments have also been discussed.

Question 9: Any other matters that you consider warrant comment.	
List any sources of information reviewed other than the documents provided by HDC:	

Advisor's opinion:	I would like to wish [Mr A] all the best as he continues to need additional treatment for his prostate cancer. He has had surgery in the presence of oligometastatic disease and whilst the evidence is not completely conclusive I believe he has a survival advantage because he has had definitive treatment of his primary by way of a robot assisted radical prostatectomy. […][28] Whilst [Mr A] would appear to have had a preference for surgery the documentation of the consultations is poor and I understand [Mr A's] consternation when being told by [Dr C] the pre operative PSMA PET CT had shown lymph node involvement. These should have been adequately discussed pre surgery and also that discussion should have been clearly recorded. It is in these areas that I feel the quality of care provided to [Mr A] has fallen short of the expected level of care. […][29]
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/ material.	
Was there a departure from the standard of care or accepted practice? • No departure; • Mild departure; • Moderate departure; or • Severe departure.	
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	
Please outline any factors that may limit your assessment of the events.	
Recommendations for improvement that may help to prevent a similar occurrence in future.	More complete documentation so that it is clear the recommended standards for informed consent have been met.

[28] Removed for privacy reasons.
[29] Removed for privacy reasons.

…

Complaint: [Dr B]/[Mr A]

Your ref: 22HDC03116

My name is Jonathan Masters. My Medical Council Number is 26350. I am a Urologist and my specialist interests are in prostate and bladder cancer and urological cancers in general. I do not have any conflicts of interest in this case.

You have thanked me for advice on the above file, which you received on 11 December 2023. You have written again to provide additional information on this complaint, and to request further comment/advice from me. As part of the information gathered to date, ACC provided HDC a copy of its external clinical advice from [a radiation oncologist]. You have also received a further response from [Dr B]. You have asked me to review the enclosed additional documentation that relates to the care provided to [Mr A] by [Dr B] and advise:

1. Whether the additional information provided alters your view/opinion about any aspect of your advice that was previously provided to this office on 11 December 2023;
2. If you consider that you have changed your view/opinion, please ensure that you provide a full explanation as to why this is;
3. In the alternative, if you consider that your previous opinion stands after receiving this additional information, please provide a full explanation as to why you have not changed your view.
4. Any other comments you wish to make on the additional information provided.

You have stated that the ACC external clinical advisor has drawn some different conclusions to your advice. You acknowledge that the ACC advisor was a radiation oncologist and not a urologist (and is therefore not a peer of [Dr B]). His advice was also provided for a different purpose. However, the advisor concludes that the surgery was unnecessary due to the surgeon not appreciating or understanding the results of [Mr A's] PSMA PET/CT scan which showed he had an inoperable disease. When reviewing your previous advice and answering the questions above, we would be grateful if you could comment on the different conclusions drawn by the ACC advisor.

1. ***Whether the additional information provided alters your view/opinion about any aspect of your advice that was previously provided to this office on 11 December 2023;***
2. ***If you consider that you have changed your view/opinion, please ensure that you provide a full explanation as to why this is;***

3. ***In the alternative, if you consider that your previous opinion stands after receiving this additional information, please provide a full explanation as to why you have not changed your view.***

In my original advice my conclusion was that surgery (radical prostatectomy) was not unnecessary. The ACC advisor has concluded that surgery was never going to be curative and that it simply exposed [Mr A] to the risks of complications of surgery. The ACC advisor (a radiation oncologist) does not disagree that treating the primary prostate cancer in the prostate was worthwhile but feels this would have been better achieved with radiotherapy than with surgery. However the ACC advisor has not considered or discussed [Mr A's] urinary symptoms particularly his very poor flow. In my experience with the radiation oncologists that I work with it is highly unlikely that they would have been happy with proceeding with radiotherapy with a urinary flow of 5ml/sec without first requesting a transurethral resection of the prostate (TURP) be carried out prior to the radiotherapy. […][30]

Whilst the chances of curing the prostate cancer with surgery alone are very slim (when the PSMA PET CT scan is taken into account) to me it would seem that a radical prostatectomy and lymph node dissection is the most appropriate treatment option for tackling the primary given the poor flow (which would likely be worse with radiotherapy and better with surgery). [Dr B] is also correct in the interpretation of the current expert advice in the urology press namely that surgery should not be dismissed as a treatment option even if the PSMA PET CT scan is consistent with local lymph node involvement provided that the MRI/CT scans are within normal limits with regards lymph node size. Whilst I suspect this expert advice may change as urologists and radiologists get better at interpreting PSMA PET CT scans it is the current standard.

Therefore I do not change my opinion that a radical prostatectomy was the most appropriate way of treating the prostate cancer based on the current urology expert panel conclusions and also that we agree that the primary cancer in the prostate should be treated. The best means of resolving the symptoms and treating the prostate cancer was surgery and not radiotherapy. The ACC advisor has simply failed to note the urinary flow rate that was the original reason for the referral.

Equally I do not change my opinion that [Mr A] was not able to make a properly informed decision about surgery because:

1) [Dr B's] documentation of the consultation that led to the radical prostatectomy being booked is very poor. The pelvic lymph nodes are simply not discussed and there is an inadequate discussion of alternative treatment approaches particularly radiotherapy.
2) This case should have been discussed in an MDM meeting with both the radiologists (to confirm and interpret the PSMA PET CT scan findings) and the radiation oncologists being present. The outcome of the meeting should have been discussed

[30] Removed for privacy reasons.

> with [Mr A] prior to proceeding with surgery. This would have given [Mr A] enough information to make an informed decision where with more complete discussion he could decide between radiotherapy (and probable prior TURP) or radical prostatectomy (and probable radiotherapy).

I do acknowledge that [Mr A] was expecting the surgery alone to be curative whereas he should have been informed that it was likely to be one part of a multimodal approach to treat his high-grade prostate cancer that was likely to include radiotherapy and chemotherapy.

Yours truly,

Jonathan G Masters 4th January 2024'