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The investigation of a complaint against Betsi Cadwaladr University Health Board

A report by the
Public Services Ombudsman for Wales
Case: 202207270

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Introduction

This report is issued under s.23 of the Public Services Ombudsman (Wales) Act 2019.

In accordance with the provisions of the Act, the report has been anonymised so that, as far as possible, any details which might cause individuals to be identified have been amended or omitted. The report therefore refers to the complainant as Mrs B.

Summary

Mrs B complained about her husband, Mr B's, care and treatment by Betsi Cadwaladr University Health Board ("the Health Board"). Mr B went to the Emergency Department ("the ED") at Wrexham Maelor Hospital in April 2022 with urinary retention. My investigation considered whether his symptoms should have led to an urgent suspected cancer referral. My investigation also considered whether the Health Board's management of Mr B's care, between April 2022 and February 2023, was clinically appropriate and in line with the suspected cancer pathway. I considered if the Health Board's communication with Mr and Mrs B, including sharing information about investigations and treatment plans, during this time was appropriate. I also considered if the likely waiting time for a biopsy in August 2022 was reasonable. Finally, my investigation considered the Health Board's complaint handling of this case.

My investigation found that Mr B was treated appropriately when he attended the ED in April 2022 and this complaint was not upheld. I found that, whilst there were elements of Mr B's care that were clinically appropriate, Mr B was denied potentially curative surgery. The decision not to offer surgery was based on the view his cancer had spread. However, there was uncertainty about whether this was the case and I concluded that he should have been offered surgery.

Mr B's treatment fell significantly outside the suspected cancer pathway target time of 62 days from suspicion of cancer to treatment. Mr B had a biopsy done privately due to an unacceptable delay in the Health Board being able to undertake this procedure. Mr B should have had the opportunity to discuss his complex investigation results and treatment plan with a senior clinician. These complaints were upheld. Finally, I found failings in the initial complaint handling of this case.

I recommended that the Health Board should:

a) Apologise to Mr and Mrs B for the failings identified.

b) Make a financial redress payment of £6,850 to Mr and Mrs B, which includes reimbursement of costs for a private test and consultation, £1,000 for the injustice caused by denying Mr B potentially curative surgery and £250 for the time and trouble caused to Mrs B for the complaint handling failings identified.

c) Share my report with relevant clinicians to reflect on my findings.

d) Review its complaint handling of this case to identify any lessons to be learned.

e) Summarise actions taken and progress made against the remedial actions and recommendations, following internal and external reviews, including those by:

- the Health Board's Urology Steering Group
- the Getting it Right First Time Team (GIRFT)
- the Royal College of Surgeons
- task and finish groups set up following review of the prostate cancer pathway.

The Health Board accepted my investigation findings and recommendations.

The Complaint

1. Mrs B complained about her husband, Mr B's, care and treatment by Betsi Cadwaladr University Health Board ("the Health Board"). The investigation considered whether:

a) The urological symptoms displayed at Mr B's attendance at Wrexham Maelor Hospital ("the First Hospital") Emergency Department ("ED") on 19 April 2022 should have led to an urgent suspected cancer referral.

b) The Health Board's management of Mr B's care between April 2022 and February 2023 was clinically appropriate and in line with the suspected cancer pathway.

c) The likely waiting time for a biopsy, in August 2022, was reasonable.

d) The Health Board communicated appropriately with Mr and Mrs B between April 2022 and February 2023, including sharing information about investigations undertaken and Mr B's treatment plan.

e) The Health Board managed Mrs B's complaint, submitted in November 2022, in line with Putting Things Right (the NHS complaints process), in particular in communicating with Mrs B.

Investigation

2. My investigator obtained comments and copies of relevant documents from the Health Board and considered these in conjunction with the evidence provided by Mrs B. They also obtained professional advice from one of my professional advisers, a Consultant Urologist, Mr David Almond ("the Adviser"). The Adviser was asked to consider whether, without the benefit of hindsight, the care or treatment had been appropriate in the situation complained about. I determine whether the standard of care was appropriate by making reference to relevant national standards or regulatory, professional or statutory guidance which applied

at the time of the events complained about. I have not included every detail investigated in this report, but I am satisfied that nothing of significance has been overlooked.

3. Both Mrs B and the Health Board were given the opportunity to see and comment on a draft of this report before the final version was issued.

Relevant legislation

4. The National Institute for Health and Care Excellence 'Prostate cancer: diagnosis and management' guideline [NG131] (published 9 May 2019, updated 15 December 2021) ("the NICE Guideline").

5. European Association of Urology Guidelines on Prostate Cancer, 2022 ("the EAU Guidelines"). The EAU develops best practice clinical guidelines for urologists.

6. Welsh Government 'Guidance for Managing Patients on the Suspected Cancer Pathway' (version 4, June 2022) ("the SCP"). This includes:

- The waiting time for patients on the SCP starts at the point at which cancer is suspected (the point of suspicion) and ends at the start of first definitive treatment. The performance target is that at least 75% of patients start their first definitive treatment within 62 days of the point of suspicion.

- Occasionally a patient is initially seen under the NHS but chooses to seek diagnosis privately and then returns to the NHS for treatment. The NHS must then communicate with the patient that their pathway will be closed from the date the patient informs they wish to seek diagnosis privately and a new pathway opened when they then inform the health board they are ready to restart their NHS pathway.

7. The Welsh Government's 'Putting Things Right: Guidance on dealing with concerns about the NHS' (version 3, November 2013) ("the PTR Guidance") was produced to provide guidance on how to effectively handle concerns according to the requirements set out in

the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011. The PTR Guidance states that when a concern is received, the date must be carefully noted, and all concerns must be acknowledged within 2 working days of receipt. When investigating concerns, bodies must ensure that the person who raised a concern is kept updated in a timely manner about the investigation.

8. The Public Services Ombudsman for Wales "Principles of Good Administration" (January 2022) outlines what bodies should do to deliver good administration and customer service. Principle 2 – being customer focused – incudes dealing with people helpfully, promptly and sensitively and ensuring people can access services easily. Principle 5 – putting things right – includes providing an appropriate range of remedies and the remedy offered should seek to put the complainant back in the position they would have been in had nothing gone wrong.

The clinical background events

9. Mr B attended the First Hospital ED on 19 April **2022** as he was unable to empty his bladder. He was noted as struggling to pass urine from 18:00 the previous day, with pain in his lower abdomen radiating towards his back. He had a similar episode 2 weeks previously. Mr B was catheterised (a procedure to insert a tube to drain urine from the bladder). An examination identified an enlarged prostate. The provisional diagnosis was urinary retention due to obstruction. Mr B was advised to make an appointment with his GP in relation to the possible prostate enlargement. It was noted a referral would be made to the urology department and to the trial without catheter ("TWOC") clinic.

10. On 16 June Mr B's GP referred him to the First Hospital's urology department due to an episode of acute urinary retention and a prostate-specific antigen ("PSA" – this is not a specific test for cancer but a marker of cancer risk; the higher the PSA level, the more likely it is that the patient has prostate cancer) level of 16. The referral was marked 'urgent suspected cancer'.

11. Mr B was seen by a consultant urological surgeon ("the First Consultant") on 12 July; a rectal examination noted an enlarged prostate. A plan was made that included a repeat PSA test (which reported an increased level of 18.3) and a multiparametric magnetic resonance imaging scan ("mpMRI" – a type of scan that produces a detailed picture of the prostate gland) to look for signs of cancer. Finasteride (medication used to treat an enlarged prostate) was also prescribed.

12. An mpMRI on 5 August concluded that there were appearances of a right sided prostatic tumour (prostate cancer) with an overall Likert score of 5 (the Likert scale is used to score the likelihood of clinically significant cancer, a score of 5 means that it is very likely you have prostate cancer that needs treatment). The disease was noted to be confined within the prostate, with a provisional radiological staging of T2a N0 MX.[1] Mr B was given the results of the PSA and mpMRI during a telephone consultation on 22 August and he was booked for an urgent prostate biopsy (a procedure where a sample of tissue from the prostate is taken to look for cancer cells).

13. On 28 September Mr B underwent a biopsy on a private basis under the care of a consultant urological surgeon ("the Second Consultant").

14. Mr B attended a private clinic appointment on 20 October for the results of his biopsy. The results showed Gleason[2] scores of 7 in 2 different areas of the prostate. The scores indicated cancer likely to grow at a moderate rate in 1 part of the prostate, with slower growth in the second area. Mr B was referred for a bone scan as an NHS patient. If the test results were clear, radical treatment options were to be considered. The Second Consultant asked a urology nurse specialist ("the Specialist Nurse") to see Mr B at the First Hospital with the results and for counselling. Mr B's interest for radical prostatectomy (surgery to remove the prostate) as a private patient was noted.

[1] The TNM system is a way of staging prostate cancer. It stands for Tumour, Node, Metastasis. T describes the size of the tumour. T2a means the cancer is completely inside the prostate gland. N describes if the cancer has spread to the lymph nodes. N0 means that the nearby lymph nodes do not contain cancer cells. M describes whether the cancer has spread (metastasised) to a different part of the body. MX means that metastasis cannot be evaluated.

[2] The Gleason score is a system used to grade prostate cancer using samples from a biopsy of the prostate. It helps predict prognosis. The higher the score, the more aggressive the cancer.

15. Mr B's bone scan on 28 October showed no evidence of metastatic bone disease (when cancer cells spread from the original cancer site to bone).

16. Mr B was seen by the Specialist Nurse on 4 November. On 7 November he was referred to a hospital outside of the Health Board area ("the Second Hospital") to consider robot assisted surgery to remove the prostate. The Health Board has a contract with an English Hospital Trust responsible for the Second Hospital for it to provide prostatectomies. This was put in place to support the delivery of prostate surgery and treatment for other urological cancers to address capacity concerns relating to the Health Board's ability to deliver cancer targets for urology.

17. The outcome of the Second Hospital urology multi-disciplinary team ("MDT") meeting on 16 December was for Mr B to undergo an urgent scan ("PSMA PET scan" – a test used to detect if and where prostate cancer has spread). It emailed the Health Board requesting this and asked the Specialist Nurse to update Mr B.

18. Mr B's PMSA PET scan on 22 December concluded that his disease was in the prostate gland, predominantly on the right side, with suspicion of skeletal metastases (where cancer has spread to the bone) in the upper spine and in a rib.

19. The First Consultant requested a magnetic resonance imaging scan ("MRI scan" – the use of strong magnetic fields and radio waves to produce detailed images of inside of the body) of Mr B's spine on 11 January **2023**. This was undertaken on 15 January. The MRI report concluded that a small lesion noted "must be regarded as suspicious for metastasis".

20. On 20 January an internal email raised concerns about communication with Mr B and requested clarification as to which consultant he was under the care of. Mr B had been seen in the NHS by the First Consultant and as a private patient by the Second Consultant.

21. The Second Hospital urology MDT on 27 January reviewed the MRI findings. It decided that Mr B was not suitable for surgery to remove the prostate in view of the spinal metastasis, and he was noted for oncology treatment by the Health Board.

22. Mr B was seen as a private patient at another hospital ("the Private Hospital") by a consultant urologist ("the Third Consultant") on 29 January for a second opinion. They noted that robotic surgery would be a reasonable way forward. While the PSMA PET or MRI scan might determine the final treatment decision, the Third Consultant said if there was any doubt, they should give him the benefit from this and proceed to radical curative treatment.

23. Mr B was seen by the Specialist Nurse on 1 February. She noted that the minutes of the Second Hospital urology MDT stated that Mr B was deemed unsuitable for surgical input. She discussed alternative treatment options with Mr B (hormones and chemotherapy). Mr B requested an oncology referral on an urgent basis. Mr B was prescribed bicalutamide (a hormonal therapy drug used to treat prostate cancer) for 4 weeks with a plan to administer Decapeptyl (another hormonal therapy drug) in 2 weeks.

24. On 9 February a urology pelvic MDT at the Private Hospital determined Mr B was for "all treatment options" with the intention to pursue curative treatment. It noted the areas within the spine and rib (as noted on the PSMA PET scan) but said that these appearances on the MRI were unclear and not completely convincing of metastases. Mr B's cancer was staged as T3a N0 M0 meaning the extent of the cancer had increased, but it had not spread to the nearby lymph nodes or elsewhere in the body.

25. Following a complaint from Mrs B to the Health Board, a radiological second opinion was obtained on 14 February. It agreed that the MRI of 15 January showed a lesion highly suspicious for spread of the cancer which corresponded to the findings of the PSMA PET on 22 December 2022.

26. Mr B was seen by the Specialist Nurse on 20 February. It was noted they had a lengthy discussion and Mr B indicated he wished to pursue oncological treatment as opposed to surgery. Decapeptyl was administered with a plan for this to be continued by his GP at 6-monthly intervals, lifelong.

27. The First Hospital urology MDT on 22 February confirmed metastatic disease of the prostate. The Private Hospital recommendation for all radical treatment options and agreement to perform prostatectomy was noted, along with Mr B's wish for oncological treatment. The plan was for hormone therapy, with referral to oncology locally for chemotherapy and radiotherapy.

28. Mr B spoke with a consultant at the Second Hospital on 17 March. They said that communication was "not up to scratch" and agreed that his complex problem should have been discussed with a consultant, not solely with the clinical nurse specialist team. Mr B was advised that the scans suggested oligometastatic disease (where the cancer has spread to only a few sites beyond the prostate).

29. Mr B was seen in the oncology clinic on 31 March and started chemotherapy.

The complaint handling background events

30. In October **2022** Mrs B raised concerns about the delays in Mr B's treatment with Healthcare Inspectorate Wales ("HIW" – the independent inspectorate and regulator of all healthcare in Wales). On 25 October, HIW's Director of Clinical Advice and Quality Assurance emailed the Health Board. They highlighted general concerns and questioned the management of patients with suspected cancer, seeking assurance in relation to Mr B's treatment, given the delays already encountered.

31. On 17 November Mrs B emailed the Surgical Site Specialty Manager, General Surgery ("the Site Specialty Manager") noting her concerns about the delays encountered in her husband's treatment. On 2 December Mrs B emailed the Health Board's concerns team stating that she had not received a response to her 17 November email and raising a formal complaint.

32. On 8 December Mrs B emailed the concerns team again and said that the lack of communication from the Health Board was "deplorable". She further indicated her wish to make a formal complaint regarding delayed

treatment, having to pay for a private biopsy due to the length of wait for one by the Health Board, and lack of communication from cancer services from 17 November.

33. On 12 December the concerns team were notified that Mrs B had called about the lack of response to her formal complaint.

34. On 13 December HIW emailed the Health Board, noting that HIW contacted the Health Board in October and November, and Mrs B contacted the Health Board making a formal complaint in November. Despite this communication, Mrs B had informed them that she had received no response or communication from the Health Board about her complaint. On the same day, the Health Board acknowledged Mrs B's complaint.

35. Between January and March **2023**, there was evidence of communication between the Health Board and Mr and Mrs B about Mr B's treatment, including with the Site Specialty Manager and the Specialist Nurse. The Health Board responded to Mrs B's complaint on 19 April 2023; it apologised for the delay in completing the investigation.

Mrs B's evidence

36. Mrs B said that the Health Board failed to refer Mr B to a urologist following his presentation at the First Hospital ED on 19 April 2022 with red flag urinary symptoms, including a very large prostate. She said this should have been done as a matter of urgency.

37. Mrs B said that they were informed in August 2022, when Mr B required a biopsy, that there was a delay of 3-4 months. They therefore arranged a private biopsy. Mrs B said there were also significant delays in the contracted-out service to the Second Hospital for curative surgery; this required further scans. As a result of these delays, harm was caused because what was initially deemed curative was subsequently not considered suitable for surgery. She said there was a significant delay, of nearly 12 months, from Mr B's presentation to treatment.

38. Mrs B also highlighted that no clinical history was taken of any bony injuries, including to the suspicious areas of Mr B's ribs/spine. This could have meant that he had received chemotherapy, and denied possible curative surgery, which may not have been appropriate.

39. Mrs B said that she and Mr B were not informed that Mr B's cancer had been regraded. She said they found out by accessing Mr B's medical records and were only informed by a clinician prior to commencing radiotherapy, at which point the clinician confirmed the cancer was incurable.

40. Mrs B said the complaint handling of her concern was inadequate. She said that formal complaints in November and December 2022, along with other requests for explanations and treatment plans, were not responded to. The Health Board's investigation response failed to address why they had been denied access to a senior consultant to explain scan results, despite numerous requests. Mrs B referenced the Second Hospital's consultant's comments, in March 2023, that a senior consultant should have discussed the complexities of Mr B's case with them.

41. Mrs B described the psychological distress of knowing that something curable at the time was now incurable. She said that, in addition to the financial cost of arranging private consultations and biopsy, this had caused significant anxiety, impacted all their future plans and reduced her husband's life expectancy. She felt they had been robbed.

42. In commenting on the draft report, Mrs B said that when Mr B attended the First Hospital ED on 19 April 2022, the referral to the urology department was not sent and Mr B's GP had to do this. Mrs B said that Mr B only expressed a wish for oncological treatment, on 22 February 2023, as the Specialist Nurse was unclear as to whether Mr B would receive ongoing monitoring from the Health Board if he chose to have surgery privately. She said his choices were made from fear due to lack of information and a desire not to delay treatment further, rather than being fully informed as, despite requests, no consultation meeting was offered. She said scans were inconclusive about metastases and, following chemotherapy, his computerised tomography scan ("CT scan" – the use of X-rays and a computer to create an image of inside of the body) did not

show any scarring to the bony lesions, which the radiologist said they would have expected to see. Mrs B said there remained a lack of clarity about which consultant Mr B was under.

The Health Board's evidence

43. In responding to Mrs B's complaint, the Health Board said that Mr B experienced significant delays following his GP referral in June 2022, which amounted to a breach of duty of care. It did not identify any qualifying liability as, despite the delay, it considered the care and treatment provided to Mr B was appropriate based upon his clinical presentation and no harm had been caused. The Second Consultant (who, although he saw Mr B on a private basis, is also a consultant at the Health Board), advised that whilst the initial delays experienced were extremely regrettable, in his professional opinion no harm had been caused to Mr B as a result.

44. The Health Board said that based on the SCP, Mr B's treatment should have taken place by 17 August 2022; he was seen on 12 July 2022 (day 26) and the outcome of the review was for an mpMRI, repeat PSA and renal function test. These were done and an appointment to review the investigation results took place on 22 August 2022 (day 67). It said the timeframe between initial consultation and review was to ensure that all the investigations were completed and reported upon. It said that Mr B then required a prostate biopsy on an urgent basis. As Mr and Mrs B had been advised that the waiting time for this was 3-4 months, they then arranged for the procedure privately.

45. In responding to this investigation, the Health Board further said that the initial date of suspicion of cancer was 16 June 2022, and this was recorded as day 0 for the purposes of the SCP. The SCP was reset with a new date of suspicion on 28 October 2022 when Mr B returned to the NHS after his private biopsy. This reset was in line with the SCP in relation to patients returning from the private sector. The Health Board said that the date of Mr B's first definitive treatment was 1 February 2023 when hormones were commenced. Mr B's pathway was reported to Welsh Government as a breach of the 62-day target in February 2023. The reason for the breach of the 62-day target was given as a delay in discussion at the First Hospital

urology MDT because histology from the private laboratory was not available. It said the pathway was complex due to the request for additional scans by the Second Hospital urology MDT (PSMA PET and MRI spine). In addition, there was the original delay for a biopsy.

46. The Health Board said that prostate cancer is slow-growing, and Mr B's bony metastases were likely to have been present before the urinary symptoms appeared, although difficult to detect on standard bone scans.

47. The Health Board explained that in September 2022 the waiting time for a biopsy was 2-4 months depending on patient availability and the patient being medically fit. It said there had been a 3-4 month wait for prostate biopsies in the summer of 2022 and that currently its waiting times were 3-4 weeks due to running weekly sessions.

48. The Health Board said that, after Mr B's private biopsy and his referral back into the care of the NHS, his case was then managed according to the SCP, including a bone scan to determine if the cancer had spread. It said Mr B was referred for consideration of curative surgery to the Second Hospital, which reviewed the histology and judged the cancer to be a higher grade than previously thought (Gleason grade 9). The Second Hospital urology MDT therefore requested more detailed and specific imaging.

49. The Health Board said PSMA PET scans are being used more widely in the staging process for high grade prostate cancer because they can detect metastatic disease earlier than traditional bone scans. If metastases are already present, surgery is not in the patient's best interests.

50. The Health Board said that all 'breach' reasons were collated and reviewed at a monthly Health Board Urology Steering Group and the following remedial actions had been noted:

a) A nurse led biopsy list started in April 2023 to increase capacity and reduce delays.

b) Enquires were being made for prostatectomy capacity closer to North Wales.

c) A new administrative process had been established centrally to ensure quicker access to biopsy specimens and reports relating to patients who have a biopsy in the private sector, to reduce delay to subsequent MDT discussion.

d) It had appointed 3 SCP validators; their role is to assist in streamlining the SCP.

e) A straight to test mpMRI pathway is to be piloted with subsequent roll out across the Health Board – it anticipates this will vastly improve the pathway for patients and reduce the number of breaches.

51. The Health Board said it had invited external reviews of the urology service from GIRFT (Get it Right First Time – a programme to improve the treatment and care of patients through in-depth reviews of services) and the Royal College of Surgeons. The resulting recommendations were being included in a Urology Improvement Plan. It had also set up 5 task and finish groups following review of the prostate cancer pathway, with a focus on reducing waiting time to diagnosis.

52. On commenting on the draft report, the Health Board said there were some very significant points of learning that it has and will continue to translate into service improvements to ensure patients receive better and safer care across the Health Board.

53. The Health Board also provided further comments explaining its reasoning for not offering Mr B surgery. It said that the decision making around treatment options for prostate cancer was based on TNM staging (see paragraph 12), taking into account findings from radiological and histopathological (examining changes in tissue samples) investigations. It provided comments from a Consultant Radiologist who said that the PSMA PET scan was performed at the request of the Second Hospital on 22 December 2022. He said it showed disease in the prostate gland and possible signs of bone metastases in a rib and spine. He said an MRI on 15 January 2023 showed a lesion on the spine, which further supported a diagnosis of bone metastasis. He commented that the EUA guidelines include discussion that a PSMA PET scan is better at detecting some

metastatic disease compared to conventional imaging. A Professor of Urology from the Second Hospital also said that a PSMA PET scan is routinely used to stage patients with high grade prostate cancer and as a means to detect metastatic disease. He reiterated that if metastasis was detected then surgery would not be curative.

54. The Health Board was therefore of the view that Mr B had metastatic incurable disease and radical surgery was not in Mr B's best interests. However, following further discussion with my investigator, the Health Board agreed to accept my findings and recommendations in full.

Professional Advice

55. The Adviser said that a rectal examination was carried out at Mr B's ED attendance on 19 April 2022, noting that Mr B was "positive for enlarged prostate". He said this suggested that urinary retention was caused by a benign prostate enlargement rather than prostate cancer. The Adviser explained that prostate cancer would have felt abnormally hard and nodular. The Adviser said that PSA testing for early, clinically undetectable, prostate cancer in April would have risked a false positive result because there had been an episode of urinary retention requiring catheterisation. The advice given to Mr B to have his prostate checked for early prostate cancer by his GP was an appropriate course of action.

56. The Adviser considered the management of Mr B's urological care between April 2022 and February 2023. He said that, following the GP referral with a raised PSA level of 16, the investigations carried out by the Health Board were consistent with the NICE Guideline. Mr B underwent an mpMRI, the first line investigation for people with suspected prostate cancer and a biopsy was advised.

57. The Adviser said that a 2–4-month wait for this "important cancer investigation" was considerably beyond the SCP target cancer treatment time. He said that all new suspected cancers should be regarded as high grade until proven otherwise and biopsied urgently within SCP timescales. The Adviser noted that Mr B would also have had his SCP clock reset due to making the decision to have the biopsy done privately.

58. When Mr B returned to the care of the NHS following the private biopsy, the Adviser said a bone scan (which subsequently showed no evidence of skeletal metastatic disease) was requested, in line with the NICE Guideline.

59. The Adviser noted that, following referral to the Second Hospital, emails suggested that Mr B's Gleason score should be upgraded from Gleason 7 to 9, but this was not documented in the Second Hospital urology MDT outcome forms.

60. The Adviser said the Second Hospital urology MDT asked the First Hospital to carry out a PSMA PET scan. He said this scanning was not mentioned as a pre-treatment staging investigation in the NICE Guideline but was discussed in the EAU Guidelines. The Adviser said that, on the basis of the PSMA PET scan and MRI scan reports, the Second Hospital urology MDT advised that surgery to remove the prostate was inappropriate because Mr B's prostate cancer had spread to the bone. The Adviser noted the First Hospital MDT on 22 February which documented the Private Hospital opinion on 9 February for all radical treatment (that is, surgical treatment), but that Mr B elected for oncology treatment. He said it appeared Mr B made this decision following a discussion with the Specialist Nurse and the background to this decision was that the Second Hospital urology MDT considered radical treatment inappropriate. The advice of the Private Hospital was disregarded.

61. The Adviser said the PSMA PET scan and MRI reports described a suspicious abnormality, not a confirmed bony metastasis. However, he said that Mr B was considered unsuitable for radical treatment by the First Hospital urology MDT because of the abnormality detected on the PSMA PET scan. He said that Mr B was therefore denied potentially curative treatment and instead was offered palliative chemoradiotherapy and hormone therapy.

62. The Adviser noted the Private Hospital had suggested that the presence of significant metastatic disease had not been proven by the PSMA PET and MRI scans. He said the only marker of disease activity for

Mr B was his PSA. This fell during the period of time between referral and treatment, which suggested that his prostate cancer had not progressed or metastasised.

63. The Adviser said that, following the GP referral with suspected prostate cancer on 16 June, treatment should have commenced on 17 August to satisfy the SCP 62-day target. However, the Adviser noted that, on this date, Mr B was yet to be reviewed with his MRI report. As previously noted, the SCP clock would have stopped when Mr B elected to have his prostate biopsy carried out privately and re-set when he was re-referred to the NHS urology clinic on 14 October with a confirmed diagnosis of prostate cancer. On 15 December, 62 days later, the Adviser noted that Mr B continued to wait for treatment for his prostate cancer to begin.

64. In the Adviser's view, there was a "huge delay" in the commencement of Mr B's treatment which was eventually started 230 days after the GP referral. In terms of the impact on Mr B, the Adviser noted that Mr B's PSA fell from 16 to 12.6 between 15 June 2022 and 1 February 2023, suggesting the disease had not progressed. That said, he noted that Mr B was started on finasteride in August 2022, which is known to halve the PSA level. In addition, he said it was possible that finasteride was having a direct suppressive effect on the disease and was not simply influencing PSA level.

65. The Adviser considered the communication with Mr and Mrs B about Mr B's investigations and treatment plans. He said that there was conflicting opinion about the correct management of Mr B's prostate cancer, with the Second Hospital urology MDT advising against surgery and the Private Hospital advising radical, curative treatment. Mr B was subsequently counselled by the Specialist Nurse at the First Hospital who followed the advice of the First Hospital urology MDT which had decided to follow the recommendation of the Second Hospital urology MDT. The Adviser already identified that, contrary to EAU guidelines, the decision whether to cure or palliate Mr B's disease was based on the result of a PSMA PET scan, a test which the EAU suggest should not be considered during clinical decision making. The Adviser agreed with Mr B that a senior consultant with a special interest in urological pelvic cancer should have

discussed the complexities of the case with him. He said the clinical relevance of the findings by the Second Hospital and Private Hospital MDTs required review and explanation by an experienced expert.

66. The Adviser noted the Health Board's comment, in response to this investigation, that prostate cancer is slow-growing, and the bony metastases were likely to have been present before the urinary symptoms appeared, although difficult to detect on the standard bone scan. He said that this was a speculative statement without supportive evidence. He said the clinical significance and history of oligometastatic disease detected with PSMA PET and MRI scanning was uncertain. Scanning at regular intervals would have revealed the rate of growth, if any, and would have helped to determine whether the abnormal focus was cancerous or non-cancerous. He said it was impossible to know when this abnormality first appeared.

67. The Adviser considered the Health Board's comments in response to the draft report. The Adviser confirmed this did not change his advice. He reiterated that the clinical outcome for patients with PSMA PET detected disease was uncertain. He said EAU guidelines were clear that aggressive treatment options, including the possibility of radical prostatectomy, should not have automatically been denied to Mr B.

Analysis and conclusions

a) Should the urological symptoms displayed at Mr B's attendance at the First Hospital's ED on 19 April 2022 have led to an urgent suspected cancer referral?

68. Taking into account the advice I have received, I am satisfied that, based on Mr B's presentation, advice to see his GP to check his prostate was the appropriate course of action. An urgent suspected cancer referral which was not indicated at this juncture. I **do not uphold** this complaint.

b) Was the Health Board's management of Mr B's care between April 2022 and February 2023 clinically appropriate and in line with the SCP.

69. There were elements of Mr B's management that were clinically appropriate, namely the request for mpMRI scan and biopsy, following the urgent suspected cancer referral by his GP, and request for a bone scan following Mr B's biopsy results. These investigations were the appropriate ones to request at these stages of Mr B's care, and in line with the NICE Guideline recommendations.

70. While the request for PSMA PET scan is not mentioned as a pre-treatment staging investigation in the NICE Guideline, the EAU Guidelines discuss the use of such scans. However, I note the advice I have received that the EAU Guidelines indicate the need for caution when making decisions about treatment based on the results of PSMA PET scanning. The EAU Guidelines suggest this test should not be considered during clinical decision-making. Nevertheless, the First Hospital urology MDT followed the recommendation of the Second Hospital urology MDT, that Mr B was not for radical treatment based on the PSMA PET and MRI scan reports.

71. I accept the advice that the decision whether to cure or palliate Mr B's disease based on the results of the PSMA PET scan was contrary to EAU Guidelines. I have considered the Health Board's comments on the draft report, that there was evidence that Mr B's cancer had spread, and it was not in his best interests to offer surgery. I have also considered the additional comments I received from the Adviser. This is a finely balanced decision that rests on whether there was evidence that Mr B's cancer had spread. On the balance of probabilities I am of the view that it was not proven Mr B's cancer had spread, there was only a suspicion. The Adviser also said these reports described a suspicious abnormality not a confirmed bony metastasis. On the basis that this was not proven, Mr B should have been offered surgery and he was therefore denied potentially curative treatment. This is a service failure.

72. This failure is compounded by the view of the Private Hospital MDT that the presence of significant metastatic disease had not been proven by the PSMA PET and MRI scans and that Mr B should have been offered

radical curative treatment options. This view was available to the First Hospital urology MDT when it made its decision against surgery. It is also noteworthy, notwithstanding the advice about the impact of finasteride (paragraph 64), that Mr B's PSA fell during the time between referral and treatment. I am guided by the advice that this suggested it was possible Mr B's prostate cancer had not progressed or metastasised during this time. This is potentially an injustice to Mr B as this decision may have impacted on the course of his treatment, depending on whether he would have chosen radical surgery if offered. That said, I must emphasise that we cannot say with any certainty, if Mr B had been offered radical surgery, and he had opted for it, whether the outcome would have been any different.

73. In relation to the SCP, as Mr B elected to have his biopsy privately, the SCP was closed at this point, with a new pathway opened when he returned to the NHS for his care. This approach was in line with the SCP; a Wales wide guidance published by Welsh Government. Even taking this into account, the Health Board breached the 62-day target initially, following the GP referral (resulting in Mr B's decision to seek a biopsy privately) and again following Mr B's return to the NHS (Mr B did not start definitive treatment until day 96). The Health Board has already accepted significant delays following the GP referral and a breach of the 62-day target. This breach was a service failure and an injustice to Mr B whose first definitive treatment was delayed as a result. I **uphold** this complaint.

c) Was the likely waiting time for the biopsy, in August 2022, appropriate.

74. If Mr B had not elected to have his biopsy privately, taking into account the waiting times for biopsies in August 2022, a further 3 to 4 months wait for this procedure would have added up to122 days to the 67 days he had already waited at the point the decision was made to request an urgent biopsy. I have taken into account the advice that all new suspected cancers should be regarded as high grade until proven otherwise and biopsied urgently and within SCP timescales. Given the importance of this investigation for Mr B's management and decision-making, this wait, significantly in excess of the SCP, was a service failure.

75. To uphold a complaint, I must be satisfied that a service failure has caused harm or injustice. Mr B was in a position where he had been told that he likely had prostate cancer, but that he had to wait 3 to 4 months for further investigations. He was left with a stark choice of choosing to wait for an NHS biopsy, not knowing the impact this would have on his prognosis or treatment or paying for this to be completed privately. This was an injustice to him. I **uphold** this complaint.

76. A key aspect of my work is remedying injustice and hardship. The underlying principle to remedy is to ensure that a public body restores the complainant to the position they would have been in if the maladministration or poor service had not occurred, when this is possible, as detailed in the Principles of Good Administration. The Health Board has previously agreed to reimburse the costs of private investigations or treatment, where appropriate, including in the case of my predecessor's previous public interest report (reference 201905373) relating to a delay in providing treatment for prostate cancer. I consider reimbursement of the cost of Mr B's private consultations and biopsy will restore him to the position he would have been in had this service failure not occurred.

d) Did the Health Board communicate appropriately with Mr and Mrs B, between April 2022 and February 2023, including sharing information about the investigations undertaken, and Mr B's treatment plan.

77. Mr B was seen by the First Consultant following the GP referral on 12 July 2022 and the Second Consultant, on a private basis, on 20 October, when he was referred back to the NHS for investigations. After this time, Mr B was seen by the Specialist Nurse with no further direct consultant input by Health Board clinicians. The Specialist Nurse met Mr B 3 times during this period, on 4 November 2022 and 1 and 20 February 2023. While she clearly shared information with Mr B about his investigation results, the outcome of the various MDTs and about his recommended treatment, I am concerned, given the complexities of Mr B's case that there was no further direct consultant input to discuss the outcomes of the investigations and the treatment plan with him.

78. The second opinion Mr B sought on a private basis conflicted with advice from the Second Hospital urology MDT (in terms of curative or palliative treatment) and his case was complex. Given these circumstances, it would have been appropriate for a consultant with the necessary speciality to have met Mr and Mrs B to discuss the investigation results and treatment options; this was the view of the Adviser which I accept. I also note that this view is supported by the opinion of the Second Hospital (see paragraph 28) and even the Health Board's own consultants questioned who the responsible consultant for Mr B's care was (see paragraph 20), given that Mr B had been seen both by the NHS and privately. Given the lack of consultant input, I am not satisfied that communication was appropriate. This is a service failure and an injustice to Mr and Mrs B, who were not provided with the level of input and information appropriate to the complexities of Mr B's case. I **uphold** this complaint.

e) Was the Health Board management of Mrs B's complaint, submitted in November 2022, in line with the PTR guidance, in particular about communication with Mrs B.

79. I am concerned that the initial management of Mrs B's complaint was not in accordance with the PTR guidance. Despite raising concerns on 17 November 2022, Mrs B did not receive an acknowledgement of her complaint for 13 working days. As the Health Board had not confirmed it was investigating her concerns, she had to follow this up on a number of occasions. She also involved HIW who contacted the Health Board several times before Mrs B's complaint was acknowledged.

80. This lack of formal acknowledgement and recognition of Mrs B's complaint was maladministration and meant that communication with her about her concerns was not timely. This was an injustice to Mrs B, as it took additional effort and the involvement of HIW before the Health Board acknowledged her complaint. The evidence shows that communication with Mr and Mrs B about their concerns and about Mr B's treatment improved after this date and until the Health Board issued its complaint response. I **uphold** this complaint to the extent that the initial management of Mrs B's complaint was contrary to the PTR Guidance and the Principles of Good Administration, which in turn meant that communication

was not of an acceptable standard initially. My recent thematic report, "Groundhog Day 2: An opportunity for cultural change in complaint handling?" June 2023 also highlighted the importance of timeliness and good communication so that complainants do not lose trust and confidence in the complaints process.

Additional comments

81. I highlighted concerns about the Health Board's delivery of treatment/investigations for prostate cancer previously in 2 public interest reports (references 201905373 and 202002273). While I have noted the ongoing actions outlined by the Health Board (see paragraph 50), it is concerning that the urology service provision, in particular in relation to prostate cancer, continues to be a problem for the Health Board. My predecessor received assurance from the Health Board that it was "grasping the nettle". However, the similarity of the concerns in this complaint raises questions about whether the Health Board's actions have been effective in improving the service.

82. It is of real concern to me that I have identified more failings in the provision of prostate cancer care, and that I have identified detriment to another patient. The Health Board has told my office of actions it has taken and is taking to achieve improvements. I have asked the Health Board for information and evidence of these in my recommendations which follow at the end of this report. I urge the Health Board to fully commit to change and improvement so people do not have cause to approach my office again with similar concerns.

83. In the last public interest report about the Health Board's prostate cancer management (202002273), I noted that HIW had identified several serious concerns following its Urological Cancer Peer Review of the Health Board in February 2014. In light of the concerns identified in this report, I will be sharing the report and its findings with HIW for it to take into consideration when planning its future work in this area.

Recommendations

84. I **recommend** that, within **1 month** of the date this report the Health Board should:

a) Provide Mr and Mrs B with a fulsome written apology for the failings identified in this report.

b) Make a financial redress payment of £6,850 to Mr and Mrs B, which includes reimbursement of £5,350 in private costs for the biopsy, reimbursement of £250 for the private consultation regarding surgery, £1,000 for the injustice caused by denying Mr B potentially curative surgery resulting in him requiring life-long treatment for incurable cancer, and £250 for the time and trouble caused to Mrs B for the complaint handling failings identified.

c) Share this report with relevant clinicians to reflect on my findings.

d) Review its complaint handling of this case to identify any lessons to be learned.

85. I recommend that, within **2 months** of the date of this report the Health Board should:

e) Summarise actions taken and the impact of the progress against the remedial action identified by its Urology Steering Group including:

- The reduction in delays following the introduction of a nurse-led biopsy list.
- Exploring options for prostatectomy capacity closer to North Wales.
- A new process to ensure quicker access to biopsy reports for those undertaken in the private sector.
- Three suspected cancer pathway validators assisting to streamline the pathway.

- A straight to mpMRI pathway to be piloted.

f) Summarise the actions taken, and impact of these actions, in addressing the recommendations made following external reviews of the urology service by GIRFT and the Royal College of Surgeons.

g) Summarise the actions taken, and impact of these actions, by the task and finish groups set up following review of the prostate cancer pathway, with a focus on reducing waiting times to diagnosis.

86. I am pleased to note that in commenting on the draft of this report the Health Board has agreed to implement these recommendations.

Michelle Morris

4 July 2024

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