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PUBLIC SERVICES OMBUDSMAN FOR WALES

The investigation of a complaint against Betsi Cadwaladr University Health Board

A report by the
Public Services Ombudsman for Wales
Case: 201905373

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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 Mr Y.

Summary

Mr Y complained that the Health Board exceeded the referral-to-treatment target for cancer waiting times for treatment of prostate cancer and that due to the delay in providing him with treatment, and the potential impact of any delay, he sought private treatment.

The Welsh Government's "Rules for Managing Referral to Treatment Waiting Times" ("the RTT Rules") at the time of the events complained about stated that: "Newly diagnosed cancer patients that have been referred as urgent suspected cancer, and confirmed as urgent by the specialist to start definitive treatment within 62 days from receipt of referral …"

The Ombudsman found that the Health Board would have missed the RTT Rules timescale in Mr Y's case by at least 106 days taking into account the estimated waiting times at the time of Mr Y's diagnosis (3 months). Considering the professional advice that early radical treatment was essential in high-risk disease, a 3 month wait for definitive treatment was unacceptable regardless of the RTT Rules. This was a service failure.

In Mr Y's case, the delay for treatment, and concern about the potential impact on his clinical condition from any delay, led to his decision to seek private treatment. The delay, well in excess of the 62-day target in Mr Y's case, caused him significant distress and anxiety, and his decision to seek private treatment sooner (rather than wait for the Health Board to provide treatment) did not lessen the impact of the Health Board's service failure on Mr Y at a very worrying time. At the time Mr Y sought private treatment, he was concerned that the cancer would spread if he waited for NHS treatment. This was an injustice to Mr Y. The complaint was **upheld**.

The Health Board agreed to the Ombudsman's recommendations that, within **6 weeks** of the date of the final report, the Health Board should:

a) Provide Mr Y with a fulsome written apology for the failing identified in this report.

b) Make a redress payment of £8,171 to Mr Y to represent the cost of his private treatment.

The Health Board agreed to the Ombudsman's recommendation that, within **4 months** of the date of the final report, the Health Board should:

c) Refer the report to the Board and ask it to set up a Task and Finish group to review the Urology service to identify where it can improve service delivery, in particular in relation to cancer treatment targets, to ensure that patients' (particularly high-risk patients) care and treatment is not compromised.

The Complaint

1. Mr Y complained that Betsi Cadwaladr University Health Board ("the Health Board") exceeded the referral-to-treatment target for cancer waiting times for treatment of prostate cancer. He was concerned that following a biopsy which confirmed a diagnosis of prostate cancer, there was a delay in providing him with an appointment for treatment. As Mr Y was concerned about the impact of the delay, he sought private treatment.

Investigation

2. I obtained comments and copies of relevant documents from the Health Board and considered those in conjunction with the evidence provided by Mr Y. Professional advice was obtained from Mr David Almond, a Consultant Urologist ("the Adviser") with extensive experience. The Adviser was asked to consider whether, without the benefit of hindsight, the care or treatment had been appropriate in the situation complained about.

3. The Ombudsman determines 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.

4. Both Mr Y 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 guidance

5. The Welsh Government's "Rules for Managing Referral to Treatment Waiting Times" ("the RTT Rules") at the time of the events complained about stated that:

> "Newly diagnosed cancer patients that have been referred as urgent suspected cancer ("USC"), and confirmed as urgent by the specialist to start definitive treatment within 62 days from receipt of referral …"

> "… the 62 days commence from the date the hospital receive the referral, not when the specialist reviewed the referral."

6. The National Institute for Health and Care Excellence ("NICE") Guidance (NG131) – Prostate cancer: diagnosis and management (May 2019) ("the NICE Guidance"). The NICE Guidance amongst other things, outlines various treatments that should be offered for medium and high-risk localised prostate cancer.

7. The Health Board's Prostate Protocol (June 2019) ("the Protocol") divides patients with prostate cancer into risk groups based on clinical stage, PSA level (prostate specific antigen – a PSA test is not a specific test for cancer but a marker of cancer risk) and Gleason score (used to grade cancer).

8. One of my predecessors issued guidance, "Principles for Remedy", which recognised that remedying injustice and hardship is a key aspect of the Ombudsman's work. It also set out how bodies should put things right when they have gone wrong. The underlying principle to remedy is to ensure that the listed authority restores the complainant to the position they would have been in if the maladministration or poor service had not occurred, when this is possible.

The background events

9. On 29 May **2019** Mr Y's GP made an urgent suspected cancer ("USC") referral to the Health Board's Urology department. Mr Y's PSA was raised (at 20µg/l).[1] The referral was received by the Health Board on 30 May and confirmed as USC due to raised PSA.

10. Mr Y was seen by a locum consultant urologist on 18 June and he was listed for a prostate biopsy. He underwent the biopsy on 28 June.

[1] µg/l stands for micrograms per litre. The higher the PSA level, the more likely it is that the patient has prostate cancer.

11. Mr Y was seen by a consultant urologist ("the Consultant") on 11 July who confirmed a diagnosis of prostate cancer (the prostate biopsy results confirmed a Gleason score of 3 + 4;[2] left lobe of prostate). Mr Y's management was listed for discussion at the next Urology Multi-Disciplinary Meeting ("the MDT").

12. A bone scan on 26 July was reported as clear. An MRI (Magnetic resonance imaging is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body) on 3 August (to stage prostate cancer on the left side) concluded that the disease was organ confined (i.e. had not spread). On 7 August the MDT recommended surgery as part of multimodal treatment.

13. On 13 August the Consultant requested that Mr Y be placed on the pathway for a prostatectomy (surgery to remove the prostate). The Consultant also wrote to a colleague asking him to see Mr Y as a private patient as Mr Y felt that the 3-month wait on the NHS pathway was too long and he was considering private treatment.

14. Mr Y arranged to see a private provider on 15 August where different treatment options and risks of surgery were explained. Mr Y opted for surgery and underwent a prostatectomy procedure privately on 27 August.

Mr Y's evidence

15. Mr Y said the Health Board failed to meet the guidelines for cancer diagnosis and treatment as it exceeded the 62-day referral to treatment pathway.

16. Mr Y said that in August **2019** he anticipated, based on information given to him by the Health Board, that the pathway would take in excess of 7 months. Mr Y therefore arranged to receive treatment from a private provider. He said he suffered financially as a result. Before arranging the private treatment, Mr Y submitted a complaint to the Health Board on 16 August, asking for a resolution to his complaint (i.e. to provide him with treatment) so that he did not have to seek private treatment. He also asked

[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.

the Health Board to explain whether his cancer would spread beyond his prostate if he waited for NHS treatment (the response was provided on 25 November, after Mr Y had his private treatment).

17. Mr Y said the biopsy, scan and MRI in July / early August reported no cancer in the right side of his prostate. However, after he underwent a prostatectomy with the private provider, he was told that cancer was present in both sides of the prostate. As the information in early August was very different from that reported in the biopsy at the end of August, Mr Y said it seemed his cancer was spreading. Mr Y said if the cancer had been treated quickly it may not have spread. He said this was a distressing thought.

The Health Board's evidence

18. The Health Board formally responded to Mr Y's complaint on 25 November **2019**. The Health Board said that Mr Y was not treated within the 62-day referral to treatment pathway, and it apologised for this. It said the length of wait for prostate treatment was reflective of demand and capacity constraints which the Health Board was striving to address. Whilst additional capacity had been secured at other hospitals, it said the demand for treatment continued to outweigh capacity.

19. In correspondence with my office, the Health Board confirmed it was undertaking work with clinicians and other urology specialist teams to deliver a sustainable service model for the future and improved management of its cancer pathways. This was with a view to improving patient flow and waiting times. It said that it was looking to secure a contract for up to 24 months to create additional capacity for prostatectomies. It confirmed that it already had a contract with another hospital outside the Health Board area for 8 prostatectomies per month but it had no other external provider and no further additional capacity had been identified (it said it obtained a one-off capacity for 16 prostatectomies from a health provider in England). It confirmed that a weekly meeting took place to discuss capacity for complex urology cancer surgery.

20. The Health Board said the cancer tracking system showed that Mr Y was added to the waiting list on 13 August 2019 and that all patients on this list had the same urgent clinical priority. It said that at the time of placing Mr Y on the waiting list, there were a total of 17 patients awaiting the same procedure. It said all patients were listed as urgent and remained on the USC pathway until treated. It said the average wait time for a prostatectomy procedure at the time Mr Y was placed on the list, was 2 to 3 months.

21. The Health Board confirmed that it was, and still is clinical practice, to offer radical radiotherapy (with androgen deprivation therapy)[3] and radical prostatectomy for treatment of organ confined prostate cancer. It said that evidence suggested that radiotherapy alone has inferior results compared to the combination (radical radiotherapy and androgen deprivation therapy) and it has been standard practice at the Health Board to offer both together for about 10 years.

22. The Health Board said that whilst it was difficult to comment on the conversation that took place with Mr Y, the clinical letters stated that Mr Y opted for radical prostatectomy which it said suggested that other treatments were discussed. It said Mr Y had a fairly high PSA test, making the possibility that the cancer was outside the prostate, higher. Surgery was therefore offered as part of multimodal therapy, meaning that if the cancer was not completely removed, Mr Y may well have needed to have radiotherapy in addition to surgery, therefore increasing the complications of treatment. It said that it is the Health Board's normal practice to give information on both surgery and radiotherapy / androgen deprivation therapy to a patient where both can be offered, and let the patient decide which one they prefer.

23. Finally, it said that a variety of treatments can be offered for intermediate and high-risk localised cancer and can include, amongst others, either radiotherapy / androgen deprivation therapy or surgery. It said this was the practice when Mr Y was seen and is still the case.

[3] A treatment for prostate cancer to reduce the level of male hormones (androgens) or stopping them from getting into prostate cancer cells. This can cause the prostate cancer to shrink or grow more slowly.

Professional Advice

24. The Adviser said that suspicion of prostate cancer was first raised in May 2019 when Mr Y's PSA was raised (20μg/l). He said with this level of PSA, the probability of prostate cancer exceeded 67%. On 11 July he said the histology of prostate biopsies confirmed the diagnosis of Gleason 3+4 prostate cancer (with a maximum core length of 13mm). He said that although subsequent imaging showed the cancer to be organ confined, the Urology MDT recommended multimodal therapy (radical prostatectomy followed by external beam radiotherapy to the pelvis),[4] this was because they assessed that this was high-risk disease. The Adviser said low risk prostate cancer is often managed non-operatively and simply observed and monitored, but in high-risk disease early radical treatment is essential.

25. The Adviser said that using Mr Y's cancer staging (T2b N0 M0),[5] grading (Gleason 3+4) and PSA level of 20μg/l, Partin tables[6] predicted a high-risk (46%) of extra prostatic extension of the disease (the spreading of the cancer out of the prostate gland) and regional lymph node involvement (18% - presence of cancer cells in the lymph nodes, small structures that work as filters for harmful substances).

26. The Adviser said the Protocol stratified risk according to PSA, T stage on imaging and Gleason grade. According to the Protocol, Mr Y's Gleason grade and T stage defined his disease as intermediate risk. That said, the Protocol also stated that if any one of the 3 parameters was above the threshold for that level of risk stratification, the risk was increased to the next level. He said that for a PSA of 10-20μg/l the risk was defined as intermediate and 20μg/l was high risk. Mr Y's PSA of 20 placed him on the threshold of high-risk disease.

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[4] External beam radiotherapy is high-energy X-ray beams targeted at the prostate to damage the cancer cells and stop them from growing and spreading to other parts of the body.

[5] The TNM system is a way of staging prostate cancer. It stands for Tumour, Node, Metastasis. T describes the size of the tumour. There are 4 main stages of cancer size in prostate cancer (T1-T4). T2b means the cancer is only half of one side of 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 to a different part of the body. M0 means the cancer has not spread to other parts of the body (information taken from https://www.cancerresearchuk.org/about-cancer/prostate-cancer/stages/tnm-staging).

[6] The Partin tables use pre-operative clinical features of prostate cancer (Gleason score, serum PSA and clinical stage) to predict whether the tumour will be confined to the prostate.

27. The Adviser said the RTT Rules stated that the target time for treatment of patients with cancer was 62 days, which he said would have been 30 July. From the information available to the Adviser his understanding was that, when surgery was suggested on 13 August 2019, there was a waiting time of up to 3 months for radical prostatectomy. Based on this information, he said the earliest time that Mr Y could have been offered radical prostatectomy through the NHS would have been 13 November, which was around 168 days after the referral was received. The Adviser said that with or without the cancer waiting time targets, the delay to the start of treatment was completely unacceptable.

28. The Adviser said that Mr Y underwent radical prostatectomy as a private patient on 27 August (4 weeks after the RTT target treatment date). He said that this short delay was unlikely to have affected Mr Y's future outcome significantly; post-operatively his PSA was unrecordable, which suggested that no viable cancer cells had been left behind. He said that, although histology of the operative specimen revealed extra prostatic extension of the disease and lymph node involvement, this was always likely because of the defining features of high-risk disease at presentation.

29. The Adviser said it was difficult to estimate how much 3 months further delay would have affected Mr Y's outcome. While there was no difference in outcome for a patient with low risk disease undergoing immediate or delayed prostatectomy, the effect of delayed treatment on patients with high risk disease was harder to predict. In addition, he said the psychological distress caused by waiting for treatment of a potentially life-threatening cancer would need to be factored in.

30. In terms of Mr Y's assertion that if his cancer had been treated quickly it may not have spread, the Adviser said that although there may be some truth in Mr Y's assertion that the delay to treatment caused local spread of disease to the opposite lobe of the prostate, he said this was very hard to quantify. He said it was more likely that the disease was always present on both sides of the prostate because the disease on the right side had not been detected pre-operatively for technical reasons. Histology of the surgical specimen revealed unexpected disease in the apical region (the end of an organ) of the prostate on the right side. He said this area of the prostate was notoriously difficult to image.

31. The Adviser said that, based on the records of Mr Y's consultations, it was unclear if all available treatment options were explained / offered to Mr Y.

32. In terms of the Health Board's actions in outsourcing treatment and its capacity to provide treatment, the Adviser said that an offer of 8 additional prostatectomies per month would be sufficient to clear the backlog within 2 months and would provide sufficient capacity to meet ongoing requirements.

Analysis and conclusions

33. In reaching my conclusions I have been assisted by the advice and explanations of the Adviser, which I accept in full. The conclusions, however, are my own.

34. Mr Y complained that the Health Board exceeded the referral-to-treatment target for cancer waiting times for treatment of prostate cancer and that due to the delay in providing him with treatment and the potential impact of any delay, he sought private treatment.

35. In accordance with the RTT Rules, Mr Y should have received definitive treatment for his cancer within 62 days of the receipt of the USC referral on 30 May 2019. Considering that Mr Y was told on 13 August that the waiting times for treatment were at that time, 3 months, Mr Y would not have realistically received treatment until 13 November, 168 days after receipt of the USC referral. The Health Board would have missed the 62-day target by 106 days. The Health Board has already acknowledged and apologised to Mr Y that it breached the RTT Rules in Mr Y's case. Taking into account the advice, that early radical treatment was essential in high-risk disease, a 3 month wait for definitive treatment was unacceptable regardless of the RTT Rules. This was a service failure. In addition, I am not satisfied that the records clearly demonstrate that all available treatment options were explained / offered to Mr Y, and I concur with the Adviser in this regard. That said, the private Surgeon explained all available treatment options to Mr Y before he opted for surgery and therefore, he was not ultimately disadvantaged. I **invite** the Health Board to reflect on this point, and the importance of clearly documenting discussions with patients when treatment options are offered / discussed.

36. To uphold a complaint, I must be satisfied that a service failure has caused harm or injustice. Whilst I have noted the advice about the difficulty in estimating the impact of a 3 month delay on clinical outcome, as Mr Y sought private treatment, the actual impact (as opposed to the potential impact of a 3 month delay) was mitigated. Mr Y's treatment was therefore not delayed to the extent it would have been had Mr Y continued to wait for treatment from the Health Board. I am also guided by the advice that a short delay between the definitive date that Mr Y should have received treatment by the Health Board and the actual date he received treatment privately was unlikely to have significantly affected Mr Y's future outcome. I also accept the advice that on the balance of probabilities (the standard of proof I apply when investigating complaints), it was more likely that the disease was present on both sides of Mr Y's prostate rather than any delay causing a spread to the right lobe of his prostate.

37. However, the diminished impact on Mr Y's clinical outcome as a result of his action in seeking and paying for earlier private treatment should not, and does not, exonerate the Health Board of its responsibility to provide necessary treatment within the timescale set out in the RTT Rules for cancer treatment, especially for a high-risk patient.

38. In Mr Y's case, the delay for treatment, and concern about the potential impact on his clinical condition from any delay, led to his decision to seek private treatment. The delay well in excess of the 62-day target in Mr Y's case, caused him significant distress and anxiety, and his decision to seek private treatment sooner, rather than wait for the Health Board to provide treatment, does not lessen the impact of the Health Board's service failure on Mr Y at a very worrying time. At the time Mr Y sought private treatment, he was concerned that the cancer would spread if he waited for NHS treatment. This was an injustice to Mr Y. I **uphold** the complaint.

39. This is not the first time my office has had cause for concern about the Health Board's delivery of treatment / investigations for prostate cancer. Last year I received 2 complaints that multiparametric magnetic resonance imagining (mp-MRI) scans (a special type of scan that creates more detailed pictures of the prostate than a standard MRI) were not made available to 2 patients in accordance with recommendations in the

NICE Guidance.[7] As a result, both patients paid for private scans. As the Health Board agreed to reimburse the costs of the private scans and set out arrangements it had put in place to provide mp-MRI scans at 3 main hospitals in North Wales to comply with the updated NICE Guidance published in May 2019, I was satisfied that the actions taken, in both these cases, resolved these individual complaints. I was also assured that appropriate arrangements had been put in place by the Health Board so that other patients were not impacted in future.

40. In addition, I issued a public interest report in October **2016**,[8] which found that, not only were there delays in diagnostic testing (including template biopsy) to determine if the patient had cancer, but when tests confirmed an aggressive form of prostate cancer, the patient had to wait a total of 132 days (from diagnosis) to receive his first definitive treatment for prostate cancer (a radical prostatectomy). The failure in diagnostic testing, specifically, a delay in undertaking a prostate template biopsy, was reported again in August **2018**.[9]

41. The Health Board said the length of wait for prostate treatment was reflective of demand and capacity constraints. While the Health Board has taken steps to address capacity issues which, based on the advice I have received, appears reasonable, it is concerning that Mr Y and 16 other urgent patients were (potentially) waiting in excess of the 62-day target for treatment in August **2019**.

42. As I am concerned that there were 16 other patients on the waiting list for a prostatectomy at the time Mr Y was placed on the list and that they were all deemed to have urgent priority, I cannot ignore the possibility that these other 16 patients may well have waited beyond the 62-day wait for treatment. Given their urgent status (and confirmation as USC), this may have had serious consequences for their prognosis / treatment. This is clearly a matter that is in the public interest and this is further supported by the related concerns about prostate treatment received by other patients

[7] Cases 201804421 & 201803742.
[8] 201503554.
[9] 201702873.

which my office has previously investigated. I have therefore commenced an Own Initiative Investigation[10] to consider these 16 cases as I am satisfied that the criteria have been met.

43. In Mr Y's case I am satisfied that he suffered an injustice for the reasons set out in paragraph 38. Had the RTT Rules not been breached, Mr Y, a high-risk patient, would not have been in a position where he had to consider and, ultimately, opt for private treatment. The distress caused by the Health Board's inability to offer treatment, well in excess of the timescales set out by the Welsh Government for treatment of cancer, understandably left Mr Y with a stark choice; wait for treatment not knowing what impact this would have on his prognosis and future treatment, or pay for private treatment to mitigate the uncertainty. In line with "the Principles of Remedy", I consider that reimbursement of the cost of that treatment will restore Mr Y to the position he would have been in had the service failure not occurred.

Recommendations

44. I **recommend** that, within **6 weeks** of the date of this report, the Health Board should:

a) Provide Mr Y with a fulsome written apology for the failing identified in this report.

b) Make a redress payment of £8,171 to Mr Y to represent the cost of his private treatment.

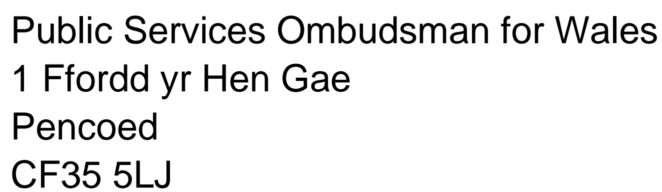
45. I **recommend** that, within **4 months** of the date of this report, the Health Board should:

c) Refer the report to the Board and ask it to set up a Task and Finish group to review the Urology service to identify where it can improve service delivery, in particular in relation to cancer treatment targets, to ensure that patients' (particularly high-risk patients) care and treatment is not compromised.

[10] Under section 4 of the Public Services Ombudsman (Wales) Act 2019.

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

Nick Bennett 3 December 2020
Ombudsman



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