Hutt Valley District Health Board

Wairarapa District Health Board

A Report by the

Health and Disability Commissioner

(Case 19HDC00728)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. In 2018, a woman in her forties at the time of events developed a painful lump in her breast that was incorrectly diagnosed as plasma cell mastitis when she in fact had inflammatory breast cancer.

2. This report concerns the delay in diagnosing the breast cancer, and the coordination of the woman's care between her local DHB, Wairarapa District Health Board (WDHB), and Hutt Valley District Board (HVDHB).

3. The report highlights the importance of ensuring that one clinician and DHB have overall responsibility for a patient's care, and that the clinicians present at multidisciplinary meetings question non-concordant results and investigate these further, and that DHBs have systems in place for alerting clinicians to abnormal test results.

Findings

4. The Commissioner found HVDHB in breach of Right 4(1) of the Code. The Commissioner was critical that the woman was diagnosed with plasma cell mastitis without questioning her non-concordant result and recommending further imaging and biopsy.

5. The Commissioner considered that there was a lack of clarity in the breast services provided by WDHB and HVDHB to ensure that one person was responsible for the woman, and had a full picture of her care. The Commissioner considered that WDHB and HVDHB failed to communicate and co-operate to ensure quality and continuity of services, and found HVDHB and WDHB in breach of Right 4(5) of the Code.

6. In addition, the Commissioner found WDHB in breach of Right 4(1) of the Code. The Commissioner was critical that WDHB failed to have in place an adequate system to alert clinicians to abnormal test results.

Recommendations

7. The Commissioner recommended that WDHB and HVDHB provide an update on the changes made in response to these events, and report on any further changes implemented.

8. The Commissioner also recommended that WDHB and HVDHB provide a written apology to the woman's husband.

Complaint and investigation

9. The Health and Disability Commissioner (HDC) received a complaint from Mr A about the services provided to his late wife, Ms A, by Wairarapa District Health Board (WDHB) and Hutt Valley District Health Board (HVDHB). The following issues were identified for investigation:

- *The appropriateness of the care provided to Ms A by Wairarapa DHB between and including October 2018 and January 2019.*
- *The appropriateness of the care provided to Ms A by Hutt Valley DHB in October 2018 and November 2018.*

10. This report is the opinion of Health and Disability Commissioner Morag McDowell.

11. The parties directly involved in the investigation were:

Ms A	Consumer
Mr A	Complainant
Wairarapa District Health Board	Provider
Hutt Valley District Health Board	Provider

12. Further information was received from:

Dr B	Breast surgeon (HVDHB)
Dr C	General surgeon (WDHB)
Dr D	Pathologist
Pathology service	

13. Also mentioned in this report:

Dr E	General surgeon

14. Independent expert advice was obtained from general surgeon Dr Richard Harman (Appendix A).

15. Ms A died from her illness in 2019. I take this opportunity to extend to her family and friends my sincere condolences.

Information gathered during investigation

16. This report concerns the delay in diagnosing Ms A, aged in her forties at the time of events, with inflammatory breast cancer, and the coordination of her care between her local DHB (WDHB), and HVDHB. In 2018, Ms A developed a painful lump in her breast that was incorrectly diagnosed as plasma cell mastitis. In fact, Ms A had inflammatory breast cancer.

17. Plasma cell mastitis is a rare inflammatory condition of the breast, associated with recurrent inflammation. Often it presents with very painful areas in the breast, and recurrent abscesses that require either aspiration under ultrasound guidance,[1] debridement,[2] or incision and drainage.[3] Usually it settles spontaneously but it may take months to several years, and sometimes it requires repeated intervention. The goals of treatment are to treat any abscesses, and to avoid disfigurement of the breast, as eventually the areas will settle.

18. Inflammatory breast cancer is a rare form of breast cancer. Symptoms include swelling, redness, pitting or thickening of the skin, and breasts that may be tender, painful, or itchy. It progresses aggressively and carries a poor prognosis.

Breast service coordination between WDHB and HVDHB

19. Ms A's local DHB, WDHB, does not have a permanent breast specialist surgeon, so it refers breast patients to HVDHB to provide breast imaging and interventional procedures on its behalf.[4] All Wairarapa general practitioner (GP) breast referrals go directly to WDHB, which then sends imaging requests to HVDHB for booking into the next available imaging appointment slot based on the level of determined urgency. At the time of these events, breast imaging for WDHB patients took place every Thursday morning at Breast Screen Central at HVDHB (the HVDHB Breast Service).

20. Despite the above arrangement, WDHB still performed some procedures locally rather than referring to HVDHB.

21. WDHB told HDC that breast cancer care for Wairarapa patients is delivered across three sites by multiple services (surgery, pathology, radiology, and radiation oncology). WDHB stated that this complex care is further complicated by its use of a locum surgeon Senior Medical Officer (consultant) workforce that provides itinerant service to WDHB. All communication following clinic reviews, results, in-patient stays, and interventions is recorded on its electronic patient record system (Concerto), which is available to all those involved in a patient's care at all facilities across all three DHBs,[5] and allows a clinician to review all data regarding a particular patient's care to date. WDHB and HVDHB contract a pathology service for their histo-pathology[6] service.

Initial presentations and investigations — 26 October to 30 October 2018

22. On 26 October 2018, Ms A presented to her GP with an increasingly painful lump in her left breast. The GP considered that Ms A had either a breast abscess or inflammatory breast cancer, and referred her to the General Surgery team at WDHB as a fast-track suspected cancer patient.

[1] The insertion of a needle to withdraw fluid.
[2] A procedure for cleaning a wound and removing infected or dead tissue.
[3] A minor surgical procedure to release pus or pressure built up under the skin.
[4] The terms of that arrangement were set out in a draft Memorandum of Agreement.
[5] DHB3, Hutt Valley DHB, and Wairarapa DHB.
[6] The diagnosis and study of diseases of the tissues, involving examining tissues and/or cells under a microscope.

23. Before WDHB had taken any action on the 26 October referral, on 29 October 2018 Ms A saw another GP at the medical centre because her condition had worsened. The GP made another referral to the surgical team at WDHB, and also ordered an urgent ultrasound scan of Ms A's left breast, which occurred at WDHB's Radiology Department the same day.

24. After her scan, Ms A went straight to the Emergency Department (ED) at WDHB, where she was told that she needed to see her GP for the results, and was discharged. The ED discharge summary from that attendance notes: "[T]here is NOT A HIGH suspicion of cancer."

25. It should be noted that according to Mr A, Ms A also contacted the HVDHB Breast Service on 26, 29, and 30 October, but was refused an appointment on the basis that "it was just an infection".

26. HVDHB told HDC that it has no record of an imaging referral arriving on 26 October. HVDHB advised that its clinic nurse, who coordinates appointments, recalls speaking to Ms A on or about 29 October 2018 and scheduling her for the first available appointment for imaging, which was Thursday 1 November 2018. HVDHB provided documentation showing that a referral for imaging was sent by WDHB and received by HVDHB on 30 October 2018.

27. The ultrasound undertaken at WDHB on 29 October was reported on 30 October 2018, and revealed a large mass on Ms A's left breast, suspicious for cancer. On receipt of the report, the GP contacted the duty surgeon on call at WDHB, who advised the GP to refer Ms A for urgent assessment in the ED.

First biopsy

28. On 30 October 2018, Ms A attended the ED at WDHB for urgent assessment. She was admitted to the surgical ward and given antibiotics, and her imaging appointment at HVDHB Breast Service for 1 November 2018 was postponed given that she had been admitted to hospital and was undergoing other treatment and investigations.

29. Ms A was discharged on 31 October 2018, with arrangements to take antibiotics, undergo a biopsy the next day[7] and a CT scan within two weeks, and for her to be followed up at the HVDHB Service.[8] The discharge summary from this admission states: "There IS A HIGH suspicion of cancer."

30. On 1 November 2018, a surgical registrar, under the supervision of a consultant general surgeon, performed an open incisional biopsy under general anaesthetic for a possible abscess. The surgical registrar noted that no pus was present, but observed a hard mass, which was biopsied and sent for testing.

[7] WDHB told HDC that the ideal course of investigation would have been to proceed with a mammogram, but that Ms A could not tolerate a mammogram as it was too painful. HVDHB also told HDC that Ms A was unable to undergo a mammogram because of the pain.

[8] On 30 October 2018, WDHB made an electronic referral (received instantly by HVDHB) for Ms A for a mammogram, noting that the urgency with which Ms A should be seen was less than two days.

31. In a follow-up email on 1 November 2018, the consultant general surgeon advised consultant breast surgeon Dr B at HVDHB: "[T]here is no clinical doubt this is a cancer." The consultant general surgeon told Dr B that a preliminary discussion with Ms A and her husband had taken place to explain the diagnosis.

32. On 2 November 2018, WDHB sent an urgent referral to the HVDHB Breast Service. HVDHB prioritised the referral as immediate[9] on 6 November 2018, and an appointment was booked for 12 November 2018.

33. On 6 November 2018, Ms A underwent a staging CT at WDHB. The CT scan reported likely breast malignancy (cancer), and a significant nodule[10] on the right lung (which could be evidence of metastatic disease[11]), but no other evidence of metastatic disease.

Reporting of first biopsy

34. On the same day as the CT scan, WDHB received the 1 November biopsy results. Unlike the ultrasound and CT scans, which reported likely malignancy, the biopsy results gave a diagnosis of an active chronic plasma cell mastitis with no evidence of malignancy.

35. The first biopsy was reported by a pathologist, Dr D, at a pathology service. He stated that his report was not reviewed by anyone else at the time of reporting. He said that he would have checked Ms A's records in Concerto, which at the time of the first biopsy included the General Surgery discharge summary from 31 October, the ED discharge summaries from 29 and 31 October, and an operation note from the open needle biopsy.

36. In an initial statement to HDC, Dr D said that while that documentation (the General Surgery discharge summary from 31 October, the ED discharge summaries from 29 and 31 October, and an operation note from the open needle biopsy) refers to a mass and a possible abscess, there is no mention of a clinical picture of inflammatory breast carcinoma. He stated that the request form for the first biopsy has "essentially no clinical details apart from the site of biopsy". He referred to the ED discharge summary from 29 October 2018, which noted: "[T]here is NOT A HIGH suspicion of cancer."

37. However, in a subsequent statement to HDC, Dr D confirmed that also available to him at the time of the reporting was the discharge summary from 31 October 2018, which noted that there was a high suspicion of cancer, and the ultrasound scan, which indicated likely malignancy. He stated that he would have been aware that malignancy was being considered, but the pain that appeared to be a prominent symptom in Ms A's presentation was unusual in cancer, and the biopsy did not show cancer.

Further presentations — 1 to 7 November 2018

38. Following the open incisional biopsy on 1 November 2018, Ms A began to experience problems with swelling, oozing, and increasing pain around the incision site, prompting her

[9] 1 is urgent, 1+ is immediate, and 2 is semi-urgent.
[10] Growth of abnormal tissue.
[11] Metastasis means that cancer has spread from where it started to a different part of the body.

to present to her GP, ED, and specialist surgeons on numerous occasions over the next two months. Those presentations are outlined further below.

39. On 7 November 2018, Ms A presented to WDHB ED, complaining of excessive serous[12] ooze and severe pain. Ms A was discharged later that day with a plan to dress the wound, continue antibiotics, and attend the scheduled appointment with Dr B at the HVDHB Breast Service. A referral was made to the district nursing service for wound care.

Multidisciplinary meeting and first appointment with Dr B at HVDHB Breast Service

40. On 12 November 2018, Ms A's case was discussed at the Hutt Breast Multidisciplinary Meeting (MDM), led by Dr B. Ten staff members were present at the MDM, four of whom were consultant specialists, and none of whom had met or examined Ms A previously.

41. At the meeting, Ms A's ultrasound, CT scan, and first biopsy results were reviewed, and, on the basis of the biopsy results, the conclusion was reached that Ms A did not have cancer, but had plasma cell mastitis.

42. HVDHB told HDC that the biopsy results were "the most trusted source" and fitted with Ms A's symptoms and presentation. Dr B commented that before the biopsy results, the HVDHB Breast Service had expected this to be a cancer based on the radiology. However, she said that the diagnosis of plasma cell mastitis fitted Ms A's presentation of a swollen, painful area of breast tissue. It was noted that the pain Ms A was experiencing is not usually associated with breast cancer.

43. In response to the provisional opinion, Mr A told HDC that at the time of events, he and his wife had reviewed other sources of information that indicated that pain was a common symptom associated with inflammatory breast cancer.

44. Dr B saw Ms A at an HVDHB Breast Service clinic after the MDM. Dr B noted that Ms A's incision site from the 1 November biopsy was gaping and moist with a surrounding oedematous (swollen) mass that was not healing.

45. Dr B partially removed the sutures from Ms A's incision site because she considered that they could be contributing to her pain. Dr B also explained to Ms A the diagnosis of plasma cell mastitis. Dr B told HDC that a mammogram could not be performed because of Ms A's pain from the wound. Dr B's reporting letter to Ms A's GP states:

> "[S]he has been on antibiotics, just stopping yesterday, and the inflammatory area she thinks has shrunk by at least 2 cm and she is more comfortable and her energy levels are improving. I think that given this is getting smaller with antibiotics with a biopsy that suggests it is infection we should be treating it as infection at this point."

[12] Of, resembling, or producing serum.

46. Dr B noted the nodules on the CT scan, and the need for a follow-up CT scan in six months' time, but wrote: "[G]iven she doesn't have breast malignancy it makes this unlikely to be breast cancer." A follow-up appointment was scheduled for three weeks' time.

47. There is no evidence that Dr B's reporting letter was copied to any WDHB clinician.

Further presentations to ED — 12 November to 1 December 2018

48. At 9.28pm on 12 November, Ms A presented to the WDHB ED with pain and a blister over the biopsy incision site, which burst while Ms A was in the waiting room. The ED doctors considered that Ms A had developed a postoperative wound infection, and discharged her with a plan for re-dressing the wound, and advice to return to ED if she felt she was deteriorating, especially with a fever or increasing pain.

49. On 1 December 2018, Ms A again attended the ED at WDHB with increasing pain and fever. She was given IV morphine and admitted overnight under the care of the General Surgery team. She was discharged the following day with a plan for her to take pain relief, attend the scheduled appointment at the Breast Service on 3 December, and seek medical attention if she had concerns such as overlying redness, worsening fevers, or intolerable pain.

Second appointment with Dr B

50. On 3 December 2018, Ms A attended a second appointment with Dr B at the HVDHB Breast Service. When reporting to Ms A's GP, Dr B noted the diagnosis of plasma cell mastitis, and said she considered that Ms A's ongoing inflammation and pain was due to a built-up fluid collection. A follow-up appointment with the Breast Service was scheduled for two weeks' time, but there is no evidence that a further appointment with Dr B occurred until after Ms A was diagnosed with cancer. There is also no evidence that any WDHB clinician was copied into Dr B's reporting letter. HVDHB told HDC that Ms A was scheduled to see Dr B on 17 December 2018, but Ms A cancelled the appointment as she was feeling too unwell to travel and therefore a biopsy was not performed.

Second opinion

51. On 13 December 2018, the GP referred Ms A to WDHB for a second opinion from general surgeon Dr E at WDHB, as Ms A was concerned about the constant discharge from the wound, and her very painful breast. It was noted that incision was the only way of reducing Ms A's pain.

52. Dr E saw Ms A on 14 December 2018 and made a plan to admit Ms A on a later date for incision, drainage, and resection of the lump.

53. On 14 December 2018, Ms A presented to WDHB ED with ongoing pain. She was discharged later that day, having been booked for incision, drainage, and resection of the lump on 21 December 2018.

Second biopsy

54. On 17 December 2018, Ms A presented to Dr E again with a large, tense swelling in the middle of her breast. Dr E, working with the diagnosis of plasma cell mastitis, drained this under local anaesthesia, obtaining a large amount of "white creamy pus". This was sent to the laboratory but no growth of bacteria was detected. Dr E arranged to see Ms A again on 21 December 2018. Dr E copied his clinic letter to Dr B.

55. On 21 December 2018, Dr E undertook an open debridement and drainage of the wound, and obtained a further specimen, which was sent for testing (second biopsy). The results for the second biopsy were not received by WDHB until 8 January 2018 (discussed further below).

First clinic appointment with Dr C at WDHB

56. At some point after 21 December 2018, Dr E ceased working at WDHB. On 27 December 2018, Ms A was seen at WDHB by general surgeon Dr C. The diagnosis at that time was plasma cell mastitis and problems with wound care. In his reporting letter to Ms A's GP, copied to Dr B, Dr C noted that the wound appeared better and the breast less inflamed. The second biopsy results from 21 December 2018 were not available at the time of this appointment.

57. Dr C told HDC that Dr E had discussed with him his concerns and described in detail Ms A's breast condition. Dr C stated: "[W]hen I first saw [Ms A], the diagnosis and obvious suffering dismayed me. Plasma cell or granulomatous mastitis can be a miserable diagnosis." Dr C said that he spoke with Dr B to ascertain how certain she was about the diagnosis, and noted that results from the second biopsy were forthcoming. He arranged to see Ms A weekly.

Reporting of second biopsy

58. The pathology service stated that the results of the second biopsy were reported and sent to Concerto on 31 December 2018 by Dr D, and showed invasive ductal carcinoma (indicating inflammatory breast cancer). Both the first and second biopsies had been reviewed by another pathologist, who had agreed with the conclusions — namely that the first biopsy did not indicate a malignancy but the second did.

59. HVDHB told HDC that the results from the second biopsy were made available on Dr E's Concerto homepage on 31 December 2018. However, at this time Dr E was no longer working at WDHB, and Ms A's care had been transferred to Dr C. As outlined further below, there is no evidence that the results of the second biopsy were brought to Dr C's attention at this time.

60. When reporting the second biopsy on 31 December, the pathologist requested immuno-histochemistry tests. A supplementary report was then issued on 9 January 2019 with those results. The pathology service stated that a supplementary report overwrites the original reporting date, which is why Concerto records the date of reporting of the second biopsy as being 9 January 2019.

Further appointment with Dr C — 3 January 2019

61. Ms A saw Dr C on 3 January 2019. In his reporting letter to Ms A's GP, again he noted the diagnosis of plasma cell mastitis, but that the biopsy results were still pending. Dr C arranged a follow-up appointment for two weeks' time. There is no evidence that the reporting letter was copied to Dr B.

Diagnosis

62. Ms A saw Dr C again on 8 January 2019. Dr C noted that Ms A's breast was slightly improved. At the time of Ms A's appointment, the biopsy results were still not available, but they were reported later that day (although the report is dated 9 January 2018). The report indicated inflammatory breast cancer,[13] and Ms A was recalled to Dr C's clinic immediately, and the change in her diagnosis was explained. She was then urgently referred to Medical Oncology at another district health board (DHB3). Dr C telephoned Dr B to advise of the diagnosis.

Subsequent events

63. Initially, Ms A's clinicians believed that the cancer was stage three and treatable, and both Dr B and Dr C advised Ms A accordingly. HVDHB advised HDC that the stage three diagnosis was based on the results from the first CT scan in November 2018.

64. Subsequently, a follow-up CT scan on 15 January 2019 identified metastases, and Ms A's diagnosis was changed to terminal stage four cancer. In response to the provisional opinion, Dr B told HDC that the CT scan on 15 January 2019 showed the progression of lung nodules confirming metastatic disease, and this was subsequent to the review of Ms A and her diagnosis of stage three cancer.

65. Sadly, Ms A passed away in 2019.

Further information

Dr C

66. Dr C told WDHB:

> "Our error was a supremely unfortunate sampling and possibly tissue processing error with a rare but plausible diagnosis made on the first biopsy that held specialists up. Almost any other result would have led to a speeded up repeat biopsy. … [Ms A] is the victim of an aggressive malignancy. I cannot say if earlier diagnosis and treatment would have made a significant difference to survival but we might have minimized the duration of her symptomatic course."

67. Dr C stated that while he cannot recall with certainty when the biopsy results were available on Concerto, he can say that they were not available to him until 8 January 2021. He said that it has been and remains his "custom and habit" to review relevant imaging and laboratory results on Concerto whenever he sees a patient. Dr C stated:

[13] The report describes an "invasive ductal carcinoma, indicative grade 3".

> "There was not then nor is there now any electronic system to alert me when a result is ready. We just have to know to look up the patient and then search for the appropriate subheadings in the patient's Concerto record. The only method for alerting us to results that are available when we aren't specifically looking at a specific patient's Concerto file is that we receive printed results that are filed by hand in our results slots in outpatients. These events all happened during a holiday period when paper results get filed sporadically."

68. Dr C further stated:

> "The emotional memory of feeling completely blindsided leaves no doubt in my mind that the delay in result availability on my Concerto system was real. … Being responsible for laboratory and imaging results that we have no control over has been a longstanding problem."

HVDHB

69. HVDHB apologised that this was such a distressing time for Ms A, Mr A, and their families, and offered its sincere condolences.

70. HVDHB noted that even with hindsight, no cancer was detected on the first biopsy. It stated that in the MDM review of the case, it was identified that given the circumstances at the time, the original diagnosis and outcome of the MDM was plausible, and the treatment and follow-up plan to manage Ms A's care was entirely appropriate. However, it acknowledged that with hindsight they could have done things differently.

71. HVDHB acknowledged that the continuity of Ms A's care was "suboptimal". It stated that Dr B remembered multiple phone calls with other clinicians, which added to the clinical documents. HVDHB further stated that the Concerto system allows clinicians in all three DHBs to see each other's electronic clinic letters, and these provide a history of the clinical engagement with, and continuity of care for, the patient.

72. HVDHB undertook a further review of the MDM as recommended by my expert advisor, general surgeon Dr Richard Harman. The review identified learning outcomes from the MDM.

WDHB

73. WDHB told HDC that on hearing that Ms A had passed away, WDHB wishes to offer its sincere condolences to Mr A and family.

74. In its review of Ms A's case, WDHB determined the following preventable causes of delay:

- Over three months, Ms A saw five different WDHB surgeons and one HVDHB surgeon. WDHB, HVDHB, and DHB3 have no agreed protocols/algorithms on diagnosis and management of breast abscess and inflammatory breast cancer.
- There is no clear pathway for breast surgical management, evidenced by GPs referring multiple times to both WDHB surgeons and HVDHB breast surgeons.

- There was confusion as to which service (WDHB or HVDHB radiology vs. Hutt Breast Centre) provides access to breast ultrasound and image-guided breast biopsy under what circumstance.
- There was a failure to confirm diagnostic concordance at the MDM.
- Early ultrasound-guided re-biopsy may have reduced the diagnostic delay.
- There was a delay in the receipt of the second biopsy results, possibly caused by inadequate staffing by the pathology service over the holiday period.

75. Ms A's oncologist noted that given the metastases on her lungs evident in the first CT scan, it is likely that the cancer was incurable from the onset of disease symptoms.

ACC

76. ACC reviewed the slides from the first and second biopsies, and agreed with the pathologists' diagnoses in each.

Responses to provisional opinion

77. Mr A, WDHB, and HVDHB were given the opportunity to respond to the relevant sections of the provisional opinion. Where appropriate, changes have been incorporated into the report.

78. Mr A told HDC that the system failed Ms A in a major way, and that the misdiagnosis contributed to her suffering and stress. Mr A stated: "All faith that [Ms A] and I had in our medical system disappeared very quickly. It felt that because [Ms A's] case was a complicated one, no one wanted to know."

79. Mr A commented that he hopes that the changes made by WDHB and HVDHB in response to these events will help to avoid a case like Ms A's from happening again.

80. WDHB stated:

> "Once again we would like to take the opportunity to express our condolences to her family. We would also reiterate that significant changes have been made to our systems in the interim, and add that a pending major upgrade of our IT systems means that electronic sign-off of results is expected to be in place within the next 4–6 months."

81. WDHB and Dr C had no further comments.

82. HVDHB accepted the provisional opinion and the proposed recommendations.

Opinion: Introduction

83. Ms A was incorrectly diagnosed with plasma cell mastitis when she had inflammatory breast cancer. It took over two months to diagnose her correctly, during which time she repeatedly presented to doctors in excruciating pain with oozing abscesses on her breast.

84. The system in place at the time of these events was that WDHB and HVDHB would jointly provide a breast service to consumers based in the Wairarapa. I consider that in this case the delay in diagnosis was preventable, and can be attributed to failures in that system. While, as discussed below, some failures are more attributable to one DHB as opposed to the other, and I acknowledge the close relationship between the two DHBs, one of the key findings in my report is how Ms A's care was affected by the lack of clarity as to which DHB and clinician had overall responsibility for her. As such, in my view, the two DHBs are equally responsible for the delay in her diagnosis.

85. In order to assist my assessment of Ms A's care, I obtained independent clinical advice from consultant breast surgeon Dr Richard Harman.

Opinion: Hutt Valley DHB — breach

86. WDHB refers breast patients to HVDHB for breast imaging and interventional procedures. HVDHB became involved in Ms A's care on or about 29 October 2018, and first saw Ms A on 12 November 2018 following an MDM the same day.

MDM — failure to question non-concordant result and investigate further

87. The clinicians present at the MDM on 12 November 2018 reviewed the first ultrasound, CT scan, and biopsy results, and arrived at a diagnosis of plasma cell mastitis, relying on the conclusions of the first biopsy results. None of the clinicians present at the MDM had examined Ms A prior to this meeting, and the WDHB clinicians involved in her care were not in attendance. HVDHB advised HDC that the biopsy results were "the most trusted source" and fitted with Ms A's symptoms and presentation. Further, cancer was not normally painful, whereas Ms A was experiencing significant pain.

88. After the MDM, all Ms A's clinicians — both at HVDHB and WDHB — deferred to the MDM's diagnosis of plasma cell mastitis, and it was not until December 2018 that a second biopsy was undertaken and the diagnosis changed.

89. My independent expert advisor, Dr Harman, advised that it was not reasonable for the clinicians to rely on the biopsy diagnosis of plasma cell mastitis in the face of the clinical picture before them, particularly as the first biopsy results suggesting no malignancy was not concordant with the ultrasound and CT scans that indicated malignancy.

90. Dr Harman said that the purpose of an MDM is to put together all the clinical information and make sure the results are concordant. The MDM had information that raised a high

suspicion of malignancy, and Dr Harman advised that the multidisciplinary team, particularly the surgeon, radiologist, and pathologist, should have been alert to the fact that this was a non-concordant result, and should have recommended further imaging and biopsy.

91. Dr Harman noted that none of the clinicians present at the MDM had examined Ms A, and advised: "If a clinician who had examined [Ms A] prior to the biopsy had been able to present her case at the MDM the diagnosis may have been made earlier."

92. I accept Dr Harman's advice. In doing so, I am mindful of the bias that comes with hindsight, as well as the complexity of Ms A's presentation. However, the non-concordant information was available to the meeting at the relevant time. In my view, the clinicians at the MDM should have questioned the non-concordant result and taken additional steps before arriving at a diagnosis. I agree with Dr Harman that HVDHB's failure to do so was a moderate departure from accepted practice.

93. Ten staff members were present at the MDM, including four consultant specialists. While there is individual accountability for the decision made, given the purpose of MDMs and the number of clinicians involved, I consider that the responsibility for the MDM's failure lies at a service level with HVDHB. In reaching this conclusion, I am also mindful that although Dr Harman advised that usually a patient would be seen by a surgeon prior to an MDM, the system at HVDHB allowed the MDM to make decisions about Ms A without any specialist present having met or examined her first. I note that there is now a new requirement that a patient reviewed at the MDM must have been seen by at least one clinician present, and I consider this appropriate.

Conclusion

94. I conclude that by diagnosing Ms A with plasma cell mastitis on 12 November 2018 without questioning the non-concordant result and recommending further imaging and biopsy, HVDHB failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[14]

Other comments

95. One of the issues raised by Mr A in his complaint related to communication between Ms A and the HVDHB Breast Service. He was concerned at what he described as several efforts to get an appointment with the Breast Service in October 2018 that were declined on the basis that Ms A only had an infection. However, HVDHB told HDC that it has no record of contact with Ms A until around 29 October 2018, and that a formal referral was received on 30 October 2018. Ms A was scheduled for the first available appointment two days later.

96. I am unable to determine exactly what contact occurred between Ms A and the Breast Service prior to 29 October 2018, if any. However, I am satisfied that once a formal referral was received by HVDHB on 30 October 2018, a timely appointment was scheduled for two days later on 1 November 2018.

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

97. Mr A was also concerned that once a diagnosis of cancer was made in January 2019, initially Ms A was told that it was stage three cancer and treatable, but then later it was confirmed that it was stage four cancer and terminal. He was concerned about the accuracy of the information provided to Ms A.

98. In response, HVDHB noted that initially its clinicians understood that it was stage three cancer, based on the results of the first CT scan in November 2018. However, a follow-up CT scan revealed metastases (spread of the cancer), which indicated a diagnosis of terminal stage four cancer. I acknowledge how confusing this must have been for Ms A and Mr A, and how distressing the change in diagnosis must have been for them. However, I also acknowledge that the clinicians gave Ms A a diagnosis based on the information available to them at the time, and that the clinical picture changed soon afterwards.

Opinion: Hutt Valley DHB and Wairarapa DHB — breach

Poor coordination of care

99. The system in place between WDHB and HVDHB for the delivery of specialist breast services was fragmented and disjointed. WDHB does not have a specialist breast surgeon, and relies on specialist breast services being provided at HVDHB. Ms A was managed by two DHBs and several different clinicians — notably Dr B at HVDHB, and Dr E and Dr C at WDHB, as well as multiple ED clinicians.

100. It was patently unclear which DHB or clinician had overall responsibility for Ms A's care. WDHB deferred to the diagnosis made by the HVDHB MDM, despite no clinician at the MDM having seen Ms A in person at the time the diagnosis was made. Although Dr E and Dr C copied Dr B into some correspondence, and the Concerto record-keeping system was shared between both DHBs, there is no evidence that Dr B was copied into all correspondence, so important information, updates, and any changes to Ms A's progression were not brought to Dr B's attention. Similarly, although I acknowledge that Dr B says that she had telephone calls with WDHB clinicians, these were undocumented, and there is no evidence that Dr B copied WDHB clinicians into her reporting letters to Ms A's GP. The WDHB clinicians relied on Dr B's expertise in breast services, but she saw Ms A only twice in the two-month period before she was diagnosed.

101. My expert advisor, Dr Harman, advised that the lack of a single clinician in charge of Ms A's care probably contributed to the lack of recognition that this was not plasma cell mastitis. The frequent change in clinicians made it difficult for any clinician to have a full picture of the progression of Ms A's condition. I note Dr Harman's advice that had there been one clinician in charge with the full clinical picture, it is possible that they would have questioned the diagnosis earlier and taken further action.

102. Dr Harman also advised that the inadequate communication contributed to the lack of continuity of care for Ms A.

103. I accept Dr Harman's advice. In my view, the lack of clarity in the breast service provided by WDHB and HVDHB is a failure for which both WDHB and HVDHB are jointly responsible. In my view, the failure to ensure that one person was responsible for Ms A and had a full picture of her care represents a failure by WDHB and HVDHB to communicate and co-operate to ensure quality and continuity of services. I therefore find both WDHB and HVDHB in breach of Right 4(5) of the Code.[15]

104. It is encouraging that both of the DHBs have recognised the lack of clarity in their breast service and have put in place a number of initiatives to improve it.

Opinion: Wairarapa DHB — breach

105. In addition to the above, I have further concerns regarding WDHB.

106. I have considered whether WDHB and its clinicians should have questioned the diagnosis of plasma mastitis sooner. In my view, it was reasonable for WDHB to rely on the specialist HVDHB breast MDM to reach an accurate diagnosis (notwithstanding my conclusion that the MDM was in error by not questioning the non-concordant advice). So far as WDHB was concerned, the MDM had collective specialist expertise upon which it should have been able to rely. My primary concern relates to the system in place for alerting clinicians to abnormal test results at WDHB.

Lack of alert system

107. Dr E at WDHB undertook a second biopsy on 21 December 2018 and sent it for testing the same day. The results were reported and became available on Concerto on 31 December 2018, but Dr C was not aware of them until 8 January 2019. I am concerned at the delay in informing Ms A of extremely significant test results.

108. HVDHB told HDC that initially the results were sent to Dr E on 31 December, but by that stage he was no longer working at WDHB. The pathology service told HDC that the results were "sent to Concerto" on 31 December 2018, but following further testing, a supplementary report was issued on 9 January 2019, which would have overwritten the original report of 31 December 2018.

109. Dr C said that he looked for the biopsy results on 3 January and again on 8 January 2019, but they were not available to him until later in the day on 8 January 2019, and this is supported by his contemporaneous documentation.

110. It is unclear to me why Dr C was unable to access the results on 3 January when apparently they were "on Concerto" at that time. It seems possible that the further testing request by pathology and the issuing of a supplementary report on 9 January may have had an impact

[15] Right 4(5) states: "Every consumer has the right to co-operation among providers to ensure quality and continuity of services."

on the accessibility of the results prior to that date. In any case, I have no reason to doubt that Dr C checked for them on 3 and 8 January, given that his statement of his usual practice is supported by his contemporaneous documentation.

111. It is clear that the results were sent to Concerto on 31 December 2018. At that time, Dr E, who ordered the results, no longer worked at WDHB, and Dr C had taken over Ms A's care. I am concerned that the system did not support the transition in Ms A's clinicians. Given that Dr E was no longer working at WDHB, it was imperative that any testing he had ordered was re-routed to the clinicians who had taken over care of his patients, and that those clinicians were alerted to the results once they became available. This was particularly important if those results were abnormal.

112. The alert system at WDHB was also inadequate. The electronic system lacked any alert option entirely, and Dr C stated that the only method at WDHB for alerting clinicians to results was hand delivery of printed results into clinicians' "results slots", which happened only sporadically over the holiday period. Such a system is outdated, and unreliable. I acknowledge that Dr C remembers feeling "completely blindsided" by the results, and stated that clinicians' responsibility for results over which they have "no control" has been a longstanding problem at WDHB.

113. Dr Harman advised that the lack of a clinical alert once the correct diagnosis was available was a critical error, and that WDHB should have a system to "red flag" abnormal results to clinicians. I wholeheartedly agree. WDHB had the information it needed to diagnose Ms A accurately and provide her with appropriate care, yet its system failed to ensure that the information reached the appropriate clinicians within an appropriate time. This contributed to an unnecessary delay for diagnostic results in a time-critical situation.

114. In my view, the failure to have an adequate alert system represents a failure by WDHB to provide services to Ms A with reasonable care and skill. Accordingly, I find WDHB in breach of Right 4(1) of the Code.

Changes made

WDHB

115. WDHB told HDC that to augment care continuity, in 2019 it created a new role of Specialty Nurse Coordinator — General Surgery. The focus of that full-time role is to maintain visibility and continuity of care for General Surgery patients across the region.

116. WDHB told HDC that it is incorporating a red flag system for abnormal results into its upgrade of its patient records system.

HVDHB

117. HVDHB told HDC that it is developing more comprehensive protocols and policies to improve the symptomatic services.

118. HVDHB said that it is aligning the surgeon's Wairarapa clinic with the breast imaging clinic to facilitate critical discussions.

119. HVDHB also told HDC that it is updating its MOU with Wairarapa to include models of care for breast patient transfer and management.

120. HVDHB stated that the systems issues between HVDHB and Wairarapa DHB that contributed to this case have been resolved, and that Wairarapa DHB clinicians now present patients to the weekly MDM.

Recommendations

121. I recommend that WDHB:

a) Provide HDC with an update on the changes it has already implemented in response to these events, and report on any further changes that have occurred subsequently, within three months of the date of this report.

b) Provide a written apology to Mr A for its breaches of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mr A.

122. I recommend that HVDHB:

a) Provide HDC with an update on the changes implemented in response to these events, and report on any further changes that have occurred subsequently, within three months of the date of this report.

b) Provide a written apology to Mr A for its breaches of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mr A.

Follow-up actions

123. A copy of this report with details identifying the parties removed, except WDHB, HVDHB, and the expert who advised on this case, will be sent to the Ministry of Health, the Health Quality & Safety Commission, the Royal Australasian College of Surgeons, the Breast Cancer Foundation New Zealand, and Te Aho o Te Kahu, the Cancer Control Agency, and will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from general surgeon Dr Richard Harman:

> "Thank you for asking me to provide advice regarding [Ms A] in the period between October 2018 and November 2018. I have no personal or professional conflict in this case.
>
> Firstly I would like to summarise the case as I have assessed. [Ms A] saw her GP on Friday 26th October who then sent an urgent referral to the General Surgical Team at [WDHB]. Appropriate processes were put in place for an appointment at the [HVDHB] Breast Clinic. This appointment was made for the Thursday 1st November which was the first available appointment. [Ms A] saw a second GP on Monday 29th October, as her condition worsened and this resulted in an ultrasound scan which was suspicious for malignancy. Indeed the GP referral letter indicated a suspicion of inflammatory cancer. It appears then that [Ms A] was then admitted to the hospital and underwent an open breast biopsy by [the surgical registrar] under the supervision of [a consultant general surgeon] on 1 November. The registrar noted there was no pus present, there was a hard mass and this was biopsied. Specimens were sent to the laboratory and urgent referral to the Breast Tumour Service at [HVDHB] was forwarded on 2nd November. At this stage [the consultant general surgeon] stated that she had no doubt this was cancer and that also a CT scan was performed on 6th November. This report in its conclusion stated that, '*It likely showed a breast mass which was likely malignant and it showed two nodules in the right lung where suspicion was raised of metastatic disease.'*
>
> [Ms A's] case was then discussed at the Hutt Breast Multidisciplinary Meeting on Monday 12th November 2018. Present at this meeting were, [Dr B Consultant Breast Surgeon, Consultant Radiologists, Consultant Pathologist, Clinical Nurse Manager Breast Clinic, Cancer Nurse Coordinator, Breast Care Nurses, Service Manager General Surgery Orthopaedics]. I note there is only one breast surgeon and one pathologist, two radiologists. I note that [Dr B] states that she had already reserved a spot for surgery due to the clinical suspicion of malignancy thus indicating that at least [Dr B] had appreciated that there was a high chance of malignancy. At this meeting quite appropriately, the pathology, radiology and histology were reviewed. I note that the consultant surgeon at this stage had not seen the patient. The diagnosis of plasma cell mastitis was decided upon despite the suspicious clinical appearance and imaging. Following the MDT meeting, it appears that [Dr B] met [Ms A] for the first time. At this [Ms A] had a radial wound and an inflamed breast. I note that it would have been difficult for [Dr B] at this time to clinically diagnose cancer, as this had already been assessed by another surgeon who operated on [Ms A] in Masterton. The appearances could well have been that of infection or chronic infection. The patient then returned to the Wairarapa where she proceeded to see [Dr C] who continued to supervise the care of assumed plasma cell mastitis for [Ms A]. [Ms A] struggled with pain and what appeared to be worsening inflammation in the breast until the 17th December when she had an appointment with another surgeon, [Dr E] who it appears, arranged for further surgery. This resulted in a further biopsy being performed on 17th December.

[Dr E] appears to have been a locum, who subsequently left the hospital. [Ms A] was then reassessed by [Dr C] on 11th January, not as a result of this second biopsy, but because she was having increased pain. However it was following this appointment that he noticed that a further biopsy had been performed by the Locum Surgeon, [Dr E]. The diagnosis of breast cancer was then realised and appropriate treatment then followed.

From my review of the case I have identified several critical errors: The MDT review should have questioned the diagnosis. The information from the GP and the imaging (radiology) all were suspicious of malignancy. This is a non-concordant result. Further biopsies should have been asked for following this meeting. There was no continuity of care for [Ms A]. Several clinicians took care of her surgically. There was inadequate communication between these clinicians. There was no clinical alert once the correct diagnosis was made on the 17th of December and because of this [Ms A's] diagnosis was again delayed until the 11th of January.

I have summarised my answers to your questions below but can expand on these should you require:

Whether it was reasonable to rely on histological diagnosis of plasma cell mastitis in November 2018, taking into account [Ms A's] nulliparity imaging results of ultrasound and CT available at that time, together with the presenting history.
I do not believe it was reasonable to rely on the diagnosis of plasma cell mastitis. The MDT should have had information that raised a high suspicious of malignancy. All members of the MDT team particularly the surgeon, radiologist and pathologist should have been alerted to the fact this was a non-concordant result. This case is complicated by the fact that it was dealt with essentially in two different places. The Wairarapa as it does not have its own breast clinic; it refers patients to the Hutt. By the time [Ms A] was assessed at the multidisciplinary meeting, she had been seen and operated on by a surgical registrar at Wairarapa, and then had the biopsy results assessed and imaging performed. The discussion at the MDT is where the error occurred. It is surprising given the clinical suspicion prior to any surgery, both clinically and radiologically, that the diagnosis of Plasma Cell Mastitis was arrived at by the MDT. I have subsequently asked whether this pathology was reviewed in the context of the high clinical suspicion of cancer. The reply from [HVDHB] pathology indicates the pathologist was unaware of the high index of suspicion, yet this was presented at the MDT with a pathologist present. The purpose of the MDT is to put all the clinical radiological and pathological information together and make sure the results are concordant. Unfortunately once the critical error by the whole MDT team occurred, the clinicians followed along the path of a benign diagnosis on the basis of the MDT decision. It is especially important that the MDT functions efficiently and accurately when it is providing advice to an offsite location.

Whether a repeat biopsy or alternative imaging such as MRI scan should have been considered prior to 21st December 2018.
Yes, I believe that further imaging and biopsy should have been requested. This should have been recommended by the multidisciplinary team at the meeting in November.

Any other matters regarding breast surgeon management that you would consider warrant comment.
[Ms A] was managed by several surgeons. WDHB does not have a specialist breast surgeon and relies on the services from [HVDHB]. Wairarapa also appears to have a changing surgical workforce and appears reliant on surgical locums. [Dr B] provided specialist advice to the surgeons in Wairarapa but these surgeons changed over the course of [Ms A's] care. It appears that [Dr B] only reviewed [Ms A] twice, and so may not have had the full picture as to [Ms A's] progress. If [Dr B] had seen [Ms A] on all of her presentations I think it would have been more likely for her to have taken further action i.e. request another biopsy or MRI. The lack of a single clinician in charge of [Ms A's] care probably contributed to the lack of recognition that this was not plasma cell mastitis. Whilst in retrospect [Dr B] could be criticised solely for not recognizing the wrong diagnosis, I believe she was reassured by the MDT findings. Further to this, I am critical of the delay in getting the results from the biopsy which was carried out by the locum surgeon on 17 December 2018, and this was not highlighted to the treating clinician in some way.

Other questions as follows:

What is the standard of care/accepted practice?
The standard of care or accepted practices in a case such as this is that it would be reviewed in a multidisciplinary meeting, and the patient would usually have been seen by a surgeon prior to this, although I note the difficulty in the Wairarapa not having its own breast clinic. I believe the MDT team has departed from the standard of care and the issue of a non-concordant result should have been noted.

If there has been a departure from the standard of care or accepted practice, how significant a departure would you consider this to be?
I believe there was a departure from the standard in this case and that the multidisciplinary team should have identified that there was a non-concordance of this result. The degree of departure is significant.

How would it be reviewed by your peers?
Most of my peers would regard this failure to identify non-concordance within the MDT and in light of the suspicion raised from the clinical history and imaging as significant.

Recommendations for improvement that may help to prevent a similar occurrence in future.
I have the following recommendations:

Hutt Valley review this case again in their MDT in light of the information that was available to them i.e. the clinical suspicion of cancer from the GP and referring surgeon and the suspicion from the Radiology reports US and CT scan. Once they have reviewed the case provide a report as to how the error occurred including any procedural or resource issues that may contribute to problems in the running of an efficient accurate MDT. The pathological slides be reviewed externally (outside of [the DHB3 region]) with the information that was available i.e. the initial GP referral and the clinical suspicion

from the referring surgeon and the suspicious ultrasound and CT scan. WDHB institute a system to red flag abnormal results particularly cancer histology to clinicians. This is particularly important when locum surgeons are being utilised to staff the hospital. Once these recommendations are through I can provide further advice as to whether further changes need to be implemented. Please don't hesitate to contact me if you require further clarification.

Yours sincerely,

Mr Richard Harman FRACS
Clinical Director
Department of General Surgery
Breast, Endocrine, Laparoscopic Melanoma & General Surgeon"

Dr Harman provided the following further advice on 20 April 2021:

"Thank you for asking me to provide further expert advice on this clinical case. I note now that both the Hutt Valley DHB and Wairarapa DHB have responded. I note the corrective actions and in particular the further MDT, the pathology review and the establishment of a red flag alert system for abnormal results.

With regard to your questions I have answered below each one.

1. Please advise whether the further response and information provided by Hutt Valley DHB changes your previous advice, and if so why. In particular, please consider:

a) The adequacy of the MDT decision and treatment plan to manage [Ms A].
I have considered the response from the Hutt Valley and the fact that they have undertaken a further review and MDT on 11 May 2020, Appendix A. The case was reviewed again and I note there were learning outcomes from the MDT:

1. **Do not MDM a patient who has not been seen by at least one attending clinician, whether a surgeon or radiologist, because clinical concordance cannot be determined.**

2. **Take responsibility as peer reviewers more seriously; be ready to insist on re-biopsy, more imaging, re-excision etc. if there is any doubt, no matter how small or not in keeping with the opinion of the rest of the MDT.**

I think this advice is useful in minimising future errors. In particular if a clinician who had examined [Ms A] prior to her biopsy had been able to present her case at the MDT the diagnosis may have been made earlier. All breast cancer requires a clinical, radiological and histological assessment and unless someone has actually examined the patient, this cannot take place. Therefore I am in agreement with the Hutt Valley's review of their MDT and I would like to thank them for carrying out this further MDT and rediscussing this very difficult case.

In respect to the MDTs I would also suggest that Wairarapa surgeons are given the ability to attend the MDT via zoom or alternative. This needs to be resourced by the Wairarapa and Hutt DHBs.

I further acknowledge that the clinical case was extremely difficult and that because it was managed on two sites, it made it very difficult for all clinicians involved.

I further note now that remedial steps have been made through a red flag system in the Concerto between Wairarapa and Hutt Valley, and this should also prevent further miscommunication and similar incidents such as [Ms A's] happening again.

I also note that the pathology was reviewed extensively by three pathologists, all of which did not pick up a diagnosis of cancer and therefore it is unlikely that the sample that was sent for the biopsy was of the actual tumour.

b) The adequacy of [Dr B's] treatment plan for [Ms A].
I have no criticism of [Dr B's] treatment plan as she understood she was dealing with an inflammatory process. [Dr B] was misled by the MDT outcome and the fact the original examination and operating surgeons were not present at the MDT.

c) Whether Hutt Valley DHB's response in the timeline below amends your previous advice in any way?
Yes I am now happy with the DHB's corrective action. I would also like to know that the DHB has set up a virtual presence for the Wairarapa offsite surgeons and clinicians to present at the MDT.

2. Please advise whether this departure from the expected standards of care represents a mild, moderate or significant departure? Please also advise where the responsibility lay for the lack of continuity or care.
This is a moderate departure from the standard of care that could be expected. I have reviewed the level of departure following the review of pathology and the review from the clinicians and the fact the diagnosis was not straightforward. However I still believe had the correct process been in place the diagnosis could have been earlier. The responsibility lies with no one person but the Wairarapa and Hutt DHBs in not ensuring that Wairarapa patients have access to an MDT and no red flag system to highlight abnormal results to a changing locum surgical workforce. I note these have been corrected as above.

3. Whether the further response and information provided by Wairarapa DHB changes your previous advice and if so why. Please also advise whether this departure from the expected standards of care represents a mild, moderate or significant departure?
I am happy with the responses and corrective action taken by the DHBs.

I can see that both Hutt Valley and Wairarapa have gone to considerable lengths to prevent this happening again and I think this is a good outcome for any future patients. I would like to know that there is now a mechanism for Wairarapa DHB clinicians to present patients at the MDT.

I have the deepest sympathy for [Ms A] and her family but I do not feel that there is any particular person that is at fault, but rather delays stem from a difficult diagnosis and a lack of systems between the two DHBs that allowed adequate communication and notification of abnormal results.

I am happy that both the Hutt Valley DHB have made changes to the way that patients are presented at the MDT and that the Wairarapa DHB have adjusted their notification system, all of which should reduce the chance of such a situation happening again.

Kind regards

Yours sincerely

Electronically sighted and approved by the author for dispatch

MR RICHARD HARMAN
Breast, Endocrine, Laparoscopic
Melanoma & General Surgeon”