Breast Surgeon, Dr C

Radiation Oncologist, Dr D

Breast Clinic

A Report by the

Health and Disability Commissioner

(Case 12HDC00413)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

Background

1. On 29 October 2009 the late Mrs A had a mastectomy, performed by breast surgeon Dr C, at a breast clinic. Following the mastectomy, Dr C sent the resected tissue for histology, which involved a range of routine tests including determining the HER2 receptor status.[1] A positive HER2 status indicates a type of cancer that tends to be more fast-growing and may respond to Herceptin, a treatment that targets HER2 positive cancers and that is given only in conjunction with chemotherapy.

2. On 18 November 2009 Mrs A met with radiation oncologist Dr D to discuss adjuvant therapy options.[2] At that time, the HER2 result was unavailable. The clinical record of this consultation states that Mrs A had a very good prognosis, and that Dr D recommended radiation and did not recommend chemotherapy. There is no record that the pending HER2 result was discussed at this consultation. Dr D stated that during this consultation Mrs A expressed a strong view that she wished to avoid chemotherapy, but this is also not recorded and is disputed by Mrs A's family.

3. On 24 November 2009 Mrs A's HER2 result became available, and it was positive. Dr C saw Mrs A on a number of subsequent occasions but never informed her of the test result. Dr D also never informed Mrs A of the positive HER2 result.

4. Mrs A underwent radiation therapy. In 2010 her radiation oncology care was transferred to a public hospital, where her HER2 result incorrectly appeared as negative on a series of seven clinic notes.

5. In 2011, public hospital radiation oncologists referred Mrs A to a medical oncologist, who obtained Mrs A's positive HER2 test result and informed her of it. This was the first occasion on which Mrs A was informed of the positive HER2 result. Mrs A was subsequently diagnosed with metastatic disease and passed away.

Findings

6. The Commissioner found that Dr C's surgical care was adequate but made adverse comment that, in the circumstances, it would have been prudent for him to have checked with Mrs A that she had received the HER2 result and that it had been discussed with her.

7. In addition, the Commissioner found that Dr D failed to provide Mrs A with all the information she would reasonably have expected to receive, including full information relating to her prognosis and her positive HER2 result. He also should have offered her a referral to a medical oncologist. In not doing so, Dr D breached Right 6(1)[3] of the Code of Health and Disability Services Consumers' Rights (the Code).

[1] HER2 is a receptor found on the surface of some cancer cells. Cancers with a high number of HER2 receptors are considered HER2 positive.
[2] Treatment given in addition to primary treatment.
[3] Right 6(1) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive."

8. The Commissioner made adverse comment about the breast clinic's patient management systems, and emphasised the importance of robust systems in the context of multidisciplinary care.

9. Adverse comment was also made about the DHB's system for managing patient records.

Complaint and investigation

10. The Commissioner received a complaint from Mr B and Mrs B about the services provided to their late mother/mother-in-law Mrs A by Dr C and Dr D at the breast clinic. The following issues were identified for investigation:

- *Whether Dr C provided services of an appropriate standard to Mrs A between October 2009 and December 2011.*
- *Whether Dr D provided services of an appropriate standard to Mrs A between October 2009 and December 2011.*
- *Whether the breast clinic provided services of an appropriate standard to Mrs A between October 2009 and December 2011.*

11. An investigation was commenced on 16 May 2013.

12. The parties directly involved in the investigation were:

Mr B	Complainant
Mrs B	Complainant
Mr A	Consumer's husband
Dr C	Breast surgeon
Dr D	Radiation oncologist
The breast clinic	Breast health care service provider

Also mentioned in this report:

Dr E	Medical oncologist

13. Information from the DHB was also reviewed.

14. Independent expert advice was obtained from breast surgeon Dr Colin Wilson (**Appendix A**) and radiation oncologist Dr John Childs (**Appendix B**).

Information gathered during investigation

Background

15. On 22 October 2009 Mrs A, then aged 59 years, had a consultation with breast surgeon Dr C at a breast clinic, following an abnormal mammogram. Dr C examined Mrs A and discussed the mammogram and clinical findings with her. The clinical notes record that Mrs A was to undergo a biopsy and that they "both expect[ed]" the biopsy to show breast cancer.

16. The clinical notes record that, on the same day, Dr C discussed Mrs A's case with two radiologists and a medical co-ordinator at a multidisciplinary assessment meeting. Mrs A subsequently had an ultrasound-guided core biopsy,[4] which revealed invasive ductal carcinoma (a type of cancer).[5]

17. On 23 October 2009 Mrs A had a follow-up consultation with Dr C to discuss possible treatment options. There is a detailed clinical record of this consultation, which states that Mrs A was "quite determined to have a mastectomy", partly because she was due to travel overseas in December that year. The clinical record states that, in light of that fact, Dr C recommended a right mastectomy and sentinel lymph node biopsy.[6]

18. On 27 October 2009 Mrs A's case was discussed at a regular multidisciplinary leaders meeting at the breast clinic. The breast clinic referred HDC to the "BreastScreen Aotearoa National Policy and Quality Standards" (the BSA Standards) in place in 2009[7] for information about how these meetings are handled and what needs to be included. The BSA Standards state that the multidisciplinary teams must include radiologists, surgeons, pathologists, medical radiation technologists, breast-care nurses, and other professionals as appropriate. According to the BSA Standards, the purpose of a multidisciplinary team is to ensure that women undergoing breast screening have a completed assessment, including, among other things, review and assessment of screening and treatment results. The meetings should preferably be weekly but at least fortnightly.

19. The clinical record of this multidisciplinary meeting (insofar as it related to Mrs A) was entered on the BSA database by the breast clinic's clinical director, and states: "The diagnosis of malignancy was noted and discussed at the Multidisciplinary Meeting at the breast clinic on 27/10/09." No further information was recorded.

[4] Removing a portion of breast tissue in order to examine it for signs of breast cancer, using an ultrasound to guide the needle to the relevant area.
[5] The most common type of breast cancer, this type of cancer has broken through the wall of a milk duct, where it originated, and spread to the surrounding breast tissue.
[6] A sentinel lymph node is the first lymph node to which cancer cells are most likely to spread from a primary tumour. A sentinel lymph node biopsy is a surgical procedure by which the sentinel lymph node is identified and removed by a surgeon and then examined by a pathologist to determine whether cancer cells are present.
[7] "BreastScreen Aotearoa National Policy & Quality Standards" published by the Ministry of Health's National Screening Unit in June 2008. These standards were updated in December 2013.

20. On 29 October 2009, Dr C performed a right mastectomy, sentinel lymph node biopsy and level 1 axillary lymph node dissection.[8] Dr C told HDC that all tissue removed during the surgery was submitted to pathologists for histological analysis. The histology request form sent to HDC included a section titled "Ordering Clinician", which was filled out as "Unknown doctor ID! Referrer not in doctor list". However, the form also included Dr C's Medical Council of New Zealand registration number, making him identifiable as the ordering clinician.

HER2 receptor status

21. As part of the histology analysis, pathologists examined Mrs A's HER2 receptor status. HER2 is a receptor found on the surface of certain cancer cells. Breast cancer tumours with a high number of HER2 receptors are described as HER2 positive, and tend to grow more quickly than other types of breast cancer.

22. The HER2 receptor status can affect the efficacy of different types of treatment. Specifically, HER2 positive cancers can respond to Herceptin,[9] while HER2 negative cancers do not. Herceptin is given only in conjunction with chemotherapy.

23. The HER2 receptor status is tested first by immunohistochemistry (IHC). If the IHC testing returns an equivocal result, further testing, called fluorescence in situ hybridisation (FISH), is undertaken to determine whether the HER2 status is positive or negative.

First postoperative consultation

24. On 5 November 2009 Mrs A had a postoperative consultation with Dr C. Dr C's record of this consultation notes that Mrs A was making a good recovery from surgery.

25. Dr C told HDC that at this consultation he discussed the pathology with Mrs A, although this is not recorded in the clinical notes. Dr C told HDC that, at the time of this consultation, the HER2 IHC testing had returned an equivocal result and the pathologists had advised that further FISH testing would be undertaken.

Oncology assessment

26. On 18 November 2009 Mrs A met with radiation oncologist Dr D to discuss adjuvant therapy. Mrs A's husband, Mr A, was also present.

Dr D's recollection

27. At this time, Mrs A's HER2 FISH result was still outstanding. Dr D stated that, during this appointment:

> "The worsened prognosis associated with HER2 positivity would have been discussed … the benefit of adjuvant chemotherapy would have been stated in absolute numbers taken from [Adjuvant! Online][10] and there would have been a

[8] A surgical procedure used to determine the necessity of further treatment based on cancer cell spread.
[9] A trade name for trastuzumab, which is used to treat breast cancers with over-expressed HER2.
[10] A widely used online tool to help healthcare providers discuss the risks and benefits of adjuvant therapy with patients.

> discussion regarding the added value of chemotherapy plus Herceptin if the HER2 status was positive."

28. Dr D told HDC that, at the time of the consultation, Mrs A "did not wish to receive chemotherapy".

29. Dr D stated that it is not his practice to recommend whether a patient receives chemotherapy or not — rather, he presents patients with "the data associated with the improvement in outcome and allow[s] them to reach a conclusion. If there is any doubt in their mind regarding the benefit of chemotherapy then they are always referred to a Medical Oncologist[11] for further discussion and clarification."

The family's recollection

30. Mr A, who was also present at the consultation, told HDC that his wife did not express strong views about chemotherapy. According to Mr A, chemotherapy was discussed in passing and in terms of "general breast cancer background" but was not suggested as an option for his wife. Mr A recalls that during this consultation Dr D said that the HER2 result was either negative or pending. Mr A also said that he is "fairly certain" that at this consultation Dr D did not talk about whether the pending HER2 FISH result would affect the treatment options available. Mr A's impression of this consultation was that, due to the success of the mastectomy, his wife could "go on living life".

31. Mrs A's son told HDC:

> "I have spoken to various members of my family and all of us are in absolute agreement that [my mother] was never offered any additional Chemotherapy treatment after her Mastectomy as the doctor was satisfied that the removal procedure had been a 'success' … To further evidence how certain we are as a family that [my mother] would never have refused treatment or options had [they] been suggested, is the fact that ... [later], [my mother] undertook numerous courses of different types of chemotherapy."

Clinical record

32. The record of this consultation is a clinical letter from Dr D to Dr C dated 18 November 2009. The letter states:

> "… The pathology report has shown two ductal carcinomata measuring 17 and 9.5 mm.
>
> … [Mrs A] has no symptoms to suggest metastatic disease and examination shows a well healed wound on the right chest wall with a small seroma. There is no evidence of metastatic disease.

[11] Radiation oncologists specialise in radiation therapy, while medical oncologists specialise in drug therapy (for example, chemotherapy).

> Her prognosis is very good and the benefit from adjuvant chemotherapy is small and this treatment has not been recommended. There is no benefit from hormone treatment as the [oestrogen/progesterone (ER/PR)] receptor status is negative.
>
> I have recommended adjuvant radiation therapy … she is aware that the risk of local recurrence is not high but it will be lowered with a course of radiotherapy to her chest wall. …"

33. Dr D told HDC that "in retrospect [his] letter could more accurately reflect the discussion that took place in the consultation and [he] should have noted that the pathology report had been discussed, the pending HER2 result was noted and the implications of this [had] been discussed".

Subsequent treatment

34. On 19 November 2009 Mrs A had a further postoperative consultation with Dr C. The clinical records state that she was recovering well from her mastectomy and make no mention of adjuvant therapy.

35. On 24 November 2009 Mrs A's definitive HER2 test result became available and was uploaded onto the breast clinic's computer system. The result was positive. As stated above, HER2 positive cancers tend to grow more quickly than other types of cancer and may respond to Herceptin, unlike other types of cancer. Mrs A was not informed of this HER2 positive result.

36. Dr D told HDC:

> "When the HER2 receptor result became available no further action was required as [Mrs A] had had a full discussion regarding the potential benefits of chemotherapy alone (if the receptor status was negative) or chemotherapy plus Herceptin if the receptor status was positive. On reflection, I have considered whether I should have informed [Mrs A] of the HER2 receptor result. In [Mrs A's] case I was much influenced by her strong view that she wanted to avoid chemotherapy."

37. On 3 December 2009 Mrs A had another postoperative consultation with Dr C. The letter Dr C wrote to Mrs A's general practitioner about this consultation states that Mrs A was recovering well. It also includes a section labelled "Diagnosis Oct 2009", which states, "HER2 Equivocal FISH Pending", despite the fact that the positive result was already available.

38. Dr C told HDC that the HER2 results "were not relevant to [his] consultations with [Mrs A] at that time as [his] focus and [Mrs A's] was on getting physically well for travel [overseas] [in December 2009]".

39. Mrs A subsequently travelled overseas and commenced radiation therapy on her return in January 2010.

40. On 6 April 2010 Dr D sent a letter to the Oncology Department at a public hospital stating that Mrs A had finished adjuvant radiation treatment six weeks previously and

had requested oncology follow-up at the public hospital in the public system. The Oncology Department was not advised in that letter that Mrs A's cancer was HER2 positive.

41. On 26 April 2010 Mrs A had a further postoperative consultation with Dr C. In the notes for this consultation, the "Diagnosis Oct 2009" section includes the words "HER2 Positive". However, there is no record that the result was discussed with Mrs A during this consultation or in subsequent consultations with Dr C.

42. The clinical record of that consultation notes that Mrs A was "concerned about her left breast". Dr C examined Mrs A and arranged for her to have an ultrasound scan of her left breast "to help provide reassurance that her left breast is normal". The ultrasound was carried out at the breast clinic that day.

43. Mrs A's HER2 status was subsequently recorded as negative in a sequence of seven radiation oncology clinic notes from the public hospital between 3 August 2010 and 1 December 2011 (discussed further below).

44. On 12 August 2011 Mrs A had a consultation with Dr C. At the time, Mrs A was due to have a shoulder operation for an unrelated condition. According to Mrs A's family:

> "[Mrs A] asked [Dr C] to confirm that she was free of cancer as she would not have undertaken the surgery had the condition returned. [Mrs A] was reassured that she was 'clear' and should proceed with the operation …"

45. Mrs A's family also said that, at the time, Mrs A had started to experience severe back pain. Mrs A's family expressed concern that Dr C attributed her back pain to the amount of gardening she did. He did not undertake additional testing.

46. In responding to this concern, Dr C referred back to the clinical record of this consultation, which states that Mrs A was due to have a shoulder operation and that she was concerned about a small lump on her left breast. The clinical record states that Dr C carried out a needle biopsy of the lump at Mrs A's request and noted that, on examination, there was no sign of recurrent cancer in her right mastectomy, and that there were no enlarged regional lymph nodes. The clinical record does not record any conversation about back pain.

47. On 8 November 2011 Mrs A presented at an oncology appointment at the public hospital with back pain. She subsequently underwent a bone scan and was diagnosed with metastatic disease.[12] Mrs A was referred to medical oncologist Dr E at the public hospital.

48. On 14 December 2011 Mrs A had her first consultation with Dr E. When Dr E reviewed Mrs A's clinical findings he found that, contrary to what was recorded in past public hospital records, her HER2 status was positive. Dr E discussed the HER2 result with Mrs A and, in early 2012, Mrs A elected to have chemotherapy treatment with Herceptin.

[12] The spread of cancer from one part of the body to a non-adjacent part of the body.

49. Sadly, the treatment was unsuccessful and Mrs A died.

Breast clinic systems

50. The breast clinic told HDC that it "provides all facets of breast disease diagnosis and treatment".

Clinical record

51. Dr D stated that, although Mrs A's positive HER2 result was available in the breast clinic's Comrad[13] database on 24 November 2009, the result appeared as still "pending" in the December 2009 clinical record because the "Diagnosis" section used on the breast clinic clinical notes was "a chronologic summary of information that is available at the time of the initial oncology consultation [on 18 November 2009]".

52. The breast clinic advised me that, since the events complained of, it has changed the "Diagnosis" section "to be updated as and when new or amended information becomes available so that it is corrected or checked at the time of the patient's next visit". In addition, the breast clinic is working with its medical database provider to improve the way the information in the "Diagnosis" section is generated.

Patient test results

53. When asked by HDC how the breast clinic handles test results, the breast clinic responded:

> "Test results requested by clinicians are received by the breast clinic via hard copy (mail) or fax and via EDI [electronic data interface] (electronically) which are accepted directly into our Comrad database. Once received, the breast nurse will place the hard copy with the [patient's] notes, either to be seen at the time of the [patient's] upcoming clinic appointment if the same day, or alternatively on the relevant clinician's mail shelf. Up until now [1 July 2013], to cut down duplication and the volume of paper notes that need to be sorted, once the reports have been accepted into Comrad via EDI, the hard copy of the results is destroyed (securely). If a result is available in the Comrad database, it will have been seen by the relevant clinician or clinicians.
>
> … [The breast clinic has] complete confidence in [Dr D] having viewed the amended pathology result containing the updated [HER2 FISH] status in this particular case when it became available approximately two weeks after the initial preliminary [HER2 IHC] report, however because of [the practice of disregarding the hard copy reports], we are aware that we are unable to prove unequivocal evidence of this.
>
> As an interim measure, we have elected to keep these signed reports with the [patient's] hard copy information folder filed at the breast clinic.
>
> We will explore with Comrad Medical Systems a method of clinicians viewing and acknowledging these results directly in the Comrad database, and collecting an audit trail as to who has viewed the results in the database and when."

[13] The breast clinic's electronic medical records database.

Other changes to service

54. The breast clinic stated that it has also instituted the following changes to its service since 2009:

- Since the end of 2010, our patients do not have an initial postoperative oncology consultation until their definitive HER2 status is available.

- In June 2012 the breast clinic introduced a weekly clinical multidisciplinary meeting (in addition to the multidisciplinary leaders meeting discussed above at paragraph 18) where clinicians (including an oncologist) discuss cases that are undergoing or due to undergo treatment in the private sector under one or more clinicians who work for the breast clinic. If the treating surgeon is unable to attend the meeting (with another surgeon deputising), a copy of the multidisciplinary meeting notes are provided to that surgeon.

Public hospital systems

55. As stated above, Mrs A's HER2 status was recorded as negative in a sequence of seven radiation oncology clinic notes from the public hospital between 3 August 2010 and 1 December 2011.

56. The DHB stated that it is unable to ascertain with certainty why Mrs A's test result was incorrectly recorded as negative. The DHB considered that the HER2 result was probably recorded as negative when Mrs A first started receiving radiation treatment at the DHB, and the error was subsequently perpetuated. The DHB stated that the relevant section of a patient's clinical record would not be reviewed or updated unless the patient's condition changed or a new therapy was being considered.

57. The DHB considered that the perpetuated error may have been a result of limited information sharing between the private and public healthcare systems at the relevant time.

58. The DHB advised that, since 2012, it has used a new [database and information sharing system]. The DHB explained that [the new system] means that patients have a single electronic record across all aspects of their clinical management, which is available to staff in both the public and private healthcare systems. The DHB considers that

> "[w]hat happened to [Mrs A] on her pathway through the private and public sector would be much less likely to occur today because of the link of information between all of the providers involved … [The DHB appreciates that] sadly, this has come too late to make a difference for [Mrs A]. However, the risks of the kind identified in her case have been a major catalyst for the comprehensive [database and information sharing] system now in place."

59. The DHB also said that it wishes to apologise to Mrs A's family that this error occurred.

Response to provisional decision

Mrs A's family

60. In response to the "information gathered" section of my provisional decision, Mrs A's son told HDC that any possible extension of his mother's life expectancy would have been "massive", especially concerning her grandchildren.

Dr C

61. In response to my provisional decision, Dr C stated that the original post-surgical histology request form showed him as the surgeon on Mrs A's ID label. He stated that the printed request form sent to HDC (which stated "Unknown doctor ID! Referrer not in doctor list") is generated by the breast clinic when reprinting histology reports, and is a software issue being addressed by the pathology laboratory and the breast clinic.

62. Dr C further stated:

> "Giving results to patients with regard to ER, PR and HER2 results invites questions from patients much beyond what these results mean … I find it better to leave this area of discussion appropriately to the oncologists who have the knowledge, training and expertise to advise patients in adjuvant therapy and not the surgeon."

63. Dr C also stated: "I am at fault for not correcting the HER2 result from pending to positive on the diagnosis section more promptly in [Mrs A's] case and I regret this." He said that the breast clinic patients are now given an information booklet filled out with their histology report, and provided HDC with a copy of the booklet.

64. Dr C told HDC that he has spent his career believing that he has always had a caring and holistic approach to his patients.

Dr D

65. In response to my provisional decision, Dr D stated, with reference to the pending HER2 result, that he has a structured approach to his consultations, and always "runs through" the pathology report, as it underpins all decision-making. However, he acknowledged that there is no documentation that a discussion about the pending HER2 result took place.

66. Regarding the extent to which chemotherapy was discussed during the 19 November 2009 consultation, Dr D stated: "Chemotherapy cannot be discussed in this setting without discussing the potential benefit and side effects. I vigorously maintain that this would have been discussed." Dr D further stated his view that

> "[a]djuvant chemotherapy is very different to therapeutic chemotherapy given in the setting of metastatic disease. … Adjuvant chemotherapy is given to patients in the post operative setting where there is no obvious disease. This treatment will only improve survival in a percentage of patients … [and most] patients will have chemotherapy with all of its side effects and no personal benefit. This concept would have been explained to [Mrs A] …"

The breast clinic

67. In response to my provisional decision, the breast clinic advised that the post-surgical histology request form sent to HDC incorrectly showed "Unknown doctor ID! Referrer not in doctor list" because

> "… the [pathology] laboratory was using only 4 digits of [Dr C's] Medical Council number ([XXXX]) instead of the full five (0[XXXX]). As the number began with a zero, this was being cut off by the lab system. Our Comrad RIS [Radiology Information System] expects the full 5 digit number, hence was not matching it with the surgeon's name. This problem has been corrected by the laboratory and is now no longer occurring."

The DHB

68. In response to my provisional decision, the DHB advised:

> "Staff vigilance around documentation and clinical records can't be emphasised enough and especially when patients are moving between private and public providers for their care and treatment as can occur with many Oncology patients. Therefore this case has been discussed at the Oncology Clinicians group meeting as a general reminder, but also as a learning opportunity as to potential risks and consequences for patients."

Opinion: Adverse comment — Dr C

Role of the surgeon

69. My independent expert advisor, breast surgeon Dr Colin Wilson, advised that the role of the surgeon in the management of breast cancer is to perform the surgery and refer to the oncologists for advice on adjuvant treatment. Dr Wilson noted that it is also customary for the surgeon to offer follow-up, which includes annual mammography and an assessment for local, regional or metastatic recurrence of breast cancer.

Surgical care — no breach

70. Dr Wilson considered that the surgical care provided to Mrs A by Dr C was "reasonable in every regard". Overall, Dr Wilson considered that Dr C had adhered to the Ministry of Health's 2009 guidelines for management of early breast cancer[14] in his treatment of Mrs A.

71. I accept Dr Wilson's advice and consider that the surgical care Dr C provided to Mrs A was adequate.

[14] Ministry of Health, New Zealand Guidelines Group, *Management of Early Breast Cancer: Evidence-based Best Practice Guideline* 2009.

Ongoing management — other comment

72. Mrs A's family state that Mrs A complained of back pain to Dr C in August 2011 but that Dr C attributed it to gardening. However, Dr C advised that his records do not document any discussion of back pain.

73. If Dr C had been told of the back pain, Dr Wilson advised that, in the circumstances, initially it would have been reasonable for him to attribute Mrs A's back pain to gardening and to wait a few weeks before arranging investigations. No investigations were arranged until Mrs A's back pain was followed up by the DHB oncologist nearly three months later.

74. I note the conflict in the evidence as to whether Mrs A discussed her back pain with Dr C, and I am unable to make a finding of fact in the circumstances.

Communication of test results — adverse comment

75. Following Mrs A's mastectomy in October 2009, Dr C sent the excised tissue for histology and testing for a number of things, including the HER2 receptor status.

76. At Mrs A's initial postoperative consultation with Dr C on 5 November 2009, the IHC testing had returned an equivocal result, and the laboratory had advised that further analysis of the HER2 receptor status would be carried out using FISH. Dr C said that he discussed the pathology with Mrs A, although this is not recorded in the clinical notes.

77. On 19 November 2009, at Mrs A's next consultation with Dr C, the HER2 FISH result was still pending.

78. On 24 November 2009 the positive HER2 FISH result became available and was loaded onto the breast clinic's computer system. The positive result meant that Mrs A's cancer was a type that was likely to grow more quickly than other types of cancer, and she may have benefited from Herceptin treatment.

79. Mrs A saw Dr C on 3 December 2009. However, Dr C did not inform Mrs A of the HER2 result, and it was still listed as "HER2 Equivocal FISH pending" on the "Diagnosis" section of the clinical record. Although the result was changed to "positive" in the "Diagnosis" section of the clinical record at Mrs A's subsequent consultation with Dr C (on 26 April 2010), he still did not inform her of the result.

80. Dr C never informed Mrs A of the result, and she did not become aware that her HER2 receptor status was positive until two years after her mastectomy.

81. Doctors owe patients a duty of care in handling patient test results, including advising patients of, and following up on, abnormal results.[15] In my view, Mrs A's positive HER2 result was an abnormal result. In general, I consider that the primary

[15] See, for example, opinions 00HDC07636, 99HDC11494, 08HDC06165, 08HDC06359, and 09HDC01505.

responsibility for advising patients of, and following up on, abnormal results rests with the clinician who ordered the tests, in this case Dr C.[16]

82. However, each case is unique to its own circumstances. In this case, different aspects of Mrs A's care were being managed by different clinicians who specialised in particular areas. I am mindful of Dr Wilson's view that sending resected tissue for histology following a mastectomy differs from ordering other tests, because there is a "standard protocol" for the types of tests ordered post mastectomy. I accept that the HER2 result was relevant to Mrs A's adjuvant therapy (provided by Dr D and later the public hospital) rather than her surgical care (provided by Dr C). Dr Wilson advised me that breast surgeons would not routinely check that post-mastectomy test results relevant to non-surgical aspects of a patient's care had been appropriately dealt with by the relevant clinicians. For these reasons I do not consider that Dr C breached the Code in this instance.

83. Nonetheless, Dr C was aware that the HER2 IHC result was equivocal and that the FISH test was not available for Mrs A's radiation oncology assessment. In addition, Dr C was the first clinician at the breast clinic to see Mrs A once the final HER2 result did become available, and he retained a key role in her ongoing care, treatment and follow-up from October 2009 to August 2011. In the circumstances, Dr C had a crucial role in ensuring the continuity of care provided to Mrs A. I consider that it would have been prudent for Dr C to have checked with Mrs A that she had received the HER2 result and that it had been discussed with her. I am of the view that Dr C should be mindful of the fact that, as a breast surgeon, he works with patients receiving multidisciplinary care, and he should take a more holistic and proactive approach to the care of patients.

Opinion: Breach — Dr D

84. Mrs A saw Dr D for an initial postoperative oncology assessment on 18 November 2009. At that time, Mrs A's HER2 IHC result was equivocal and her HER2 FISH result was pending.

Factual findings

85. The clinical record, Dr D's evidence, and Mr A's recollection of this consultation differ. In order to assess the standard of care provided by Dr D to Mrs A, it is necessary for me to assess the available evidence about what was discussed.

86. According to the clinical record, Dr D considered that Mrs A's prognosis was "very good and the benefit from adjuvant chemotherapy [would have been] small and this treatment [was not] recommended". There is no record that Mrs A expressed a particular view about chemotherapy or of a discussion about the pending HER2 result and its potential effects on her treatment options.

[16] See opinions 08HDC06359 and 10HDC01419.

87. Dr D told HDC that he has a structured approach to his consultations and, as part of that approach, would have discussed with Mrs A her histology, including the pending HER2 result and its potential effects on treatment options. Dr D also said that Mrs A had a "strong view that she wanted to avoid chemotherapy". Dr D stated that if a patient has any doubt in his or her mind about the benefit of chemotherapy, he or she is always referred to a medical oncologist. There is no record that Mrs A was referred to a medical oncologist.

88. In contrast, Mrs A's family members, including her husband, who was present at the appointment, believe that Mrs A did not have a strong view about avoiding chemotherapy. Mr A told HDC that chemotherapy was discussed in terms of "general breast cancer background" but not as an option for his wife. Mr A also told HDC that he recalls Dr D saying that the HER2 result was either negative or pending. Mr A was "fairly certain" that Dr D did not discuss the possible effects of a positive or negative result for the pending HER2 test on treatment options.

89. The Medical Council of New Zealand's standards require that doctors must keep clear and accurate patient records that report, among other things, information provided to patients.[17] Baragwanath J stated in his decision in *Patient A v Nelson–Marlborough District Health Board*[18] that it is through the medical record that healthcare providers have the power to produce definitive proof of a particular matter. This Office has previously stated[19] that "this applies to all health professionals who are obliged to keep appropriate patient records. Health professionals whose evidence is based solely on their subsequent recollections (in the absence of written records offering definitive proof) may find their evidence discounted."

90. The written record in this case states that treatment options were "recommended" and "not recommended" but does not contain further detail about the discussion that occurred in relation to those recommendations. It does not record that Mrs A expressed a desire not to undergo chemotherapy. Mrs A's family members, including Mr A, are unequivocal that she would have been open to treatment options presented to her. I therefore consider that there is no evidence to support Dr D's assertion that Mrs A had strong views about avoiding chemotherapy.

91. Regarding the pending HER2 result, there is no written record that it was discussed. According to Dr D, he would have discussed with Mrs A the pending result and its potential implications. Mr A recalls that Dr D said that the HER2 result was either negative or pending, and he is fairly certain that the implications of the pending result were not discussed. On the basis of that evidence, I consider that it is more likely than not that the pending HER2 result was referenced at least in passing, but I am not satisfied that its potential effects on treatment were discussed in adequate detail.

[17] Medical Council of New Zealand, *Good medical practice*. See also the Medical Council of New Zealand publication "The maintenance and retention of patient records" (August 2008).
[18] *Patient A v Nelson–Marlborough District Health Board* (HC BLE CIV-2003-204-14, 15 March 2005).
[19] Opinion 08HDC10236, 28 November 2008, at page 11.

Information provided

Prognosis and potential referral to medical oncologist

92. As a health services consumer, Mrs A had a right to the information that a reasonable consumer in her circumstances would expect to receive, including an explanation of her condition and her treatment options.[20]

93. My independent expert advisor, radiation oncologist Dr John Childs, considered that, while it was reasonable for Dr D to offer interim prognostic advice in the absence of a definitive HER2 result, the written record suggests that the prognostic advice that was offered was not of a reasonable standard. In particular, Dr Childs stated that, while Mrs A's prognosis could be considered "good", he assessed Mrs A's risk of relapsing with metastatic breast cancer (irrespective of the positive HER2 result) as "at least moderate". According to Dr Childs' estimates, Mrs A (who was 59 years old at the time) had up to a 20% risk of dying within ten years without any adjuvant therapy.

94. Dr Childs was of the view that the moderate risk of metastasis is not adequately reflected in the clinical notes, which state that Mrs A's prognosis was "very good", that the risk of local recurrence is "not high" and that "there is no evidence of metastatic disease".

95. Dr Childs was of the view that Mrs A's cancer had features that made it slightly different from typical breast cancers, and should have "raised flags". These features included the negative ER/PR status, itself an adverse factor; the fact that the cancer was multifocal (ie, more than one tumour had been identified); and, as became apparent after Dr D's consultation with Mrs A, the positive HER2 result.

96. Dr Childs further commented that, based on his overall evaluation of Mrs A's prognostic factors (including, as later became apparent, that her cancer was HER2 positive), he considers that Dr D should have offered Mrs A the option of a referral to a medical oncologist.

97. There is no record that Dr D offered Mrs A the option of a referral to a medical oncologist at the time of the November 2009 consultation or when the HER2 positive result became available. Dr D's evidence, as outlined above, implies that he did not do so because of Mrs A's strong view that she wished to avoid chemotherapy. Dr D further stated to HDC that he believes Mrs A's views about chemotherapy influenced his decision not to contact her when the HER2 result became available. However, as stated above, I do not accept that Mrs A expressed a strong view that she wished to avoid chemotherapy. Even if she had done so, I consider that Mrs A should have been offered the option of a referral to a medical oncologist to obtain further information about her condition (including the effect of the positive HER2 result) and the relative benefit of chemotherapy in light of that condition.

98. Overall, I consider that the information Dr D provided to Mrs A about her prognosis and treatment options was inadequate.

[20] Right 6(1) of the Code.

HER2 result

99. Mrs A also had the right to receive information about the results of her tests.[21] Mrs A's positive HER2 result was not communicated to her and, as such, she did not know that she had a type of cancer that would tend to grow more quickly than other types of cancer, and that she might benefit from Herceptin. This was directly relevant to her adjuvant therapy options.

100. I am mindful of Dr Childs' view that, while the relative benefit of adjuvant chemotherapy with Herceptin in Mrs A's case would have been small — approximately 5–7% — patients do sometimes elect to have treatments with a relatively small potential benefit. Dr Childs considered that the relative benefit of Herceptin with chemotherapy would be at a "threshold" of what patients would consider worth pursuing. He noted that, while Mrs A's prognosis does not necessarily mean that adjuvant chemotherapy with Herceptin should have been undertaken, the option should have been discussed with Mrs A in light of all the relevant information.

101. Irrespective of whether the pending HER2 result was discussed on 18 November 2009, I consider that Mrs A should have been informed of the positive HER2 result when it became available. Because she did not receive that information, Mrs A did not have all the information relevant to her condition when making her decision about treatment options, and was not given the opportunity to reconsider her decision about treatment options when further information did become available.

Conclusion

102. It is impossible to tell, in hindsight, whether Mrs A's positive HER2 status would have affected her decision about adjuvant therapy options. Regardless of that fact, she should have been given the option to make decisions about her care in light of all of the relevant information, including that test result. I consider that, even in the event that the pending result was discussed with her, subsequent knowledge of the positive result (which impacted on her prognosis) and/or a referral to a medical oncologist would have provided her with more complete information about her condition. I am of the view that Dr D failed to provide Mrs A with all the information she would reasonably have expected to receive, including offering her the option of a referral to a medical oncologist and providing full information relating to her prognosis and her positive HER2 result and, as such, I find that Dr D breached Right 6(1) of the Code.

Opinion: Adverse comment — Breast clinic

103. I consider that it was the responsibility of individual clinicians to inform Mrs A of her positive HER2 result and discuss all the relevant options with her, and that the failure to do so was a matter of individual judgement.

104. However, I consider that Mrs A's case has revealed deficiencies in the breast clinic's systems. The copy of Mrs A's post-mastectomy histology request form sent to HDC

[21] Right 6(1)(f) of the Code.

incorrectly stated "Unknown doctor ID! Referrer not in doctor list" under the heading "Ordering Clinician". The request form did include Dr C's Medical Council of New Zealand registration, and therefore he is identifiable as the ordering clinician. Nonetheless, my expert, Dr Wilson, considered that this is an unsatisfactory standard of information, which could lead to a report failing to reach an ordering clinician. It is clear that Mrs A's HER2 result did in fact reach Dr D, although there is no audit trail to confirm this.

105. In addition, there was no alert system on the breast clinic's patient database to notify clinicians that new test results had been received and that follow-up (such as informing a patient) may be required. Further, Mrs A's HER2 result incorrectly appeared as "HER2 Equivocal FISH pending" at the first opportunity that the breast clinic clinicians would have had to discuss the positive result with Mrs A (during Dr C's consultation on 3 December 2009).

106. The breast clinic provides patients with a range of services from a number of different types of clinician. In my view, it is important that, given the multidisciplinary nature of breast cancer diagnosis and treatment, the breast clinic's systems for managing patient records are sufficiently robust and provide safeguards to ensure that patients receive all information relevant to their care.

107. I note that, since these events occurred, the breast clinic has made a number of changes to its service and intends to make further changes to its patient database.

Opinion: Adverse comment — The DHB

108. I am concerned that Mrs A's HER2 result appeared incorrectly as negative on a series of the public hospital clinical notes. As I have previously stated, accurate and comprehensive patient records are the primary tool for providing continuity of care.[22] It is therefore imperative that district health boards providing a wide range of services to consumers have suitable systems in place to manage patient records appropriately. I note that the DHB's systems for managing patient records have changed significantly since the time of these events.

109. I am also mindful of Dr Childs' advice that the incorrect reference to a negative HER2 result would not have impacted the frequency and nature of the radiation follow-up that Mrs A was receiving. Dr Childs noted that the correct HER2 result would have become relevant only in relation to the type of therapy offered at relapse. When there was evidence that Mrs A's cancer had metastasised and her treatment plan should be reconsidered, the public hospital's medical oncologist, Dr E, appropriately obtained the correct HER2 result.

110. In light of these facts, while I consider the repetition of the incorrect test result in Mrs A's records concerning, I do not find that the DHB breached the Code.

[22] See also Opinions 10HDC00610 and 12HDC00555, available at www.hdc.org.nz.

Recommendations

111. In accordance with the recommendation made in the provisional opinion, Dr D has provided a written apology to Mrs A's family for his breach of the Code.

112. I recommend that, within three months of the date of issue of this report, the breast clinic report to HDC on any changes it has made, or intends to make, to its patient management database, especially in regard to alert systems, the audit trail for test results, and improvements to the way the "Diagnosis" section in clinical records is generated.

Follow-up actions

113.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr D's name.

- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent breast surgeon advice to the Commissioner

The following expert advice was obtained from Dr Colin Wilson on 16 December 2013:

"On behalf of the Commissioner you have requested expert advice from me on the following:

1. The care provided to [Mrs A] by [Dr C]
2. Concerns raised by [Mr B]

I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. I practice as a Specialist General Surgeon and I am a member of the Breast Section of the Royal Australasian College of Surgeons. I qualified M.B.,Ch.B. in 1975 and F.R.A.C.S. in 1983.

[List of documentation reviewed redacted for brevity.]

The care provided to [Mrs A] by [Dr C]

[Mrs A] was recalled following a screening mammogram which identified two abnormalities in her right breast. Her details were discussed at a multidisciplinary assessment meeting and she was examined by [Dr C] prior to a biopsy being performed.

The report from [Dr C] at this consultation describes the findings, gives a comprehensive medical history and explains what was told to [Mrs A]. (22/10/2009).

At a follow-up consultation on 23/10/2009 [Dr C] explained that an MRI scan would be required if conservative surgery was to be done because there were two cancers. [Mrs A] decided not to pursue conservative surgery and requested a mastectomy without reconstruction.

[Dr C] had explained all the necessary information for [Mrs A] to make an informed decision and he also gave her literature to read. Prompt surgical treatment was organised within one week.

[Mrs A] had a sentinel node biopsy and because [Dr C] was concerned about minimal radioactive uptake in this node he performed a limited removal of further nodes to add to the certainty of SNB alone. This was done at the same time as her mastectomy.

[Mrs A] made a satisfactory recovery from her surgery.

The role of the surgeon in the management of Breast Cancer is to perform the surgery and refer to the Oncologists for advice on adjuvant treatment. Recommendations for radiotherapy, hormonal therapy and chemotherapy are entirely in the domain of the Oncologists.

It is customary for the surgeon to offer follow-up which includes annual mammography and an assessment for local, regional or metastatic recurrence of breast cancer.

At the time [Dr C] referred [Mrs A] to [Dr D], Oncologist, the FISH test for HER 2 Status was pending. His letters of 5/11/2009 and 3/12/2009 indicate that the FISH result was still pending. [Dr C's] report of 26 April 2010 to [Dr D] included the HER 2 Positive finding.

I do not know if [Dr C] knew this result at the time he saw [Mrs A] on 26 April 2010 or whether he had to contact the Laboratory for this result after seeing her. However the result was forwarded to [Dr D] who had the responsibility of deciding whether or not this would change the advice on adjuvant chemotherapy.

[Dr C] reviewed [Mrs A's] progress and his notes indicate that there were no symptoms or signs of local or regional recurrent disease.

The management of Early Breast Cancer was formalised in New Zealand in 2009 when the Ministry of Health published an Evidence based Best Practice Guideline as advised by the Guideline Development Team. The content of the Guidelines was endorsed by the Royal Australasian College of Surgeons, The Royal Australasian and New Zealand College of Radiologists and The Cancer Society. It is and will remain the basis for the accepted management of Breast Cancer. These guidelines have been adhered to by [Dr C]. I believe that the surgical care provided to [Mrs A] by [Dr C] was reasonable in every regard.

Concerns raised by [Mr B]

1. FISH testing for HER 2 status

The original histology report indicated that the HER 2 status was equivocal and that a more precise analysis was required in the form of Fluorescent In Situ Hybridisation (FISH) analysis.

This test was done in [another region] and a result should [have been] available in a few weeks.

I note that the original Histology Request form was incorrectly filled in as under the heading of 'Ordering Clinician' the request form has 'Unknown doctor! Referrer not in doctor list'. This form did have the NZMC number of […] which is the NZMC number for [Dr C]. This is an unsatisfactory standard of information supplied with the Histology Request form and could lead to a failure in a report from reaching the ordering clinician.

The 'observation date' on the Lab form is 29 Oct 2009 and the result of the FISH was downloaded to [the breast clinic] on 24 Nov 2009. Therefore the result would not have been available at the initial oncology appointment on 18 Nov 2009.

I do not have enough information to determine whether the FISH result was sent to [Dr C] at all or if he had to contact the Laboratory for this result when he saw [Mrs A] on 24 April 2010.

I note that [Dr C] correctly stated FISH pending when he referred [Mrs A] to [Dr D]. [Dr D's] letter acknowledged this pending status.

[Dr C] then updated the Her 2 status from FISH pending to FISH positive in his letter of 20/4/2011 with a copy to [Dr D].

The radiation oncology letters from [locum radiation oncologist] (10/1/2011), [registrar] (10/5/2011), [consultant radiation oncologist] (8/11/2011), [doctor] (25/11/2011) all state that the Her 2 status is negative.

It was never negative but rather pending until it became Positive by FISH analysis.

This error had been repeated at each consultation with the radiation oncologists and therefore an opportunity had been missed to discuss the significance of a positive result.

The pos HER 2 status is an adverse prognostic factor which had not been discussed until [Mrs A] was reviewed by [Dr E].

I understand that you are seeking an opinion from an oncologist as to whether the Her 2 positive status would have changed the advice given on adjuvant chemotherapy.

There has been a breakdown in the communication of the FISH result at a number of levels.

2. Late diagnosis of metastatic disease

Unfortunately this pattern for metastatic breast cancer is common.

A patient can have a very good prognosis and then develop widespread metastases with minimal symptoms.

[Dr C] did not have any clinical concerns and his examination of [Mrs A's] spine did not identify any cause for concern. Back pain is a very common complaint and that he had attributed this to her gardening seems reasonable at that stage of [Mrs A's] presentation.

Summary of key issues

- It is evident that the positive FISH result was overlooked by the Oncology clinicians. An explanation is required for the incorrect entry of Her 2 negative status. The Her 2 status was pending until it became positive. It was never negative. [Dr E] identified this error.
- I understand that you are seeking an Oncology opinion as to the significance that this could have had on [Mrs A's] management and prognosis.
- Could [Mrs A's] condition of metastatic involvement been diagnosed sooner? In hindsight I think that was possible but when there are other reasons for back pain one is prepared to wait a few weeks before arranging investigations."

Further advice provided by Dr Wilson to HDC on 20 February 2014

"Post-mastectomy histology testing is different from ordering other sorts of tests … because, following a mastectomy, there is a standard protocol of tests ordered. In this case, [Dr C] did everything he should have. The HER2 was relevant to [Mrs A's] oncology care rather than her surgical care. It was therefore the

> radiation oncologist's responsibility to discuss the HER2 test result with [Mrs A]. At the most, [Dr C's] responsibility would be to forward the test result on to the radiation oncologist, and in this case he did so. It would have been a bonus if he had informed [Mrs A] of the result or mentioned it to her. Usually, surgeons do not have a reason to check or chase up test results that are not relevant to the care they are providing."

In addition, Dr Wilson said that he was surprised that Mrs A or her family did not ask for the outcome of the FISH testing as, in his view, the impact of that test result would have been discussed with Mrs A by the radiation oncologist.

Appendix B — Independent radiation oncologist advice to the Commissioner

The following expert advice was obtained from radiation oncologist Dr John Childs:

"**Background**

1. I am a Radiation Oncologist and have been in public radiation oncology practice with the Auckland District Health Board since 1991. I have specialist qualifications as a Fellow of the Royal Australian and New Zealand College of Radiologists in Radiation Oncology (FRANZCR) and a Fellow of the Royal Australasian College of Physicians (FRACP). I have broad experience in the management of all cancer types including breast cancer.

2. [Mrs A] was diagnosed with a multifocal invasive duct carcinoma of the right breast (multifocal Grade 2 invasive ductal carcinoma T1 N0 M0) in October 2009 for which she had a mastectomy and level one axillary clearance followed by post operative radiotherapy to the right chest wall in February 2010.

3. The right mastectomy histology ([a] Laboratory) specimen confirmed two foci of invasive duct carcinoma one measuring 17mm and the other 9.5mm. The oestrogen (ER) and progesterone (PR) receptors were negative. The Her-2 receptor was equivocal on immunohistochemistry (score 2+) and referred for FISH testing. The final histology report including the FISH test result was entered into [the breast clinic's] patient information system 24th November 2009 after the post operative consultations of [Mrs A] with [Dr D] or [Dr C]. There is no record that the FISH result was discussed by [Dr C] or [Dr D] with the patient.

4. [Dr D] recommended that [Mrs A] have post operative radiotherapy. He advised that because she had a very good prognosis the benefit from adjuvant chemotherapy would be small this was not recommended. He also advised that hormone therapy would not be of benefit. [Mrs A] received a course of post operative radiotherapy to the right chest wall.

5. [Mrs A] received regular follow-up by [Dr C] and through the Radiation Oncology Department at the public hospital following her treatment.

6. [Mrs A] was referred to [Dr E] (Medical Oncologist) in December 2011 with bone metastases from breast cancer. Review confirmed, in an updated pathology report (14/12/2011), that Her-2 had tested positive on FISH testing.

7. A letter to the HDC (29/3/2012) from [Mrs A's] Daughter-in-law raises concern that the FISH test result may have altered the earlier treatment and that the positive result was not acknowledged for over 2 years. The family wish to have an explanation for the delay to recognise the positive Her-2 receptor result and to ensure steps are taken to reduce the risk of this happening to other patients.

8. The advice requested by the Health and Disability Commissioner is to comment on whether the care provided by [Dr C] and [Dr D] was appropriate and in particular to comment on:

a. Was it reasonable for [Dr D] to have offered the prognostic and treatment advice on 18th November 2009 in the absence of a definitive result for Her-2 receptor status and was such advice consistent with accepted standards.

b. Would a further discussion with the patient regarding prognosis and adjuvant treatment be expected once the Her-2 status was found to be positive.

c. Should the patient have been notified by [Dr C] or [Dr D] of the abnormal Her-2 result once it was known irrespective of whether it would impact on the treatment undertaken.

d. Is the persistent referral in the radiation oncology notes to (incorrect) negative Her-2 status likely to have impacted negatively on the nature or frequency of follow-up in that department.

Summary of Clinical History

9. [Mrs A] was diagnosed with carcinoma of the right breast following screening mammography on 22 October 2009. She had a right mastectomy and level 1 axillary dissection by [Dr C] on 30/10/2009. Histology confirmed a grade 2 multifocal invasive ductal carcinoma that was oestrogen (ER) and progesterone receptor (PR) negative. The largest tumour measured 17mm and the smaller tumour 9.5mm. The axillary lymph nodes did not contain metastatic tumour.

10. [Dr C] saw [Mrs A] for a postoperative consultation on 5/11/2009 and advised referral to an oncologist for the option of postoperative radiotherapy. His letter notes that the Her-2 was equivocal with a pending FISH result.

11. [Dr D] saw [Mrs A] on 18/11/2009 and recommended postoperative radiotherapy to the right chest wall. [Dr D] noted that there were two adverse features of a close surgical margin with a negative ER and PR. The letter notes that the Her-2 was equivocal with FISH pending. [Dr D] states that because [Mrs A] had a very good prognosis the benefit from adjuvant chemotherapy would be small and that this had not been recommended. He also notes there would be no benefit from hormone therapy because the receptor status was negative.

12. [Dr D's] letter to the HDC (17/5/2012) states that at the time of the consultation the Her-2 receptor result was not available and this would not have changed the decision for recommending adjuvant chemotherapy. The result was available in [the breast clinic's] system within 2 weeks of his consultation and signed off by a clinician. The Her-2 result was not discussed with [Mrs A].

13. [Dr D's] letter to HDC (17/5/2012) states that a decision was made with [Mrs A] not to recommend chemotherapy and therefore a medical oncology referral was not made. It was decided that knowledge of the Her-2 status did not change the plan for treatment because adjuvant trastusumab (which is often indicated in Her-2 positive breast cancer) is given in combination with chemotherapy and not used as a single agent.

14. [Mrs A] was given postoperative radiotherapy to the right chest wall from 18/1/2010 to 9/2/2010 receiving 40Gy in 16 fractions over 4 weeks in the Radiation Oncology Department at the public hospital. [Dr D] saw [Mrs A] for post radiotherapy follow-up on 24/3/2010 when no problems were noted and arrangements were made for continued follow up through the Oncology Department at the public hospital.

15. [Mrs A] was seen for regular follow-up in the Radiation Oncology Department; over this time the oncology letters continued to state that the Her-2 was negative.

a. The first follow-up was on 3/8/2010 by [an] (Oncology Registrar) where arrangements [were] made for a routine follow up in 3 months. The clinic note from this consultation records that the Her-2 was negative.

b. The next follow up was by [a] (locum Radiation Oncologist) on 23/11/2010 when no problems were noted and again the clinic letter records the Her-2 as negative.

c. [The locum radiation oncologist] saw her again on 10/1/2011 with a concern about changes on her right chest wall. The clinical findings [were] considered to [be] consistent with local post radiotherapy changes.

d. Follow up on 10/5/2011 by [a] (registrar) reported no concerns and 6 month follow up was arranged.

16. [Dr C] also saw [Mrs A] for regular follow up. A follow up letter on 12/8/2011 notes a probable left breast cyst but no concern about recurrent cancer. The letter from this consultation also notes that the breast tumour was Her-2 positive.

17. When [the] (consultant radiation oncologist) saw [Mrs A] for follow up on 8/11/2011 she reported three months of left sciatic pain and right chest wall tenderness. A bone scan was requested. The letter from this visit also states that Her-2 was negative. The bone scan (17/11/2011) confirmed bone metastases (spread of cancer to the bone) with involvement of the lumbosacral spine and right 8th rib for which palliative radiotherapy was given and completed on 28/11/2011. A staging CT scan was arranged which also confirmed lung metastases (spread of cancer to the lungs).

18. [An] (Oncology Registrar for [Dr E] Medical Oncologist) saw [Mrs A] on 14/12/2011. At this consultation the previous results were reviewed and the

original FISH analysis found to have confirmed Her-2 positive breast cancer. [Mrs A] was commenced [on] palliative chemotherapy using Docetaxel and trastusumab (Herceptin) on 5/1/2012. By February 2012 she was found to have progressive metastases and her chemotherapy treatment was changed to oral capecitabine. [Mrs A] … continued under medical oncology care.

Assessment

19. [Mrs A] had a 1.7 cm multifocal grade 2 node negative invasive ductal carcinoma of the right breast (stage T1N0MO) that was ER, PR and Her 2 positive. Using the Adjuvant Online prognostic tool (http://www.adjuvantonline.com) it is estimated, excluding any prognostic impact of Her-2 positivity, there was a 13% risk of death from breast cancer at 10 years that may be reduced by up to 5% with adjuvant chemotherapy. The risk for relapse of breast cancer was 25% at 10 years and estimated this is reduced by up to 9% with adjuvant chemotherapy.

20. Selection of higher-risk node-negative women for considering adjuvant systemic therapy involves balancing the expected gains against the adverse effects. A number of other prognostic tools can also be used to estimate survival from breast cancer and guide decision about the risks and benefits of adjuvant chemotherapy. Based on prognostic assessments from the US National Cancer Institute (and similar published tools) for node negative breast cancer a grade 2 tumour of 1 to 2 cm in size placed her in an intermediate risk for relapse with metastatic breast. The absence of ER and PR with Her-2 positivity is also of prognostic significance and potentially placed her in a high-risk category.

Recommendation

21. The advice provided by [Dr D] to [Mrs A] based on the preliminary information was that she had a very good prognosis with a low risk for breast cancer relapse and a decision was made that she did not require referral to consider the option for adjuvant chemotherapy. It is documented in the correspondence to the HDC that the result of the Her 2 result became known within 2 weeks of the post surgery consultations with both [Dr C] and [Dr D]. The influence of knowledge of the Her-2 receptor status on the patient's decision not to consider adjuvant chemotherapy cannot be retrospectively assessed.

a. It was reasonable for [Dr D] to offer interim prognostic advice in the absence of a definitive result for Her-2 receptor status however the preliminary advice does not appear to have been offered to a reasonable standard. Based on the prognostic estimates [Mrs A] had at least a moderate risk for relapsing with metastatic breast cancer and although she may have declined an option for chemotherapy the offer of referral to a medical oncologist would have been reasonable. Detail of the advice offered to her is not documented except that she was informed the risk for relapse was low and she was advised that because of a 'low risk' adjuvant chemotherapy was not indicated.

b. Once the Her-2 receptor status was known it would be reasonable to expect that a further discussion was had with the patient regarding the implication of

the result on the initial decision. A patient decision about adjuvant chemotherapy may have changed with knowledge of the Her-2 result however [Dr D] states that knowledge of the Her-2 receptor status did not change the advice he would have offered. The lack of a further discussion with the patient about the Her-2 result fell below an acceptable standard.

c. It would be expected that the positive Her-2 result should have been discussed with the patient either by [Dr C] or [Dr D] once it was known irrespective of whether there would have been any change in the decision to recommend adjuvant chemotherapy.

d. [Mrs A] received both regular surgical and radiation follow-up and was investigated promptly once there were concerns requiring further investigation. The frequency and nature of the follow-up would not have changed with a knowledge of the Her-2 result however knowledge of the result would influence the type of therapy given offered at relapse.

22. Based on my evaluation of the prognostic factors including the Her-2 positivity a Medical Oncology assessment should have been offered if the patient had agreed to this. Although it is not clearly documented, it can be inferred from [Dr D's] response that [Mrs A] had decided not to consider chemotherapy and therefore a referral was not made. The discussion of prognosis by [Dr D] with [Mrs A] is not documented in detail. The prognostic advice offered by [Dr D] is assessed to be a moderate departure from expected standards.

23. It cannot be known for certain whether [Mrs A] would have made a different decision about adjuvant treatment had she been aware of the Her-2 result. The assessment without knowledge of the Her-2 result or informing [Mrs A] once the Her-2 result was available is assessed to be a mild departure from expected standards.

24. It is recommended that an independent Medical Oncology opinion is also obtained regarding assessment of standards for providing advice on breast cancer prognosis and the indications for considering the options for adjuvant chemotherapy.

John Childs
20th October 2012"

Further expert advice provided on 11 March 2014:

"*[Mrs A's] prognosis without adjuvant therapy*
According to the 'Predict' online tool, which is similar to 'Adjuvant! Online' and is (and was in 2009) widely used and available, [Mrs A's] prognostic factors, taking into account only her primary tumour (which measured about 1.7cm), indicated that, without any adjuvant therapy (including radiation), she had an 87% survival rate within five years, and 81% within ten years. Taking into account [Mrs A's] multifocal disease, including the smaller tumour that measured about 0.9cm, her survival rate without adjuvant therapy could fall as low as 83% within five years and 76% within ten years.

The positive HER2 result was an adverse feature that would lessen the above survival rates by about 2–3%.

[Mrs A's] prognosis with adjuvant chemotherapy plus Herceptin
With chemotherapy plus Herceptin, the survival rates based on the primary tumour changed from 87% to 93% within five years and 81% to 88% within ten years. The lower the survival rate, the higher the potential benefit of adjuvant chemotherapy plus Herceptin.

Overall, the absolute benefit of chemotherapy plus Herceptin would have been between 5–7%. This can be considered a small benefit, but is at the threshold of what patients may or may not consider worth pursuing.

In considering the above it is important to remember that, while survival rates and the benefit of Herceptin (with chemotherapy) for HER2 positive cancers was well understood at the time, it is better understood now.

The information communicated by [Dr D] according to the clinical records
[Mrs A's] prognosis could be considered good (but not 'very good'), bearing in mind that terms like 'good' and 'very good' are subjective. Based on the estimates outlined above [Mrs A] had up to a 20% risk of dying within 10 years. Given that, at age 59, as a New Zealand woman [Mrs A] could have a life expectancy of about 20 years, this was important information that should have been communicated to her.

[Mrs A's] cancer had features that made it slightly different from typical breast cancers and should have raised flags, including the negative ER/PR status (itself an adverse factor), the positive HER2 result, and the fact that the cancer was multifocal. While these factors do not necessarily mean that adjuvant chemotherapy should have been undertaken, these factors should have been discussed with [Mrs A] and all relevant information (including the relative benefit of treatment options) should have been provided to her. The relative benefit of adjuvant chemotherapy plus Herceptin in [Mrs A's] case represents a borderline and difficult area, which is why it's all the more important that all relevant information is given to patients and discussed with them.

This case highlights the fact that a clinician's views about the importance of prognostic information, and a patient's/their family's views about the importance of prognostic information can differ significantly. Patients will sometimes elect to undertake treatment that has a relatively small chance of benefiting them, and should be given the option to make that decision. This case also highlights the value of multidisciplinary input, for example from a radiation oncologist and a medical oncologist, who can give different perspectives on treatment options and their relative benefits.

The use of the Predict and Adjuvant! Online tools
Use of the Predict and adjuvant online prognostic tools. Both these tools provide assessment of survival probability based on key prognostic factors for breast cancer and essentially both tools are very similar, PREDICT is a UK NHS developed tool while adjuvant online was developed in the US. The key difference is that the PREDICT tool includes prognostic assessment for the presence or absence of Her 2 whereas the Adjuvant On Line tool does not include this at present. The other key difference is that the Adjuvant Online tool also allows assessment of risk for cancer relapse (recurrence) whereas the PREDICT tool does not, however assessment of the risk of relapse (as opposed to survival) is considered to be less reliable."