Hutt Valley District Health Board

Capital and Coast District Health Board

A Report by the

Health and Disability Commissioner

(Case 15HDC01289)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. On 13 January 2015, Mrs A attended the Capital and Coast DHB (CCDHB) Breast Service, where a 2–3cm mass in her right breast was noted and a biopsy was arranged.

2. On 13 January 2015, Mrs A underwent an ultrasound-guided right breast core biopsy at CCDHB. The biopsy pathology result identified infiltrating ductal carcinoma grade 2, and was classified ER/PR positive (endocrine receptor positive — indicating cancer cell growth occurring in response to oestrogen or progesterone). At that stage, HER2 (human epidermal growth factor receptor-type 2) test results were pending. HER2 is a type of protein that positions on the surface of normal cells, sending messages to the cell to grow and reproduce. In HER2-positive breast cancer, cells may reproduce very quickly.

3. At the time, the standard process for all HER2 results that were equivocal, was that they were to be sent for an additional clarifying test — a FISH (fluorescent in situ hybridisation) test performed separately at an external Laboratory 3. FISH testing looks for gene changes in cells and is required to establish whether Herceptin or chemotherapy would be beneficial. FISH testing is reported as either being not amplified (negative), equivocal, or positive.

4. On 27 January 2015, Mrs A met with a CCDHB general and breast surgeon, Dr B, and Mrs A chose the treatment option of a mastectomy with immediate reconstruction.

5. On 4 February 2015 the result of HER2 testing was reported by the CCDHB laboratory as equivocal. FISH testing was requested on 9 February 2015. On 19 February 2015 the FISH result was received by an external laboratory (Laboratory 3) and was reported on 24 February 2015 as negative.

6. On 19 February 2015, Mrs A saw Dr C, a plastic surgeon at HVDHB and mastectomy and breast reconstruction was scheduled. On 3 March 2015, the joint surgery was undertaken by Dr B and Dr C at HVDHB. Dr C told HDC that when patients are admitted to HVDHB, an "event" number is created in the name of the admitting surgeon. On the day of the procedure, tissue specimens were obtained and sent from theatre to the HVDHB laboratory.

7. Although Dr B of CCDHB had requested histology, the tissue samples sent to the HVDHB laboratory were requested using the HVDHB "event" number. Histology results were automatically sent to the admitting consultant, Dr C, who was listed on the report as the requesting clinician. These results were then available to view on the HVDHB electronic system, Concerto, which was visible to CCDHB staff through e-Tree (the Wellington region IT system). The system in place meant that results were able to be sent only to the clinician linked to the patient event number. Management of Mrs A's breast cancer remained under the care of Dr B. Mrs A was seen by Dr B on 17 March 2015 and given her results, which were ERPR positive with HER2

results pending. The case was discussed at the unit's (multidisciplinary) MDM meeting on 17 March 2015 and a decision was made to refer to oncology if Mrs A was HER2 positive. On 2 April 2015, the HER2 result was reported by the HVDHB laboratory as equivocal and that FISH testing would be performed.

8. The results were reported to the CCDHB Breast MDM, and the MDM document records updated as "HER2 equivocal. For FISH testing." The CCDHB system in place at the time however did not monitor progress of equivocal HER2 results that were yet to be finalised. There was no process in place for the MDM to further follow up patients with equivocal HER2 results awaiting FISH testing.

9. On 10 April 2015, FISH testing was logged by Laboratory 3 as having been requested. On 15 April 2015, FISH testing was completed and reported as a positive result. Although the FISH amplified (positive) report was sent by Laboratory 3 to the HVDHB pathology department on 15 April 2015, the FISH amplified (positive) report was not seen by the HVDHB pathology team until 29 June 2015 (about 11 weeks later). Unfortunately, on 29 June the delay that had already occurred was not noticed by pathology staff.

10. In the first week of August 2015, a breast specialty nurse became aware of the HER2 amplified (positive) result and action was taken to immediately place Mrs A's case for discussion at the next MDM. At the meeting it was decided that Mrs A would benefit from a medical oncology referral, for discussion about the possibility of chemotherapy.

Findings summary

11. The HVDHB system in place at the time did not accommodate the foreseeable test result dissemination requirements of a patient undergoing a combined procedure, across two DHBs, as in this case. The system in place at the time did not alert the requesting clinician to the results. HVDHB did not provide services to Mrs A with reasonable care and skill and breached Right 4(1) of the Code.

12. At the time of the events complained about, there was shared governance and responsibility across both CCDHB and HVDHB for the laboratory operations. There was an approximately 12 week period, from 2 April 2015 when the FISH test was deemed necessary, until 29 June 2015 when laboratory staff saw the positive result. In addition, there was also a failure to recognise the delay that had already occurred, meaning that the result was not actually acted on until the first week of August 2015. While it is acknowledged that the main delay occurred in laboratory process, overall this was not acceptable. HVDHB and CCDHB did not ensure quality and continuity of services to Mrs A and breached Right 4(5) of the Code.

13. There was no existing system in place at the time, including via the Breast MDM, to follow up progress of equivocal HER2 results that were yet to be finalised. CCDHB did not provide services to Mrs A with reasonable care and skill, and breached Right 4(1) of the Code.

Complaint and investigation

14. The Commissioner received a complaint from Mrs A about the services provided to her by Capital and Coast District Health Board (CCDHB) and Hutt Valley District Health Board (HVDHB).

15. The following issues were identified for investigation:

- *Whether Capital and Coast District Health Board provided Mrs A with care of an appropriate standard.*
- *Whether Hutt Valley District Health Board provided Mrs A with care of an appropriate standard.*

16. The key parties referred to in the report are:

Mrs A	Consumer/complainant
Dr B	Breast, endocrine, and general surgeon, CCDHB
Dr C	Plastic surgeon, HVDHB
Capital and Coast District Health Board	Provider
Hutt Valley District Health Board	Provider

17. Information from Dr D, a general practitioner, was also reviewed.

18. Independent expert advice was obtained from a breast, endocrine, laparoscopic, melanoma & general surgeon, Richard Harman (**Appendix A**).

Information gathered during investigation

Introduction

19. In mid-December 2014, Mrs A (then aged 63 years) found a lump in her right breast.

20. On 8 January 2015, Mrs A saw her general practitioner (GP), Dr D, and the following day Mrs A had a diagnostic mammogram and ultrasound, which she paid for privately. The mammogram and ultrasound showed a mass, and she was referred back to Dr D. Mrs A saw Dr D that afternoon, and Dr D immediately referred Mrs A to the CCDHB Breast Service, CCDHB.

CCDHB and HVDHB hospital laboratories — oversight structure

21. Prior to March 2014, CCDHB operated two hospital laboratories. HVDHB operated one hospital laboratory at HVDHB.

22. From 2012, CCDHB and HVDHB hospital laboratories began a process of organisational integration, with all laboratories becoming "Joint Lab" on 1 March 2014.

23. A "Joint Lab" leadership group was formed in November 2014 to lead the two hospital laboratories through a transition period of November 2014 to October 2015.

24. The Terms of Reference for the leadership group stated:

> "The "Joint Lab" leadership group is accountable and responsible for developing strategy and making decisions about the operation of the Hospital Laboratories, in a time of transition and change."

25. During the transition, the "Joint Lab" leadership group met fortnightly. The "Joint Lab" leadership group reported to a Hospital Laboratory Services Governance Group (governance group) that was formed to provide oversight of the Hospital Laboratories ("Joint Lab") Change Plan for the period from November 2014 to October 2015, as well as advice and support for "Joint Lab" as required. The governance group included clinical and non-clinical leaders from across both CCDHB and HVDHB.

26. The stated Terms of Reference for the governance group included to:

> "…
>
> - provide high level leadership and oversight of accountabilities for the Hospital Laboratories during the implementation of the Integrated Laboratory Services Strategy, in accordance with approvals from and relevant policies of the Boards of the 3 DHBs
> - maintain oversight of and support for the interfaces and linkages between:
>   — the procurement process for Integrated Laboratory Services
>   — the transition process, including working with any new provider
>   — any change process for Hospital Laboratories staff, including union engagement
>   — ongoing delivery of Hospital Laboratory services during a time of change until at least the end of October 2015."

27. CCDHB told HDC that at the time of these events the HVDHB hospital laboratory was managed via CCDHB as "Joint Lab" at most levels.

Breast Service appointment, CCDHB

28. On 13 January 2015, Mrs A attended the Breast Service and was examined physically. On palpation a 2–3cm mass in the lower inner aspect of her right breast was noted. The breast lump was suspicious for malignancy, and a biopsy of the lesion was arranged. Review was scheduled for two weeks' time to discuss the biopsy findings.

Biopsy, CCDHB

29. On 13 January 2015, Mrs A underwent an ultrasound-guided right breast core biopsy at the Radiology Department. Two 14g core biopsy samples were obtained and sent to the CCDHB laboratory for pathological analysis.

30. On 17 January 2015, the breast core biopsy pathology result was reported. It identified infiltrating ductal carcinoma grade 2,[1] and was classified ER/PR positive (endocrine receptor positive — indicating cancer cell growth occurring in response to oestrogen or progesterone).

HER2 and FISH testing

31. At that stage, HER2 (human epidermal growth factor receptor-type 2) results (part of standard testing) were pending. HER2 is a type of protein that positions on the surface of normal cells, sending messages to the cell to grow and reproduce. In HER2-positive breast cancer, cells may reproduce very quickly. Patients with HER2-positive breast cancer have an abnormally large number of HER2 proteins on the cancer cells. This means that the tumour has the potential to grow and spread at a much faster rate.

32. HER2 testing is interpreted and reported as either HER2 0/1+ (a negative result), HER2 2+ (an equivocal result), or HER2 3+ (a positive result).

33. At the time, the standard CCDHB process for all HER2 results that were equivocal was that they were to be sent for an additional clarifying test — a FISH (fluorescent in situ hybridisation) test performed separately at Laboratory 3.[2] FISH testing looks for gene changes in cells and is required to establish whether Herceptin or chemotherapy would be beneficial. FISH testing is reported as either being not amplified (negative), equivocal, or positive.

34. Mrs A stated: "All this took place in a period of 9 days since my appointment with my GP, a level of urgency that reassured me enormously."

Dr B, CCDHB

35. On 27 January 2015, Mrs A met with a general and breast surgeon, Dr B, at CCDHB. Dr B's resulting clinic letter stated that on examination Mrs A had a vaguely palpable lesion in the right inferior medial quadrant of her breast, prominent on the ultrasound. There was no obvious right lymphadenopathy.

36. Dr B's clinic letter stated that there was a diagnosis of right breast cancer, an ER/PR positive result, and that the HER2 result was pending.

37. Treatment options were discussed with Mrs A. Mrs A said that it was made clear to her that with the option of a mastectomy and immediate reconstruction, whether she

[1] Tumours are graded on a scale of 1 to 3, where 1 is the slowest and 3 is the fastest growing type of tumour. Tumours with higher grades are more likely to need chemotherapy.

[2] Laboratory 3 is an IANZ accredited laboratory contracted to provide comprehensive genetic testing services to an extensive region of New Zealand through the Crown Funding Agreement.

would need further treatment would depend on the results of further tests, which would be conducted after surgery on the actual tumour.

38. Mrs A told HDC:

> "I advised that I wished to have a mastectomy and immediate reconstruction. [Dr B] advised that I would require an appointment at Plastics at [HVDHB] and that she would come out to [HVDHB] to remove the breast, the Plastic Surgeon would then take over to do the reconstruction, and that surgery would be around 6.5 hours … I greatly preferred to choose an option that reduced my chances of having to have additional treatment if possible."

39. Dr B sent an urgent request to the Plastics Department at HVDHB to see Mrs A for discussion about immediate reconstruction to be performed at the time of mastectomy (as CCDHB does not perform this type of surgery).

40. Dr B also arranged for Mrs A to have an urgent referral to a genetic counselling service for an assessment of her overall cancer risk.

HER2 result (core biopsy sample)

41. On 4 February 2015 (as a supplement to the report generated on 17 January 2015), the result of HER2 testing of the core biopsy sample was reported by the CCDHB laboratory as being equivocal (neither negative nor positive at that stage). Therefore, FISH testing was to be performed.

42. As the HER2 result was equivocal, FISH testing was requested by the laboratory on 9 February 2015.

FISH result (core biopsy sample)

43. On 19 February 2015 (as a second supplement to the report generated on 17 January), the FISH result in relation to the core biopsy was received by Laboratory 3 to the CCDHB laboratory, and was reported on 24 February as negative.

CCDHB results process

44. CCDHB told HDC that the process of sending results to a consultant is underpinned by an electronic sign-off process (as evidence of having been viewed). The result is sent for sign-off to the surgeon whose name is assigned to the patient "event" number (see below). CCDHB told HDC that the process is set up to enable the medical person responsible for coordinating the test result being the doctor who requested the test from the laboratory.

45. CCDHB told HDC that when a result is sent to the electronic system, an alert goes to the requesting doctor receiving the result in the electronic health record (EHR). The doctor can receive the alert when logged in to the EHR. The alert is a notification that there is a laboratory result to sign off. This process is used for both the initial and supplementary reporting of results.

46. Dr B told HDC that the initial core biopsy was performed at CCDHB, and she was notified of the initial pathology result and the two supplements (the HER2 and FISH results).

Dr C, HVDHB

47. On 19 February 2015, Mrs A attended her appointment with Dr C, a plastic surgeon at HVDHB. Mrs A was a suitable candidate for immediate reconstruction, and the surgery (mastectomy and breast reconstruction) was scheduled for 3 March 2015.

Combined surgery, 3 March 2015

48. On 3 March 2015, the combined DHB procedure surgery was undertaken by Dr B of CCDHB (performing mastectomy and sentinel node biopsy) and Dr C of HVDHB (performing breast reconstruction).

49. The surgery took place at HVDHB. Dr C told HDC that when patients are admitted to HVDHB, an "event" number is created in the name of the admitting surgeon. Dr C said that in this case he was the admitting surgeon because "the main surgical issues perioperatively are due to the reconstruction".

50. On the day of the procedure, the breast tissue and lymph node tissue specimens obtained during the surgery were sent from the operating theatre to the HVDHB laboratory.

51. The histology request form for the specimens was completed and signed by Dr B. Dr C told HDC that he had no involvement in the completion of the request form, and that this was normal practice in such clinical circumstances.

52. The HVDHB system in place at the time did not ensure that all treating clinicians (in this case, Drs B and C) received a copy of the pathology results.

53. Although Dr B of CCDHB had requested histology on the specimens taken from the 3 March 2015 surgery, the tissue samples sent to the HVDHB laboratory were requested using the HVDHB "event" number. Histology results were automatically sent to the admitting consultant, Dr C, and were listed on the report (incorrectly) as having been requested by Dr C. These results were then available to view on the HVDHB electronic system, Concerto, which was visible to CCDHB staff through e-Tree[3] (through the Wellington region IT system). The results were recorded as having been sent to Dr C. The system in place meant that results were able to be sent only to the clinician linked to the patient event number.

54. Dr C told HDC that the responsibility for the management of Mrs A's breast cancer, including following up the test results, rested entirely with the breast surgeon (Dr B). Therefore, he would not action the results he received in that respect, nor would he

[3] e-Tree is an electronic inter-DHB clinical information sharing system. CCDHB and HVDHB use the same type of electronic health record system (EHR).

discuss the findings with the patient. Unless specifically requested, ordinarily he would not send on to the treating surgeon a copy of any results that come through his system. Dr C said that he did not discuss the pathology results with Dr B, or put in place any process for forwarding to her the results he received, as this would have been out of the ordinary, and had not been requested by Dr B.

55. The management of the breast cancer issues remained under the care of Dr B at CCDHB. Mrs A was discharged from HVDHB on 9 March 2015.

16 March histology (surgery specimen)

56. On 16 March 2015, a histology report regarding the surgery specimens taken was authorised (signed off as having been viewed) by the HVDHB laboratory. It reported a superficial medial tumour site, a 17mm tumour size, and grade 2 invasive ductal carcinoma.

Postoperative review, HVDHB

57. On 16 March 2015, Mrs A was seen by a plastic surgery registrar for surgical wound problems. The wounds were dressed, swabs were taken, and Mrs A was started on flucloxacillin (an antibiotic) and sent to have blood taken for testing.

Postoperative review, CCDHB

58. On 17 March 2015, Dr B reviewed Mrs A postoperatively at CCDHB Breast Service.

59. The histology results from the tissue taken during the 3 March 2015 surgery were available to CCDHB and Dr B, and Dr B discussed the results with Mrs A. Dr B's clinic letter noted that the breast cancer was "17mm grade 2 ER/PR positive invasive ductal carcinoma". None of the sentinel lymph nodes were affected, and the HER2 result from the tissue obtained during surgery was pending. In the absence of an HER2 result at that point, Mrs A was prescribed tamoxifen.[4]

60. Mrs A told HDC that she cannot recall much of the discussion with Dr B. Mrs A recalled that she was shown a report indicating that oestrogen and progesterone were both positive, but that her HER2 results were to follow.

61. Mrs A said she understood that her lymph nodes were clear and that she did not require any radiotherapy or chemotherapy. She said she was advised that she did not need to revisit the Breast Service again until September 2015 for a check-up. She felt that this indicated that the cancer had been dealt with.

62. Dr B told HDC:

> "[Mrs A] was also told that her case would be discussed at the breast MDM [multidisciplinary meeting] later that day, but it would not be expected that she would require any radiotherapy or chemotherapy as her HER2 results were negative on the initial core biopsy."

[4] A non-steroidal anti-oestrogen medication that is used to treat breast cancer by blocking hormonal effects on cancer cells.

MDM, 17 March 2015

63. Mrs A's case was presented at a CCDHB multidisciplinary meeting (MDM) while her HER2 result was pending. Cancer patient MDMs at CCDHB are held weekly.

64. The outcome (recorded on an MDM document available for future updating where applicable) was that a medical oncology referral would occur only if the HER2 result was deemed positive.

Wound debridement, 21 March 2015

65. Mrs A's recovery after her discharge on 9 March 2015 was hampered by wound infections. On 21 March 2015, Mrs A required debridement[5] and washout at HVDHB. Mrs A was discharged on 25 March 2015, and visited district nurses for dressing changes.

Genetic counselling service

66. On 31 March 2015, the genetic counselling service wrote to Mrs A (copied to her GP and to Dr B) following on from a telephone conversation Mrs A had had with a senior genetic counsellor. Mrs A was deemed to fall into a "potentially high-risk" group for breast cancer.

HER2 testing (surgery specimen), 2 April

67. On 2 April 2015 (as a supplement to the 16 March 2015 histology report), the HER2 result relating to the tissue obtained during the 3 March surgery was reported by the HVDHB laboratory as 2+, meaning that the result was equivocal and that FISH testing would be performed on the specimen.

68. The HVDHB laboratory services records state: "FISH testing will be performed."

69. On 7 April 2015, the HER2 equivocal result from the 3 March surgery specimen was authorised/signed off and entered into the HVDHB electronic Concerto system by HVDHB laboratory staff.

MDM

70. The results were reported to the CCDHB Breast MDM, and the MDM document record updated as "HER2 equivocal. For FISH testing." CCDHB told HDC that the process for a Breast MDM is that a few days before the meeting the pathologist on the MDM panel receives a list of patients to be discussed, and that when the pathologist attends the meeting, any relevant slides and results are brought for review.

71. The CCDHB system in place at the time, however, did not monitor progress of equivocal HER2 results that were yet to be finalised. There was no process in place for the MDM to further follow up patients with equivocal HER2 results awaiting FISH testing. Mrs A's name was not on the list of the subsequent MDM.

[5] Removal of dead tissue from the wound.

72. On 10 April 2015, FISH testing was logged by Laboratory 3 as having been requested.

FISH testing (surgery specimen), 15 April

73. On 15 April 2015, the FISH testing was completed and reported by Laboratory 3 as a positive result.

Reporting of FISH results

74. Keeping in mind the CCDHB results procedure described earlier, there was no direct interface between Laboratory 3 and the EHR for CCDHB.

75. Laboratory 3 FISH reports are sent only to the requesting pathology department (in this case, the HVDHB laboratory) as an email and as a paper copy. The FISH report then has to be transcribed into the DHB electronic laboratory information system as a supplementary report attached to the original histology report. When authorised/signed off by the requesting pathology team, it is then available on the EHR for other clinicians to view.

76. On 15 April 2015, the FISH amplified (positive) report was sent by Laboratory 3 to the HVDHB pathology department.

Further debridement

77. On 14 April 2015, Mrs A was readmitted to HVDHB for further debridement and a skin graft. Mrs A was discharged the next day, with a vacuum dressing on the wound to assist healing. Mrs A had another admission to HVDHB on 28 April, for further debridement. Eventually Mrs A recovered from her surgery and was discharged on 30 April.

Delay in turnaround time from cytogenetics report to pathology sign-off

78. CCDHB told HDC that in the normal course of events, an expected time frame for FISH testing, from request through to reporting, is two weeks.

79. Although the FISH amplified (positive) report was sent by Laboratory 3 to the HVDHB pathology department on 15 April 2015, the FISH amplified (positive) report was not seen by the HVDHB pathology team until 29 June 2015 (almost 11 weeks later). The supplementary report incorporating that FISH result was then completed and attached to the original histology report. This was then authorised/signed off and uploaded onto the HVDHB electronic reporting system, meaning that other clinicians (including CCDHB clinicians) could view it. Unfortunately, on 29 June the delay that had already occurred was not noticed by pathology staff.

80. As a result of the use of the patient "event" number, as described earlier, Dr B was not alerted to the positive FISH result.[6]

81. Dr B stated:

[6] Dr C was on leave.

> "Due to sheer volume of results that the breast service receives (>850 histology results with up to 500 amendments, >2000 blood test results, >2000 radiology reports) we need to be able to, and should be able to rely on the inbuilt alerts in the electronic reporting and sign off system currently employed by CCDHB. With these sorts of numbers it is impossible to keep manual records of every test pending and so as a clinician when I log into Concerto I expect to see it flagged that there are results to be signed off. In this case the flag never came and it took the lab nearly three months to report the FISH results."

82. Dr B said that all the CCDHB clinicians rely on the EHR to alert them to new and amended pathology results, and the system employed linked results to a patient event number and not to the requesting clinician. While Dr B requested the histology, the results did not go to Dr B, nor was there any flag in the system to alert her to the results being available.

83. CCDHB told HDC that the reasons for the delay in turnaround time included administrative issues:

- At the time of the event, an average of 300 slides a week were being received per full-time pathologist at HVDHB — a high workload.
- The maximum of two of five pathologist staff were on annual leave.
- The time between the HER2 equivocal result of 2 April and FISH testing specimen receipt on 10 April included a weekend and the Easter period.
- Process delays included HER2 stains being batched and run only 1–2 times per week, and a process in place for HER2 stains to be double read slowed the turn-around time.
- The process did not allow for easy identification of HER2 stains amidst high volumes of other diagnostic slides.

HER2 positive result acted on

84. In the first week of August 2015, a breast specialty nurse became aware of the HER2 amplified (positive) result. The breast specialty nurse had been checking the notes to see whether Mrs A could come off her list for regular telephone checks, as Mrs A seemed to be managing on the tamoxifen. At this stage, the nurse noticed an additional report that stated that Mrs A was HER2 positive, and that she should be considered for chemotherapy post recovery from surgery.

85. Dr B was made aware of this by the nurse, and immediately proactively placed Mrs A's case for discussion at the next MDM on 11 August 2015. At this meeting it was decided that Mrs A would benefit from a medical oncology referral, for discussion about the possibility of chemotherapy. Mrs A's GP, Dr D, became aware of the positive HER2 result when she received details of the MDM meeting.

86. On 14 August 2015, Mrs A was contacted by the Breast Service, CCDHB, asking her to come in on the following Tuesday. On 18 August 2015, she attended the Breast Service and was advised of the HER2 test result. Mrs A was referred to the medical

oncology team for review and, subsequently, made a decision to turn down further treatment after being advised that there was little research evidence to support or disprove the effectiveness of further treatment seven months after surgery.

Subsequent events and changes to services

Private Laboratory/3DHB integrated laboratory services

87. As mentioned earlier, in October/November 2015, a phased transition to an integrated 3DHB laboratory service (through the Private Laboratory[7]) occurred, and with this came changes and a standardised process, including easier identification of immunostain slides, streamlined HER2 requesting and reporting, and that when a FISH test is ordered a supplementary report is left active and visible.

88. CCDHB also reviewed opportunities with the Private Laboratory to improve the electronic sign-off process (via an electronic portal) to allow the primary team to be attached to both an event number and an additional doctor.[8]

SAC3 review conducted

89. The delay in Mrs A being advised of her positive HER2 test result was recorded as a reportable event, and an SAC3[9] review was conducted by CCDHB. The review was completed on 29 October 2015.

90. CCDHB told HDC that review findings were made following discussions with HVDHB laboratory staff, in particular the pathologists, about the potential risks in the system that led to the incident, and the potential solutions.

91. In addition, CCDHB reiterated that at the time of events the "Joint Lab" leadership group:

- provided clinical governance prior to and during the transition to the Private Laboratory;
- included clinical leadership across CCDHB and HVDHB; and
- directed the SAC review (which included interviews with HVDHB staff).

92. HVDHB told HDC that it concurred with the above points regarding the "Joint Lab" leadership group.

93. The review was completed two days prior to the transition to the Private Laboratory service, so in addition to feedback to the "Joint Lab" leadership group, the recommendations were presented to the Private Laboratory quality team.

[7] The Private Laboratory was not directly involved in the incident under investigation by HDC. The Private Laboratory is a separate and distinct laboratory service from Laboratory 3.
[8] CCDHB policy "Sign off of CCDHB Laboratory and Radiology Electronic Results". Document 1.101560. Issued 20 August 2015.
[9] The Severity Assessment Code (SAC) is a numerical rating that defines the severity of an adverse event and, as a consequence, the required level of reporting and investigation to be undertaken for the event.

94. The review found that the key reasons for the delay in turnaround time of results were as follows:

- There was no system to distinguish patient result report emails from all other emails.
- The tracking and reconciliation of FISH reports sent to the laboratory was described as poor.
- Additional FISH testing was not able to be tracked, leading to an inability to identify or monitor overdue results. (At the time this was reliant on individuals setting up their own tracking, with no support backup.)
- There was no receipting of either electronic or hard copy reports, which did not allow for a flagging system for overdue results.

95. CCDHB and Laboratory 3 made some interim changes to standardise the process for communicating FISH reports, including standardising email subject lines with headings "Patient Report", and tagging emails as high priority.

96. A workflow change was identified to ensure that there was a reconciling process for FISH reports, and to allow centralised reporting of overdue reports within the laboratory.

97. A direct interface between Laboratory 3 and the electronic health record of CCDHB was to be explored.

98. The review team noted that further review was needed of the MDM process and the management of results between treating facilities, to ensure that a treating clinician has all relevant information.

99. The review recommended that:

- The laboratory implement a standardised approach for anatomical pathology to ensure that additional testing can be tracked centrally.
- A direct interface between Laboratory 3 and patients' electronic health records be established.

Audit

100. An audit was also conducted of previously requested FISH testing against reporting timeframes, and it was found that there were no other incidents of delayed or missing reports identified.

101. CCDHB also developed guidelines to support clinical staff involved in combined CCDHB/HVDHB procedures and test result management.

Dr B

102. As a result of this case, Dr B said that she introduced two safety nets. She does not finalise audit forms until she has personally sighted final histology results, including HER2 results, and she now keeps on her home page of Concerto a separate list of patients on whom she operates at HVDHB.

Capital and Coast DHB Breast Service Review

103. In August 2016, terms of reference for a CCDHB Breast Service Review were completed and signed off by a steering committee. A working group review team met regularly and completed a confirmed and authorised review report in May 2017.[10]

104. The review highlighted a number of areas of the service that could be improved to enhance and fully utilise the capacity of the service's patient care and coordination. These areas were referral management, radiology ordering, surgical resource, management of its MDM, specimen result management, surveillance regimes, and resource requirement.

105. The working group suggested 11 recommendations to the steering committee. Those relevant to this case were:

- Updating Breast MDM terms of reference to include responsibilities of its members; and all outstanding actions from MDMs to be documented and referred to at commencement of subsequent meetings.
- Auditing of HER2 reporting times.
- Investigating the process for result allocation when surgery is performed at HVDHB to determine whether Wellington surgeons can be provided with results automatically.
- Investigating alternative means for regulating the requesting of follow-up testing and appointments.

Turnaround times (TATS)

106. In response to the provisional report, CCDHB stated that the Private Laboratory is working closely with CCDHB to ensure turn-around-times (TATS) are monitored to enable results to be identified to the clinical teams responsible for patient care at the earliest opportunity.

107. CCDHB advised that the Private Laboratory has given CCDHB confidence in its reporting as per *Standards of Service Provision for Breast Cancer Patients in New Zealand 2013*, section 4.22, and while HER2 reporting is not mentioned in these standards, CCDHB has confidence in the Private Laboratory to provide quick and accurate HER2 testing.

[10] Copy provided to HDC.

108. Going forward, the Private Laboratory will endeavour to provide both the TATs (initial report) and a HER2 TAT. Urgent HER2 will continue to be processed as soon as practicable from time of request.

109. Within the past 12 months effort has been made to streamline and document the HER2 reporting process, providing results in a timely and safe manner. This includes tracking, control monitoring, double reporting by breast pathologists and electronic reporting by Genetics services.

Private Laboratory

110. As mentioned earlier, the Private Laboratory was not directly involved in the incident under investigation. However, in response to the provisional report, the Private Laboratory requested the following comments be noted:

- Following the review of the laboratory Her-2 IHC (immunohistochemistry) and FISH reporting process, Laboratory 3 now report their Her-2 FISH results directly into MAP/Concerto for clinician sign off, rather than via a third partly laboratory pathologist. This new reporting system is provided in addition to email and hard copy results that are sent to the requesting Pathologist for addition to the original histology report.
- Wellington SCL Anatomical Pathology department is currently exploring IT solutions for regular overdue Her-2 IHC/FISH report audit in their new laboratory information system.
- The Private Laboratory Anatomical Pathology department will explore IT solutions for providing a copy of all authorised Her-2 IHC/FISH reports to the Breast MDM.
- Her-2 turnaround times are satisfactory. This has been confirmed with oncology clinicians.

Responses to provisional opinion

111. Feedback from Mrs A has been incorporated into the "information gathered" section of the report where appropriate.

112. CCDHB considered that the provisional report oversimplified the complex electronic system that individual DHBs operate to manage results along with the laboratory services, and the clinicians who participate in the care of their patients when working at different DHBs can equally be challenging. CCDHB was of the view that it had a system that performed as intended at the time i.e. as the surgeon was not responsible for the event they were not directed the result.

113. CCDHB responded that from the period of time the CCDHB Laboratory 3's laboratory received the request from the HVDHB pathology department until 15 April 2015, when the CCDHB Laboratory 3's laboratory sent the test back to the HVDHB pathology department, it considers that there was no delay by the CCDHB

cytogenetics service, and that the main reasons for delays were as a result of HVDHB issues which was the employing DHB, however CCDHB acknowledged that it did contribute to operational oversight and that the One Lab leadership group included clinical leadership across CCDHB and HVDHB.

114. CCDHB said that the One Lab leadership group was established to oversee transition from CCDHB and HVDHB, to a single provider. The leadership group did not intend to act as a proxy employer, and that at the time of the event the pathology department reporting lines were HVDHB transitioning to the Private Laboratory.

115. CCDHB responded that it understood how the provisional report concluded the MDM process lacked a mechanism to ensure previously unresolved or outstanding results which were historically not automatically placed upon the agenda of the next MDM meeting, and that it had rectified this along with the updating of the terms of reference as per the Breast Service review

116. HVDHB updated HDC that the following measures are now in place:

- Visiting surgeons involved in cases now have their name highlighted on the pathology request forms so that primary pathology reports are forwarded to them as well as to the named HVDHB clinician.
- When results are received by plastic surgeons regarding such patients, they are noted and manually sent to the treating surgeon.
- The pathway by which requesting clinicians receive additional tests based on the original histology specimen, is now administered by the Private Laboratory.

Opinion

Preliminary comment

117. While I acknowledge the improvements made to services after this incident, including transitioning to one integrated outsourced Private Laboratory service very soon afterwards, at the time of Mrs A's care in mid-2015 a number of hospital systems in place in relation to the laboratory processing, circulation, and follow-up of test results stemming from her combined surgery, did not function optimally.

118. The system in which Dr B and Dr C were working had a flaw, which meant that Dr B was not alerted to test results being available to her.

119. Mrs A endured an unnecessary delay in her test results being processed and received and, ultimately, a delayed referral for medical oncology treatment. In my view, Mrs A was let down by the system in place at that time.

120. As observed by my expert advisor, Dr Richard Harman:

> "The situation is complex and is largely the result of system error or lack of systems to deal with delay in receiving the FISH testing that is required to establish if Herceptin or chemotherapy would be beneficial."

121. Three key system issues are examined below.

Opinion: Hutt Valley DHB — breach

Combined surgical procedure — event number

122. On 3 March 2015, the combined surgery took place at HVDHB. When admitted to HVDHB, an "event" number was created in the name of the admitting surgeon, Dr C.

123. A histology request for the breast tissue and lymph node tissue specimens obtained during the surgery was completed by Dr B of CCDHB. Problematically, those surgical tissue samples were linked to the HVDHB "event" number and Dr C, and not to Dr B, the ordering clinician.

124. There was no system in place at HVDHB at the time to ensure that all treating clinicians were alerted to and received a copy of the ensuing results. Histology results were automatically sent to the admitting consultant (in this case, Dr C), although I note that the results were later available on the HVDHB Concerto system, and were visible to all staff, including CCDHB staff, through the Wellington region IT system (e-Tree).

125. Dr C, who did not order the histology, told HDC that a copy of the histology results was available to him through the electronic system, but he did not action this, as responsibility for the management of Mrs A's breast cancer rested with Dr B. The HVDHB laboratory results relating to the surgery specimens were listed on the report as having been requested by Dr C because, as explained above, the patient "event" number was linked to Dr C. The results system in place meant that results were sent only to the clinician linked to the patient event number.

126. I am concerned that the HVDHB system in place at the time did not accommodate the foreseeable test result dissemination requirements of a patient undergoing a combined procedure, across two DHBs, as in this case. The system in place at the time did not alert the requesting clinician to the results. Accordingly, in my opinion, HVDHB did not provide services to Mrs A with reasonable care and skill and breached Right 4(1) of the Code.

Opinion: Hutt Valley DHB & Capital and Coast DHB — breach

Laboratory delay

127. At the time of the events complained about, there was shared governance and shared responsibility across both CCDHB and HVDHB for the laboratory operations, including the deficiencies identified.

128. On 10 April 2015, HER2 FISH testing was logged by Laboratory 3 as having been requested.

129. On 15 April 2015, Mrs A's FISH testing was completed and reported by Laboratory 3 as positive.

130. On 15 April 2015, the positive FISH report was sent by Laboratory 3 as an email to the requesting (HVDHB) pathology department, and a paper copy was also sent. The expected time frame for FISH testing, from its request through to reporting, is two weeks.

131. It was not until 29 June 2015 that the FISH amplified (positive) result was seen by the HVDHB pathology team. This resulted in completion of a supplementary report incorporating that FISH result, which was then attached to the original histology report — and then authorised and uploaded onto the HVDHB electronic reporting system, meaning that other clinicians (including CCDHB clinicians) could then view it.

132. Although the results were available to Dr B, she was not alerted to the positive HER2 result. Dr B said that all CCDHB clinicians rely on the EHR to alert them to new and amended pathology results, and the system employed linked results to a patient event number, and not to the requesting clinician. While Dr B requested the histology, the results were linked to the event number of Mrs A's admission to HVDHB under Dr C, and the results did not go to Dr B. Nor was there any system to alert her to the results being available.

133. I am mindful of Dr Harman's view that Dr B is in no way at fault, and "the delay is a result of a systems error that needs correction by the hospital as a whole". In my view, while ideally Dr B could have employed safety-netting strategies in relation to a test she ordered for Mrs A (such as those strategies she later implemented as a result of this case), I am mindful that Dr B was working in a flawed system. I consider that it was reasonable for Dr B to expect to be supported by a system of appropriate alerts and electronic reporting. Having considered the circumstances of this case, I am of the view that the failure to follow up was largely caused by systems deficiencies and delays.

134. The SAC3 review found that key systems issues involved in the delay in turnaround time were as follows:

- There was no system to distinguish patient result report emails from all other emails.

- The tracking and reconciliation of FISH reports sent to the laboratory was poor.
- Additional FISH testing was not able to be tracked, leading to an inability to identify or monitor overdue results.
- There was no receipting of either electronic or hard copy reports, which did not allow for a flagging system for overdue results.

135. Reasons for the delay in turnaround time included laboratory administrative and resourcing issues:

- At the time of the event, an average of 300 slides a week were being received per full-time pathologist at HVDHB — a high workload.
- The maximum of two of five pathologist staff were on annual leave.
- The time between the HER2 equivocal result of 2 April and FISH testing specimen receipt on 10 April included a weekend and the Easter period.
- Process delays included HER2 stains being batched and run only 1–2 times per week, and a process in place for HER2 stains to be double-read slowed the turn-around time.
- The process did not allow for easy identification of HER2 stains amidst high volumes of other diagnostic slides.

136. Dr Harman considers the delay in obtaining the pathology report from the laboratory to be a departure from the expected standard, and he would class it as a moderate departure.

137. It is concerning that there was an approximate 12 week period, from 2 April 2015 when the FISH test was deemed necessary, until 29 June 2015 when laboratory staff saw the positive result. In addition, there was also a failure to recognise the delay that had already occurred, meaning that the result was not actually acted on until the first week of August 2015. While I acknowledge that the main delay occurred in laboratory process, in my view, overall this was not acceptable. I remain of the view that HVDHB and CCDHB did not ensure quality and continuity of services to Mrs A and breached Right 4(5) of the Code.

Opinion: Capital and Coast DHB — breach

Equivocal HER2 results

138. On 17 March 2015, Mrs A was reviewed postoperatively by Dr B at CCDHB. The histology results from the tissue taken during the 3 March 2015 surgery were available to Dr B, and were discussed with Mrs A.

139. At that point, the HER2 result was pending.

140. Mrs A's case was presented at a CCDHB multidisciplinary meeting (MDM) while her HER2 result was pending. The outcome (recorded on an MDM document available for future updating where applicable) was that a medical oncology referral would occur only if the HER2 result was deemed positive.

141. On 2 April 2015 (as a supplement to the 16 March 2015 histology report), the HER2 result relating to the tissue obtained during the 3 March surgery was reported by the HVDHB laboratory as 2+, meaning that the result was equivocal. Therefore, FISH testing was to be performed on the specimen.

142. On 7 April 2015, the HER2 equivocal result was authorised/signed off and entered into the HVDHB electronic system by the HVDHB laboratory.

143. The results were reported to the CCDHB Breast MDM, and the MDM document was updated as "HER2 equivocal. For FISH testing." The process for a Breast MDM is that a few days before the meeting the pathologist on the MDM panel receives a list of patients to be discussed, and when the pathologist attends the meeting, any relevant slides and results are brought for review.

144. The CCDHB system in place at the time, however, did not monitor progress of equivocal HER2 results that were yet to be finalised. There was no process in place for the MDM to further follow up patients with equivocal HER2 results awaiting FISH testing. Mrs A's name was not on the list of the subsequent MDM.

145. Dr Harman advised that when Mrs A's results for HER2 were equivocal, the system should have included further MDM discussion, as a final treatment decision is not able to be made without the FISH results. Dr Harman said that all DHBs and Breast Services need to build in check systems where the HER2 is equivocal, to ensure that the cases are discussed further at the MDM to finalise the treatment options and allow appropriate referral to oncology.

146. It was suboptimal that there was no existing system in place at the time, including via the Breast MDM, to follow up progress of equivocal HER2 results that were yet to be finalised. Accordingly, in my opinion, CCDHB did not provide services to Mrs A with reasonable care and skill, and breached Right 4(1) of the Code.

Recommendations

147. I recommend that HVDHB liaise with CCDHB and the Private Laboratory clinical leaders and report back an update to HDC, within three months of this report, on the following:

a) The effectiveness of the electronic sign-off process that allows the primary team to be attached to both an event number and an additional doctor.

b) The standardised process established for communicating FISH reports.

c) The reconciling process put in place for FISH reports to allow centralised reporting of overdue reports.

d) The implementation of a standardised approach for anatomical pathology to ensure that additional testing can be tracked centrally.

148. I also recommend that Hutt Valley District Health Board provide a formal written apology to Mrs A. The apology is to be sent to HDC for forwarding, within three weeks of this report.

149. I recommend that CCDHB liaise with HVDHB and the Private Laboratory clinical leaders and report back an update to HDC, within three months of this report, on the following:

a) The outcome of its review of the MDM process.

b) The guidelines established to support clinical staff involved in combined CCDHB/HVDHB procedures and test result management, to include reference to audit of dissemination of test results in previous combined mastectomy/reconstruction procedures.

c) The progress made toward a direct interface between Laboratory 3 and the electronic health record.

d) The implementation of the recommendations arising out of the CCDHB Breast Service Review, including:

(i) Updating the Breast Service MDM terms of reference.
(ii) Auditing of HER2 reporting times.
(iii) Investigating the process for result allocation when surgery is performed at HVDHB.
(iv) Regulating the requesting of follow-up testing and appointments.

150. I also recommend that CCDHB provide a formal written apology to Mrs A. The apology is to be sent to HDC for forwarding, within three weeks of the date of this report.

Follow-up actions

151. A copy of this report with details identifying the parties removed, except CCDHB and HVDHB and the expert who advised on this case, will be sent to the HQSC, the National CMO group, and Central TAS, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent surgeon's advice to the Commissioner

The following expert advice was obtained from a breast, endocrine, laparoscopic, melanoma & general surgeon, Richard Harman:

> "I have now had the opportunity to review and consider the complaint against [CCDHB] Breast Clinic and [HVDHB] Plastics Unit, your reference C15HDC01289. I have reviewed the letter of complaint from [Mrs A], the response and clinical notes from [the GP], the response and clinical notes from CCDHB and response and clinical notes from Hutt Valley DHB.
>
> To summarize the situation [Mrs A] visited her GP on 8th January 2015 regarding a right breast cancer. She was offered the appropriate options for surgery and opted for a mastectomy with immediate reconstruction. The surgery was undertaken by [Dr B] of CCDHB and [Dr C] of HVDHB. [Mrs A] experienced some significant complications from the surgery but eventually recovered well by the end of April from all of her surgery.
>
> She was seen by [Dr B] at CCDHB on the 17th March 2015 and given the results of her breast cancer which was ERPR positive and HER2 results were pending. The case was discussed appropriately at the unit's MDT meeting and decision was made to refer to oncology if she was HER 2 positive. HER2 results were sent for FISH but the final report did not surface until the 14th August when she was informed that she should re-visit [Dr B] as her tumour was HER2 positive and that she could be considered for chemotherapy.
>
> [Mrs A] has complained regarding this, due to the length of time that it has taken for her results to be finalised.
>
> The situation is complex and is largely the result of system error or lack of systems to deal with delay in receiving the FISH testing that is required to establish if Herceptin or chemotherapy would be beneficial.
>
> In review of the notes it appears that the initial HER2 equivocal result was discussed at the Multidisciplinary Team Meeting sometime in March however because the results were not available, decision to refer to oncology was not made. The MDT result states 'Medical oncology referral only if HER2 positive'.
>
> It appears these results were then not followed up on which resulted in the delay and the subsequent complaint.
>
> Your letter has asked for the following:
>
> 1) In cases where immediate reconstruction follows a mastectomy, who holds the clinical responsibility for the management of histology and receptor testing results?

2) Please comment on the overall management of [Mrs A's] test results, including if the test results were provided and acted upon in a timely and appropriate manner.
3) a) Do you believe [Mrs A] should have received chemotherapy or other adjuvant therapy earlier than the timing illustrated in this case?
   b) Do you believe the delay in receiving the therapy was significant enough to potentially affect [Mrs A's] long term prognosis?
4) Any other comments you wish to make about [Mrs A's] post operative, or test result management.
5) Any comments you may wish to make in regards to the systems I place for test result management between HVDHB and CCDHB? In particular, are the remedial measures described sufficient to prevent a similar issue to this occurring in the future?

I will answer each of your questions in turn:

1. The primary consultant for oncology is the Breast Surgeon or the treating oncologist. In this case the responsibility for the test result would lie with [Dr B] as no oncologist had been consulted. In cases where an oncologist is consulted the oncologist is giving the treatment and therefore holds the responsibility.

2. The delay in [Dr B] and the MDT receiving the results is largely a systems error and needs to be further addressed by the manager and clinical lead of the breast service at CCDHB to prevent this happening again. [Mrs A's] test results were not acted upon in a timely manner and there appears to be two areas that need attention.

   2.1. **Delay in laboratory reporting and adequate notification.** The manager and the service need to ensure that the FISH results when required are available to the treating clinician (and MDT coordinator) in a timely manner and this should ideally be within 2 weeks of the surgery. The HER2 result is part of the pathology report and as such the pathology report is not finalized until this time. In this case the pathologist did not finalize the report until 29/6/2015 when the surgery took place on the 3/3/2015. As it was the cytogenetic lab did not complete the FISH testing until the 15/4/15 which is 6 weeks since the surgery. The reason for this delay in pathological reporting requires further explanation from the service manager. Once the result was available it appears the results were not sent to the treating clinician [Dr B] or the MDT coordinator.

   2.2. **Lack of a system by the service to follow up on equivocal HER 2 results.** When [Mrs A's] results for HER2 were not ready the MDT should keep her file open because the treatment decision cannot be made without the FISH results. A system needs to be developed by the clinical lead of the breast service and the manager of the service so

these MDT results are not finalized until such time. It would be impossible for [Dr B] or any clinician to keep track or follow up on the finalized results without an adequate system of reporting and notification. One method would be for the MDT coordinator to not finalize the results or chase these up as part of the finalization of the MDT report. Once the MDT coordinator has the finalized pathology result the case can be re discussed and if positive as in [Mrs A's] case the appropriate referral can be made to oncology. i.e. [Mrs A's] case should have been re discussed in April when the FISH results were available in the MDT and then the appropriate referral would have been made.

3.

3.1. Ideally [Mrs A] would have received her chemotherapy and or Herceptin starting in late March or early April if her results had been processed at an appropriate time.

3.2. I do not think the delay would have affected her long term prognosis or it would be extremely unlikely if she had the treatment after a delay, however it would not be considered best practice.

4. I have covered this above but as discussed above the case should have been left open until the MDT could finalize [Mrs A's] results. The breast service needs to develop and be resourced appropriately to check on the final results. This could be done by an MDT Co-oordinator or Breast nurse.

We need to be reassured that CCDHB Breast Service has an MDT coordinator or breast nurse who is adequately resourced to follow up on these results. The pathology service should develop systems to ensure the results get to the MDT coordinator, as well as the correct treating clinician. In addition, it is important that plastics service at HVDHB ensure that the treating oncological surgeon ([Dr B] in this case) and the breast MDT get a copy of the pathology result.

There also appears to be a delay in obtaining the results. As discussed work needs to be done with the pathology department regarding the delays in reporting of both the standard pathology and the finalized FISH results and if longer than 2 weeks the reason behind this.

The manager of the CCDHB Breast Service should liaise [with] the pathology service to improve reporting times and ensure that appropriate notification of results especially to the MDT coordinator and treating clinician is guaranteed. Work needs to be undertaken with the lead breast surgeon [and] the pathology service to ensure that a system is set in place so that patients with an equivocal HER 2 result are re presented for discussion at the MDT to allow appropriate and timely referral to oncology.

5. It does not appear that adequate measures have been put in place by the Breast Service at CCDHB to stop this from happening again. My suggestions are above.

   In regard to this being a departure from normal practice. As [Dr B] has not been provided with an adequate system to receive results I do not believe [Dr B] has departed from the expected standard.

I believe the delay in obtaining the pathology report from the laboratory is a departure from the expected standard and I would class this as moderate.

In regards to the systems error, I believe this is also a departure from the expected standard but because this may well be occurring in other DHBs I could only classify this as minor. The situation occurs because the FISH testing is part of the pathology result and the pathology report cannot be finalized until this has happened, also it is a fairly recent addition that we are more dependent on HER2 results with treatments available. All DHBs and breast clinics need to build in check systems where the HER2 is equivocal to ensure that the cases are discussed at the MDT to finalize the treatment options and allow appropriate referral to oncology. The other alternative is for the pathology report not to be issued until the FISH is completed.

It is important to emphasize that apart from what appears to be a long delay in obtaining a finalized pathology report (from 3/3/15 to the 15/4/15) this is a systems error and requires an understanding of the manager of the service and the treating clinicians and pathology service to work together to build a system that does not let down patients such as [Mrs A].

It may well be that an important outcome from this case is to emphasise the importance of all DHBs or practitioners in this speciality to have a robust system to prevent similar incidents.

Please let me know if you need anything further or have questions regarding this report.

With kind regards

Yours sincerely

Mr Richard Harman"

Mr Harman provided the following further comments:

"I have now reviewed the further information provided and you have asked me to comment further as to whether this alters the advice I gave earlier. In particular you have asked me whether I can comment on the systems issues that were raised by this case and the subsequent SAC3 review and its recommendations.

There is a response that I have reviewed from Capital & Coast. This again outlines the time delay from when the core biopsy was performed on the 17th January to the final results of the pathology testing which was reported on the 29th June 2015. The patient was then informed of the result on the 18th August 2015. Capital & Coast also outlines the corrective action that has taken place with the pathology department and reporting of the HER2 results.

I understand there is a review of the Breast Service and implementation of guidelines to avoid this happening again. The final report from the Breast Service is not yet available but it does appear that significant action has been taken in the interim.

In terms of the delay in the reporting of the pathology certain factors were responsible in particular:

1. A very high workload placed on the pathologists at this time and a number of pathologists on leave.
2. No process to identify HER2 stains amidst other high volumes of work — this has now been corrected.
3. A transition of the laboratory to the Private Laboratory.
4. No system in place to ensure all treating clinicians received a copy of the pathology report — now corrected.

All of the above appears to have contributed to the delay in the pathology report reaching the correct clinicians.

I also note that a retrospective audit has been performed and no other patients have been affected and this appears to be an isolated event.

Therefore it seems that [Mrs A's] delay in her reporting of her pathology was a result of staffing and systems issues within the pathology which appear to now have been corrected.

I believe that the significant delay from the 15th April when the FISH HER2 amplified positive test was generated and the 29th June when the pathologists actually authorised the report, a delay of 2 months will now be eliminated with the changes that CCDHB has made to their pathology service.

I note that there is a report requested from [Dr B] but from the information I have received I cannot see that [Dr B] is in any way at fault. The delay is a result of a systems error that needs correction by the hospital as a whole. I note that we are awaiting the review of the report on the Breast Service so as to mitigate a repeat of this.

You have asked me to clarify with the information that I now have from pathology services whether this is a departure from the standard. I believe the

delay in the pathology service reporting to their Breast Service is beyond what would be expected to be the standard. However, there are mitigating circumstances as discussed above.

It will be useful also to have the review of the Breast Service and understand how they are going to ensure that all patients and clinicians receive their final HER2 report so that their treatment may be planned with this information.

I believe that it is unlikely that this delay although significant will result in any harm to [Mrs A].

I think that the CCDHB have made considerable efforts to ensure that the delay that occurred to [Mrs A] is unlikely to happen again.

I look forward to receiving the review of the Breast Service. Please let me know if you require any further information.

Yours sincerely

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