HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Surgical and oncological care of woman diagnosed with unilateral breast cancer

Executive summary

1. Mrs A was diagnosed with unilateral breast cancer (cancer that has developed in one breast) in early January 2018. She had a bilateral (double) mastectomy with immediate reconstructive surgery on 26 February 2018 and commenced chemotherapy on 18 May 2018. At the outset, I acknowledge the impact this diagnosis and the subsequent treatment has had on Mrs A and her whānau.

2. In June 2022, Mr A, Mrs A's husband, complained to the Health and Disability Commissioner (HDC) on her behalf regarding the care and treatment she received from Health New Zealand | Te Whatu Ora Lakes (Health NZ) and consultant general surgeon, Dr B. Essentially, Mr A asked HDC to investigate the:

- decision-making around commencing adjuvant chemotherapy;[1]
- dose of chemotherapy administered to Mrs A; and
- standard of breast surgery and whether the surgery was necessary.

3. HDC proposed finding a breach of Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code), which states that every consumer has the right to services provided with reasonable care and skill, to Health NZ regarding a significant medication error with Mrs A's chemotherapy drug. This breach has been accepted by Health NZ.

4. I make an adverse comment about Health NZ in relation to the failure to proactively consider information relevant to the post-surgical treatment option of chemotherapy for Mrs A.

5. I also make an 'other' comment in relation to the provision of psychological support by Health NZ to women dealing with a breast cancer diagnosis.

Recommendations

6. I recommend that Health NZ

- provide a written apology to Mrs and Mr A for the deficiencies in care outlined in this report, and that the apology be sent to HDC within three weeks of the date of this report for forwarding to Mrs and Mr A;
- provide an update as to the changes made to systems and processes to prevent further chemotherapy errors occurring and that the update be sent to HDC, alongside a review of the effectiveness of any such changes, within three months of the date of this report;
- develop and conduct an audit to evaluate the decision-making and outcomes of the Rotorua Multidisciplinary Breast Meeting Intervention (MDM), including the extent to

[1] A cancer treatment that is given after primary treatments, such as surgery.

Names have been removed (except Health New Zealand | Te Whatu Ora Lakes and the clinical advisor on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

which relevant clinical information is proactively considered once it is received, and to provide to HDC the first round of the audit's summary of findings, with any corrective actions to be implemented, within six months of the date of this report; and

- provide any further update on the psychological support it offers to women under its care with a diagnosis of breast cancer (I acknowledge that a clinical psychologist has now been employed).

Background

Surgery

7. Mrs A was diagnosed with unilateral left breast cancer in January 2018 after finding a lump in late 2017. She underwent a number of diagnostic tests, including a mammogram, an ultrasound-guided core biopsy, and magnetic resonance imaging (MRI), to estimate the size and stage of the disease. The investigations determined the cancer to be grade 3[2] and multifocal with a total area of approximately 5.5cm. It had not spread to the lymph nodes or other areas of the body.

8. Mrs A commenced tamoxifen (a drug that inhibits oestrogen-induced growth of hormone-sensitive tumours such as Mrs A's[3]) on 12 January 2018.

9. Due to the multifocal nature of her disease, the consensus of the MDM (a weekly meeting of specialist surgeons, radiologists, oncologists, pathologists, and specialist cancer nurses) held on 24 January 2018 was that left breast conservation would not be effective, even with neoadjuvant[4] chemotherapy. As such, a full left breast mastectomy was recommended.

10. Mr and Mrs A told HDC that Mrs A decided to undergo a preventive right breast mastectomy due to concerns about physical appearance and the seemingly rapid onset of her cancer. The clinical records indicate that her mother's history of breast cancer recurrence was another factor. Dr B, Mrs A's surgeon, told HDC he would not usually recommend preventive surgery; however, if a patient requests this and there is relevant clinical indication, he may proceed. Mr and Mrs A state they do not recall Dr B advising against a double mastectomy.

11. The clinical records reflect several consultations between Mrs A and Dr B, as well as regular phone calls with a specialist breast cancer nurse, before the surgery. Mrs A's concern about the risk of cancer developing in her right breast was raised frequently, and she was noted to be particularly anxious regarding the wait for surgery. Consideration was given as to whether chemotherapy should be undertaken before or after the mastectomy and an option for the correction of Mrs A's ptosis[5] is mentioned in the clinical record. Mrs A was given a 2010 guide about breast reconstruction (published by the British Association of

[2] Grade 3 cancer cells and tissue look very abnormal. These cancers are considered poorly differentiated, since they no longer have an architectural structure or pattern. They are considered high grade and grow quickly.
[3] Mrs A's tumour was ER+/PR+/HER2+ (triple positive). This meant her breast cancer cells used oestrogen receptors (ER), progesterone receptors (PR), and the human epidermal growth factor 2 (HER2) protein to grow. HER2+ breast cancers grow quickly and are thought to be more aggressive than other forms.
[4] Chemotherapy taking place before surgery.
[5] Drooping of breasts due to loss of skin elasticity and changes in breast tissue that may be caused by ageing, pregnancy, weight fluctuations, or genetics.

Plastic Reconstruction and Aesthetic Surgeons), and it was documented that she was informed about the risk of 'implant loss and not being a perfect match'.

12. Mrs A underwent the double mastectomy and reconstructive surgery privately on 26 February 2018. She opted for implants that were slightly larger than her original breast size that were placed subpectorally.[6]

13. On 14 March 2018, Dr B noted 'initial superior fullness' (volume and roundness at the upper part of the breast); however, as it was so soon after the surgery, he felt it would likely resolve in time. Mrs A raised concern regarding the outcome of the reconstruction in January 2021 and again in June/July 2021 when she was reviewed by both the specialist breast cancer nurse and Dr B. He recorded 'bilateral high-riding implants with lack of inferior pole fullness and slightly misplaced nipples' (meaning both of Mrs A's implants were sitting unnaturally high on her chest). Dr B discussed management options. Mr and Mrs A said they asked for a second opinion from another plastic surgery team, to which Dr B agreed. Dr B stated that, with hindsight, smaller implants would have reduced some of the problems that occurred.

Chemotherapy

14. After Mrs A's mastectomy and reconstructive surgery, her case was discussed at MDMs on 14 and 21 March 2018. Information was sent to a consultant medical oncologist at Lakes Hospital. As the tumour was HER2 positive, the consultant medical oncologist did not recommend chemotherapy and Herceptin as, in her view, the survival benefit would be marginal (1.2–1.3%), but she did recommend continuation of tamoxifen.

15. The histology results (tissue analysis of the tumour) were reviewed by the original reporting pathologists on 22 March 2018, the day following the MDM and the consultant medical oncologist opinion. The size of the tumour removed following surgery was reported to be 1.6cm (significantly smaller than the size calculated following the MRI prior to surgery)[7] and was initially staged at pT1.[8] The amended report states 'it is possible that the maximum dimension of the invasive tumour is greater than the previously reported … maximum dimension … could upgrade the stage to pT2'.

16. The minutes from the post-surgical MDM on 21 March 2018 also note that Mrs A had requested referral to medical oncology. This referral was received by Health NZ on 13 April 2018, and Mrs A was seen by another consultant medical oncologist at Lakes Hospital, Dr C, on 1 May 2018. The outcome of this appointment was a recommendation for chemotherapy to commence due to the upgrade of staging from the histology report.[9] In a clinical letter, Dr C noted that he explained to Mrs A there was some evidence that the time elapsed since her surgery (over 60 days) may lead to worse outcomes from chemotherapy; however, other

[6] Implants placed under the pectoral (chest) muscle.

[7] Independent clinical advice (see Appendix A) notes: 'All preoperative tests are estimates with different sensitivity and specificity' and 'The 100% specific test is post-operative pathology … It is extremely rare to have an exact match of the preoperative measurements and post operative results.'

[8] pT1 tumours are 2cm or smaller in diameter, pT2 tumours are between 2 and 5cm.

[9] This refers to the classification system used to determine the extent of cancer and its spread. It categorises breast cancer into four stages based on tumour size, node involvement, and metastasis (spread of cancer to distant organs).

studies showed no difference if chemotherapy was commenced within four months of surgery.[10] He noted that, while it was likely the surgery had cured her cancer, the continuation of tamoxifen was most beneficial for increasing Mrs A's 10-year survival chances (estimated at 78%), and the addition of chemotherapy and Herceptin would further increase her chance of survival to 86–88%.

17. On 5 May 2018, Mrs A had a private consultation with a consultant medical oncologist at the private hospital, Dr D, to discuss the potential for chemotherapy. Dr D's view was that, due to Mrs A's high-grade, pT2 breast cancer, adjuvant chemotherapy would reduce her risk of future, systemic cancer.

18. Mrs A's chemotherapy regimen was undertaken by Health NZ and had two phases. First, an initial four-cycle treatment of doxorubicin and cyclophosphamide (commonly known as the 'AC' regimen)[11] commenced on 18 May 2018 and was completed on 24 July 2018 without incident, other than Mrs A experiencing known side effects of the treatment.

19. The second phase of Mrs A's chemotherapy regimen was to be a weekly dose of paclitaxel[12] for 12 weeks and Herceptin[13] for a total of six months. Mrs A commenced this regimen on 20 August 2018. Her weekly dose of paclitaxel should have been 145mg (80mg per m^2) infused over one hour; however, the clinical nurse manager (CNM) of the chemotherapy unit at Rotorua, told HDC that, at her first treatment, Mrs A received the equivalent of a three-weekly dose of 320mg (175mg per m^2) infused over one hour.[14] This is confirmed by the medication chart, which also shows Herceptin was given at the correct dose and rate. The CNM stated that she identified the error on 23 August 2018, notified Dr C and cancelled Mrs A's next dose of paclitaxel.

20. The nursing notes show a nurse spoke to Mrs A on 24 August 2018, who reported experiencing pain in her knees and numbness in her feet. The notes also indicate that Mrs A spoke to Dr C at some point prior to her next chemotherapy appointment on 28 August 2018; he was aware of the side effects she had experienced but was not overly concerned at this stage. Mr and Mrs A state that Mrs A did not speak to Dr C in the week leading up to 28 August 2018.

21. Mr and Mrs A stated that, despite reporting the side effects, they were not informed of the dosing error until the appointment on 28 August 2018 and that they thought Mrs A had been given paclitaxel on that date. The clinical records indicate that only Herceptin was administered at this appointment to account for the increased dose of paclitaxel the week before.

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[10] These studies related to triple negative breast cancer (Mrs A's disease was 'triple positive') and were conducted before the availability of Herceptin.
[11] Both drugs work to damage the DNA of cancer cells to prevent them from reproducing.
[12] Conventional chemotherapy drug that kills cancer cells or slows their growth.
[13] Targeted monoclonal antibody that attaches to the HER2 protein on the surface of cancer cells, blocking growth signals.
[14] The three-weekly dose would typically be infused over three hours.

22. Mrs A continued with her chemotherapy as planned from 4 September 2018; however, with each cycle, she continued to suffer a range of side effects that impacted her quality of life. Paclitaxel chemotherapy ended on 17 September 2018 (before the full 12-week cycle was complete); Herceptin continued for a total of 6 months.

23. A clinic letter dated 21 September 2018 indicates that an apology for the medication error was provided to Mrs A by Dr C and that she had been aware of the plan to pause paclitaxel. It also acknowledges that the adverse effects of chemotherapy were compounded by the initial dosing error. Mr and Mrs A said they were aware of a decision to pause (and eventually not re-start) paclitaxel if the side effects became too much for Mrs A. They were not aware of any pause before that; nor do they recall an apology being made by Dr C.

24. The CNM highlighted the following factors regarding the medication error:

- The medication chart printed at the start of phase two of the chemotherapy was for a three-weekly protocol, rather than Mrs A's one-weekly protocol.
- The CNM and the pharmacy failed to notice this error.
- Two further registered chemotherapy-trained nurses did not identify the error and gave the higher dose at the faster rate for the weekly chemotherapy.
- No Datix[15] report was completed in relation to the error.

Analysis

25. There are three issues for me to determine: whether Mrs A received an appropriate standard of care in relation to the:

(a) surgery – in terms of its technical requirements, together with whether it was required at all;

(b) decisions regarding the role of adjuvant chemotherapy; and

(c) medication error, including whether open disclosure of the error occurred within an appropriate timeframe.

26. To assist me in determining whether the Code has been breached in respect of the above issues, I obtained independent clinical advice from Dr Garth Poole, consultant general surgeon (see **Appendix A**). I have also considered clinical advice provided to the Accident Compensation Corporation (ACC)[16] by a consultant oncoplastic breast and general surgeon as well as the clinical records and other information.

27. It is not disputed that Mrs A had an unsatisfactory outcome from her breast reconstruction, for which she has since required further surgical revision, as well as requiring further cancer treatment in the form of chemotherapy. Following the advice received in her ACC treatment

[15] Datix is an incident reporting system used widely by healthcare providers.
[16] Mrs A made a treatment injury claim to ACC regarding the high-riding implants, and the advice was sought from the expert as part of this claim.

injury claim (described immediately below), Mrs A was understandably concerned that an alternative, less extreme treatment option may have been available to her.

28. The ACC advisor's opinion was that 'the high riding implants and lateral nipple deviation relate to technical errors and poor selection of operative procedure.' She also raised concerns regarding the diagnostic process, although noted that she was not provided with the preoperative clinic letters. Her concerns included the following:

- The treatment and surgery were not appropriate based on the histology alone, and breast-conserving surgery with radiology provides better long-term outcomes.
- She was critical of a lack of consideration given to Mrs A's ptosis and the size of the implant. She suggests these further contributed to the poor outcome.
- Neoadjuvant chemotherapy could have offered additional time for Mrs A to consider her surgical options and undergo genetic screening.[17]
- Mrs A's mother's breast cancer diagnosis in her 50s was not an indicator for preventive surgery on the right breast.
- A clinical psychology assessment may have been beneficial, given Mrs A's anxieties surrounding her diagnosis and family history.

29. It is important to note that HDC's expert had the benefit of clinical information that was not available to the ACC advisor, including Dr B's preoperative clinic letters and notes from the preoperative MDMs. Dr Poole did not identify any departures in the standard of surgical care provided to Mrs A and noted the following:

- The decision to recommend a mastectomy was correct, and the decision to perform bilateral surgery was appropriate.
- The operation was of an adequate standard for the time.
- Mrs A's cosmetic results were 'adequate at best', and revision is required for optimum results. He notes this is common in immediate reconstruction.
- Grade 3 tumours usually need adjuvant chemotherapy, and the size of the tumour is of modest importance.

30. It is apparent when comparing Dr Poole's advice with that of the ACC advisor that there is a conflict as to whether the surgery was appropriate and if the outcome was due to poor surgical technique or an accepted risk of immediate reconstructive surgery. While I acknowledge the concerns raised in the ACC advisor's report, I have preferred Dr Poole's advice for several reasons. First, Dr Poole's advice was prepared for the purpose of HDC's assessment of the standard of care Mrs A received. In contrast, the ACC advice addressed the issue of whether Mrs A experienced a treatment injury that led to the high-riding implants. Importantly, that advice was prepared without the benefit of reviewing the preoperative clinical documentation (such as Dr B's consultation notes and the MDM reports) that Dr Poole reviewed. The ACC advice is based only on the operative and postoperative documentation. In my opinion, the preoperative documentation was

[17] Mrs A did receive genetic screening after the surgery.

essential for understanding the totality of Mrs A's care and to minimise the risk of hindsight bias.

Appropriateness of Mrs A's surgery

31. I accept Dr Poole's advice that the decision for mastectomy was appropriate, noting the type and stage of cancer that Mrs A had. I am also satisfied the clinical records reflect that multidisciplinary discussions took place, which indicated a mastectomy was appropriate and that less invasive, breast-conserving surgery was not indicated in Mrs A's case as the pre-surgical scans indicated her disease was multifocal. Noting that the tumour was smaller than expected when the surgery was conducted, such reduction may have reflected a good response to tamoxifen, although Dr Poole has suggested that it is more likely that the MRI overestimated the size. That did not alter his view that the surgery was appropriate.

32. Clinical records reflect that Dr B was aware of Mrs A's ptosis and discussed options to remedy this with her. Dr B suggested that financial constraints meant that correcting the ptosis was not addressed during the reconstructive surgery, although this is clearly disputed by Mr A. I note that Mrs A's surgery was undertaken privately; some elements were covered by health insurance, and some were self-funded. However, the information gathered by this Office does not contain the reasoning for individual decisions made by Mrs A prior to surgery (such as consideration of medical advice or available funding options) and, considering the time passed since the surgery was undertaken, a finding cannot be made regarding this aspect of care.

33. Mr and Mrs A agree that it was Mrs A's choice to proceed with a preventive mastectomy of the right breast because the cancer was very aggressive and had come on quickly, and for cosmetic reasons. They also say they were not advised against the double mastectomy by Dr B and that every decision taken preoperatively was led by Dr B's advice. Dr B stated that he would not proceed with such surgery unless raised by the patient and there were clinical indicators to support it. Dr B acknowledges that Mrs A's family history was not a 'hard clinical indicator' but raises a number of other factors that favoured the decision for the preventive right breast mastectomy. Ultimately, I accept Dr Poole's advice that, while surgery on the right breast did not offer Mrs A a survival advantage, the decision to perform a double mastectomy was appropriate on the basis of improved symmetry, family history, and Mrs A's psychological wellbeing.

34. The poor cosmetic outcome of the surgery is acknowledged. Dr B has stated that he has since moved away from submuscular implantation, although commented it was the standard procedure in 2018. He also accepted that, with hindsight, smaller implants would have reduced some of the problems that occurred. Dr Poole has reviewed the full clinical file and has stated that the surgical technique used by Dr B was of an adequate standard for the time (2018). I accept his advice. Regrettably, Mrs A experienced adverse effects that were documented risks of bilateral breast reconstruction, which, according to Dr Poole, has approximately four times the complication rate of unilateral surgery. This had a detrimental impact on Mrs A's wellbeing as she continued to undergo further treatment for her cancer, and subsequently.

35. I also accept Dr Poole's advice that reasonable information was provided to Mrs A in advance of the surgery. In this respect I note that Mrs A's first consultation with Dr B was on 12 January 2018, with two further preoperative consultations, as well as further discussion on the morning of surgery (26 February 2018). There were also at least four contacts with the specialist breast cancer nurse. I am satisfied that Mrs A was appropriately advised about her options and that she had adequate time to consider her choices that were undoubtedly made with reference to what Dr B had advised her. She was also provided with written material.

36. In respect of the written leaflets provided at the first consultation, it is important to note that they were from 2010[18] and produced for the National Health Service in England. While elements of breast cancer care would be the same, consideration should have been given to the age of the information and New Zealand's different healthcare environment (given the different options available depending on whether the surgery was publicly funded, self-funded, or approved via insurance). Dr B advised that he ensured the spoken and written information provided to Mrs A was current.

37. Additionally, as Mrs A was noted to be anxious and required multiple, extensive consultations with the specialist breast cancer nurse and Dr B, I consider that psychological support may have been beneficial to Mrs A as she came to terms with the difficult decisions she was required to make following her diagnosis. I note that this was not offered due to there being no clinical psychologist at Health NZ at the time.

Chemotherapy

38. Mr and Mrs A are concerned that the treatment plan for postoperative chemotherapy was inexplicably changed to not being required and that it was only reinstated once they requested an oncology appointment and advised the oncologist of the original size of the tumour. They are further concerned that chemotherapy may not have been required.

39. It is clear that chemotherapy was discussed as a possible treatment option with Mrs A prior to surgery but not as the sole option for the treatment of her cancer. A mastectomy was clearly the recommended treatment as noted at the MDM on 24 January 2018 after the MRI results. However, Mr and Mrs A were of the understanding that chemotherapy would be required after the surgery.

40. Notwithstanding this belief, the clinical records show the view that chemotherapy would not offer a survival benefit. This was discussed at two MDMs on 14 and 21 March 2018, and indeed, there is a clinical note from an oncologist that, because the tumour was HER2 positive, there would only be a marginal survival benefit. Chemotherapy was therefore not recommended.

41. I have little difficulty concluding this was contrary to what Mr and Mrs A had been expecting.

[18] Dr B advised that, in 2018, the most relevant and updated leaflets available were dated 2010. The leaflets were not updated until 2023.

42. However, after the oncology advice was given, the histology results were received and reviewed (on 22 March 2018, the day after the MDM) showing Mrs A's tumour staging had increased from pT1 to pT2. This information was critical to the later decision to reinstate chemotherapy treatment.

43. No evidence has been provided to indicate that the decision regarding chemotherapy was reviewed in subsequent MDMs in light of the increased staging. Moreover, the subsequent referral to oncology was only at Mrs A's request.

44. Dr Poole commented on the oncological decision-making, stating that it was inconsistent. He states that a grade 3 tumour in a young fit woman needs adjuvant chemotherapy and that the size of the tumour is only of modest importance. As a result, he has questioned the postoperative oncology plan following the last MDM on 21 March 2018 (not to provide chemotherapy). While Dr Poole is not a direct oncological peer, I acknowledge his scope of practice includes working directly with oncology services and that he regularly relies on such information to determine surgical treatment options. Given this, I am satisfied he has the requisite knowledge of tumour grading and how this informs treatment options, including chemotherapy. I accept Dr Poole's comments in relation to this aspect of Mrs A's care and note Dr C and Dr D also identified that adjuvant chemotherapy was beneficial for Mrs A.

Medication error

45. It is not in dispute that Mrs A received a three-weekly dose of paclitaxel on 20 August 2018 in error. In relation to the dosing error, Health NZ has identified that multiple staff members failed to identify that the wrong medication chart had been printed or that the dose was well in excess of what had been ordered. This resulted in Mrs A being given a three-weekly dose of paclitaxel, which was delivered at the rate a weekly dose should have been given (infused over 1 hour). Mrs A experienced significant pain and discomfort from the side effects of the increased dose as a result.

46. Mr and Mrs A report that they did not find out about the error until the following week and stated that Mrs A's chemotherapy continued as normal that day. However, the contemporaneous clinical notes show the error was identified after three days, an appropriate plan was put in place, and communication was made with Mrs A about the error prior to her next appointment (a phone call from Dr C). Given the time that has elapsed and the impact this may have on the accuracy of recollections, I accept the contemporaneous record that the error was identified, remedial action was taken, and Mr and Mrs A were informed at the time.

Health NZ – breach

47. Health NZ has accepted that an incorrect dose of paclitaxel was given in error to Mrs A and that this was in breach of Right 4(1) of the Code – the right to have services provided with reasonable care and skill. Given the number of clinicians that failed to identify the error, a systemic failing is highly likely regarding the safeguards surrounding the prescribing of potent chemotherapy drugs, and there were missed opportunities to have identified the error. This incident had a serious detrimental impact on Mrs A and was acknowledged to have compounded the already significant side effects of the chemotherapy. I also consider it of particular concern that a Datix report was not made – noting that such reports are

intended to help organisations not just to track errors but also to look for causes and improve patient safety. For these reasons, I find Health NZ in breach of right 4(1) of the Code.

Health NZ – adverse comment

48. I am also concerned about the decision-making process relating to Mrs A's adjuvant chemotherapy, particularly that Mrs A's case does not appear to have been reviewed at MDM following the histology update on 22 March 2018. Three separate clinicians[19] have identified that chemotherapy was indicated based on information that was available at the time, yet it was only due to Mrs A requesting an oncology appointment, and not the post-surgical MDM, that adjuvant chemotherapy was confirmed as appropriate and commenced. In this respect, I accept that Mrs A sought the oncology opinion out of confusion that the treatment plan had changed from that initially agreed to (mastectomy and chemotherapy). This criticism highlights the failure of a system to reconsider fresh information having a direct bearing on the appropriate cancer treatment. I have made a recommendation to address this concern, at paragraph 6 (bullet point 3).

Health NZ – other comment

49. Given the significance of the decisions to be made, particularly of preventive mastectomy, and noting Mrs A's anxiety, I consider there was an opportunity for Mrs A to have been offered psychological support during the initial pre-surgical phase of her cancer treatment in order to provide reassurance and alleviate some of her anxieties. I note that updated guidelines (Ministry of Health's 2021 'Breast Reconstruction: national guidelines for best practice'), which were not available at the time of Mrs A's care, now recommend comprehensive psychological assessment for all patients.

50. Dr B advised that there was no clinical psychologist at Rotorua Hospital when Mrs A was receiving treatment in 2018. While breast care nurses endeavoured to fulfil this role, the only realistic option was for Mrs A to seek psychological support privately. I note that a clinical psychologist has now been employed, and women who are dealing with a breast cancer diagnosis are being referred accordingly.

Dr B – no breach

51. Notwithstanding the clearly unacceptable cosmetic result of Mrs A's breast reconstruction, and Mr and Mrs A's concerns that a mastectomy may not have been indicated (as suggested by the ACC advisor), I have concluded, based on the advice of Dr Poole, that the relevant standard of care (as at 2018) was met in terms of the appropriateness of the decision to proceed to mastectomy, the surgical technique, and the adequacy of information and time for Mrs A to have made an informed choice. Therefore, there is no breach of the Code in relation to Dr B.

Conclusion

52. For the reasons outlined above, I consider that Health NZ has not provided services to Mrs A with reasonable care and skill. Accordingly, I find Health NZ in breach of Right 4(1) of the

[19] Dr C, Dr Poole and Dr D. Dr C had not commenced employment at Health NZ at the time of the 21 March 2018 MDM.

Code. I also make an adverse comment regarding Health NZ's management of post-surgical histology results that were directly relevant to Mrs A's treatment options and particularly adjuvant chemotherapy. I make an 'other' comment in relation to the provision of psychological support by Health NZ to women dealing with a breast cancer diagnosis.

Distribution

53. A copy of this report with details identifying the parties removed, except Health New Zealand | Te Whatu Ora Lakes and the advisor on this case, will be sent to Te Aho o Te Kahu, the Cancer Control Agency and placed on the HDC website, www.hdc.org.nz, for educational purposes.

Morag McDowell
Health and Disability Commissioner

Appendix A: Independent clinical advice to the Commissioner

The following advice was obtained from consultant general surgeon (with special interest in breach cancer) Dr Garth Poole.

'Independent clinical advice to Health and Disability Commissioner

Complaint:	**Mrs [A] / Dr [B]**
Our ref:	**22HDC01559**
Independent advisor:	**Dr Garth Poole**

I have been asked to provide clinical advice to HDC on case number 22HDC01559. I have read and agree to follow HDC's Guidelines for Independent Advisors.

I am not aware of any personal or professional conflicts of interest with any of the parties involved in this complaint.

I am aware that my report should use simple and clear language and explain complex or technical medical terms.

Qualifications, training and experience relevant to the area of expertise involved:	• MBChB Otago 1985, FRACS 1994 • General Surgeon with Breast Cancer, Acute Surgery, Upper GI, HPB, Laparoscopic and Hernia interests. • 26 years as HDC expert advisor. • 24 years NZMC competence reviews external assessor • Foundation surgeon (1996) CMDHB breast cancer clinic (director 2005–15) • Protocols founder CMDHB breast cancer clinic 1996 • Fellowship Nottingham Breast Cancer Unit 1995 • 58 academic publications including seven in breast cancer research
Documents provided by HDC:	1. Complaint dated 27 June 2022 2. Further comments from complainant 2024 3. [Dr B]'s response 18 January 2023 and appendices 4. [Dr B]'s response 30 October 2024 5. Additional clinical records from Health NZ 6. Clinical records from [the private hospital]
Referral instructions from HDC:	1. Whether the bilateral mastectomy was clinically indicated for [Mrs A], including the adequacy of assessments and/or investigations undertaken prior, and whether [Dr B]'s explanations for proceeding with this option were reasonable. 2. What information was usually provided to a patient prior to undertaking this surgery in 2018.

	3. Whether the surgery was performed to accepted standards on 26 February 2018, including comment on the approach/technique used. 4. Any other matters that you consider warrant comment or amount to a departure from accepted standards.

Factual summary of clinical care provided complaint:

Brief summary of clinical events:	a) COMPLAINANT'S PERCEPTION (note: the quality of the consumer's account is extremely good. It has been reproduced with minor corrections and edits) "In late 2017 [Mrs A] noticed a lump in her breast. She was referred to Rotorua Hospital and diagnosed with breast cancer. After an MRI we were informed that the breast could not be saved as the lump was too large compared to the size of the breast and there were satellite lesions of cancer throughout the breast. There was a brief conversation about whether chemotherapy should take place before or after surgery. There was a small delay before the surgery in which [Mrs A] took tamoxifen. She underwent a double mastectomy in February 2018. [Mrs A] elected to have the second breast removed partly because the cancer was very aggressive and had come on quickly and partly because she couldn't face having unequal breasts. Straight after the surgery [Dr B] reported that due to the tamoxifen the lump had reduced in size and the satellite lesions had cleared up. After her recovery from surgery we were told that there would be no need for chemotherapy. Whilst happy about this we were confused, as we had been told it was a certainty at the beginning. After some time we managed to get a referral to an oncologist to raise our concerns. He was confused about why we needed to see him and said that even if chemo was required it was too late to be effective. It was only when we pointed out that they had made all their calculations on the reduced size of the tumour post-surgery, rather than the initial size, that the penny dropped.

	[Mrs A] was then told that chemotherapy would be required after all. When [Mrs A] started her 2nd phase of chemo however after the first dose, she had some issues. She was in pain and felt like she was on fire. She called up and was told it was normal. When we reported this to the chemo nurse at the next appointment she said she knew why the reaction had happened. She had got the dose wrong and given [Mrs A] a double dose at too fast a rate. She then proceeded to give [Mrs A] the normal dose. [Mrs A] never really recovered from this incident and suffered greatly through chemotherapy. It was eventually stopped early due to her condition. The oncologist did say that people are given the dose that [Mrs A] was initially given, but this ignored the rate it was given at, and the fact that those people receive chemo every other week whilst [Mrs A] went on to have her next dose with only a one-week gap. [Mrs A] was also increasingly unhappy about her breast reconstruction, performed by [Dr B]. She felt that it was a poor job right from the start but also had to contend with the trauma of cancer, surgery and chemo. She tried to ignore it but got to the point she couldn't look at herself in the mirror. Despite several hospital check-ups, nobody else raised it as an issue. Eventually [Mrs A] told the hospital she wasn't happy and [Dr B] accepted that it might need looking at. We asked for a referral to someone else and an ACC claim was lodged. We had possibly undergone such extreme surgery that was not required. As such this complaint is two-fold. Firstly that the care and treatment [Mrs A] received was poor to say the least. From us having to point out the decisions around chemo were wrong, and why, to the overdose of chemo to the sub-standard surgery. Secondly, was the surgery required? Quite frankly the four years have been a nightmare.”

	The summary of the complaints is: a. Was the preoperative sizing by examination, ultrasound, mammogram and MRI accurate? b. Was mastectomy needed? c. Was bilateral mastectomy indicated? d. Was the reconstruction satisfactory? e. Was oncology decision-making accurate? f. Was communication adequate? It is important to view the complaints and responses with an understanding of time frame and probabilities. This case is a relatively common scenario 1. All tests have a sensitivity and specificity. A sensitive test will pick up all pathology as well overall with a wide safety margin (false positive). A specific test will only call a result when absolutely certain but misses many (false negative) 2. A breast surgeon will endeavour to do conservative surgery on the breast and axilla if possible, unless the radiology, pathology or the patient choice dictates otherwise. 3. The investigation of a breast cancer evolves in step wise fashion with a number of steps with different sensitivities and specificities. Advice given on day one will change as more information is gathered until the final preoperative discussion. This is particularly important in operative choices. 4. The 100% specific test is postoperative pathology. At this point there is a total reset as this result will set the tone for adjuvant treatment and 15-year prognosis. It is extremely rare to have an exact match of the preoperative measurements and the postoperative results.

Question 1: Whether the bilateral mastectomy was clinically indicated for [Mrs A], including the adequacy of assessments and/or investigations undertaken prior, and whether [Dr B]'s explanations for proceeding with this option were reasonable.	
List any sources of information reviewed	The CMDHB (Middlemore hospital) breast cancer MDM is the main source of information.

other than the documents provided by HDC:	This meeting is held weekly and currently over 500 cases of breast cancer are discussed per year (76 in 1996). This meeting covers all the issues in the case. This meeting is based on evolved 30-year protocols and extensive international and local academic research. The unit has also published in several areas and consists of members who belong to BSANZ and the Auckland Breast Cancer Study group. Each case is discussed with an emphasis on the recommended treatment and what choices should be offered. The six surgeons take care to "stack" the recommendations vertically so that a patient is aware of the best option. A choice is always given when the survival options are equivalent. The three main breast operations are: 1. Partial mastectomy (+/-) partial reconstruction 2. Full mastectomy 3. Full mastectomy with reconstruction (immediate or delayed) There is either a recommended operation or a situation in which there is a choice. Factors include tumour-to-breast size ratio, position, previous surgery, radiation intolerance, multifocality, age, strong family history, BRCA gene, occupation, sport, partner views. Partial mastectomy is a good option in about 50% of patients (NSABP06). An incorrect recommendation for partial surgery may lead to reoperation in up to 50% of patients due to positive margins or recurrence. The axillary surgery is based on preoperative information and has the following options: 1. No surgery 2. Sentinel node biopsy 3. Axillary sample 4. Axillary dissection (level 1, 2, 3) (SNAC study RACS)

	Radiotherapy is recommended based on partial mastectomy, size of tumour, lymph nodes, grade, margin, multifocality, recurrence, receptors. Radiotherapy reduces recurrence by 75% and has some survival advantage. Systemic treatment (hormones, chemotherapy) is recommended based on positive lymph nodes, grade, size, age, comorbidities, cancer receptors (ER, PR, HER2). Systemic therapy reduces death by 20% in every prognostic group. Increasingly, the systemic treatment is given preoperatively (neoadjuvant) if the tumour is large, high grade and if the receptors are favourable. Occasionally the chemotherapy is given to reduce the tumour size to allow for partial mastectomy. Tumour response to preoperative chemotherapy is variable and is graded 1–5 (Miller-Payne) The geometry of the response is divided into two main groups: 1. overall shape and size the same but "Swiss cheese" effect 2. tumour shrinkage concentrically, "apple goes to walnut" Large multifocal tumours are not favourable for shrinkage, and partial mastectomy surgery is rare. The formula for volume of a sphere is R to the power of three. Therefore, a 5cm diameter tumour is roughly five times bigger in volume than a 3cm diameter tumour (5x5x5 = 125 cubic cm and 3x3x3 = 27 cubic cm). Breast size/weight has a roughly 10 times variation from patient to patient (from 200g to 2kg) (Rayen, Poole et al).
Advisor's opinion:	**The decision to recommend mastectomy was correct.** Extensive assessment with examination, ultrasound, mammogram and MRI eventually arrived at a size of about 50mm (up from 26mm on ultrasound/mammogram), with multifocality. Due to the equation (4/3piR3) the volume of the largest estimate (MRI) was approximately seven times bigger than the smallest estimate (ultrasound). Size estimate is more difficult in premenopausal women and in dense breasts and in certain types of cancer.

	MRI is an excellent tool for finding unexpected tumours. However, overestimation of tumour size by MRI is relatively common. It is [a] sensitive test. **The decision to perform bilateral surgery was appropriate.** Bilateral surgery is often performed due to patient choice Family history, symmetry and balance, sporting interests, husband support and psychological wellbeing are all relevant. There was no survival advantage from this surgery in this case. The surgery was more extensive than doing two separate operations. There is, however, an advantage to having one big operation for symmetry and psychological wellbeing. The healing time is significant.
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/material.	**Standard of care was appropriate**. The decision-making would have been supported by the CMDHB MDM and most cancer units in Australasia.
Was there a departure from the standard of care or accepted practice? • No departure; • Mild departure; • Moderate departure; or • Severe departure.	**No departure from accepted practice**. There was evidence of a clear diagnosis, multiple consultations from the surgeon and nurse, and time to digest the information.
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	**Satisfactory care.** The diagnosis and surgical care would be supported by the CMDHB MDM
Please outline any factors that may limit your assessment of the events.	No limitations. Clear concise communication from the family and the HDC.
Recommendations for improvement that may	Emphasising to all women with breast cancer that diagnosis and treatment has multiple evolving steps.

help to prevent a similar occurrence in future.	It is important to outline what is a recommendation and what is a choice.

Question 2: What information was usually provided to a patient prior to undertaking this surgery in 2018.	
List any sources of information reviewed other than the documents provided by HDC:	CMDHB MDM
Advisor's opinion:	The information transfer in this case was reasonable. A patient in this situation will should be cared for by a breast cancer team. This will involve a diagnostic phase with a surgeon, nurse specialist, radiology, pathology, and MDM. Information packs are given. Consultations will be multiple, especially if choices are offered. The patient will have support and often the internet allows for questions to be raised.
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/material.	Accepted standard of care occurred consistent with 2017/2018 CMDHB MDM.

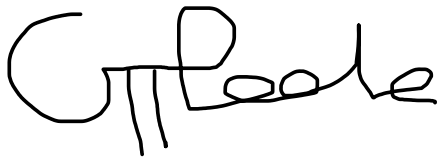
Question 3: Whether the surgery was performed to accepted standards on 26 February 2018, including comment on the approach/technique used.	
List any sources of information reviewed other than the documents provided by HDC:	CMDHB MDM
Advisor's opinion:	The surgery in this case was to an accepted standard. Bilateral surgery has approximately four times the complication rate of unilateral. The breast operative site requires lymphatic drainage to heal. Part of that healing relies on the opposite side in unilateral cases.

	Despite these increased complication rates, one large operation has benefits psychologically and in achieving symmetry. The cosmetic results in this case are only adequate at best. This is common in immediate reconstruction, and revision is clearly needed to get optimum results. Matching the prophylactic side to the treatment side is challenging due to the cancer surgery needing to be closer to the skin in some areas. Implant surgery has challenges with size of implant, migration, cleavage symmetry, nipple height, nipple sensation. The body can react differently to the implant on the side with axillary surgery.
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/material.	This operation was of an adequate standard at this time. CMDHB MDM
Was there a departure from the standard of care or accepted practice? • No departure; • Mild departure; • Moderate departure; or • Severe departure.	No departure
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	Accepted. CMDHB MDM
Please outline any factors that may limit your assessment of the events.	Nil
Recommendations for improvement that may help to prevent a similar occurrence in future.	It is helpful to compartmentalise advice and expectations. Initial phase is diagnosis and sizing and recommendations for cancer surgery. Next was the decision to have prophylactic surgery.

	Next was reconstruction It is important to keep recommendations and choices separate. Each intervention has pros and cons and complications, which are probably best discussed at each junctional decision. Careful understanding that the diagnostic and treatment process is stepwise. All preoperative tests are estimates with different sensitivity and specificity. Recommendations and choices should be carefully explained.

Question 4: Any other matters that you consider warrant comment or amount to a departure from accepted standards.	
List any sources of information reviewed other than the documents provided by HDC:	CMDHB MDM
Advisor's opinion:	1. The tamoxifen almost certainly did not drastically reduce tumour size preoperatively. It is far more likely the MRI overestimated the size and multifocal nature. 2. The decisions by oncology are inconsistent in this. A grade 3 tumour in a young fit woman needs adjuvant therapy, usually chemotherapy. The size is of modest importance. Adjuvant therapy reduces death by 20%. 1) The receptors were inconsistent in various correspondence especially HER2. 2) The consumer is intelligent and perceptive. They have been required to process an enormous amount of information. Some information is a recommendation, and some information is a choice. They have gone through a diagnostic phase, a consultative phase, a surgical phase and postoperative phase, an oncology phase and a follow-up phase.

What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/material.	Accepted practice.
Was there a departure from the standard of care or accepted practice? • No departure; • Mild departure; • Moderate departure; or • Severe departure.	Possibly a moderate departure in the postoperative oncology plan. This will be addressed through separate advice.
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	The surgical care was satisfactory (CMDHB MDM).
Please outline any factors that may limit your assessment of the events.	No limitations
Recommendations for improvement that may help to prevent a similar occurrence in future.	It is helpful to compartmentalise advice and expectations. Initial phase is diagnosis and sizing and recommendations for cancer surgery. Next was the decision to have prophylactic surgery. Next was reconstruction. It is important to keep recommendations and choices separate. Each intervention has pros and cons and complications, which are probably best discussed at each junctional decision. Careful understanding that the diagnostic and treatment process is stepwise. All preoperative tests are estimates with different sensitivity and specificity. Recommendations and choices should be carefully explained

By signing this report, I agree to HDC correcting any formatting, spelling, or grammar issues on the proviso that the substance of the report and any quoted material remains unchanged.
 Signature:
Name: Dr Garth Poole
Date of Advice: 23 September 2025