Health New Zealand|Te Whatu Ora Lakes
General Surgeon, Dr B

A Report by the
Health and Disability Commissioner

(Case 20HDC00204)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report relates to the care provided to a woman in 2018 by a general surgeon and Health New Zealand|Te Whatu Ora (Health NZ) in relation to her breast cancer. Primarily the woman was concerned about the standard of reconstruction surgery undertaken following a double mastectomy. However, as the investigation progressed, other issues emerged, including whether the woman had received appropriate advice regarding her treatment options. The woman's care was managed through the breast service, but because of the structure of the service, no clinician had overall responsibility for her care prior to her planned surgery. As a result, on the morning of surgery, the general surgeon questioned the woman's treatment plan, which included whether she should proceed with the planned procedure that day.

2. The report also discusses the adequacy of the general surgeon's preoperative discussions with the woman about the risks and benefits of a prophylactic double mastectomy in light of her risk of cancer recurrence or life expectancy.

Findings

3. The Commissioner considered that the system in place to guide the woman through her breast cancer treatment was inadequate, in that during the stages of diagnosis and forming of the initial treatment plan, no clinician held ultimate responsibility for her care. The Commissioner found Health NZ in breach of Right 4(5) of the Code for the lack of cooperation among providers to ensure that the woman received continuity of care.

4. The Commissioner considered that the woman was not counselled adequately on the benefits and risks of prophylactic double mastectomy and the alternative treatment options available to her in light of her circumstances. The Commissioner found the general surgeon in breach of Right 6(1) of the Code for failing to provide appropriate information to the woman to allow her to make a fully informed decision on her treatment. Accordingly, the surgeon was also found in breach of Right 7(1) of the Code for failing to obtain the woman's informed consent for the double mastectomy.

Recommendations

5. The Commissioner recommended that Health NZ provide an apology to the woman and update HDC on its new guidelines around prophylactic mastectomies, including a prompt for clinicians to consider a referral for patient counselling and multidisciplinary consideration. The Commissioner also recommended that Health NZ use an anonymised version of this report for staff training.

6. The Commissioner recommended that the general surgeon provide an apology to the woman; complete the HDC online learning modules; and undertake an audit of his clinical documentation and advise HDC of the remedial actions taken for any identified deficiencies.

Complaint and investigation

7. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided to her by Dr B and Health New Zealand|Te Whatu Ora (Health NZ) Lakes (formerly Lakes District Health Board).[1]

8. The following issues were identified for investigation:

- *Whether Health New Zealand|Te Whatu Ora provided Ms A with an appropriate standard of care in 2018.*
- *Whether Dr B provided Ms A with an appropriate standard of care in 2018.*

9. The parties directly involved in the investigation were:

Ms A	Consumer
Dr B	Consultant general surgeon/provider
Health NZ Lakes	Provider

10. Further information was received from the Accident Compensation Corporation (ACC), Dr C (a consultant general surgeon), Dr D (a general surgeon), CNS E (a clinical nurse specialist), and Dr F (a general surgeon).

11. Independent advice was obtained from Dr Sally Langley, a plastic and reconstructive surgeon (Appendix A), and Dr Erica Whineray Kelly, a general surgeon (Appendix C).

12. Treatment injury advice obtained by ACC from Dr G, an oncoplastic breast and general surgeon, is included as Appendix B.

Information gathered during investigation

Diagnosis and initial appointments

13. On 26 March 2018, Ms A had a tissue biopsy of her left breast. A report dated 29 March identified a small tumour. On 4 April 2018, Ms A was told that she had breast cancer.

14. A record of a Health NZ multidisciplinary meeting (MDM) dated 4 April 2018 states that Ms A was diagnosed with a Grade 1[2] invasive[3] carcinoma. It records the recommended surgery

[1] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Te Whatu Ora|Health New Zealand. All references in this report to Lakes District Health Board now refer to Health NZ Lakes.
[2] A low grade indicates that the cancer is slow growing and less likely to spread.
[3] 'Invasive' in this case is used to mean a true cancer as opposed to a pre-cancer. Pre-cancers in breast tissue are usually carcinoma cells confined to the breast ducts or lobules that have not broken out to grow in the surrounding tissue.

as a wide local excision (WLE)[4] and sentinel node biopsy (SNB[5]), and that for the right breast, no treatment was required at that stage. A handwritten comment states: 'Family H[is]t[ory] post-menopausal Breast Ca[ncer].' A general surgeon, Dr D, said that family history is considered at the MDMs.

15. Health NZ provided HDC with nursing notes recording discussions between Ms A and a clinical nurse specialist (CNS), CNS E. The 4 April 2018 note records their discussions about the diagnosis and treatment options, including breast reconstruction. Ms A was given the opportunity to ask questions.

16. Dr D also saw Ms A on 4 April after the MDM (which he attended). Dr D told HDC that he would have discussed the MDM treatment recommendations with Ms A, all surgical options, the complications of the therapy, and the required postoperative need for radiotherapy. However, HDC was not provided with any clinical notes specifically recording that these issues were discussed with Ms A on 4 April.

17. An outpatient clinic letter[6] prepared by Dr D stated:

> '[Ms A] has had an opportunity to discuss this with her friend and her mother who has had breast cancer and a number of other individuals and is very keen to head for a conservative approach.'

18. The clinic letter did not contain any further details about Ms A's mother's cancer. However, Ms A told HDC that in respect of her family history, she had been questioned about it and had provided her mother's history of bilateral[7] breast cancer to both general surgeon Dr C and CNS E.

19. General surgeon Dr B (who had not yet met Ms A) told HDC that on 6 April, his breast cancer nurse also obtained the family history of bilateral breast cancer (and nil else) and asked Dr B to refer Ms A to the genetic services for testing, which he did. Dr B told HDC that this was requested prior to Ms A being allocated to his care and onto his operating list, and that he had no knowledge of Ms A as a patient at this point. Dr B stated: 'I progressed the referral as part of the shared administrative tasks that take place in the operation of the Breast Service.'

20. In response to the provisional opinion, Dr B told HDC that CNS E informed him that the referral to the genetic services had not been made by the clinician responsible for Ms A 'despite her request' (it is unclear who this clinician was) and therefore she asked Dr B to do it. He said that, as far as he was aware, the clinicians concerned 'knew about this [genetic] referral' and his belief was that the other clinicians were 'dealing with the situation'.

[4] The surgical removal of a tumour along with a surrounding margin of normal tissue.
[5] Where the first lymph nodes to which cancer cells are likely to have spread are removed to analyse whether the cancer has spread.
[6] A letter sent to patients following their clinic appointment outlining the discussions and advice of the clinician.
[7] Bilateral breast cancer is a type of cancer in which tumours are found simultaneously within both breasts.

21. Dr B told HDC that no notification is received when patients are transferred on to a particular surgeon's surgical list until the surgeon receives the theatre list for the day in question (usually 24–48 hours prior to the day of surgery). He said:

> 'The shared-care service, in the context of full workloads in a busy provincial hospital, relies on accurate and appropriate care provided at each patient interaction, prior to surgical procedures taking place. This is required where workloads and scheduling often make it impossible to arrange a clinic appointment to address any "missing information" at short notice.'

Excision and biopsy

22. On 3 May 2018, Ms A attended Rotorua Hospital to undergo a WLE with SNB to remove the tumour. She met with Dr B for the first time at this appointment.

23. Ms A's mother attended the hospital with her. Dr B told HDC that during discussions with him about family history, Ms A's mother explained that in addition to her own breast cancer,[8] other family members had suffered various cancers, including breast cancer. Ms A said that prior to 3 May 2018, she had not told breast clinic staff about any family cancers other than her mother's because she had been unaware of them. Accordingly, at this point none of the other clinicians involved in Ms A's care were aware of this additional history.

Dr B

24. In respect of what information Dr B was aware of prior to meeting Ms A and her mother on 3 May, Dr B said that he had reviewed Ms A's clinical file and noted a comment by another clinician about Ms A's mother's breast cancer. He said that he was unaware of the nature of Ms A's mother's breast cancer or of the additional family history. Dr B said that the information he was aware of prior to 3 May 'raised some questions', and he considered there to be evidence of some familial risk factors. He said that it was unclear to him at this stage how far these risk factors had been explored. In response to the provisional opinion, Dr B said that if he had been aware that this history of the additional family cancers had not been taken at all, he would have informed the other clinicians (in the service) about this new finding.

25. Dr B said that he considered some of the information learned on 3 May to be 'significant', including 'the extent of the family history of cancer [and] the nature of [Ms A's] mother's cancer as triple negative'.

26. Dr B told HDC that patients with triple negative cancer (such as Ms A's mother) are recommended to have genetic testing done, as certain types of genetic abnormalities can be passed down from mother to daughter, meaning that Ms A's mother's history[9] of cancer may have increased the risk of cancer in Ms A. At this stage, Ms A had not yet completed her genetic testing, although, as noted above, a referral for that testing had been made on 6 April. Dr B explained that if Ms A's testing had revealed a genetic link, it could have

[8] Ms A's mother had suffered bilateral immediate post-menopausal breast cancer that was triple negative (a type of breast cancer that does not have any of the three receptors commonly found on breast cancer cells).
[9] Ms A's mother had not undergone any genetic testing, as her tumours preceded the guidelines.

changed the recommendation for surgery, so that breast conservation was no longer the preferred option, and instead a mastectomy[10] may have been recommended.

27. Dr B advised that definitive surgery undertaken in a single sitting typically results in better outcomes, as there is less chance of swelling due to prior surgery or infection, the surgeon is going through native tissues (ie, the patient's own breast tissue), and the incision position is not constrained by previous surgery.

Health NZ

28. In a letter from Dr F, Health NZ Lakes explained why Ms A met Dr B for the first time only on the morning of her surgery (3 May 2018). Dr F said that the breast clinic is held once per week, and the three consultant surgeons (Dr B, Dr C, and Dr D) see patients on a rotational basis. Patients are seen and treated by 'the service' rather than a particular clinician. Dr F noted that the clinical nurse specialist ensures that when a patient is managed through the breast service, they are kept up to date with care plans (which provides continuity of care). The clinical nurse specialist also arranges further surgical consultations preoperatively or postoperatively depending on the patient's needs.

29. Dr F commented that Health NZ has not found this approach to be a concern for patients. He said that any confusion around Ms A (referring here to the fact that her full and significant family history was discovered only on the day of her scheduled surgery) was the result of a family history that was not fully appreciated at the time of her MDM discussion to determine the appropriate surgical recommendations.

Discussions about procedure

30. Ms A told HDC that on learning of the additional family history on 3 May, Dr B gave her the option to reconsider the excision and biopsy procedure she was scheduled to have that day, as additional surgery might be required to minimise the chance of reoccurrence. Ms A said that at this point she was fully prepped for surgery, including having had a radioactive dye[11] injected the previous day and a hook wire[12] inserted that morning.

31. Dr B said that he advised Ms A that if she elected to wait, the wire in situ would be removed, and they could consider using agents like Tamoxifen[13] to stop the development of the tumour.

32. Dr B said that he also explained to Ms A the implications of significant family history, the heightened risk of further cancer if a genetic link was established, and the ways in which this could be managed. He said that he advised Ms A of the possible implications/risks of proceeding with the WLE and SNB (being that future reconstructions may be more complicated). Dr B said that he also discussed with Ms A the potential benefits of going

[10] Surgical removal of the breast tissue.
[11] A harmless dye and a weak radioactive solution are injected into the patient to locate the sentinel nodes.
[12] If there is an abnormality in the breast that cannot be felt easily but requires surgical removal, a hook wire can be used as a marker for the surgeon, with its tip at the site of the abnormality. The 'hook' at the end of the wire prevents the wire from moving out of position before the surgery.
[13] A hormone therapy used to treat hormone receptor-positive breast cancer.

ahead with the WLE and SNB procedure, and that it was open to her to continue with the procedure and afterwards they 'could expedite the family history assessment so that an appropriate way forward could be ascertained'. He told HDC:

> 'I made it clear to [Ms A] that in light of the new information, it was open to her to delay the operation until we had the results of the genetic testing, and better understood what we might be dealing with.'

33. Dr B said that Ms A had not had these discussions previously.

34. In response to the provisional opinion, Dr B said that he believed that the other clinicians were 'dealing with the situation' (see paragraphs 20–21 above) and that this is why he did not bring Ms A back to the clinic to take a more detailed history following the appointment on 3 May.

35. The information that Dr B said he discussed with Ms A (as noted in paragraphs 30–32) is not recorded in the clinical notes.

36. Dr B said that he offered Ms A some time to consider her options, but Ms A elected to proceed with the surgery for which she had been prepared, and Dr B performed the WLE and SNB.

37. Dr B documented that the type of incision he used in the WLE was a 'concentric mastopexy type incision', although later he advised HDC that this was an error, and the incision should have been described as a 'crescentic' mastopexy.

Post-excision

38. A nursing note from 4 May 2018 by CNS E records the postoperative care discussions with Ms A, including that Ms A was 'full of questions' about next steps and the possibility of a mastectomy. The note also records a discussion about mastectomy and that Ms A was provided with related information.

39. On 16 May 2018, Ms A attended a postoperative appointment with Dr B. The results of the biopsy showed that the operation had been successful, and Ms A was referred for radiotherapy and drug therapy[14] to complete her treatment.

40. The results of the genetic testing were still not available at that time, but Dr B provided Ms A with a pamphlet titled 'Royal Marsden NHS foundation Trust: A Beginner's Guide to the BRCA1 and BRCA2[15]'. In response to the provisional opinion, he said that he drew Ms A's attention specifically to a section that deals with available options that do not involve surgery, a section that details different surgical approaches used, and a section that deals with the mechanisms of screening and risk reduction. Dr B said that he discussed these sections in detail with Ms A, and he provided this pamphlet because the nature of Ms A's mother's breast cancer was highly suggestive of BRCA abnormalities. Dr B also provided Ms

[14] Tamoxifen, a drug used to treat and prevent breast cancer.
[15] BRCA1 and BRCA2 are genes that, if mutated, greatly increase an individual's chance of breast cancer.

A with the BAPRAS[16] guide to breast reconstruction, and the Aotearoa New Zealand Ministry of Health guidelines on Management of Early Breast Cancer.[17]

41. An MDM record from 16 May 2018 notes details of the WLE and SNB surgery and the biopsy result and records the family history as: 'Patient's mother has had x2 breast cancer triple negative post-menopausal and grandmother bowel ca[ncer].' The treatment recommendation was for radiation therapy, endocrine therapy (with the note, '[Ms A] not keen on endocrine therapy but willing to discuss'), and a further referral to genetics.

42. Dr B told HDC that he saw Ms A again on 18 May 2018 with her mother present, at which time they discussed genetic defects and the implications of these, including that a negative result (in respect of the genetic testing) would be only in respect of known genetic abnormalities, and that it did not mean that Ms A was not at risk from unknown genetic cancer risks.

Mastectomy

Initial discussions: 18–28 May 2018

43. A nursing note from 18 May 2018 made after the meeting with Dr B records CNS E's telephone advice that Ms A needed only a radiotherapy referral at this point, and that she should await the genetics results to determine whether a bilateral mastectomy was required. In response to the provisional opinion, CNS E told HDC: 'Despite our best efforts to dissuade her from undertaking further surgery, we were unable to change her mind.' No detail has been provided regarding the efforts made, and such discussions are not noted in the clinical record.

44. Ms A saw Dr B again on 28 May 2018. A telephone note (made by a Health NZ breast cancer nurse) records that this clinic appointment was initiated by Ms A, and that she had specifically asked to discuss a bilateral mastectomy because she was concerned about reoccurrence of her breast cancer. At this time, the results of the genetic testing were still not available, but they discussed a bilateral mastectomy and immediate reconstruction. Dr B explained to HDC that it was Ms A who wished to discuss a prophylactic bilateral mastectomy. He said that he provided her with information on reconstruction, explaining the different possible procedures, and the pros and cons of each. He said that he gave Ms A the opportunity to ask any questions and advised her to review the printed resources he had provided previously.

45. A letter written by Dr B to Ms A's GP dated 28 May 2018 records the discussions at the appointment that day. The letter notes:

> 'We went into details about [if she should] undergo reconstruction, what would be best for her. [Ms A] has agreed to undergo bilateral implant-based reconstruction after also

[16] British Association of Plastic Reconstructive and Aesthetic Surgeons.
[17] https://www.health.govt.nz/system/files/documents/publications/mgmt-of-early-breast-cancer-aug09.pdf Accessed 25 July 2022.

considering latissimus dorsi and bilateral DIEP, TRAM reconstructions.[18] She was measured up and implants were ordered today.'

46. In response to the provisional opinion, Dr B told HDC:

> 'It is my usual discussion with patients that prophylactic mastectomy removes 95% of breast tissue, but not all and a small risk still persists. I am sure that this discussion was undertaken with [Ms A].'

47. There is nothing in the clinical notes to indicate that this information was discussed with Ms A.

48. There is also nothing in the clinical notes that documents a discussion about whether the surgery was appropriate in light of the lack of information about genetic testing, or whether the surgery would be beneficial in terms of preventing cancer recurrence/reducing Ms A's risk of death from cancer. Ms A stated that she could not recall whether anyone spent time with her exploring her reasons for choosing mastectomy, and she told HDC that she does not recall discussing the possibility of a single mastectomy rather than a contralateral mastectomy.

49. In response to the provisional opinion, Dr B told HDC that all his discussions with Ms A about options, risks, and benefits of surgery were supplemented by detailed discussions between CNS E and Ms A. He said that this is why he did not take detailed notes of these discussions. He said: '[CNS E] informed me that [Ms A] could not be dissuaded from proceeding to more radical surgery.' In addition, Dr B said that the evidence that prophylactic mastectomy does not offer a survival benefit over alternative options was not current at the time of the events, and that '[r]eports of a significant reduction in occurrence of second breast cancers were available [at that time]'.

50. Ms A opted for a bilateral mastectomy with immediate reconstruction. She told HDC that she opted for implant-based reconstruction, as she did not have the fat volume available for reconstruction and, as a very physical person, she did not want to use either shoulder or abdominal muscles. She was advised to have the implants inserted under the pectoral muscles to help cover them.

Results of genetic testing — 11 June 2018

51. The results of the genetic testing were communicated to Ms A in a telephone call on 11 June 2018 and a follow-up letter on 12 June 2018. The tests revealed no recognised genetic abnormality. The 12 June letter records Ms A's mother's cancer, and that '[o]ther reported cancer history includes, bowel, brain, prostate and additional breast cancers'. Based on the

[18] Instead of using a synthetic implant to reconstruct the breast, it is possible to use the patient's own tissue. A latissimus dorsi flap reconstruction uses the patient's back muscle (and skin, fat, and blood vessels) to replace the lost breast tissue. A DIEP flap reconstruction uses fat, skin, and blood vessels (but no muscle) from the lower stomach, and a TRAM flap reconstruction uses skin, fat, blood vessels, and part or all of the underlying 'six pack' muscle.

test results, the letter predicted between a 4% and 18% chance of contralateral breast cancer for Ms A over the following 5 to 25 years respectively. The letter also states:

> '[I]t is difficult to predict what [your cancer] risks are likely to be. It is possible that there is a genetic risk in your family, but that you have not inherited it and your diagnosis of breast cancer is not genetically linked to your mother's diagnosis. However, there is also a chance that there is a genetic link in your family in a gene that we have not done testing in.'

Further discussions/consent for mastectomy — 13 June 2018

52. Ms A saw Dr B again on 13 June 2018. By that time, Ms A was aware of the results of the genetic testing. Dr B told HDC that at the 13 June clinic appointment, he worked through the consent form for the mastectomy and reconstruction surgery with Ms A.

53. A letter from Dr B to Ms A's GP of 14 June 2018 records the discussions, including the benefits and risks of the surgery (including the risk of implant loss, bleeding, and infection), scars, possible effects of the chosen incision type, and a likely loss of feeling in Ms A's nipples. It was also discussed that Dr B could not guarantee that the breasts would be perfectly symmetrical. A 2cm nipple lift was also planned to match the mastopexy carried out on the left-hand side in the earlier operation.

54. Dr B told HDC that he advised Ms A that further surgery might be required in the future, and he discussed with her the reduction in risk of cancer recurrence arising from the mastectomy.

55. Ms A told HDC that she spent considerable time educating herself on the relative risks and benefits of mastectomy versus radiation therapy, including a visit to another hospital's Radiation Oncology Department to learn about the risks of radiation therapy. She said that she chose mastectomy mainly because she was concerned about the potential long-term risks of radiation damage. Ms A also told HDC that no clinicians attempted to dissuade her from choosing mastectomy over radiation therapy, and she could not recall whether anyone spent time with her exploring her reasons for choosing mastectomy.

56. Dr B told HDC that Ms A had communicated anxiety about developing further cancers and was motivated to preserve her health. He said that he considered that it was appropriate to take Ms A's preferences into account and undertake the requested procedure. Dr B said that despite the results of the genetic testing, he did not consider the risk associated with Ms A's family history of cancer to be minimal. He said that the genetics team confirmed that Ms A had a higher risk of developing breast cancer than the normal population 'and were not definitive that the family history described prompted no risk'. Dr B referenced an email of 11 June 2018 from the genetic counsellor, which confirmed that uncertainty remained regarding Ms A's risk for bilateral breast cancer and that the possibility of a genetic link to her mother's cancer could not be excluded.

57. In view of the WLE and the genetic results, and following her own research, Ms A decided not to undergo radiation therapy and endocrine therapy (which was the recommended next step after a WLE and SNP), instead opting for a mastectomy.

58. There is no evidence that other treatment options were considered further following receipt of the genetic test results, nor that the benefits of the surgery or Ms A's reasons for wanting the surgery were explored. Dr B told HDC:

> 'Ultimately, I did not consider it was my role to persuade or dissuade/discourage [Ms A] from a particular choice. I considered my role … was to provide her with information relevant to the procedure, including the risks, benefits and alternatives — and leave it to [Ms A] to decide what she wished to do.'

59. In response to the provisional opinion, Dr B said: 'The alternative treatment options available to [Ms A] following the results of genetic testing are the same options we already had discussed.'

60. The consent form signed by Ms A on 13 June 2018 states the risks discussed as bleeding, infection, 'not a perfect match', '?secondary surgery', and a handwritten comment that is illegible. The form also states:

> 'I agree that I have been able to discuss the proposed treatment/procedure with the Health Professional named below who has explained the possible benefits and risks to me of the treatment/procedure(s) relating to my clinical history and condition.'

Rationale for bilateral mastectomy and reconstruction

61. In respect of the decision to perform a mastectomy on Ms A's left breast, Dr B told HDC that he considered radiotherapy was the 'opportune course' to pursue in the circumstances, while the genetic information was awaited. However, following this and Ms A's decision not to undergo radiotherapy, Dr B said the surgical management option of mastectomy 'was entirely appropriate and indicated (where radiotherapy was not taking place) for the [left breast]'. He said that the WLE is 'complete' only if accompanied by postoperative radiotherapy, and (following the WLE & SNB on 3 May) Ms A chose not to undergo radiotherapy. Dr B said that even in the absence of significant family history, all patients with breast cancer have the surgical option of either a WLE or a mastectomy.

62. In respect of the decision to perform a mastectomy on Ms A's right breast, Dr B initially said that prophylactic contralateral mastectomy[19] is offered to all patients, should they request it — which Ms A did, after the option was explained to her. Dr B said that it is not unusual for prospectively high-risk patients to ask for a contralateral prophylactic mastectomy, and the treatment option is not reserved for patients with aggressive disease.

63. However, in a later response to HDC, Dr B said that he wishes to make clear that it was not (and is not) common or usual practice to offer contralateral prophylactic mastectomy, and that the above comments were made only in respect to Ms A's case. Dr B said that while it

[19] In addition to removal of the breast where the tumour was found, removal of the other breast.

is clear from his initial management recommendations that he did not propose contralateral mastectomy as the preferred course, prophylactic mastectomy is an available procedure in New Zealand in such qualifying circumstances.[20] He stated:

> '[W]hen faced with an anxious patient, and documented evidence of some risk, a prophylactic mastectomy can be proposed as an option. Sometimes, patients proactively [propose] it themselves … If patients asked me about it, I provided them with information and recommendations appropriate to their particular circumstances.'

64. In explaining the rationale of performing the bilateral mastectomy, Dr B also referenced the results of the genetic testing and that he did not consider the risk associated with Ms A's family history of cancer to be 'minimal' (discussed further at paragraph 56 above).

65. In responding to Ms A's complaint, Health NZ included a letter from another consultant general surgeon, Dr C. Dr C had seen Ms A earlier in her treatment journey on 28 March 2018. In the letter, Dr C commented:

> 'Looking through this patient's notes, I am perplexed by two issues:
>
> 1. Why this patient refused radiotherapy treatment immediately after her initial surgery.
>
> 2. Why this patient was ultimately offered extensive surgery in the form of bilateral mastectomy including a prophylactic contralateral mastectomy given this patient's essentially minimal risk factors pertaining to her family history and tumour characteristics. This surgical option was not discussed at any of our breast cancer MDM's.'

66. Dr B told HDC that the therapeutic decisions made at the MDMs were made without appreciation of Ms A's 'very significant risk of developing familial breast cancer'.

67. A report obtained by ACC from Dr G, an oncoplastic breast and general surgeon, following a later treatment injury claim by Ms A, commented on whether a bilateral mastectomy was indicated in Ms A's case. Dr G's report is annexed to this report (Appendix B). Dr G wrote:

> '[T]his small cancer, if managed with the standard method of WLE followed by Radiotherapy, would have likely been the only cancer episode in this patient's lifetime … Based on documentation provided by ACC, there is no compelling evidence to support double mastectomy in [Ms A's] case. The long-term outcome for small early breast cancers is equivalent for breast conservation followed by Radiotherapy, compared to

[20] Dr B referenced the Ministry of Health Guidelines for 'best practice' breast reconstruction: 'Some women with unilateral breast cancer are advised to have a contralateral mastectomy due to medical reasons such as a proven high familial or genetic risk of breast cancer. Others may wish to discuss their eligibility for a contralateral mastectomy either at the time of the initial treatment or at a later date due to the patient's perception of increased risk of cancer recurrence and associated anxiety or body image, symmetry, and comfort preferences' (Buchanan et al 2016, Hawley et al 2014).

mastectomy alone. In other words, there is no survival advantage by undergoing a mastectomy with small breast cancers.'

Procedure — 21 June 2018

68. On 21 June 2018, Ms A underwent a bilateral mastectomy and implant reconstruction. The procedure used Mentor brand silicone implants[21] placed underneath the pectoral muscles, and a synthetic mesh[22] to cover the lower part of the implant, attached to the muscle by sutures. Thin skin flaps were raised to cover the new material. The nipples were preserved using a 'lollipop' type vertical incision.

69. The theatre report for the operation records the indications for the surgery as: 'Previous wide local excision plus sentinel lymph node biopsy. Family history +++. After genetic testing patient chose to have a bilateral mastectomy and reconstruction.'

70. Ms A told HDC that the procedure appeared to go well but, on waking, she was concerned about the asymmetrical size and position of the breasts. She also said that she had read that it was best practice to review the colour of the nipples post-surgery to ascertain if there are any issues with blood supply, but the dressings were opaque and did not allow for this to be done. She said that she raised the issue with a nurse in the recovery ward but was told that they were following standard practice.

Postoperative recovery

71. When the dressings were removed on 29 June 2018 by a community nurse, necrosis[23] was noticeable on both nipples.

72. On 1 July 2018, Ms A attended the Rotorua Hospital outpatient clinic and saw another consultant. The visit took place because Ms A had a cough, and the cough had triggered pain around the site of the recent surgery. The clinical record of the visit states that the pain could be sharp in nature, felt somewhat muscular, and was associated with movement.

73. On 4 July 2018, Ms A saw Dr B again. At that appointment, Dr B debrided[24] both nipples. There was a small amount of necrosis on the left nipple, but the right nipple contained a larger patch with no nipple protruding. Ms A told HDC that she was not prepared for the outcome of the debridement and had driven herself to the appointment and had no support person present. In response to the provisional opinion, she said that she was prepared for a 'few millimeters' of dead tissue to be removed, 'not the entire protruding nipple … All that was left was a large hole that took several months to heal. This remains to be a very traumatic memory.'

74. Dr B told HDC that prior to the 4 July appointment, he had explained to Ms A what the procedure would involve — specifically that he proposed to undertake a partial edge

[21] Mentor CPG332 implants. In a response to HDC, Dr B refers to having previously trialled the use of Motiva brand implants, but the theatre report records that Mentor brand implants were used in Ms A's case.
[22] TIGR mesh.
[23] Dead tissue.
[24] Removal of the dead tissue, usually surgically.

debridement, which required the removal of a few millimeters of dead tissue from the nipple for the purpose of avoiding infection. Dr B explained that prevention of infection is paramount in these cases as, if the implant gets infected, this will lead to its removal.

75. The nursing notes record that at an appointment on 10 August 2018 for a dressing change, Ms A told CNS E that she had been having difficulty with her mental and emotional health post-treatment. Ms A was referred to a cancer psychologist to assist with coming to terms with cancer recovery. It was noted at that appointment that the nipples were healing.

76. The nipples healed eventually, and a letter from Dr B to a main centre hospital (Hospital 2) dated 12 December 2018 recorded the result. The letter states:

> '[Ms A] unfortunately suffered from partial nipple necrosis, bilaterally, right more than the left. This recovered in due course and she had a reasonable result on the left side.'

Breast deformities

77. On 29 August 2018, at the Breast Clinic at Rotorua Hospital, Ms A raised concerns with Dr B about the obvious lack of symmetry in her breasts. Dr B advised Ms A to give it more time for the implants to settle.

78. Ms A also raised concerns about the deformities at subsequent follow-up appointments with CNS E. A nursing note dated 25 September 2018 records Ms A's concerns around the asymmetry of her breasts, rippling on the left breast, and the right breast sitting higher than the left. The note records that Ms A was scheduled for review in December 2018 once there had been several more months of healing, and at that time there could be discussion around improvements, with the possibility of lipomodelling.[25]

79. Ms A saw Dr B again on 31 October 2018 and raised the lack of symmetry and a rippling effect that was evident on the left breast. Ms A told HDC that Dr B advised that following debridement, the healing process required for the wound would have slowed down the settling of the implants, and they should allow approximately six months from the surgery date before making any further decisions.

80. Dr B became concerned that the deformities were caused by 'flipping' of the implants, and so he referred Ms A for an ultrasound. The ultrasound on 11 December 2018 showed that the implants had not flipped.

81. On 12 December 2018, Dr B told Ms A that he did not think the outcome of the surgery was acceptable and referred her for possible remedial surgery. The referral letter recorded Ms A's concerns as '[r]ippling of the implant (especially when she exercises), slightly high riding right implant, [and] slight lateralisation of the left nipple'.

[25] Lipomodelling is when a surgeon moves fat from one area of the body to another to improve the look and feel of the breast.

82. Dr B discussed the cause of some of the deformities in a letter to HDC, explaining that at the time of the surgery, he did not fully appreciate how physically active Ms A was, and the associated possibility of a rupture of the join between the mesh and pectoral muscle.

83. On 17 December 2018, Ms A was seen by a private plastic surgeon, whose findings were as follows:

> 'We can see some obvious discrepancies, the first is that she has had some partial necrosis of the right nipple with what appears to be a circumvertical scar completed at the same time as the mastectomy. The breasts differ in position of the device and also that there is difference in height. There is a suggestion that she may have a rotation of one or both devices and the right breast seems to sit higher on the chest wall. I have put a tape measure around her neck and we can see that the left nipple areolar complex is sitting eccentric on the breast mound. She has a 13cm wide implant but this sits about 8cm from the medial border of the implant and only 4cm from the lateral border. The rippling is quite evident in the upper poles. She is able to contract the pec major muscles and give a very strong and obvious animation deformity. Her scars look slightly hypertrophic[26].'

84. Ms A told HDC that as of 25 August 2022, she had had three further remedial surgeries to correct the defects with the breast reconstruction, and she may need further surgery in the future.

Further information

Information provided to Ms A

85. HDC asked Dr B and Health NZ what information was provided to Ms A before she decided to proceed with the bilateral mastectomy and reconstruction. Some of the information and the associated discussions are noted above. In addition, CNS E provided HDC with a long list of pamphlets and other documents that were given to Ms A.

86. CNS E also told HDC:

> 'There were conversations had post first surgery, around genetics and determining family history, as you would expect [Ms A] was very motivated about future health and reducing her risks of recurrence. At this stage referral to radiotherapy was completed. Support given to [Ms A] for her choices in surgery, providing information in print form and verbal. Risks, complications, healing times and recovery, the used of breast [sic] to help support reconstruction and follow up. I had many conversation[s] and t[e]xt messaging with [Ms A], where [I] offered information, referrals and support.'

87. In relation to the results of the genetic testing and the biopsy, Dr B provided HDC with detailed pamphlets he said were given to Ms A and advised that it is his usual practice to use these to supplement discussions with patients.

[26] Thicker than normal.

88. In relation to the implants, Dr B provided a copy of the BAPRAS guide to breast reconstruction and told HDC that his normal practice is to ask patients to read the relevant information on the implants in the guide. He said that this information then forms the basis of a discussion on the implants in the consultation.

89. In addition to other information about breast reconstruction, the BAPRAS guide states:

> 'Look and feel: It can be difficult to get a natural breast shape with an implant alone and so these kinds of reconstructions are best for women with relatively small breasts that do not droop at all, or if both breasts are being removed.
>
> …
>
> Potential problems: Implants are prone to hardening, deflation, visible folds and creases, and do not give good results if you have to have radiotherapy either before or after the reconstruction is carried out.'

90. The BAPRAS guide also includes some basic information about silicone implants, including:

> 'If your breast is reconstructed using an implant on its own, a silicone prosthesis is inserted under the skin and muscle of the chest to replace the volume of breast tissue that has been removed at the time of mastectomy. This is quite a simple operation that does not involve scars elsewhere on your body. The implant will be very like one that is used in cosmetic surgery.'

91. In relation to the information discussed at the consultations, Dr B told HDC:

> 'I would discuss the type of implants: round/tear drop (anatomical) shaped. We would also discuss the implant placement, position after mastectomy and that reconstructed breasts look different to normal breasts and have less ptosis (droop). We also inform the patients that the final outcome will be evident after 3 to 6 months.
>
> We address possible complications, specifically the small risk of infection and thereafter removal (4–6%). Long term, there is a risk of capsular contracture[27] and second surgery (in about 30% of patients). I would have discussed a small risk of BIA-ALCL — breast implant associated-anaplastic large cell lymphoma[28] (about 1 in 3000). We have now changed to using Motiva implants that do not have this risk.
>
> The patients are then measured up for implants and sizes are discussed (option of going smaller or larger) and their wishes are taken into consideration when ordering them.
>
> The patients have the option to discuss things further with the breast care nurse and in the normal course he/she will have a sample implant for the patients to see and feel. All patients have direct contact numbers to the breast care nurse to contact and discuss

[27] Where the capsule of scar tissue that forms around the breast implant becomes unusually hard and starts to contract around the implant. This can lead to aesthetic problems and pain in the breasts.
[28] A rare type of cancer that can develop in the scar tissue capsule and fluid surrounding a breast implant.

> their doubts and concerns. Additional appointments are made by the breast care nurse with her and with me as required.
>
> [Ms A] had the opportunity to re-confirm her choice on implants on 13 June 2018 — and again on the day of the (second) surgery.'

92. In relation to post-surgery activity, three pamphlets were provided to HDC that were given to Ms A. These pamphlets contain information about post-surgery activities and exercises. One of the pamphlets contains the warning:

> 'If you've recently had a breast reconstruction, talk to the surgeon who did the operation or your physiotherapist before you start or continue with any exercises, and follow their advice.'

93. Dr B also told HDC that the breast care nurse (in this case CNS E) would discuss the contents of these documents, and possibly the physiotherapy team would also. He said that the information is provided either during the preoperative consultation, where the patient is consented for the surgery, or on discharge.

94. CNS E told HDC that Ms A had a tough time in the healing process, and she was an 'active relaxer'. CNS E said that generally she encourages mobility and gentle exercise for at least the first six weeks and advises patients to pace themselves and allow their bodies to heal, while supporting emotional wellbeing. In response to the provisional opinion, CNS E told HDC:

> 'Post-surgery care and exercise restrictions had been discussed with [Ms A]. I clearly remember her coming back to ask if she could use the exercise bike. [Dr B] and I told her to avoid heavy exercise and to gradually build up over the next 6 months. Driving was only to be undertaken after 3–4 weeks.'

95. Ms A's clinical records note that she was seen by a physiotherapist on 22 June 2018, the day after the surgery, and that she was given a handout, advised to do 'Stage 1 exercises' until the drain had been removed, and advised that she should do no heavy lifting for 6–8 weeks.

96. A breast nurse note from 23 June 2018 records: '[E]xercises covered.'

ACC

97. An application by Ms A to ACC for a treatment injury claim was successful, and ACC agreed to cover the injury that led to the migration and rotation of the implants, and the superficial nipple necrosis.

98. The ACC documents provided to HDC include a report by an oncoplastic breast and general surgeon, Dr G (see Appendix B). Dr G's report included discussion about the post-surgery advice normally given to breast reconstruction patients. Dr G advised:

> 'Patients need to be given very clear instructions about the restrictions in activities after surgery and to avoid any lifting/pulling/pushing for at least 3 months to try and prevent

these complications. Patients need to be advised against driving for at least 8–10 weeks after surgery …'

Ms A

99. In respect of the information provided on post-surgery activity, Ms A said that she was surprised by Dr G's report. She does not recall being told anything as specific as the restrictions suggested by Dr G, and said that she limited her activity, but not to that extent. She stated that she is a physical person and did a lot of exercise at the time. She said that no information was given to her about not driving, and she would not have done so had she been advised not to drive. She recalls that the plastic surgeon who carried out her remedial surgery explained that a rupture between the mesh and the pectoral muscles had occurred, but Ms A said that she does not believe it was because of physical activity.

100. In January 2020, Ms A told HDC:

> 'I'm still facing major surgery to fix the reconstruction that took place in June 2018 … I no longer feel like I got off lightly, in fact I regret my decision to have a double mastectomy due to the complications that were caused by it and the effect that it's had on my life … I'm upset that what I have been going through since the double mastectomy wouldn't likely have been required if best practice methods had been used. The impact for myself and my family has been significant and ongoing. I have not come to terms with my body post-surgery and have been seeing a psychologist since August 2018.'

Responses to provisional report

101. Ms A was given the opportunity to respond to the 'information gathered' section of the provisional report. Where relevant, her comments have been incorporated into this report.

102. Health NZ was given the opportunity to respond to relevant sections of the provisional report. Where relevant, Health NZ's comments have been incorporated into this report.

103. Dr B was given the opportunity to respond to relevant sections of the provisional report. Where relevant, his comments have been incorporated into this report. In addition, Dr B said:

> 'I again wish to express my apologies for the cosmetic outcomes and reiterate my previous responses … My team and I have reflected deeply on the care provided to [Ms A] and how we can use this experience as a learning opportunity to improve our practice … We are deeply apologetic that [Ms A] felt the care provided to her was not adequate and I do not believe this to be a reflection of my usual practice.'

104. Regarding why Ms A was not offered psychological support prior to her decision to undergo a mastectomy, Dr B told HDC:

> 'I do agree that a clinical psychologist is useful in such matters. Unfortunately, there has not been a consistent availability of such a person at the DHB. In their absence, [CNS E] does discuss all options independently and ensure[s] patients are well informed … In

> [Ms A's] case time was a critical consideration and referring her to the Breast Cancer Foundation was not reasonably practical when breast care nurses are trained to help patients make decisions like this.'

Opinion: Introduction

105. The issues for me to determine are:

a) Whether there was appropriate continuity of care — noting in particular that Ms A met her surgeon, Dr B, for the first time on the day of her initial surgery;

b) Whether there was adequate consideration of Ms A's family history of cancer prior to treatment options being offered and considered;

c) Whether Ms A was counselled adequately on the rationale for, and risks/benefits of, the double mastectomy surgery;

d) Whether Ms A's surgery was conducted with reasonable care and skill; and

e) Whether Ms A was counselled adequately in respect of her postoperative exercise.

106. I obtained independent advice from a general plastic and reconstructive surgeon, Dr Sally Langley. I have relied on this advice to determine these issues in relation to Dr B and Health NZ. In addition, I obtained independent advice from a general surgeon, Dr Erica Whineray, who has provided further advice on the care provided by Dr B.

Opinion: Health NZ Lakes — breach

Knowledge of family history and preoperative discussion before WLE

107. On the day of her first surgery, Ms A was put in an extraordinarily difficult position. Specifically, she was asked to re-consider the proposed surgery having prepared mentally and physically for a particular treatment of her cancer, including having had dye injected and a hook wire inserted into her breast. This was, in my opinion, an unacceptable and avoidable situation.

108. HDC asked Health NZ why Ms A met Dr B for the first time only on the day of her first surgery, and what steps were in place to promote continuity of care.

109. Dr F (on behalf of Health NZ) advised that the breast clinic is held once per week, and the three consultant surgeons (Dr B, Dr C, and Dr D) see patients on a rotational basis. He said that patients are seen and treated by 'the service' rather than a particular clinician and are booked as appropriate for their needs. Dr F said that any confusion around Ms A (referring here to the fact that her full and significant family history was discovered only on the day of

her scheduled surgery) was the result of a family history that was not fully appreciated at the time of her MDM discussion to determine the appropriate surgical recommendations.

110. Dr B told HDC that no notification is received when patients are transferred on to a particular surgeon's surgical list until the surgeon receives the theatre list for the day in question (usually 24–48 hours prior to the surgery). He said:

> 'The shared-care service, in the context of full workloads in a busy provincial hospital, relies on accurate and appropriate care provided at each patient interaction, prior to surgical procedures taking place. This is required where workloads and scheduling often make it impossible to arrange a clinic appointment to address any "missing information" at short notice.'

111. Dr Whineray was asked to comment on whether Dr B should have been aware of Ms A's additional family history of cancer (the family history in addition to her mother's history of breast cancer) prior to his meeting with her on the morning of the surgery on 3 May 2018. Dr Whineray advised that possibly Dr B should have been aware of this history, but as Ms A was a 'pool patient', Dr B was reliant on the assessment by the two other surgeons who met with Ms A in clinic prior to 3 May (Dr D and Dr C).

112. Dr Whineray advised that even prior to a known diagnosis, during a standard breast clinic appointment the initial surgeon should have elicited the family history of Ms A's mother's bilateral breast cancer. Dr Whineray said that additional history of other cancers is not always known by the patient at the time of diagnosis and becomes apparent with subsequent appointments. However, Dr Whineray advised that it is standard practice to ask the patient specifically about the risk factors for breast cancer, including family history of breast or ovarian or related cancers, and to document the presence or absence of these risk factors. Dr Whineray advised that the failure to do so in this case constitutes a moderate departure from accepted standards.

113. I accept Dr Whineray's advice. In my view, when several different clinicians are involved in a patient's care journey, there is an inherent risk of important information being missed. Accordingly, it is the responsibility of Health NZ to have processes in place to mitigate this risk. I am concerned that the full details of Ms A's mother's cancer do not appear to have been elicited prior to the first surgery (they are not documented) and there do not appear to have been any further enquiries made as to further family history. The comments made by Dr B and the other breast surgeons relating to discussions about family history show that there was uncertainty and confusion about what information had already been elicited, and whose responsibility it was to obtain that information.

114. I have also considered the appropriateness of Dr B's discussion with Ms A about other options prior to her undergoing the WLE surgery on 3 May (discussed in paragraphs 116–118 below) and, if considered inappropriate, where responsibility lies.

115. Dr B is clear that the genetics referral he made on 6 April was an administrative task, and that he did not have any knowledge of Ms A prior to her being placed on his surgical list

(around 24–48 hours prior to the surgery on 3 May). As I have found below, it is my view that Dr B was in a difficult position on the morning of 3 May, having no knowledge of Ms A nor the additional family history of cancer, and that in the circumstances of him discovering additional information that in his view was relevant to the treatment plan, he provided Ms A with the information that she needed to make an informed decision about whether to proceed with the WLE procedure that day. Although this was undertaken at an inappropriate time and in a less-than-ideal environment, I do not consider this wholly the fault of Dr B.

116. In my view, Dr B was operating within a system that did not allow for appropriate continuity of care. This stemmed from a failure in earlier appointments to elicit the full history of Ms A's mother's cancer, although sufficient clinical history was established to warrant a genetics referral one month prior to Ms A's surgery. Regrettably, there was also no clinical consideration given to the significance of this referral (with the potential to gather further relevant family history, and the results of genetic testing), and therefore, no consideration was given to how the missing history/genetic results might impact on the treatment plan. The genetic referral alone should have prompted a discussion with Ms A and possibly the MDM before her proposed surgery date.

117. In this respect, I note Dr Whineray's advice that once Ms A's mother's general history of breast cancer had been established and the genetics referral made, 'the threshold for considering a familial syndrome was reached'. This means that the options that Dr B discussed with Ms A on 3 May could have been discussed with her prior to the morning of her procedure if adequate procedures had been in place to facilitate those discussions.

118. Right 4(5) of the Code stipulates that every consumer has the right to co-operation among providers to ensure quality and continuity of services. In Ms A's case, the system in place to guide her through her breast cancer treatment was inadequate in that in the stages of diagnosis and forming of the initial treatment plan, no clinician held ultimate responsibility for her care. This resulted in a wholly unsatisfactory situation where on the morning of her planned WLE procedure on 3 May, the treatment plan was questioned in a manner that placed unnecessary stress on Ms A. Accordingly, I find that Health NZ Lakes failed to ensure cooperation among providers to ensure that Ms A was provided continuity of care, in breach of Right 4(5) of the Code.

Opinion: Dr B — breach

Preoperative discussion before WLE & SNB — adverse comment

119. Prior to Ms A undergoing the WLE & SNB on 3 May 2018, she met with Dr B for the first time. Ms A's mother was present at this appointment and advised Dr B of the nature of her cancer as well as additional familial cancer information. On learning this information, Dr B gave Ms A the option to reconsider the WLE & SNB procedure she was scheduled to have that day.

120. Dr B explained his rationale for raising alternative treatment options just before the scheduled surgery:

a) Prior to 3 May 2018 he was unaware of Ms A's family history of cancer other than that Ms A's mother had had breast cancer previously (information that he had learned on reading Ms A's clinical notes from another clinician);

b) He considered that the additional family history he elicited and the fact that Ms A's mother's cancer was 'triple negative' was significant to the treatment options;

c) That a genetic defect or significant family history could come with a risk of recurrence that could change his advice around management and interventions (including that a mastectomy may have been recommended); and

d) That if further surgery was required, definitive surgery undertaken in a single sitting typically results in better outcomes.

121. In relation to what Dr B discussed with Ms A prior to the procedure, he said that he advised Ms A that if she elected to wait, the wire in situ would be removed and they could consider using agents to stop the development of the tumour in the meantime. He said that he explained to Ms A the implications of significant family history, the heightened risk of further cancer if a genetic link was established, and ways in which this could be managed. Dr B said that he advised Ms A of the possible implications/risks of proceeding with the WLE & SNB (being that future reconstructions may be more complicated), and the potential benefits of going ahead with the procedure. He said that he also explained that it was open to her to proceed with the procedure and afterwards look to expedite the genetic testing. However, there is no record in the clinical notes of the details of this discussion. Dr B said that he offered Ms A time to consider her options, but she elected to proceed with the WLE & SNB procedure that day.

122. My independent advisor, Dr Whineray, advised that the additional familial history that Dr B became aware of on 3 May was (in her view) not clinically significant, in that once Ms A's mother's history of breast cancer had been established and the genetics referral made, 'the threshold for considering a familial syndrome was reached'. This meant that the options that Dr B discussed with Ms A on 3 May could have been discussed with her prior to the morning of her procedure.

123. In particular, Dr Whineray's opinion is that on receiving some family history and making the genetics referral on 6 April 2018, Dr B should have brought Ms A back to the clinic at that stage, to take a more detailed family history and to discuss the implications of the family history on her treatment options (including whether or not she should proceed with the planned WLE & SNB and radiotherapy or wait for the genetic results and decide on her treatment options then). Dr Whineray advised:

> 'It is not uncommon to proceed with the cancer treatment for the cancer a patient already has, and attend to the genetic assessment and risk reduction options later if a pathologenic variant is detected. In this case, [Ms A's] primary cancer was small and

low-grade — there was enough time to wait for the genetics result to come through whilst counselling her on the treatment options and providing time to decide.'

124. Dr B said that the genetics referral was requested by him prior to Ms A being allocated to his care and onto his operating list, and that he had no knowledge of Ms A as a patient at this point. As outlined above, he also said that he progressed the referral as part of the shared administrative tasks that take place in the operation of the breast service. In addition, Dr B said that no notification is received when patients are transferred onto a particular surgeon's list, until the surgeon receives the theatre list for the day in question (usually about 24–48 hours prior to the surgery).

125. In response to Dr B's comments, Dr Whineray said that a doctor is responsible for the referrals they make and the tests they order. She said that irrespective of the fact that Ms A had not yet been allocated to his surgical list on 6 April (when the genetics referral was made), having personally referred Ms A for genetics assessment he was responsible for the outcome. Dr Whineray maintained her criticism of Dr B's decision to alert Ms A to the potential change of plan on the day of surgery and considered this to be a moderate departure from accepted standards.

126. I also note Dr Langley's advice that the discussion was carried out at an inappropriate time. She said that raising the possibility of alternative treatment just before Ms A was to be anaesthetised was inappropriate, as this is not a good way to enter general anaesthetic (with concern or doubt about the procedure about to be done).

127. Dr Langley advised that discussion of a different course of treatment immediately prior to an operation would be acceptable if it was serious, major, and with significant consequences. She considered that in Ms A's circumstances, the concern about family history could have been assessed and addressed later. The alternative operation, bilateral mastectomy with or without reconstruction, could also have been discussed later. Dr Langley also considered that the WLE and SNB was the standard requirement for Ms A's breast cancer at that stage and may well have been the only operation that she required. In addition, Dr Langley does not believe that undergoing the operation would have affected the consideration of Ms A's family history of breast cancer and its consequences, or subsequent mastectomies and reconstructions. Dr Langley also disagreed with Dr B that a single operation has more acceptable or predictable results.

128. I note that Dr G's advice also supports the view that it was inappropriate for Dr B to conduct the discussion regarding other treatment options with Ms A immediately prior to her planned WLE & SNB procedure.

129. I acknowledge the advice from Dr Langley, Dr Whineray, and Dr G, and I agree that it was inappropriate for Ms A to be notified of other treatment options immediately prior to her planned WLE & SNB procedure. I also accept that Ms A's mother's general history of breast cancer was enough to meet the threshold for considering familial syndrome as it prompted the genetics referral. In my view, Ms A was placed in this unacceptable position as a consequence of the system of care (as discussed in the previous section).

130. Dr B was in a difficult situation on 3 May, in part owing to the way the breast service operated — and in particular that a 'service' model of patient management did not enable clinical ownership and responsibility for Ms A's care. This issue is addressed above in relation to Health NZ Lakes (and is relevant to this discussion). All clinicians, including Dr B, were unaware of Ms A's additional family history prior to the morning of 3 May. Unfortunately, the additional information about Ms A's mother's cancer had either not been elicited by previous clinicians who had seen Ms A or was not offered when requested. The results of the genetic testing were also unavailable at this time, and Dr B regarded his referral to genetics as an 'administrative' task.

131. In my view, Dr B had limited options available to him at the time. Dr B could have proceeded with the surgery without having a discussion about the potential significance of the family history on the treatment recommendations, thereby not subjecting Ms A to extra stress or worry. With this option, a later appointment could have been made at a time when Ms A was in the right frame of mind to be considering treatment options in light of the benefits and risks of each.

132. Dr B's other option was to give Ms A all the relevant information and ask her to make a decision based on full information, but subject her to the extra stress and worry. This extra stress and worry had the potential to affect her response to the operation she was about to undergo or affect her recovery. Ms A could also have chosen to abort the scheduled operation, either to take time to consider her options fully, or to opt for a prophylactic mastectomy instead.

133. Despite the comments of my advisors and the additional advice from Dr G, I cannot be overly critical of Dr B in this situation. He had a difficult judgement call to make, with disadvantages to any option he chose. In previous decisions, I have stressed that central to the effectiveness of informed consent is that a patient should have all the relevant information to consider before making any treatment decisions. If relevant information is withheld from a patient, consent is not informed.

134. Taking all this context into account and noting the recent allocation of Ms A's surgery to Dr B, and that he obtained new information that in his clinical judgement affected the potential treatment pathway, I am satisfied that Dr B acted reasonably in advising Ms A accordingly. I have also considered that by providing Ms A with additional information about alternative treatment options, Dr B respected the key principle of informed consent.

135. Notwithstanding this, I am mildly concerned that Dr B did not identify Ms A's mother's cancer history prior to Ms A being prepared for surgery (ie, when Ms A was placed on his surgical list 24–48 hours prior to the surgery) given that this history met the threshold for considering familial syndrome. In addition, I am concerned that Dr B did not think critically at the time of the genetics referral, particularly as he has acknowledged that the family history and genetic risk could have been significant to the treatment plan. Although he regarded the referral as an administrative task, and may have assumed that others were managing Ms A's care, he had the opportunity, as the clinician making the referral (noting also that usually a referrer would have responsibility to manage the results), to consider its

implications for the patient, and consider whether the referral and treatment plan should be re-considered and discussed with the patient, other clinicians, and/or at an MDM.

Decision to perform mastectomy and information provided — breach

Summary of facts

136. On 16 May 2018, Ms A was advised that the result of the SNB showed that her cancer had likely not spread, and that it was therefore likely that the WLE had removed all the cancer. Ms A saw Dr B on 28 May and records show that Ms A requested this appointment as she wanted to discuss a bilateral mastectomy because she was concerned about recurrence of her breast cancer. At this time, the results of the genetic testing were still not available. Dr B told HDC that he provided Ms A with information on reconstruction, explaining different possible procedures, and the pros and cons of each. He said that he gave Ms A the opportunity to ask any questions and advised her to review the printed resources he had provided previously.

137. In response to the provisional opinion, Dr B said that it is his usual practice to advise patients that a prophylactic mastectomy removes 95% of breast tissue, but not all, and a small risk of recurrence still persists. He told HDC: 'I am sure that this discussion was undertaken with [Ms A].' Dr B also said that the evidence that prophylactic mastectomy does not offer a survival benefit over alternative options was not current at the time of the events, and that '[r]eports of a significant reduction in occurrence of second breast cancers were available [at that time]'.

138. Dr B said that all his discussions with Ms A about options, risks and benefits of surgery were supplemented by detailed discussions between CNS E and Ms A, and that is why he did not take detailed notes of these discussions. He said that CNS E told him that Ms A could not be dissuaded from proceeding to more radical surgery. Nothing in the clinical notes from this appointment documents a discussion about whether the surgery was appropriate, noting that, at this point, the genetic testing had not been concluded, or whether the surgery would be beneficial in terms of preventing cancer recurrence/reducing Ms A's risk of death from cancer. In addition, Ms A stated that she could not recall whether anyone spent time with her exploring her reasons for choosing mastectomy or whether anyone discussed with her the possibility of removing only the breast that had been affected by cancer (a single mastectomy).

139. On 11 June, Ms A was advised of the result of the genetic testing, which revealed that there were no recognised genetic abnormalities. Dr G's report for ACC (which Dr Langley had not seen before she prepared her advice) explains in detail what the results mean in practice. Dr G advised:

> '[Ms A] had a small 10mm low grade (Grade 1) invasive cancer … [Ms A's] 5- and 10-year survival was calculated at 98% with surgery alone; with less than 1% survival benefit from Endocrine therapy. This tool does not account for [r]adiation therapy, which is a local treatment to the breast. In other words, this small cancer, if managed with the standard method of WLE followed by Radiotherapy, would have likely been the only cancer episode in this patient's lifetime.

> [Ms A's] genetic testing was also negative and therefore [she] was not a high-risk patient, despite family history. One clinic letter suggests "strong family history" but without any details. Preoperative clinic letter by another SMO indicates patient's mother had postmenopausal breast cancer but without any other breast or ovarian cancer history in the family and would not be categorised as significant family history. Variation in clinician assessment can often result in erroneous risk stratification, unnecessary anxiety for the patient, excessive screening measures or unnecessary risk-reducing surgery.
>
> …
>
> Based on documentation provided by ACC, there is no compelling evidence to support double mastectomy in [Ms A's] case.
>
> The long-term outcome for small early breast cancers is equivalent for breast conservation followed by Radiotherapy, compared to mastectomy alone. In other words, there is no survival advantage by undergoing a mastectomy with small breast cancers.'

140. Ms A saw Dr B again on 13 June 2018, by which time the results of the genetic testing were available. Dr B told HDC that at this appointment, he worked through the consent form for the mastectomy and reconstruction surgery with Ms A.

141. Dr B told HDC that Ms A had communicated anxiety about developing further cancers and was motivated to preserve her health. He said that he considered that it was appropriate to take Ms A's preferences into account and undertake the requested procedure. He commented:

> 'Ultimately, I did not consider it was my role to persuade or dissuade/discourage [Ms A] from a particular choice. I considered my role to was to provide her with information relevant to the procedure, including the risks, benefits and alternatives — and leave it to [Ms A] to decide what she wished to do.'

142. Dr B said that despite the results of the genetic testing, he did not consider the risk associated with Ms A's family history of cancer to be minimal.

143. A letter from Dr B to Ms A's GP of 14 June records the discussions between Ms A and Dr B, including the benefits and risks of the surgery (including the risk of implant loss, bleeding, and infection), scars, possible effects of the chosen incision type, and a likely loss of feeling in Ms A's nipples. It was also discussed that Dr B could not guarantee that the breasts would be perfectly symmetrical, and that Ms A might require further surgery in the future.

144. The consent form signed by Ms A on 13 June 2018 states the risks discussed as bleeding, infection, 'not a perfect match', '?secondary surgery', and a handwritten comment that is illegible. There is no evidence that other treatment options were considered further following receipt of the genetic test results, nor that the benefits of the surgery or Ms A's reasons for wanting the surgery were explored. I note both Dr B's and CNS E's responses to

the provisional opinion, in which they describe being unable to change Ms A's mind about the procedure. Dr B describes setting out the options and risks with reference to a leaflet that was provided to Ms A. However, as noted elsewhere in this opinion, there is no documented evidence of such discussions, and this evidence must be viewed in light of Dr B's further evidence that there were reports of a significant reduction in occurrence of second breast cancers with prophylactic mastectomies, as well as, in his view, benefits to her proceeding with the surgery in the absence of radiotherapy.

145. Ms A said that she chose mastectomy mainly because she was concerned about the potential long-term risks of radiation damage. She also told HDC that no clinicians attempted to dissuade her from choosing mastectomy over radiation therapy.

Psychology input

146. ACC advisor Dr G commented that in cases where a patient requests a prophylactic mastectomy despite no evidence of increased cancer risk, time should be taken to allay any fears the patient has about reoccurrence or personal biases around treatment complications. Dr G also noted that it is advisable to seek a formal assessment by a clinical psychologist in this setting, and that the patient should be counselled adequately *against* having a double mastectomy (my emphasis). She advised that there is little evidence of these steps having been carried out in Ms A's case. Dr G commented that if there is no survival advantage or benefit from a bilateral mastectomy, she would expect to see clear and detailed discussion about the issue documented in the patient notes.

147. Similarly, Dr Whineray considered that Ms A was not counselled adequately regarding the risks and benefits of preventative surgery. Dr Whineray also advised that it may have been warranted to refer Ms A to a clinical psychologist, as it is common to see decision regret following preventative surgery in an active woman of Ms A's age. Dr Whineray noted:

> 'If [Ms A] [was] still keen on surgery at that point after being presented with all the possible things that could go wrong, then you have an informed patient who is likely to be satisfied with the outcome.'

148. In response, Dr B said that he agrees that psychological input in such a decision would be helpful, but the breast service in Rotorua is limited in its availability to offer this. Dr B stated:

> 'Through the relevant period and in the years since, there hasn't consistently been a psychologist that is able to provide this service.'

149. Dr Whineray advised that in the absence of an available psychologist in the service, a referral could be made to organisations such as the Breast Cancer Foundation. She said that another option is using time delay and speaking to other clinicians, 'as a means to ensure that a patient is not making the decision out of the usual anxiety associated with a breast cancer diagnosis as further surgery may not address the underlying concern'.

150. Dr Whineray advised that as there is limited access to a psychologist in Rotorua, she would consider the failure to seek psychological input to be a mild departure from acceptable practice.

Discussion

151. On the evidence before me, it is clear that Ms A had educated herself on both the radiotherapy option and the mastectomy procedure, and that she wished to proceed with a prophylactic double mastectomy. I acknowledge that Dr B considered the prophylactic mastectomy to be a reasonable treatment option for Ms A in light of her clear wishes for the procedure, her choice not to undergo radiotherapy following the WLE (making the WLE procedure 'incomplete'), and her family history of cancer. Considering the above reasoning, and that Ms A had clearly educated herself on the prophylactic mastectomy and wished to proceed, I accept that the mastectomy may have been a reasonable treatment option to consider. However, despite Ms A taking all steps to educate herself on the treatment options, Dr B still had a responsibility to ensure that Ms A had all the relevant information prior to consenting to the procedure. I will discuss this in detail below.

152. Dr Whineray identified that the genetic testing had shown no pathological genetic variant, and, whilst it was an 'inconclusive result' (consistent with the time), it would now be declared not a carrier. Dr Whineray advised that in light of the inconclusive result, the surgeon would then review the risk profile according to the genetic tree.

153. The genetics team had counselled Ms A that the risk of another breast cancer was up to 18% at 25 years compared to the normal population at 11%. There was therefore an 82% chance that Ms A would ***not*** develop another cancer. In relation to whether or not Ms A was fully informed of the meaning of the risk profile, Dr Whineray advised:

> 'Patients consistently over-estimate their risk of contralateral breast cancer so it is important that time is spent explaining what these numbers mean; for every patient like [Ms A], less than 1 in a group of 100 would develop another breast cancer each year. And whilst bilateral mastectomy would reduce the chance of her developing another breast cancer, there is NO survival benefit. It will not reduce breast cancer death.'

154. I note that although Dr B advised this Office that he discussed with Ms A the reduction of risk of cancer recurrence arising from the mastectomy, there is nothing in the clinical notes to illustrate that this occurred. I also note Ms A's comments that she does not recall anyone exploring with her the reasons for choosing mastectomy, and that she does not recall anyone dissuading her from undergoing the procedure.

155. In response to the provisional opinion, Dr B said that the evidence that prophylactic mastectomy does not offer a survival benefit over alternative options was not current at the time of the events, and that '[r]eports of a significant reduction in occurrence of second breast cancers were available [at that time]'.

156. Dr Whineray was asked to comment on this submission, specifically whether in 2018, at the time of events, it was known that prophylactic mastectomy does not offer a survival benefit over alternative options. Dr Whineray advised that in 2018 it was in fact known that prophylactic mastectomy does not offer a survival benefit. Dr Whineray provided references to the research, which I have reviewed. I accept Dr Whineray's advice.

157. It is clear that Ms A was provided information about the mastectomy. Dr B and CNS E provided Ms A with relevant printed materials and had discussions with her about risks (Dr B notes that he discussed implant loss, bleeding, infection, scars, possible asymmetry and loss to nipple sensation), complications, healing times, recovery, genetic factors, details of the implants and the surgical procedure, cosmetic outcomes, and the risk that further surgery would be required.

158. However, whilst it is clear that Ms A was aware of less aggressive treatment options (such as WLE and radiation), there is nothing in Ms A's patient notes or in Dr B's evidence to suggest that the risks of cancer recurrence and long-term survival with the various treatment options were discussed with her adequately to allow her to make an informed choice about prophylactic mastectomy. That is, there is no evidence of discussion about the relative future cancer risks between having the mastectomy (including that having the mastectomy would not lower the risk of death from breast cancer), having no treatment, or completing an alternative course of treatment (ie, the radiotherapy and drug therapy). Whilst CNS E did advise Ms A to wait until the genetic testing had been completed before making a decision, Ms A has stated that on receipt of the results of the genetic testing, she does not recall whether anyone spent time with her exploring her reasons for choosing a mastectomy. There is also no evidence in the clinical documentation that this occurred, and I note Dr B's comment that he did not regard it as his role to attempt to dissuade her.

159. Based on the information available to me, I find it more likely than not that Dr B did not counsel Ms A adequately on the risks and benefits of the mastectomy procedure and alternative treatment options, particularly in relation to future cancer risks.

160. Dr Whineray advised that if Ms A did not understand that the mastectomy procedure would reduce but not eliminate her chance of developing another breast cancer, and would not change her life expectancy, then she would consider the failure of Dr B to counsel on these points to be a moderate departure from accepted standards.

161. I agree. Whilst I appreciate that clinicians must respect a consumer's wishes on medical decisions, in my view, if a consumer requests treatment that has little clinical evidence for its use over less aggressive treatments, I would expect to see greater care taken to explore the reasons why the consumer is electing those treatments, and clear documentation of that process. I also note that there were no MDM discussions about a prophylactic mastectomy either before or after the WLE. Although I accept that ultimately it is the treating clinician who, in consultation with the patient, determines the best course of treatment, the inclusion of other voices and opinions in the process may have produced a more satisfactory outcome for Ms A. Dr C's letter suggests that he, at least, would have counselled against a prophylactic mastectomy had it been discussed at an MDM. Ultimately, I am concerned that Dr B did not counsel Ms A adequately on the risks and benefits, including her future cancer risk, before proceeding with the double mastectomy.

Conclusion

162. Right 6(1) of the Code states that all consumers have the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including

an explanation of the options available, including an assessment of the expected risks, side effects, and benefits. In my view, by failing to counsel Ms A adequately on the benefits and associated risks of the mastectomy and alternative treatment options, particularly in light of the results of the genetic testing, Dr B failed to provide appropriate information to Ms A to allow her to make a fully informed decision on her treatment. It follows that Dr B also breached Right 7(1) of the Code, which states that services may be provided to a consumer only where that consumer has made an informed choice and given informed consent. As I have found that Ms A was not provided with the appropriate information by Dr B, it is my view that she was not in a position to give informed consent to the mastectomy procedure.

163. I do not consider the failure to refer to a clinical psychologist to be a serious failing, in light of the service limitations at Rotorua. That said, it is important to acknowledge the value of counselling and support in these circumstances and, accordingly, recommendations and comment on this issue are made below at paragraph 193b).

Outcome of bilateral mastectomy and reconstruction

Whether surgery was performed with reasonable care and skill — no breach

164. Ms A's main complaint relates to the outcome of the bilateral mastectomy and reconstruction. She told HDC that she regrets the decision to have a bilateral mastectomy due to the complications caused by it, and the effect it has had on her life. She believes that best practice methods were not used in the reconstruction, and therefore she is facing major revision surgery and the associated recovery. At the time of writing, Ms A had had five surgeries.

165. In this respect, Ms A's complaint stems from findings by Dr G in the ACC report relating to the rippling effect evident, especially on her left breast post-reconstruction, and to nipple necrosis and positioning of the implants.

166. In relation to the rippling effect, Dr G advised that this was most likely caused by the use of soft implants combined with the thin mastectomy skin flaps at the time of surgery. In addition, the sutures along the pectoral muscle and TIGR mesh had snapped before the TIGR mesh had integrated with the host tissue, probably due to early use of the muscle or the very thin muscle flap.

167. In respect of the nipple necrosis, Dr G listed several factors that can contribute to the appearance of necrosis following surgery. She noted that superficial necrosis is a recognised complication in 10–15% of mastectomy cases, and complete nipple necrosis is seen in 3–5% of cases where a mastopexy-type incision is used with nipple-sparing and implant-based reconstruction.

168. Regarding the position of the implants, Dr G noted:

a) The difference in implant height is often caused by inaccurate mark-up prior to surgery and intraoperative assessment during implant placement.

b) The lateral displacement of the implant could be caused by the early breaking of the sutures holding the pectoral muscle to the flaps, or by the pocket being too large for the implant. In Ms A's case, the implant pocket may have been too large.

169. Dr Langley also commented on the reasons for the post-surgery deformities. She advised that a relatively poor cosmetic result is not unusual after implant reconstructive surgery. She said that it is reasonably common to need a further procedure to excise skin along the line of the inframammary fold,[29] and it is also not unusual to have asymmetry and poor attachment/definition of those folds. This can require further surgery to reattach the folds. She also said that it is not unusual to have some grooving and rippling of the breast skin. This may be improved by careful fat grafting, which should be available in the public hospital. Lastly, she advised that it is not unusual to have early and late asymmetry despite the surgeon's best endeavours, and further surgery to try to improve this is often required.

170. Dr Langley is not critical of Dr B's surgical technique, nor is she directly critical of the cosmetic outcome of the bilateral mastectomy and reconstruction.

171. Considering the advice of both Dr Langley and Dr G, I am not critical of the skill and care with which Dr B performed the surgery. Although Dr G listed several factors that could have contributed to the deformities, it is far from clear whether any blameworthy conduct by Dr B resulted in the deformities. I note that Dr G's report was produced for the specific purpose of determining whether there was a treatment injury for ACC claim purposes, and not to determine whether Dr B departed from the standard of care expected of him. I accept Dr Langley's advice that a poor cosmetic result is not unusual in breast reconstruction surgery, and often remedial surgery is required to correct this.

Information provided before surgery about possible deformities and implant types — no breach

172. Throughout the clinical documentation there are references to the advice provided to Ms A about potential asymmetry, and the possibility of further surgery being required to correct defects in the future. Both Dr B and CNS E described discussions they had with Ms A at various points, including discussions on cosmetic outcomes. However, I cannot see any specific discussion about the possibility of a rippling effect following the surgery.

173. Dr Langley commented that although Dr B provided Ms A with considerable information, he appears not to have given her details about the silicone gel breast implants themselves, and the specific outcome concerns and complications related to them. However, Dr Langley did not identify any departure in respect of the information given to Ms A about the possibility of unsatisfactory outcomes from the surgery. Dr B told HDC that the BAPRAS guide to breast reconstruction does contain details on silicone breast implants, and he uses that as a basis for discussions in the consultation.

174. Although it is not clear whether the specific risk of rippling with the type of implant used in Ms A's reconstruction was discussed, I note that Ms A was warned of the risk of deformities and the potential need for corrective surgery, and was provided with substantial printed

[29] The crease along the lower edge of the breast.

material, including information about silicone implants. The BAPRAS guide specifically mentions that implants are prone to visible folds and creases. Ms A had the opportunity to ask questions of Dr B. Accordingly, whilst I acknowledge the advice of my independent advisor, I consider that Ms A was provided with sufficient information by Dr B before her mastectomy and reconstruction, except in the area of post-surgery physical activity.

Information provided before surgery about physical activity — adverse comment

175. Dr G noted the importance of limiting physical exertion in the weeks after surgery. She counsels her patients to avoid lifting, pushing, or pulling anything heavier than a cup of tea for six weeks after surgery. She stated:

> 'Patients need to be given very clear instructions about the restrictions in activities after surgery and to avoid any lifting/pulling/pushing for at least 3 months to try and prevent these complications. Patients need to be advised against driving for at least 8–10 weeks after surgery; provided there are no wound complications; and longer, if there are any wound problems. Preoperative education by Breast Care Nurses and detailed Patient information leaflets specific to type of reconstruction, can help minimise these complications.'

176. Ms A said that she was surprised by Dr G's report. She cannot recall being told anything as specific as the restrictions suggested by Dr G, and said that she limited her activity, but not to the level suggested by Dr G. She stated that she is a physical person and did a lot of exercise at that time. Ms A said that no information was given to her about not driving, and that she would not have driven to her appointment less than two weeks after the surgery if she had been advised not to drive.

177. In response to the provisional opinion, CNS E told HDC:

> 'Post-surgery care and exercise restrictions had been discussed with [Ms A]. I clearly remember her coming back to ask if she could use the exercise bike. [Dr B] and I told her to avoid heavy exercise and to gradually build up over the next 6 months. Driving was only to be undertaken after 3–4 weeks.'

178. However, there is nothing in the clinical record about specific activity restrictions being provided to Ms A. Dr Langley similarly commented that she was not provided with information about the activity restrictions given to Ms A.

179. Dr B and CNS E provided information to HDC about the advice and printed material they gave Ms A in respect of the level of physical activity she *should* undertake post-surgery. The printed materials comprise three pamphlets detailing the exercises and physiotherapy that a breast surgery patient should carry out in the weeks post-surgery. The pamphlets focus on the exercises that should be carried out rather than on details of specific limitations on physical activity. However, the pamphlets note that patients should build up gradually to moderate and regular activity, avoid uncomfortable exercises, go at a pace at which they feel comfortable, and avoid heavy lifting.

180. There is an absence of information about what level of activity might be harmful or might cause the kinds of deformities suffered by Ms A. I suspect that this is because it is dependent on the patient and/or the type of surgery. I note that the Breast Cancer Care document 'Exercises after Breast Cancer Surgery' contains the warning:

> 'If you've recently had a breast reconstruction, talk to the surgeon who did the operation or your physiotherapist before you start or continue with any exercises, and follow their advice.'

181. In terms of the specific advice provided by Dr B, he said that it was the breast cancer nurse who discussed the contents of the pamphlets, and perhaps also the physiotherapy team. CNS E told HDC that Ms A was an 'active relaxer' and that she had a tough time during the healing process. CNS E said that generally she encourages mobility and gentle exercises for the first six weeks, and she advises patients to pace themselves. I can find no specific mention of discussions around post-surgery activity in the nursing documentation, except a note by the breast nurse on 23 June 2018, which states: '[E]xercises covered.'

182. The clinical notes by a physiotherapist on 22 June 2018 record that Ms A was given a handout advising her to do 'Stage 1 exercises'[30] until the drain had been removed, and that she should do no heavy lifting for 6–8 weeks.

183. I note also that on 1 July 2018 Ms A attended the Rotorua Hospital outpatient clinic with a cough that had triggered pain around the site of her recent surgery.

184. The cause of Ms A's breast deformities is not entirely clear, particularly the rupture of the sutures attaching the TIGR mesh to Ms A's pectoral muscles. Regardless of how the deformities occurred, I find it concerning that other than the advice to avoid heavy lifting, there is no specific mention of how Ms A should limit her physical activity following the surgery. Dr G noted that she advises her patients on activity restrictions in much greater detail than appears to have occurred in Ms A's case, including that patients should avoid lifting, pushing, or pulling anything heavier than a cup of tea for six weeks after surgery, and that patients should avoid driving for eight to ten weeks after surgery. I note with concern that Ms A drove herself to her appointment on 4 July 2018 (at which the necrosis on her nipples was debrided). That appointment was only two weeks after her surgery, and Ms A commented that she did not feel prepared for the outcome of the debridement, and no one had advised her to avoid driving.

185. I am also concerned that more care was not taken by Dr B, as the responsible clinician, to ensure that Ms A understood both the level of physical activity to which she should limit herself in the weeks after her surgery, and also the potential consequences of undertaking too much physical activity. Although Dr B may rely on the clinical nurse specialist and the physiotherapy department to an extent, as the operating consultant it remained his responsibility to ensure that Ms A understood the particular risks of any reconstruction

[30] From the Health NZ Lakes Physiotherapy handout — very light exercises to be carried out from the day after surgery until the drain is removed.

method. Ms A was an active person, and her level of activity in the weeks following surgery may have increased the risk of rupturing her sutures.

Changes made

186. Dr F told HDC that a guideline around prophylactic mastectomies is under development.

187. I note with approval that Health NZ Lakes has made changes to its MDM form to include specific discussions about family history. Dr B told HDC that the Health NZ Lakes MDM form was amended on his prompting to include family history as a compulsory discussion topic. He said that now that it is a required discussion point, and further and appropriate detail is collected by clinicians and presented to the full team to inform discussions on treatment plans. I am reassured by these process improvements.

188. In response to the provisional opinion, Health NZ Lakes said that it has agreed on a 'rotating roster' whereby an agreed consultant surgeon would accept responsibility for referrals, and therefore the outcomes of patients referred to the service. The roster has been set up on a two-weekly rotation among the four surgeons in the service, and the responsible surgeon ensures that appropriate outcomes and management plans are instituted for each patient.

189. In response to the provisional opinion, Health NZ Lakes advised HDC of its current pathway for patients presenting to Rotorua Hospital requesting or wishing to explore the option of a prophylactic mastectomy (based on a genetic test). Health NZ Lakes said that the patient would meet with a surgeon, and, if prophylactic mastectomy is an option, a referral is made to a tertiary institution for review.

190. Dr B also told HDC that he now always asks patients for breast reconstruction whether they are in the habit of performing very heavy exercises. If they answer yes, he does not advise retro-pectoral reconstruction, and instead considers them for a pre-pectoral reconstruction (which does not produce the 'window shading' effect, as the pectoral muscle is not separated from the chest wall).

191. Dr B also told HDC that since early 2019, when they became available, patients have been given the option of using form-stable anatomical implants, and all patients are now warned about the possibility of rippling when considering the use of ergonomic implants.

192. In response to the provisional opinion, Dr B told HDC that he has implemented a tick-box sheet that documents the discussions had between clinicians and patients, and a list of the leaflets provided. He also said that he has implemented a process whereby discussions on reconstruction are part of a separate appointment. Dr B said: 'A brief discussion on reconstruction will be held initially and a specific reconstruction appointment will be scheduled for a week later.'

Recommendations

Health NZ Lakes

193. I recommend that Health NZ Lakes:

a) Provide a written apology to Ms A for the failings identified in this report. The apology is to be provided to HDC within three weeks of the date of this report, for forwarding to Ms A.

b) Provide an update to HDC on the new guideline around prophylactic mastectomies and, in the event that the following is not included in the guideline, consider including a prompt for clinicians to consider (1) a referral for patient counselling, and (2) MDM consideration for such patients, within three months of the date of this report;

c) Use an anonymised version of this report as a basis for staff training at Health NZ Lakes for staff involved in breast surgery, focusing particularly on:

   i. discussions with patients about alternative treatment options and how the risks of each option are quantified to patients (and documentation of those discussions); and

   ii. discussions with patients about limitations on physical activity following surgery, and the risks associated with overexertion (and documentation of those discussions);

   and provide HDC with evidence of the training within six months of the date of this report.

Dr B

194. I recommend that Dr B:

a) Provide a written apology to Ms A for the failings identified in this report. Dr B is to provide the apology to HDC within three weeks of the date of this report, for forwarding to Ms A.

b) Complete the HDC online learning modules and provide HDC with the certificate of completion within three months of the date of this report.

c) Undertake an audit of his clinical documentation covering the three-month period prior to the date of this report, in order to identify:

   i. any patients who have not been provided with details of the relative risks and benefits of different treatment options;

   ii. any patients who have not been provided with sufficient information to enable them to understand both the levels of physical activity to which they should limit themselves in the weeks after surgery, and also the potential consequences of undertaking too much physical activity; and

   iii. in respect of both paragraph i and ii above, to identify whether such discussions have been documented adequately.

I recommend that Dr B report back to HDC with the results of the audit, and any steps taken to resolve any deficiencies, within three months of the date of this report.

Follow-up actions

195. A copy of this report with details identifying the parties removed, except Health NZ Lakes, Rotorua Hospital, and the advisors on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.

196. A copy of this report with details identifying the parties removed, except Health NZ Lakes, Rotorua Hospital, and the advisors on this case, will be sent to Breast SurgANZ.

197. A copy of this report with details identifying the parties removed, except Health NZ Lakes, Rotorua Hospital, and the advisors on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from Dr Sally Langley, a plastic and reconstructive surgeon:

'I have been asked by the Commissioner to provide expert advice on the care provided by [Dr B] to [Ms A] in 2018.

I have been sent the file of notes which I have read and summarized.

1. Letter of complaint dated 29/01/2020
2. Lakes District Health Board's response dated 7 April 2020
3. Clinical records from Lakes District Health Board
4. Photographs following surgery

I do not have a conflict of interest.

I work as a general plastic and reconstructive surgeon in Christchurch. I do breast reconstructive surgery of all types including methods similar to what has been done here.

I have read the HDC Guidelines for Independent Advisors.

I have been asked to comment on the care [Ms A] received by [Dr B] for breast cancer. I understand that [Ms A's] concerns relate to:

— The outcome (cosmetic results) of her surgery — asymmetry, rippling, hypertrophic scar etc.

— Nipples not checked post-surgery, she had issues with necrosis of nipples post-surgery.

— Lack of information regarding the nature and extent of nipple debridement undertaken on 4 July 2018

I have been asked to comment on:

1. Was the nature of the surgery performed on [Ms A] on 3 May 2018 including *oncoplastic concentric mastopexy type incision* an accepted approach in the clinical scenario described?
2. Was there adequate pre-operative information provided to [Ms A] regarding potential risks associated with her later mastectomy and implant surgery? Was there adequate documentation regarding the information provided?
3. Taking into account all the available clinical information, do you feel the procedure performed by [Dr B] on 21 June 2018 was undertaken in a manner consistent with accepted practice, including pre-operative and intra-operative assessments and documentation of these assessments? Is it possible to attribute [Ms A's] poor

cosmetic outcome of surgery to any factor/s that represent/s a departure from accepted practice?

4. Was [Ms A's] post-operative monitoring, particularly in relation to assessment of nipple and skin flap viability, undertaken and documented in a manner consistent with accepted practice in the 48 hours following surgery on 21 June 2018?
5. The adequacy of [Ms A's] outpatient management by [Dr B] including:
   — The office procedure (nipple debridement) performed on 4 July 2018.
   — Information provided to [Ms A] regarding activity restrictions.
   — Timeliness of referral for a second opinion regarding the poor cosmetic outcome of [Ms A's] breast surgery.

SUMMARY of documents sent

COMPLAINT

I have read the letter of complaint written by [Ms A]. She outlines her breast cancer diagnosis on 04/04/2018, Grade 1, 10mm left breast. Her mother had had breast cancer and there was a significant family history of breast cancer and other cancers. [Ms A] opted to have bilateral mastectomies rather than excision and radiotherapy. She did not require chemotherapy. On 03/05/2018 at Rotorua Hospital she underwent left partial mastectomy by [Dr B] who she met that morning for the first time. She says that [Dr B] gave her the option to consider the lumpectomy as additional surgery may be required to minimize recurrence. She was already fully prepped for the surgery (lumpectomy/partial mastectomy) — she had been injected with the radioactive dye for sentinel node biopsy and she had the hook wire in place. [Ms A] decided to go ahead.

On 16/05/2018 [Ms A] had a postoperative appointment with [Dr B]. She was referred for radiotherapy appointment and genetic services before making a decision on "double" mastectomy to be done approximately 6 weeks later. *(There must have been discussion about the histology report of the lumpectomy at this clinic appointment — check).*

On 28/05/2018 [Ms A] saw [Dr B] for discussion re bilateral mastectomy and immediate reconstruction. [Ms A] opted for immediate reconstruction, implant-based as she did not have enough fat volume required and was very physical (*I am not sure whether [Dr B] was planning "fat grafting" or referral for an abdominally based flap reconstruction).*

On 13/06/2018 [Ms A] saw [Dr B] again at clinic and she asked him if there was any advantage in going privately since she had medical insurance. His advice was that she would be welcome to get a second opinion, but the outcome advised would very likely be the same procedure …

On 21/06/2018 [Ms A] underwent the operation, bilateral mastectomies and implant reconstruction. She noticed on awakening that she was concerned about the size and position of her breasts. She says they were very obviously asymmetrical. [Ms A] says that the dressing did not allow the nipples to be checked. [Ms A] had read that it was

advised to check the nipples after surgery re blood supply. [Ms A] raised concern with the nurses in recovery and they were doing what was advised.

On 04/07/2018 [Ms A] saw [Dr B] at breast clinic and he debrided both nipples. This was a relatively minor amount on the left but on the right no nipple was left protruding. This was carried out at clinic with no anaesthetic. [Ms A] was not prepared for the outcome and she had no support person present. The debrided nipple areas were slow to heal. The option of a skin graft was discussed.

On 15/08/2018, 5 weeks after the operation, the right was starting to heal and [Ms A] was referred to a cancer psychologist.

On 29/08/2018 [Ms A] raised concern about the obvious lack of symmetry and the rippling effect primarily on the left. [Dr B] advised her that the debridement had slowed down the healing process and slowed the settling of the implants. She was to give it more time.

On 31/10/2018 she saw another surgeon which resulted in her having an ultrasound to check whether the implants had flipped as they were quite out of shape. The ultrasound did not show any abnormalities. She was advised to wait 6 months.

On 12/12/2018 [Dr B] advised that the surgery outcome was not acceptable and referred her to plastic surgeons at [Hospital 2].

On 17/12/2018 [Ms A] was seen at the [private] clinic. The findings were listed as:

— Asymmetry with different heights of implants and volume disparity
— Right nipple necrosis
— Lateral deviation left nipple
— Rippling upper poles
— Significant animation deformity
— Hypertrophic scar
— Upward migration pectoralis major muscles “window shading”
— Likely rotation implant

[Ms A] summarises by saying that she is still facing major surgery to fix the reconstruction. She became pregnant [in 2019]. She regrets the decision to have double mastectomy. She says that the best practice methods were not used in her reconstruction. She is concerned about the recovery from further surgery with … small children.

[Ms A] wants reassurance that Lakes DHB takes steps to minimize the chance of this injury occurring for other patients. “No-one should go through this”. She wants an apology and compensation for harm and opportunities lost.

Lakes DHB
The Lakes District Health Board (Lakes DHB) clinical notes have been sent.

On 03/05/2018 [Ms A] underwent the operation "Left oncoplastic WLE" (wide local excision) (hook-wire guided) and SNB (sentinel node biopsy) as concentric mastopexy. This is also referred to as "partial mastectomy". [Dr B] describes in the operation record dissection to the pectoralis fascia. I have read the histology report of this specimen and it measured 49 x 35 x 10mm and weighed 5.9g. The margins were close for invasive and incomplete for DCIS.

On 19/06/2018 [Ms A] attended Lakes DHB for pre-operative assessment. She was medically assessed as fit and healthy. She had a history of palpitations. She had one [child] and was not pregnant. Her height was 163cm, weight 70kg and her BMI is documented as 22 (my calculation is BMI 26.35 but either height or weight might be documented incorrectly since her pre-operative photograph looks more like BMI 22). She was a non-smoker.

The consent for the operation was signed (I think that it is signed by [Dr B]) on 13/06/2018. The risks listed are bleeding, infection, implant loss, "not a perfect match" and something else which I cannot read.

The operation took place on 21/06/2018 — bilateral mastectomy and implant/mesh reconstruction; left therapeutic and right prophylactic.

The implants used are Mentor CPG332, 495cc each side. The mesh used is TIGR mesh. The implants are subpectoral with mesh inferiorly. The approach was a "vertical mastopexy". [Dr B] describes bilateral "lollipop" incisions.

The histology report has been reviewed. The right breast specimen measured 160 x 165 x 40mm and weight 145g (I find this weight puzzling — it should have been more similar to the 498g left). The left specimen measured 150 x 175 x 42mm and weighed 498g.

The nursing records have been sent. On 29/06/2018 the district nurse noted blackening of both nipples and nurse organized for [Ms A] to attend [Dr B's] clinic in early July.

On 10/07/2018 [Dr B] noted superficial necrosis right breast and 25ml fluid aspirated.

On 18/07/2018 [Ms A] saw [Dr F] who was concerned about skin breakdown over implant.

On 27/07/2018 she underwent debridement of nipple necrosis. On 02/08/2018 the debrided right breast was reviewed and was much improved. On 10/08/2018 improvement was noted right breast. [Ms A] was having difficulty with mental and emotional health and was referred to psychologist.

On 15/08/2018 [Dr B] states that [Ms A] was making excellent progress. He also noted that she had concerns about size of the implants and size difference. She was advised to wait for 2 months. The right nipple complex had slight slough below it.

On 23/08/2018 she was feeling much improved and was finding that seeing [a] (psychologist) was helping. She was having body identity issues. On 25/09.2018 [Ms A] was seen at clinic with possible inflammation. Only slight was found. [Ms A] was very concerned about asymmetry and she was for review in December with respect to possible improvement maybe lipomodelling but that was out of reach for her (she was told only available privately funded).

On 29/08/2018 [Ms A] had questions about the long-term cosmetic result. They had a detailed discussion and the option of private lipomodelling was discussed. To be reviewed in 3 months.

On 13/12 2018 the nurse had a phone call from [Ms A] requesting referral to a private plastic surgeon for assessment. She had private medical insurance.

[Ms A] had ultrasounds done on 30/08/2018 and 11/12/2018. For both no abnormality was found. The implants were intact with no evidence of displacement or rotation.

On 31/10/2018 the issues mentioned were documented.

There is a referral letter written by [Dr B] to plastic surgeons at [Hospital 2] for opinion and advice following the surgery and nipple necrosis right greater than left. [Dr B] says in his letter that there is a reasonable result left but there is concern re rippling especially with exercise; slightly high riding right implant; slight lateralization left nipple. He mentions that there had been concern that implants had "flipped" especially left but ultrasound suggested not. The referral was received on 17/01/2019 and declined on 05/02/2019.

On 14/12/2018 [Dr B] wrote a referral to [a private] plastic surgeon outlining the above-mentioned concerns.

Lakes DHB Response

[Dr B] has written a response to the HDC request on 30/03/2020. He documents the series of events leading up to the complaint. I will not repeat all of the history as he has documented but I will emphasise a few features.

The initial referral was on 12/03/2018 by GP as fast-track for mammogram and ultrasound. On 27/03/2018 the first contact with a breast nurse was made. On 28/03/2018 [Ms A] had her first surgical appointment with [Dr C]. She was then seen by a second surgeon [Dr D] on 04/04/2018 and was listed for surgery with [Dr B] who she met on the day of the surgery, 21/06/2018, for the first time. It was at this meeting in the holding area for the operation that [Dr B] mentioned alternative operations. He warned her that any intervention can reduce her options and potentially complicate matters in due course. She went ahead with the WLE and SNB. At follow-up there is no mention of the histology report discussion but a plan was made for bilateral mastectomies and reconstruction. [Ms A] was referred for genetic testing and also for assessment re role of radiotherapy. It is documented that [Ms A] opted for implant reconstruction. Photos were taken at that stage and have been seen in the file. They

show a woman of average slim build with flat ptotic breasts. The left has a recent scar around the superior areolar margin. The left nipple sits a couple of centimetres higher than the right. [Dr B] goes on to document that the surgery was done as planned on 21/06/2018. He says that he sat her up during the operation to check for good symmetry. He used a Smith & Nephew "honey-comb" dressing. She was discharged on 23/06/2018. The partial nipple necrosis was subsequently noted. He referred [Ms A] to plastic surgery at [Hospital 2] in December 2018.

[Dr B] goes on to give his opinion. He mentions implants and that he had previously used Allergan implants but due to the warning about BIA-ALCL (Breast-Implant-Associated Anaplastic Large Cell Lymphoma) he had changed to using Motiva ergonomics implants. (He does not mention the Mentor brand implants which he is documented to have used for [Ms A]. I think he has incorrectly recalled using Motiva rather than Mentor.) (Also I have not seen any documentation of his discussions with [Ms A] about silicone gel breast implants and in particular BIA-ALCL since he has now mentioned it.) [Dr B] does reflect that [Ms A] was very physical and possibly ruptured the join between the mesh and the pectoral muscle causing "window-shading". (I have not read any description of this having occurred, being suspected or ultrasound/MRI documentation). He says that the window-shading was more evident on the left. He advises to look at the post-operative photos, subsequently sent to me. [Dr B] refers to this as a "seminal case" and subsequently he has changed his practice. He now has a physical activity discussion and if the patient is very active he places the implants pre-pectoral. He does a 360 degree mesh wrap so has no risk of window-shading. He says he now has the option of using form stable anatomical implants since early 2019 (when they became available). (The implants he used, Mentor CPG are anatomical form-stable and have been available for many years). He also now warns patients of the possibility of upper pole rippling.

[Dr B], for the Lakes DHB, has sent supporting documents. He also explains several things. He says that he had to raise the mastectomy flaps very thin and used knife and scissor dissection and no diathermy. He says that the flaps can look pale initially but mostly recover. He talks about the "honey-comb" dressing and wound assessment after surgery. [Ms A] had no haematoma or decreased flap viability.

This file also includes genetic counsellor letters explaining that the genetic testing process takes several months and that the result was negative for BRCA1 and BRCA2.

Photographs following surgery:

24/06/2018 Photograph of breasts which have undergone surgery. The "honeycomb" dressings are present vertically oriented on each side, over the nipples. The left breast looks slightly fuller than the right.

08/07/2018 Photograph of the chest/breasts with a grey dressing gown covering shoulders and lateral sides of breasts. The right breast has partial necrosis of the nipple.

There is mild bulging of the lower pole. The left breast looks fuller and broader and the nipple is slightly elevated compared with the right. I cannot see nipple necrosis.

30/11/2019 The photograph shows chest and breasts. It is not a symmetrical photo. The left breast looks bigger than the right. The lower ends of the scars look full on each side. There is rippling and grooving of the skin. The nipple-areolar complexes look good. I cannot really see the nipple on the right. The left nipple sits higher than the right. (Left shoulder elevated). The inframammary fold looks lower on the left. The vertical skin scar is longer on the left compared to the right.

I have been asked to comment on:

1. Was the nature of the surgery performed on [Ms A] on 3 May 2018 including oncoplastic concentric mastopexy type incision an accepted approach in the clinical scenario described?

Yes. The incision made as I have seen in the photograph (pages 11–13 of 14 in Lakes DHB response docs 30 March) was appropriate.

I can see a healed incision along the superior border of the left areola from 9 o'clock medially to 3 o'clock laterally. This would have given direct access to the tumour which had been identified by the hook wire. [Dr B] refers to it is a "concentric mastopexy" but I can see a healing wound of only the superior half of the areolar margin. The term "concentric" refers to a full circumferential incision. An incision along the areolar margin would be a standard incision for a breast general surgeon to approach a centrally sited breast tumour. A true "concentric mastopexy" incision which goes around the whole perimeter of the areola and excises a rim of skin, would be unusual and unnecessary and would for that operation add risks of nipple-areolar ischaemia. I wonder whether [Dr B] has incorrectly referred to a standard "hemi-areolar" incision as a "concentric mastopexy" or "circumferential incision". [Ms A] would have no indication for an actual mastopexy (breast lift — skin tightening) and for breasts which are symmetrical, mastopexies would need to be considered for each side, for symmetry. An actual mastopexy would have excised skin or at least epidermis leaving the nipple to survive on dermal blood supply. A mastopexy would be unusual as the approach for doing a unilateral WLE.

The specimen removed was small and weighed only 5.9g. This weight, 5.9g, seems a quite small weight to me. I suspect that a larger specimen could have been excised at that time to be surer of clearing the tumour margins. If needed an opinion could be gained from a breast cancer surgeon.

There is no mention of skin included in the specimen sent for histology.

2. Was there adequate pre-operative information provided to [Ms A] regarding potential risks associated with her later mastectomy and implant surgery? Was there adequate documentation regarding the information provided?

I have not seen the extent of pre-operative information given to [Ms A] so I find it difficult to comment. [Dr B] has sent to HDC standard information pamphlets about breast reconstruction which can be given to patients. I have not seen letters documenting what was actually discussed with [Ms A] re breast reconstruction, options, implants, outcome, recovery. [Ms A] was seen several times by [Dr B] and by CNS E, breast cancer nurse. There is a lot of information required to be given to a woman with breast cancer ie cancer information, treatment options, genetic testing and its relevance, and then there is a lot of information about breast reconstruction and options of techniques. I think it might not be possible to deliver every component of information to a patient in this situation and also for the patient to take on and remember all of the information.

I am unable to assess the adequacy of pre-operative information provided.

3. Taking into account all the available clinical information, do you feel the procedure performed by [Dr B] on 21 June 2018 was undertaken in a manner consistent with accepted practice, including pre-operative and intra-operative assessments and documentation of these assessments? Is it possible to attribute [Ms A's] poor cosmetic outcome of surgery to any factor/s that represent/s a departure from accepted practice?

The cosmetic outcome as judged by viewing the photograph taken on 30/11/2019 is not ideal, but not unusual. The features have been described above. There is no doubt that there is a poor cosmetic outcome as perceived by [Ms A] and certain features of her outcome have been described.

The operative procedure as described by [Dr B] is of standard nipple-sparing mastectomies and immediate reconstruction with submuscular implants plus TIGR mesh to the lower poles. This partial coverage with either mesh or acellular dermal matrix is widely practised either with "direct-to-implant" or two-staged with tissue expander and then implant replacement a few months later. The type of implant used, Mentor CPG, (form-stable anatomical silicone implant) is a standard widely used implant in New Zealand. TIGR mesh, an absorbable mesh, is reasonably common too. Raising thin skin flaps is required for the more complete removal of breast tissue.

The pre-operative discussion just prior to the 03/05/2018 WLE and SNB was inappropriate. I do not think that he should have raised the possibilities of alternative management when she was already heading into the operating theatre with hook wire in place and radioactive dye injected. I know that [Ms A] had been seen by two other surgeons previously and [Dr B] was the third surgeon to become involved, but that timing was poor. Also, I feel he was incorrect with some of his comments. Doing the WLE at that stage could very likely have been definitive surgical treatment and there might indeed have been no indication for further surgery, depending on the histology report. I cannot see that the WLE would have had any risk of compromise of the result of subsequent surgery.

Pre-operative discussion prior to the mastectomy operations should have included extensive discussions about the indications for the surgery, the effectiveness of the cancer risk reduction, options for reconstructive methods, complications of reconstructive techniques, specific information about silicone gel implants (how long they last; capsular contracture, rupture intra- and extra-capsular; infection and consequences; implant failure and removal; asymmetry; implant position; implant rotation and flipping; satisfaction re size and shape; rippling; feel of implants; sensation; changes with age and body weight; late problems such as BIA-ALCL). I have not seen such a discussion referred to. Also with breast implant concerns there is the consideration re availability of further surgery (funding) depending on what the problem might be. It needs to be mentioned that there is a high likelihood of the need for further surgery for some change or concern over the years.

[Ms A] discussed whether she could have a second opinion and is entitled to have sought that prior to the mastectomies and reconstructions. She had medical insurance and could indeed have been funded to see a plastic surgeon in Tauranga, Hamilton, Auckland etc. The vertical mastopexy approach is well known to leave some flattening of the lower breast early on and fullness of skin inferiorly. It is reasonably common to need a further procedure to excise skin along the line of the inframammary fold.

After mastectomy and breast reconstruction it is not unusual to have asymmetry of the inframammary folds and poor attachment/definition of the inframammary folds. This can require further surgery to reattach the inframammary folds.

It is not unusual to have some grooving and rippling of the breast skin. This may be improved by carefully undertaken fat grafting, which should be available in the public hospital.

It is not unusual to have early and late asymmetry despite the surgeon's best endeavours and further surgery to try and improve that may be required.

The operation undertaken by [Dr B] is acceptable standard of practice.

The relatively poor cosmetic result is not unusual after implant reconstructive surgery. Patients undergoing this surgery should be counselled/warned in advance of the possible shortfalls and need for early and late revisional surgery.

4. Was [Ms A's] post-operative monitoring, particularly in relation to assessment of nipple and skin flap viability, undertaken and documented in a manner consistent with accepted practice in the 48 hours following surgery on 21 June 2018?

I have no concern re the post-operative monitoring. Having a partially occlusive dressing over the wounds and nipples is acceptable. Many of us would prefer to see the skin of the mastectomy flaps and nipples. However, inspection of partially ischaemic nipples would not alter the course unless there was some other reason for compromise such as seroma, haematoma or infection which there was not.

5. The adequacy of [Ms A's] outpatient management by [Dr B] including:

— The office procedure (nipple debridement) performed on 4 July 2018.
— Information provided to [Ms A] regarding activity restrictions.
— Timeliness of referral for a second opinion regarding the poor cosmetic outcome of [Ms A's] breast surgery.

[Dr B's] outpatient management of [Ms A] has been acceptable.

Undertaking debridement of necrotic wound/nipple tissue at the rooms at the time of an appointment is acceptable. If there is wound/nipple necrosis the surgeon would usually wait a few weeks until it was "declaring" itself and then debride at the rooms or if more major, arrange for the debridement to be done at hospital under general anaesthetic. However, it is unfortunate that [Ms A] did not have a support person with her since this requirement can be psychologically stressful.

I have not been provided with information about activity restrictions given to [Ms A].

The referral for a second opinion was done at an appropriate time. Usually the problems with the result would not be apparent for several months and indeed the best advice early on is to wait and see. Further surgery would not usually be considered for many months unless there was something major not right.'

Following her review of the response by Health NZ, the following further advice was obtained from Dr Langley:

'Thanks for asking me to review the response from Lakes DHB and in particular [Dr B] with respect to [Ms A] and the report that I provided on 16.8.2020.

I have read through my report again and I have read the documentation sent in response to it.

The relevant parts of the response relate to [Dr B's] comments.

The responses will be commented on as follows:

1. What was discussed with [Ms A] prior to her surgeries, including by [Dr C] and [Dr D], and the breast cancer nurse. In particular, we would appreciate receiving a more detailed response from [Dr B] regarding the information he provided to [Ms A] pre operatively regarding the risks, side effects and benefits of the surgery?

[Dr B] has explained that he provided [Ms A] with considerable information but he has not given details of silicone gel breast implants themselves and the specific outcome concerns and complications related to them.

2. Dr Langley's comment that [Dr B] has inconsistently and/or incorrectly documented and/or recalled some matters, in particular the incision and type of implants used.

[Dr B] has confirmed that the implants used were Mentor brand implants and this was clearly documented in the operation note.

[Dr B] did incorrectly refer to the use of Motiva implants when they were not relevant to this patient.

[Dr B] has explained that he did incorrectly use the term "concentric mastopexy incision" and he meant to use the term "crescentic mastopexy" (incorrectly documented as cresentric instead of crescentic). He has still referred to the procedure as mastopexy whereas I believe it would have been an incision rather than a mastopexy. I am not aware that he performed the mastopexy which is a breast lift or reshaping operation involving excision of skin, elevation or shifting of the nipple and changing the breast shape. The term mastopexy I believe was incorrectly used again. The incorrect use of the term mastopexy is confusing in this case. There would have been no indication to undertake a mastopexy at the time of the wide local excision of the breast cancer, and also the patient had not been counselled and prepared for a mastopexy. If it is documented as a mastopexy, the patient may believe that she has had the mastopexy with consequences of that.

3. Dr Langley's criticism that [Dr B's] discussion with [Ms A] raising the possibilities of alternative management just prior to surgery on 3 May 2018 was inappropriate.

[Dr B] has I think inappropriately brought up the issue of alternative treatments at an inappropriate time. I would accept discussion of a different course of treatment immediately prior to the operation if it was serious, major and with significant consequences. The concern about family history could have been assessed and addressed later. The alternative operation, bilateral mastectomies with or without reconstruction, could have been discussed later. The lesser operation, wide local excision and sentinel node biopsy, was the standard requirement for [Ms A's] breast cancer at that stage and may well have been the only operation that she would have needed. I believe that it was inappropriate for [Dr B] to bring up these issues immediately prior to the planned operation that had required significant preparation. I do not believe that undergoing this operation would have affected consideration of family history of breast cancer and its consequences, or subsequent mastectomies and reconstructions.

4. The basis on which [Dr B] makes the comment that there was window shading.

[Dr B] appropriately explains that this was related to the plastic surgeon's letter, and I agree with that. It is a clinical assessment and judgement of a feature that occurs.

I trust that these further comments will be helpful and I am prepared to provide further comment as needed.'

Following her review of further provider responses, the following further advice was received from Dr Langley:

> 'I apologise for the delay in replying to you. You have mentioned that I should respond by 17/11/2020.
>
> I have re-read my report and I have read the reports that you have sent through from [the] quality, risk and clinical governance director, Rotorua Hospital, and from [Dr B]. [Dr B] has also sent the operation note from 21/06/2018 and I am sure that I had been provided with that previously.
>
> [The quality, risk and clinical governance director's] response is appropriate and outlines the surgeons involved and the involvement of [CNS E], clinical nurse specialist. She lists the educational documents that had been provided to [Ms A].
>
> 2. [Dr B] has made comments with respect to most of my comments. He agrees that he had incorrectly documented or recalled some matters in particular the incisions and I still believe he still does not realise his inaccuracies in terminology. ("Concentric mastopexy" instead of "hemiareolar incision"). He has still referred to the operation as a "mastopexy" when it is unlikely to have been that.
>
> 3. [Dr B] has tried to explain that he was put in a difficult situation being presented with the patient already prepared for surgery. I still consider that it was inappropriate for him to raise concern about the type of surgery planned to be done at that attendance. He should have been aware of who was on his operating list and what was planned.
>
> I consider that [Ms A] was prepared for the standard surgical treatment and that could be clarified with a breast cancer surgeon if necessary.
>
> [Dr B] has confirmed that he used Mentor brand silicone implants and indeed that is what is documented. I had just referred to his own comments about Motiva implants when he had previously commented on this patient's implants.
>
> I still think that raising the possibility of alternative operative treatment just before [Ms A] was to be anaesthetised was inappropriate. That is not a good way to enter a general anaesthetic ie with some concern or doubt about the procedure due to be done a few minutes later.
>
> [Dr B] has again stated that a single sitting operation has more acceptable and predictable results. I dispute this. Also the more extensive potentially problematic surgery (bilateral mastectomies and implant reconstructions) might not have been needed.
>
> The family history of breast cancer concern is usually discussed at clinic appointments and the multidisciplinary meetings. It can be discussed after surgery.

There is a lot of information to be delivered to the patient with breast cancer and it is a stressful time. Adding in discussion about prophylactic mastectomies and then methods of reconstruction and their outcome is a huge amount of information for women to take on and understand. It is quite possible for some aspects of treatment and some complications and outcome concerns to be missed, not remembered, not documented. The clinical nurse specialists have been invaluable in these situations.

Please let me know if further comments will be required.'

Appendix B: ACC treatment injury advice

The following advice was obtained by the ACC from Dr G, an oncoplastic breast and general surgeon, for the purpose of assessing [Ms A's] treatment injury claim:

> 'Thank you for asking me to provide an independent specialist opinion for [Ms A].
>
> …
>
> All notes provided by ACC have been reviewed and a summary of clinical events is outlined.
>
> [Ms A] presented to Rotorua Hospital with a new RIGHT breast lump @ 1:00 position on 28th March 2018. At the time of her diagnosis, she was [in her forties]. Diagnostic Breast imaging (report not included) suggests the RIGHT breast lump was likely benign and confirmed on core biopsy. An incidental non-palpable LEFT breast cancer @ 8:00 position, was identified and confirmed as a low-grade invasive cancer; Estrogen receptor (ER) positive and Progesterone receptor (PR) positive. HER-2 receptor status was equivocal with FISH test pending. None of the subsequent letters mention final HER-2 status with FISH analysis. Laboratory results have not been supplied as part of hospital documentation.
>
> [Ms A] met with 3 different surgeons for preoperative assessment, which is possibly reflective of local practice and was given appropriate advice for a small early LEFT breast cancer. MDM discussion on 04.04.18 recommended Wide local excision (WLE) + Sentinel node biopsy (SNB) for the newly diagnosed LEFT breast cancer. Imaging and biopsy results of the RIGHT breast lump confirmed benign concordance and the MDT felt appropriate to leave it alone.
>
> Patient was placed on a Waiting List for a LEFT breast hook-wire WLE + SNB. The clinic letter on 04.04.18 indicates the patient was "very keen to head for a conservative option" after discussing with her mother and other friends who had previously undergone breast cancer treatment. She was informed about the local challenges with off-site Nuclear medicine facility and need for hook-wire localisation for a non-palpable tumour on the morning of surgery. Anaesthetic assessment on 11.04.18 indicates normal BMI of 22 (weight 70 kg) and non-smoking status (Smoking Assessment form) in a fit and well ASA1 patient.
>
> [Ms A] underwent LEFT breast hook-wire Wide local excision with Sentinel node biopsy on 02.05.18 performed by [Dr B]. Operative notes mention a "concentric mastopexy type incision" for the WLE and a separate axillary incision where a "few" lymph nodes were retrieved for SNB and Frozen section. Formal histology report is not available but clinic letters document 10mm Grade 1 invasive ductal cancer (IDC) with DCIS (total size of DCIS not mentioned); clear of radial margins but superficial and deep margins "clear but close". The clinic letter 16.05.18 does not indicate exact measurements of close margins or the results of Sentinel node biopsy.

Post-operative MDM 16.05.18 with recommendations for Radiotherapy and Tamoxifen is documented in the clinic letters although Post-operative MDM notes have not been provided as part of ACC documentation. Post-operative haematoma was noted at the WLE site, but without any infection. A referral for Radiation therapy at the patient's request, was arranged at post-operative review clinic on 16.05.18.

"Significant family history" is documented in one post-operative clinic letter by [Dr B] on 16.05.18 but without any specific details. Patient was being managed by the Genetic Services in Auckland but there is no documentation from the Genetic Services provided by the hospital. Preoperative clinic letter on 28.03.18 by another surgeon mentions patient's mother had postmenopausal breast cancer but without any other family history.

Patient's histology (10mm Grade 1 IDC; ER+ and probable HER-2 negative receptor status) is unlikely to be linked to BRCA1, BRCA2, ATM, PALB or TP53 gene mutation. Patient underwent genetic testing which returned as "uninformative" — please note this is the older system of reporting and most labs would now routinely indicate if a pathogenic mutation was identified or not. Current system of reporting would indicate a negative outcome for [Ms A] and patient categorised as being at or slightly above population risk. The clinic letter on 13.06.18 also indicates negative results for gene types tested.

[Ms A] was reviewed in clinic again on 28.05.18 to discuss bilateral mastectomy with immediate reconstruction. The letter suggests discussion around all options and patient's decision to undergo implant-based reconstruction in favour of autologous reconstruction. Clinic notes indicate that the patient was measured (measurements not included) and implants ordered. The genetic results were not available at the time.

Patient was reviewed again on 13.06.18 indicates patient's decision to proceed with BILATERAL mastectomy and implant reconstruction. Clinic letter documents that patient was counselled about implant loss, bleeding, infection, loss of nipple sensation and asymmetry. Possibility of secondary surgery was also mentioned. Scar placement was discussed and clinic letter indicates patient's desire to have a vertical incision to achieve more taunt breasts and raise the nipple by 2cm in the form of mastopexy.

A copy of the BAPRAS "Your Guide to Breast Reconstruction" has been provided with hospital documentation to ACC. This information leaflet is designed for NHS patients and last updated in 2010. Some of the information is outdated and there is no specific mention about nipple necrosis depending on type of mastectomy incision, skin flap necrosis, asymmetry, animation, capsular contracture (the leaflet mentions rippling) or Breast implant associated-ALCL.

[Ms A] underwent "BILATERAL mastectomy + bilateral mesh and implant reconstruction + bilateral mastopexy" with use of "vertical incision (lollipop)" on 21.06.18. Mentor CPG332 implants (495CC) were placed in the subpectoral pocket with TIGR mesh for lower pole support. Operation note does not indicate use of dermal flap; as suggested

in follow up clinic letter by [a surgical registrar] on 25.07.18. Discharge summary mentions patient being a current smoker; which is contrary to Smoking Assessment form filled by [a nurse] on 03.05.18 indicating patient was a non-smoker.

Post-operative recovery was complicated by partial RIGHT nipple necrosis (error in clinic letters which suggests LEFT), requiring debridement and which was slow to heal. Patient was also admitted acutely for chest infection confirmed on Chest x-ray and routine blood tests. Follow up clinic letter on 15.08.18 indicates [Ms A's] concerns with shape and uneven nipple height. Clinic letter acknowledged patient's emotional trauma secondary to events following her surgery and plans to see a Psychologist. USS was arranged to check for seroma collection but Radiology report has not been provided in the hospital documentation from ACC.

[Ms A] was reviewed by [Dr B] on 29.08.18 and patient questioned about long term cosmetic outcome and was advised about lipo-modelling. Further consultation on 31.10.18 with issues re asymmetry due to high-riding RIGHT implant and lateralisation of LEFT nipple were noted. Patient also expressed concern about rippling of implant and [Dr B] felt the implant had "flipped" for which an USS was arranged. The results of USS have not been provided with the ACC documentation.

[Ms A] was referred to a Plastic Surgeon for assessment of cosmetic outcome of BILATERAL mastectomy with reconstruction performed in June 2018. Asymmetry with different heights of implant and volume disparity, RIGHT nipple necrosis, lateral deviation of the LEFT nipple, rippling in the upper pole of each breast, significant animation deformity, hypertrophic scar, upward migration of pectoral muscles "window shaded" effect and likely rotation of implant; were noted during two separate consultations with the Plastic Surgeon. Patient is currently awaiting revision surgery.

1. Can you please advise how the symptom of breast implant rippling has developed?

"Breast implant rippling" in the early stages can occur due to use of softer implants; which are normally designed for breast augmentation. Implant-based reconstruction following skin-sparing or nipple-sparing mastectomy is a well-established technique. Some degree of rippling can occur over time and retropectoral implant placement helps to minimise this effect in the upper pole. Thin mastectomy skin flaps can also contribute to this effect in very slim/low BMI patients.

Due to increasing concerns with BIA-ALCL (breast implant associated Anaplastic large cell Lymphoma), a rare form of cancer associated with silicone implants first reported in 1997; many surgeons have switched to Mentor implants due to lowest reported incidence of ALCL compared to other commercially available breast implants. The trade-off with softer CPG (Contour Profile Gel) Mentor implants is a lower ALCL risk against higher incidence of rippling, compared with firmer implants such as Natrelle (Allergan 410 series). One recent publication compared breast augmentation between Mentor CPG and Allergan 410 series; where the incidence of rippling was 5-times higher with Mentor CPG compared to Allergan 410 series (1).

Many surgeons in Europe and USA have also reverted to saline implants due to concerns with ACLC; however, the risk of rippling and capsular contracture is even higher with saline implants (2).

Patients therefore need to be counselled about the difference in procedure, type of implants used, and the rationale behind off-setting risk of ALCL with repeated surgery to correct rippling and capsular contracture. This is more obvious in slimmer patients and Lipo-filling can be used to correct some of the rippling deformity.

The introduction of ADM or biological mesh resulted in a huge global uptake of implant-based reconstruction since the mid-90's. Early learning curve for surgeons, consistent and predictable results, less donor site morbidity compared to autologous flaps, shorter hospital stay, shorter recovery, ability to maintain the breast skin envelope and the integrity of the inframammary fold (IMF); are some of the reasons for higher rates of implant reconstructions. There are many biological and synthetic meshes which are commercially available. Synthetic absorbable TIGR mesh, is a co-polymer of lactide and trimethylene carbonate, which integrates well with the host tissue and is completely re-absorbed in 18–24 months. In my experience, the wrinkling effect from TIGR mesh is far less than many of the ADMs currently available.

Traditionally, the implant is placed in a pocket created by lifting the pectoral muscle off the chest wall (retropectoral implant reconstruction). This provides an additional layer over the upper 2/3 of the implant. Retropectoral placement however results in "animation" every time patients uses the pectoral muscle.

Prepectoral implant placement with complete ADM coverage has been described for small to medium sized breast reconstruction for patients preferring a more natural appearance (ptotic reconstruction) without animation. This is usually recommended for physically active patients and allows early use of upper body exercises. Prepectoral implant placement is less suitable for skin-reducing techniques (mastopexy incision) in larger breasted patients, due to the weight of the implant and potential risk of implant infection.

Capsular contracture, or formation of capsule around the implant; occurs with variable frequency and is dependent on the host tissue reaction to the implant. In some women, the implant remains relatively soft and mobile while in others, the implant becomes firmer with progression of capsule formation. Capsule formation usually occurs after 12–18 months (sometimes years) after surgery. Revision surgery may be required, depending on degree of symptoms (pain).

a. Can you please advise if this has resulted in tissue harm or damage?

The early rippling effect in this patient has most likely been caused by the following:

1. Use of softer implants (Mentor soft gel implant CPG332 — tall height/medium profile). This is more pronounced in slimmer patients or with thin mastectomy skin flaps at the time of surgery (please refer to operation note).

2. The sutures along edge of the pectoral muscle and TIGR mesh may have snapped due to early use of muscle or very thin muscle flap, before the TIGR mesh has integrated with the host tissue. This has resulted in "window-shade" effect where the pectoral muscle has migrated upwards and is tethered to the chest wall and the bulk of the implant is lying under the skin flap. The TIGR mesh, which does not resorb completely for at least 24–36 months, is no longer providing the lower pole support for the 495CC implant.

The tissue damage has been caused by the pectoral muscle being torn off the TIGR mesh. To correct this defect is very difficult as the muscle gets contracted and is virtually impossible to stretch back to its original position.

It is uncertain if the patient was adequately counselled about the possibility of significant rippling with this particular implant design or whether lipo-modelling was planned at a later stage to address this. This is an unwanted effect of surgery due to very thin mastectomy skin flaps in the superior pole. There are no details in the Operative notes to indicate if interrupted or continuous sutures were employed to secure the TIGR mesh to the pectoral muscle. There is risk of continuous sutures unravelling completely if the knot slips at one end or if the muscle snaps off the sutures at one area.

2. Can you please discuss the root cause of the following physical injuries (tissue harm or damage)/symptoms, please step us through your reasoning and why any alternative conclusion doesn't apply here?

a. Bilateral superficial nipple skin necrosis?

Clinic letter documents LEFT nipple partial necrosis requiring debridement but the clinical photograph and Plastic surgeon letter indicates RIGHT nipple involvement.

Post-operative ward round notes have not been supplied with ACC documentation. Information has been obtained from clinic letters and discharge summary by the house officer. Hand-written Breast Care Nurses notes on 29.06.18 mention "blackening of both nipples" noted by District Nurses during dressing change 8 days post-surgery and for clinic review to be brought forward. It is unclear if the nipple viability was assessed in the early post-operative period on the ward and what measures were taken to determine whether this was a salvageable complication.

Full thickness nipple necrosis can occur with "mastopexy" type skin incision and if only 2cm nipple lift (as suggested by clinic letter) was planned. The blood supply to the nipple with this procedure is based on a very narrow superior pedicle; measuring between 3–4cm wide. The operation note does not indicate whether the pedicle was superiorly based, which is the commonest technique most surgeons employ. If the flap is kinked (pedicle too short or thick/excessive swelling/wound closed under tension), the blood supply to the nipple could be compromised and result in nipple necrosis. Nipple necrosis with this procedure can also occur if the implant size is too big for the skin envelope and cause tension on wound closure. This does not appear to be the case according to

post-operative photograph supplied. The photograph does suggest the implant pocket is too large for the size of implant used. Sustained low blood pressure in the initial post-operative period, excessive swelling or acute bleeding complications; are other factors which could compromise nipple viability.

Venous engorgement due to swelling or tension in suture line (dusky appearance of the nipple) is normally evident during surgery or within 24 hours. If recognised early, circulation can be restored with timely surgical intervention. Arterial compromise usually occurs within the first 24–48 hours after surgery due to swelling, low blood pressure or kinking of vessels. Plastic Surgery ward nurses are trained to monitor nipple and skin flap viability with regular hourly checks in the initial 24 hours after surgery. Colour, capillary refill and temperature, form part of routine observations to check the viability of nipple and skin flap. Post-operative flap observations have not been included in hospital notes provided to ACC.

Superficial epidermal necrolysis is a recognised complication in 10–15% cases, where only the top layer of the epidermis is affected. This presents as a blister or peeling of the very top layer of nipple in the initial weeks after surgery. The nipple itself remains pink and viable, and special dressings allow the skin to heal without secondary infection or need for surgical intervention. Swabs to check for infection with appropriate antibiotic cover also helps expedite wound healing. In darker complexion patients, this can result in paler areolar which can be corrected with medical tattooing, once the wounds have completely healed.

I normally quote a 1% risk of complete nipple necrosis for IMF based incision and 3–5% risk for mastopexy type incision with nipple-sparing mastectomy and implant-based reconstruction. There is a wide range in the incidence of nipple necrosis following nipple-sparing mastectomy and implant reconstruction between 2.5% to 38.7% quoted in literature (3,6). The risk is higher in smokers, patients on Nicotine replacement, diabetics, hypertensives and those on anti-platelet medication (due to bleeding complications), large breasted women (>500gm mastectomy specimen weight) or when the estimated nipple lift is > 8–10cm. Mastopexy type incision (Wise-pattern) with implant reconstruction is best avoided in these high-risk patients. Type of dissection during mastectomy can also contribute to skin flap and nipple necrosis, particularly in thin patients. Use of tumescent dissection versus diathermy can result in higher rates of skin flap or nipple necrosis with large mastectomy specimens, smokers and diabetics (5). Use of SPY-technology can be helpful in selective patients to confirm viable flaps at the end of mastectomy but is not a substitute for careful surgical technique (6).

Please note there is a discrepancy about the patient's smoking status: the discharge summary after the BILATERAL procedure indicates patient is a current smoker but the Smoking Assessment form documents patient is a non-smoker. Clinic letters do not mention smoking status at all.

In selected patients, a dual pedicle nipple-sparing/skin-reducing mastectomy (Modified McKissock technique) provides better blood supply to the nipple. This is an alternative

approach for large breasted women who wish to down-size to a smaller breast size after reconstruction (4).

Difference in implant height/displaced left and right implants/rotation of left breast?

Commonest reason for difference in implant height is inaccurate mark-up prior to surgery and intraoperative assessment during implant placement with mesh. Detailed measurement of patient's breast size, volume, ptosis, position of nipple (supra-sternal notch to nipple distance), distance of nipple from midline, distance from nipple to inframammary fold (IMF) and the position of IMF on each side; form part of preoperative assessment. Most women have some degree of asymmetry which needs to be considered when planning BILATERAL mastectomy with reconstruction. Small degrees of asymmetry is usually acceptable by most patients, however difference in height and nipple position is less tolerated.

Marking the area of skin to be de-epithelialized for the new nipple position needs to be done carefully. With the "mastopexy" type incision described by [Dr B] (also termed modified Goldilocks mastectomy or Wise pattern with superior pedicle nipple-sparing mastectomy); marking out the position of the new nipple at the outset can create this situation as the final mastectomy skin envelope may vary.

Even with one operating surgeon, the position of the implants could vary if the position of the IMF and base of the breast is not marked and assessed regularly during surgery. Correct positioning of the TIGR mesh, taking care to map out the IMF and ensuring that the pectoral muscle is equally stretched over the implant; is essential in BILATERAL cases. Thickness of the pectoral muscle and tone (based on patient's level of upper body strength) can influence ability of sutures to hold the mesh to the muscle edge. At the end of reconstruction, many surgeons routinely "sit-up" patients on the operating table while still anaesthetised, to determine the position of both implants and check for symmetry. Any disparity in position can be rectified at this stage.

Lateral displacement of the implant could also be explained by premature disruption of the pectoral muscle from the mesh or if there was inadequate cover of the lateral part of the implant with mesh. The TIGR mesh needs to be snug and sutured along almost the entire length of the IMF to avoid lateral migration of a heavy implant.

Large pocket for the implant can also cause lateral migration or rotation of the implant. This is usually less of an issue with TIGR mesh but depends on the technique employed during surgery.

If "taunt" breast or cleavage was desired by the patient, round implants with full projection could have avoided any issue with implant rotation.

Good symmetry in the early weeks after surgery but becoming asymmetrical with time, could be due to the "window-shade" effect described earlier with disruption of the sutures along the edge of the pectoral muscle. The heavy 495CC implant is then no longer supported by the TIGR mesh and migrates downwards, the pectoral muscle

migrates upwards and gets tethered to the chest wall ("window-shade" effect) and animation becomes more pronounced.

Patients need to be given very clear instructions about the restrictions in activities after surgery and to avoid any lifting/pulling/pushing for at least 3 months to try and prevent these complications. Patients need to be advised against driving for at least 8–10 weeks after surgery; provided there are no wound complications; and longer, if there are any wound problems. Preoperative education by Breast Care Nurses and detailed Patient information leaflets specific to type of reconstruction, can help minimise these complications.

BCN handwritten notes indicate patient's concerns about the cosmetic outcome of surgery with asymmetry, soon after the original surgery. No pre-operative or post-operative medical imaging have been provided by the hospital to offer assessment about the cosmetic outcome during the early weeks following surgery.

b. If you have identified an injury in question 1, please discuss the root cause of this physical injury?

I have outlined the following two components to patient injury:

1) Extensive procedure: Patient's first operation notes from 02.05.18 indicate "Oncoplastic concentric mastopexy type incision". A small 10mm non-palpable tumour in a moderate to large sized breast, usually does not warrant complex Oncoplastic Round block procedure. Simple periareolar incision near the 8:00 position usually provides adequate access to remove the primary tumour under hook-wire localisation, without the need for concentric incision with higher risk of nipple necrosis. The preoperative breast size has been estimated based on clinical photograph supplied and size of implant used for the second surgery. This type of Round block/Tennis racquet incision is appropriate for small A and B-cup sized breasts to counteract nipple deviation following WLE and Radiotherapy.

The only indication for Round block incision in this setting would be asymmetric breast and nipple position which was being corrected as part of WLE. The preoperative clinic letters do not indicate any breast size, asymmetry in volume or position of the LEFT nipple to warrant this procedure.

Preoperative breast size, breast measurements and final histology with breast weight, have not been documented in any clinic correspondence and histology report has not been supplied to ACC.

Patient had 3 consultations after her original WLE and prior to BILATERAL mastectomy with implant reconstruction, suggesting due process. Clinic letter indicates patient's desire for BILATERAL mastectomy but there is no documentation about efforts to dissuade the patient from undergoing extensive surgery. [Ms A] had a small 10mm low grade (Grade 1) invasive cancer, which was strongly Estrogen receptor positive and HER-2 negative (final FISH results not included in hospital documentation).

According to NHS Predict (an online tool used by many Oncologists); [Ms A's] 5- and 10-year survival was calculated at 98% with surgery alone; with less than 1% survival benefit from Endocrine therapy. This tool does not account for Radiation therapy, which is a local treatment to the breast. In other words, this small cancer, if managed with the standard method of WLE followed by Radiotherapy, would have likely been the only cancer episode in this patient's lifetime.

[Ms A's] genetic testing was also negative and therefore was not a high-risk patient, despite family history. One clinic letter suggests "strong family history" but without any details. Preoperative clinic letter by another SMO indicates patient's mother had postmenopausal breast cancer but without any other breast or ovarian cancer history in the family and would not be categorised as significant family history. Variation in clinician assessment can often result in erroneous risk stratification, unnecessary anxiety for the patient, excessive screening measures or unnecessary risk-reducing surgery. BOADICEA and EviQ are currently used for risk stratification by Genetic Service and confirmation of all known family history of cancer from the National Cancer Registry. Risk assessment and genetic testing is normally under the auspices of the Genetic Services. Based on documentation provided by ACC, there is no compelling evidence to support double mastectomy in [Ms A's] case.

The long-term outcome for small early breast cancers is equivalent for breast conservation followed by Radiotherapy, compared to mastectomy alone. In other words, there is no survival advantage by undergoing a mastectomy with small breast cancers. Using the above NHS Predict model for [Ms A's] histology; if 100 women aged 40 with the same sized cancer underwent standard treatment (WLE + Radiotherapy); 98 would be alive and well without any cancer recurrence after 10 years.

In New Zealand, there are many women who live in geographically remote areas with poor access to Radiotherapy units. This accounts for higher mastectomy rates over breast conservation in rural NZ. There is no documentation in the clinic letters to suggest remote access was the primary motivation for avoiding Radiotherapy in [Ms A's] case. Equally many patients are influenced by well-meaning relatives and friends against Radiotherapy due to their personal bias around treatment complications. There is no documentation to suggest increased anxiety re Radiotherapy side effects. Sometimes a formal discussion with Radiation Oncologists can help allay any concerns around perceived complications with Radiotherapy.

Many women are understandably anxious once they are diagnosed with breast cancer and it is not uncommon for them to request a double mastectomy (so called Angelina Jolie effect). Many surgeons are faced with this scenario on a regular basis. It takes time to reassure patients and to explain their individual risk based on tumour biology. Unlike BRCA1 and BRCA2 mutation carriers, there is no survival advantage or benefit with a double mastectomy in women with a small Grade 1 breast cancer. If despite clear and detailed discussion, the patient remains keen on double mastectomy, then it needs to be documented accordingly in the clinical notes.

It is also advisable to seek a formal assessment by a Clinical Psychologist in this setting. The clinical letters do not indicate any heightened anxiety demonstrated by [Ms A] or if the patient had been adequately counselled against having a double mastectomy. There was no referral to the Clinical Psychologist after the original WLE surgery and before the patient requested BILATERAL mastectomy. A formal CP assessment could have helped the patient rationalise the true extent of her individual risk based on personal and family history of breast cancer, determine underlying motivation for seeking double mastectomy with reconstruction and help with decision-making. More importantly, an experienced CP can determine if patient has realistic expectations from surgery and help them work through the concept of "decision-regret".

Despite all these measures, a handful of patients may continue to request double mastectomy. Provided their motivation for surgery is not fuelled by anxiety or unrealistic expectations from reconstructive surgery because they are dissatisfied with the size/shape of their native breasts, have a good understanding about the complexity of surgery, able to demonstrate compliance with post-operative instructions during recovery, understand the implications of poor outcome and potential risks and complications of surgery; then it would be reasonable to proceed with double mastectomy, after clearly documenting the above.

It is possible, these conversations did take place between [Ms A] and her treating surgeon; but it is difficult to advocate in the absence of robust documentation.

2) Poor cosmetic outcome incurred by the patient: Post-operative medical imaging supplied by ACC includes one photograph; which appears to have been taken by the patient and not by a Medical Illustration photographer. There is rippling effect in the superior aspect of both breasts, asymmetry in terms of volume and nipple position, loss of superior pole and "bottoming out" effect on the LEFT side. The Personal Breast Sculptor Report from the [private plastic surgery clinic] also demonstrates asymmetry in volume and lateral deviation of LEFT nipple, with longer nipple to IMF distance on the LEFT.

There are no preoperative photographs to document patient's normal breast appearance prior to surgery and which should form part of any Oncoplastic surgical records. There are no measurements in any of the clinical documentation to indicate original breast size, degree of ptosis, nipple to IMF distance, distribution of breast parenchyma, any asymmetry between the two sides in terms of size, nipple position or IMF. None of the preoperative clinical notes provide any indication of patient's cup size or desired breast size after reconstruction. The only documentation in a clinic letter suggests the patient's desire to have "vertical incision" and to have nipple raised by 2cm, in order to achieve a "taunt" appearance. It is uncertain how a vertical incision approach to mastectomy was requested by a non-medically trained patient.

Apart from the BAPRAS leaflet, there is no documentation that the patient received adequate preoperative education by the surgeon or Breast Care Nurses, with clear

guidance on what to expect during recovery or restriction in activities after BILATERAL surgery.

It is my practice to educate patients about avoiding any strenuous activities which involve lifting, pulling or pushing anything heavier than a "cup of tea" for at least 6 weeks after surgery. Patients are advised to avoid driving for 10–12 weeks; subject to wound healing or wound related complications. All gym related activities, swimming in pools, hot tubs, ocean or river etc. is also discouraged for at least 6 months to allow the reconstruction to settle and heal completely. It is important to ensure adequate social support before embarking on complex BILATERAL reconstructive surgery; as patients are unable to undertake routine household activities for 3–4 months.

Managing patient's expectation forms a significant part of the preoperative consultation. It is not uncommon for many patients to undertake online research which may or may not provide realistic pictures about post-operative outcome. Women with large or ptotic breasts often seek BILATERAL mastectomy with reconstruction in the hope of achieving better cosmetic outcome compared to their preoperative appearance. It is important to counsel patients that mastectomy with reconstruction can never replace a normal appearing breast and that the main objective of a double mastectomy is oncological safety and risk reduction.

Many surgeons show clinical photographs of their own results of similar procedures to women prior to surgery to give them some idea of what to expect and forms part of informed consent.

The patient has consulted [a private plastic surgeon] in December 2018 to discuss the outcome of her reconstruction and for consideration of revision surgery. He also notes use of softer implants and "window-shade" effect of the pectoral muscle which was not providing the muscle coverage desired and marked animation deformity. The commonest reason for this effect is premature disruption of sutures along the edge of the pectoral muscle secured to the TIGR mesh. Operative notes do not indicate whether interrupted or continuous 2/0 Polysorb was used to secure the TIGR mesh. Continuous sutures could potentially unravel if the knot slips or breaks. This deformity can be very difficult to correct in slim patients.

3. Can you please discuss the background population risk of these occurring?

Patients at increased risk for nipple necrosis and poor cosmetic outcome after "vertical incision" (Wise pattern nipple-sparing mastectomy with superior pedicle alone) and implant reconstruction, include:

Patient factors: Smokers, raised BMI, connective disorders, diabetics, hypertensive patients, those on steroids and anti-coagulants/anti-platelet therapy, bleeding disorders, immunocompromised patients (such as after Chemotherapy), previous Radiotherapy, large breast volume (>500gm mastectomy specimen weight), large implant size (>/=500cc). Poor quality pectoral muscle due to inadequate upper body strength and use which could tear away from the mesh.

Technical factors which could increase risk include:

1. Inaccurate marking prior to surgery and distance of each nipple from the midline has not been measured before and during surgery (after implant placement) and committing to final nipple position.

2. Damage to pectoral nerves resulting in pectoral muscle atrophy. Plastic surgery assessment indicates the patient is able to tense the pectoral muscle suggesting intact innervation.

3. Implant pocket too large for the size of implant — this can cause the implant to rotate/flip.

4. TIGR mesh and pectoral muscle have not been pulled together to provide a snug fit around the lower pole of the implant.

5. Very thin mastectomy skin flap which can compromise vascular supply to the nipple via a very small superior pedicle.

6. Use of harsh diathermy settings during dissection. (Safer to use PlasmaBlade which has lower tissue temperatures and reduces risk of flap compromise).

7. Technique for mastectomy with tumescent vs. diathermy blade; higher risk of skin flap and nipple necrosis with tumescent technique in high risk patients and large mastectomy specimen weight (5).

8. Continuous suture to secure TIGR mesh to edge of pectoral muscle. If this suture snaps at one edge, the entire suture could unravel resulting in the window-shade effect and pectoral muscle migrating upwards.

9. TIGR mesh may not have been secured to the lateral IMF to prevent larger implants from migrating laterally. The size of TIGR mesh is not documented in the operation notes (15x20cm sized TIGR mesh would have been necessary for a 495CC implant).

4. Taking into account all of her particular circumstances, please discuss the likelihood of this occurring in her case? Please provide statistical analysis?

Statements provided in Sections 1–3 highlight lack of information on following:

1. Medical photographs of preoperative and post-operative stages.

2. Histology report with breast weights.

3. Operation note does not indicate breast weight.

4. Operation note does not indicate type of dissection: tumescent hydro-dissection or diathermy blade. The risk of skin flap and nipple necrosis is slightly higher with tumescent technique in high risk patients (smokers, diabetics and large mastectomy specimen weight) (5)

5. Based on clinical photograph provided, the implant used was likely too small for the pocket.

6. If patient was positioned up during surgery to determine implant position on each side and ensure symmetry in terms of implant position.

7. Preoperative photographs with measurements of native breast base, nipple height and distance from midline, IMF position and desired nipple position and markings.

8. Clear discussion about patient's actual risk despite new breast cancer diagnosis in the context of family history.

9. Whether patient was adequately counselled against an unnecessary double mastectomy; after Genetic testing with negative results.

10. Confirmation of patient's understanding about the complexity about the surgery, potential risks and complications and whether the patient had realistic expectations about surgery. This is difficult to quantify or confirm accurately and Clinical Psychologist report may have helped the team gain some understanding about the patient's motivation for double mastectomy.

11. Preoperative breast size and desired final breast cup-size/volume is not documented.

12. Patient was not informed about the potential risk of nipple necrosis with this technique according to the clinic letter.

"**Potential problems:** Implants are prone to hardening, deflation, visible folds and creases, and do not give good results if you have to have radiotherapy either before or after the reconstruction is carried out." This is the only section about risks associated with implant reconstruction in the BAPRAS information leaflet. The leaflet does not give any information about nipple-sparing or skin-sparing mastectomy, or the risks associated with each technique.

[Ms A] was a slim patient with BMI of 22 and a non-smoker at the time of her diagnosis. There were no underlying medical conditions which could have resulted in higher complication rate. Patient did not require Radiotherapy or Chemotherapy, which could have increased the risk of wound related complications or reconstruction failure.

Based on all the information provided, the likelihood of nipple necrosis in this patient is approximately 3–5% in my practices. For larger mastectomy specimen weights, bi-pedicle approach could have helped reduce the risk of nipple necrosis due to dual vascular supply (4).

Accurate marking, checking nipple position at the end of the procedure, sitting patient up intraoperatively to check for nipple position and implant position, reducing the weight of the implant on the suture line and NAC, preoperative patient education and

clear post-operative instructions re restriction in activities; are some factors which could have helped avoid poor cosmetic outcome for this patient.

There is insufficient information in the clinical documentation provided to ACC to fully appreciate the extent of informed consent and adequacy of preoperative patient education. It is not uncommon for patients to have a limited or inaccurate understanding about complex surgery or the associated risks/complications. Multifactorial causes include, underlying anxiety secondary to cancer diagnosis, insufficient time spent during individual clinical consultations, patient's inability to articulate their lack of understanding/feeling embarrassed in a busy clinical setting, overoptimistic belief that they would not have any complications, difficulty remembering all the instructions by the doctors and nurses (despite clear documentation), and variation in interpretation of what is being said by the surgeon/ nurses versus what is actually understood by the patient. A well trained BCN is invaluable in educating the patient and family on how to prepare for complex surgery and what to expect during recovery, go through all the documentation with the patient and reiterate all the instructions by the surgeon (sometimes repeatedly), to ensure clear understanding by the patient; while constantly serving as their advocate in the health system.'

Appendix C: Independent clinical advice to Commissioner

Independent clinical advice from general surgeon Dr Erica Whineray was provided to HDC on 15 August 2023:

> 'I have been asked to provide an opinion to the Commissioner on case number 20HDC00204, and I have read and agree to follow the Commissioner's Guidelines for Independent Advisors, and that I am not aware of any conflicts of interest.
>
> I am a general surgeon having completed my MBChB (Otago University) in 1995 and FRACS (General Surgery) with the Royal Australasian College of Surgeons in 2004. I have completed a fellowship in oncoplastic surgery, and for the last 18 years have sub-specialised in breast cancer, working at Breast Screen Waitemata Northland, Auckland Breast Centre, and WDHB (until 2010). I was one of two highest volume private breast cancer surgeons in NZ. In 2023, I shifted into health strategy, consulting, and governance with a non-clinical APC with the NZ Medical Council.
>
> Expert advice requested:
>
> Should [Dr B] have been aware of the additional family history before he met with [Ms A] and her mother on 3 May 2018 (and if so, who should have elicited that information)?;
>
> Compared to the information [Dr B] was already in possession of, was that additional family history clinically significant, and could it have changed the recommendation for surgery as [Dr B] stated?; and
>
> Given the biopsy and genetic test results, should [Dr B] have made more efforts to dissuade [Ms A] from undergoing a prophylactic bilateral mastectomy?
>
> I have been provided with and have reviewed the following:
>
> 1. Letter of complaint submitted to HDC 29 January 2020 (including ACC advice report of Dr G);
>
> [Dr B's] responses dated 30 March 2020, undated (but received at HDC 9 June 2020) plus enclosures, 7 October 2020, and 15 July 2021 plus enclosures;
>
> [Ms A's] relevant clinical records;
>
> Advice from Dr Sally Langley dated 16 August 2020, 25 October 2020, and 18 November 2020;
>
> Letter from [Dr C] dated 30 September 2020;
>
> Letter from Lakes DHB dated 14 October 2020 plus enclosures;
>
> Letter from [CNS E] (undated);
>
> Letter from [Dr F] dated 3 August 2021; and

Letter from [Dr D] dated 2 August 2021.

My Advice is as follows:

Should [Dr B] have been aware of the additional family history before he met with [Ms A] and her mother on 3 May 2018 (and if so, who should have elicited that information)?

Possibly, however as [Ms A] was a "pool patient", [Dr B] was reliant on the assessment by the two other surgeons who met with [Ms A] in clinic before surgery.

Even prior to a known diagnosis, during a standard breast clinic appointment the initial surgeon should have elicited the family history of a mother's bilateral breast cancer. Additional family history of other cancers is not always known by the patient at the time of diagnosis and becomes apparent with subsequent appointments. It is standard of care to specifically ask the patient about the risk factors for breast cancer, and these include: *family history of breast or ovarian or related cancers*[1]. The presence *or absence* of these risk factors should be documented. I do not have access to the pre-operative clinical notes however the letters from [Dr C] and [Dr D] do not document the presence or absence of associated cancers, or specifics regarding [Ms A's] mother so I cannot confirm if [Ms A] was screened for this. This is the standard of care and failure to do so is a moderate departure from accepted practice.

Compared to the information [Dr B] was already in possession of, was that additional family history clinically significant, and could it have changed the recommendation for surgery as [Dr B] stated?

No, it was not clinically significant. Once [Ms A's] mother's history of bilateral breast cancer was established and the genetics referral was made, the threshold for considering a familial cancer syndrome was reached.

[Dr B] writes (page 6, [Dr B] Response and Enclosures 15th July):

On 6th April, my breast care nurse obtained a history of bilateral breast cancer (and nil else) and asked me to refer [Ms A] to the genetic services for testing — which I did.

It was <u>that</u> information that met the threshold for a genetics assessment, and once the question had been asked, the additional family history becomes non-contributory. [Ms A] should have been brought back to clinic THEN by [Dr B] who was then her allocated surgeon, firstly to take a more detailed family history, and also to discuss the implications of this and her options for treatment:

Should [Ms A] proceed with the planned WLE, SNB/Radio for the cancer she has, and sort out the genetics result later;

Or should she wait for the genetics results and decide on her treatment options then.

It is not uncommon to proceed with the cancer treatment for the cancer a patient already has, and attend to the genetic assessment and risk reduction options later if a

pathologenic variant is detected. In this case, [Ms A's] primary cancer was small and low grade — there was enough time to wait for the genetics result to come through whilst counselling her on the treatment options and providing time to decide.

Semi-urgent referrals to the genetic service are part of the January 2014 Standards of Service

Provision Breast Cancer Patients[2].

Semi-urgent referrals — initial contact by phone within five working days:

- *Newly diagnosed woman with high risk family history being referred for surgical decision-making purposes (eg, whether to undergo breast-conserving surgery or mastectomy; or whether to undergo bilateral mastectomy with or without reconstruction).*

There was a month between the genetics referral and her surgery, so I am critical of the decision to alert [Ms A] to the potential change of plan on the day of surgery. This is a moderate departure from acceptable practice and as you can see from the other reports (Dr G, Dr Langley), has not been viewed positively by [Dr B's] surgical peers.

3. Given the biopsy and genetic test results, should [Dr B] have made more efforts to dissuade [Ms A] from undergoing a prophylactic bilateral mastectomy?

Yes, I do not believe that [Ms A] was adequately counselled regarding the risks and benefits of preventative surgery in her case.

The genetic testing showed no pathological genetic variant in ATM, BRCa1/2, PALB2 and TP 53 genes, and whilst this was given an "inconclusive result" consistent with the time, it would now be declared not a carrier. I would be discouraging [Ms A] from having bilateral surgery as the risks outweigh the benefits in her case.

Given the inconclusive result, the surgeon then reviews the risks according to the family tree: [Ms A's] mother had post-menopausal breast cancer, and whilst TRN, it occurred at 50 and 58 years and she is still alive which suggest these are sporadic and not genetic cancers. [Ms A's] mother also has no first degree relative with breast, ovarian or prostate cancer. [A relative] had prostate cancer … which at that age, is considered sporadic and not hereditary. Both [Ms A's] maternal grandparents lived to a reasonably old age which is not consistent with a family tree with a cancer-causing pathological variant.

The genetics team had counselled [Ms A] that her risk of another breast cancer was up to 18% at 25 years compared to the normal population at 11%, and hence an 82% chance that she would *not* develop another cancer. Patients consistently over-estimate their risk of contralateral breast cancer so it is important that time is spent explaining what these numbers mean; for every patient like [Ms A], less than 1 in a group of 100 would develop another breast cancer each year. And whilst a bilateral mastectomy

would reduce the chance of her developing another breast cancer, there is NO survival benefit. It will not reduce breast cancer death. I do not have clinical documentation that this conversation took place. [Ms A] was not going to die of the low grade cancer that she had just had treated, and further bilateral surgery was not going to improve her survival by preventing a second primary.

CPM does not appear to be associated with a survival benefit, with the possible exception of BRCA carriers.[3]

There should have been further discussion around the possible cosmetic and psychosocial outcomes: Was [Ms A] aware that as the breast tissue was being removed, her implant reconstruction would not look like the 'celebrity augmentation'; that some people are unhappy afterwards with the cosmesis and secondary surgery is very common; changes to sexuality may occur; the implants may impair pectoral muscle function; that bilateral surgery has twice the complication rate of single side surgery[3]; and that her neo-breasts will be very different.

[Dr B] notes (page 7 [Dr B] and Enclosures July 15th) that he discussed implant loss, bleeding, infection, scars, possible asymmetry and change to nipple sensation. I cannot see further discussion of possible outcomes that I have noted in the paragraph above, nor can I see documentation that [Ms A] had seen any patient photographs from [Dr B] for further information and managing expectations.

[Dr B] writes: Regarding the contra-lateral prophylactic mastectomy for the right breast, we offer prophylactic contra-lateral mastectomy for all patients, should they request it — which [Ms A] did, after the option was explained to her.

This is incorrect: All patients do not have the option of a contralateral prophylactic mastectomy at their request. Patients do not have the option to request the removal of healthy tissues or organs without indication. That sits outside of any guideline and this would be viewed poorly by surgical peers.

I would also like to understand why [Ms A] had consented to radiotherapy and then changed her mind. That would be important in understanding her drive for bilateral surgery. If [Ms A] was clear she still wanted bilateral mastectomy and reconstruction, then it is important to understand the motivation. A referral to a clinical psychologist is often warranted as it is common to see decision-regret following preventative surgery in active women of [Ms A's] age. If [Ms A] is still keen on surgery at that point after being presented with all the possible things that could go wrong, then you have an informed patient who is likely to be satisfied with the outcome.

I am unable to determine if these discussions have taken place from the information I have been provided.

Limitations:
I do not have the pre-surgical clinic notes from the breast clinic and breast care nurse and have relied on the statements from the clinicians that have been provided to me.

Future Recommendations:

Develop a breast clinic proforma document with a minimum agreed data set that the surgeons complete for "pool patients" so that important information is collected and shared.

Discuss all cases for preventative mastectomy at the MDM.

Work with existing patients to gather a group of women who are happy to discuss their experience of the various procedures, and show their reconstruction to other women who are contemplating this surgery.

Offer formal clinical psychology appointments to patients considering prophylactic surgery.

Patient should see photos of "good" and "bad" surgical outcomes to make an informed decision.

Other Comments:

1. BMI [Ms A] has a BMI of 26. Throughout all the reports the BMI is documented at 22 which comes from an incorrect calculation from a pre-operative assessment.

The actual: Height 163 cm, Weight 70 Kg, BMI 26.3

From [Ms A] letter "Complaint and ACC advice"

I questioned [Dr B] if there would be an advantage in considering private healthcare for a reconstruction as I have medical insurance. His advice was that I would be welcome to consider a second opinion but that the outcome advised would very likely be for the same procedure …

I am concerned that the request for private or a second opinion was not adequately managed from the statement above. It is not ethical to refer a patient to your own private practice, and private insurance would have offered her the option of two-surgeon surgery with the reconstruction performed by a plastic surgeon, or another surgeon which could also have taken place in or outside of Rotorua.

Genetic "mutation" or "defect" are referred to in multiple reports in this file. The terms now used are pathological genetic variant or pathogenic variant.

Yours faithfully,

Dr Erica Whineray Kelly,
FRACS

References:

1. Ministry of Health https://www.health.govt.nz/system/files/documents/publications/mgmt-of-early-breast-cancer-aug09.pdf

2. Cancer Hub NZ https://cancerhub.net/index.php/standards-of-service-provision-for-breast-cancer-patients-in-new-zealand-provisional/

3. Contralateral Prophylactic Mastectomy (CPM) Consensus Statement from the American Society of Breast Surgeons: Data on CPM Outcomes and Risks https://link.springer.com/content/pdf/10.1245/s10434-016-5443-5.pdf'

Further information was provided to HDC by Dr Whineray on 22 December 2023:

'Thank you for your request for further information. In reply to your email dated 21st December 2023 with the following attachments which I have reviewed my opinion is as follows:

[Dr B's] reply dated 1st November 2023 which also includes new patient notes.

Te Whatu Ora response [Dr C] 10th October 2023

Te Whatu Ora response … 10th October 2023

In response:

Should [Dr B] have been aware of the additional family history before he met with [Ms A] and her mother on 3 May 2018 (and if so, who should have elicited that information)?

Taking [Dr B's] detailed response into consideration demonstrates that there is a systems failure in the shared-care of the breast clinic with information regarding family history not being clearly documented or "owned". [Dr C] … did not elicit the family history of bilateral breast cancer nor the triple receptor negative nature of the tumours (although [Ms A] may not have known or understood the significance of the latter). The original referral letter to the breast clinic from the GP states "*FHx-mum with breast cancer [in her fifties], 2 x partial mastectomy"* which is not further documented in their clinic letters.

Compared to the information [Dr B] was already in possession of, was that additional family history clinically significant, and could it have changed the recommendation for surgery as [Dr B] stated?

As per my previous letter, the threshold for a genetics referral had been met when it was requested. In medicine, a doctor is responsible for the referrals they make and the tests they order, so even though [Dr B] says that this patient had not been allocated to him, having personally referred [Ms A] for genetics assessment meant that he was responsible for the outcome. This also suggests a systems problem within the breast

clinic for not establishing who takes responsibility for pooled patients before allocation to an operating list.

Regardless of any genetics delay, I maintain my opinion dated 15th August that there was a month between referral and surgery to discuss the plan for surgery in view of the request for a genetics assessment. This discussion should not have taken place on the day of surgery.

From your email:

In addition, could you please advise on the following:

You stated in your advice that patients do not have the option of a contralateral prophylactic mastectomy at their request, and that this sits outside of any guideline and would be viewed poorly by surgical peers.

That is correct and [Dr B] concurs with this in his letter dated 1st November. That statement from me was addressing an earlier justification [Dr B] had made for performing the surgery at the request of the patient.

[Dr B] writes: Regarding the contra-lateral prophylactic mastectomy for the right breast, we offer prophylactic contra-lateral mastectomy for all patients, should they request it — which [Ms A] did, after the option was explained to her.

In this case, [Ms A] had been offered this procedure so was not requesting it *per se*.

You said that a referral to a clinical psychologist is often warranted as it is common to see decision regret following preventative surgery. You advised that if [Ms A] was still keen on surgery after being presented with all the possible things that could go wrong, then "you have an informed patient who is likely to be satisfied with the outcome". However, you advised that you are unable to determine whether or not these discussions took place from the information provided.

As you rightly note, the difficulty I have is in determining from the notes the level of discussion that took place. It appeared that [Ms A] had decided on post-operative radiotherapy, and was booked for the same, before changing her mind. In the ACC letter from [Ms A], she states: *I really want to be around for my [children]* indicating that her concern was life-expectancy. There is no survival benefit to [Ms A] having this bilateral mastectomy surgery. This was not going to impact her life-expectancy and I cannot see that she was told this or understood this. When [Dr B] says he has discussed the "*risks and benefits"*, the risks and complications are discussed but I cannot see the benefits listed.

[Dr B] states*: "Ultimately, I did not consider it was my role to persuade or dissuade/ discourage [Ms A] from a particular choice. I considered my role was to provide her with information relevant to the procedure, including the risks, benefits and alternatives — and leave it to [Ms A] to decide what she wished to do."*

"The reduction in risk of cancer recurrence arising from the procedure in question was discussed."

I am unable to see that from the notes, unless they are in the private clinic letters, however there is no comment on survival which is her stated reason for surgery and a *reduction in cancer recurrence* is not the same. If it were clear from the notes that [Ms A] understood that this could reduce but not eliminate her chance of developing another breast cancer, and would not change her life-expectancy, and having already been offered it by the breast service then it is reasonable that the surgery should proceed. If [Ms A] did not understand this, and that is her stated reason for surgery, then that is a moderate departure from accepted standards.

If [Ms A] wanted the bilateral surgery because of anxiety around fear of a new cancer or recurrence, then I would want a psychologist to see her. In the case of Rotorua, where [Dr B] states that there is an absence of this service, then counsellors who are available through such organisations as the Breast Cancer Foundation is an option as one would remain concerned about the surgery addressing these concerns. Another option is using time delay and speaking to other patients as a means to ensure that a patient is not making the decision out of the usual anxiety associated with a breast cancer diagnosis as further surgery may not address the underlying concern. As there is a limitation of access in Rotorua, I would call this a mild departure from acceptable practice only, and it is good to see that the breast clinic has incorporated time delay into their protocol.

With any investigation, it is difficult to know what is said in the room and what the recollection is from all parties. And, one limitation I have is that I have not seen the original HDC complaint from [Ms A] to determine if she is concerned about the treatment because of the complications or because she views the bilateral surgery as unnecessary. That will speak to whether she sees herself as being fully informed before the surgery or not.

Let me know if you would like any further comments.

Yours faithfully,

Dr Erica Whineray Kelly, FRACS'

On 27 August 2024 Dr Whineray provided a response to the following question:

'Question: [Dr B] has responded to the provisional opinion, advising that at the time of the events (in 2018) it was not known that there was no survival benefit to having a prophylactic mastectomy. Accordingly, can you please provide advice on the below question:

In 2018 at the time of the surgery, was prophylactic mastectomy considered to offer a survival benefit over alternative options, and, has thinking changed over that time?

Response (Dr Whineray): It was known in 2018 that there was no survival benefit to a prophylactic mastectomy.'