Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

# A Decision by the Deputy Health and Disability Commissioner

# (Case 21HDC01573)


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## Introduction

1. This report is the opinion of Dr Vanessa Caldwell, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

2. The report discusses the care provided to Ms B by obstetrician and gynaecologist Dr A at a public hospital (Health New Zealand|Te Whatu Ora (Health NZ)).

3. On 21 February 2019, Ms B underwent surgery for a suspected burst ovarian cyst in her left fallopian tube. Ms B said that prior to the surgery, she was advised that her left ovary and fallopian tube might need to be removed, but that her right ovary and fallopian tube would not be affected by the surgery. Ms B said that following the surgery, she did not find out that her right fallopian tube had been removed until February 2020 when she returned to her GP with new abdominal pain.

4. The following issues were identified for investigation:

- *Whether Health New Zealand|Te Whatu Ora provided Ms B with an appropriate standard of care at the public hospital in February 2019, in particular [in] respect of the informed consent process for surgery, the communication between clinical staff, and the accuracy of the information provided post-operatively.*



*Names have been removed (except the advisor) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.*

- *Whether Dr A provided Ms B with an appropriate standard of care at the public hospital in February 2019, in particular [in] respect of the informed consent process for surgery, the communication between clinical staff, and the accuracy of the information provided post-operatively.*

5. The parties directly involved in the investigation were:

| | |
|---|---|
| Dr A | Obstetrician & gynaecologist/provider |
| Ms B | Consumer/complainant |
| Health NZ | Group provider |

## Summary of events

### Background

6. Ms B (aged in her forties at the time of the events) told HDC that in January 2019, she collapsed at work due to abdominal pain and was taken to hospital, but the cause of her pain was not found.

7. On 5 February 2019, Ms B's GP referred her to the Gynaecology Department at the public hospital. The referral stated that Ms B had presented acutely to another hospital over the previous weekend with severe right iliac fossa (lower abdominal) pain. It also noted that Ms B had undergone an ultrasound that day (5 February), which showed free fluid and a 5cm solid ovarian mass on the left side. The referral stated that she was not particularly tender on the left side but 'remain[ed] sore on the right [side]'. The referral noted that the mass required review, and that there was also an incidental finding of an endometrial polyp.[1]

### Gynaecology clinic appointment — 20 February 2019

8. On 20 February, Ms B attended the Gynaecology Department for an appointment with consultant obstetrician and gynaecologist Dr D.

9. Dr D documented that Ms B had a family history of breast cancer, but no family history of ovarian cancer or bowel cancer. Dr D used the Risk of Malignancy Index (RMI) tool for ovarian cancer to assess the risk of the ovarian cyst being malignant. RMI is calculated based on menopausal status, CA 125 level,[2] and ultrasound score. An RMI score greater than 200 indicates a high risk for malignancy. An RMI score between 25 to 200 indicates intermediate risk, and an RMI score less than 25 indicates low risk. Ms B had a score of 10 (low risk for malignancy).

10. Dr D documented that the plan was for Ms B to be admitted to hospital to undergo surgery the following day. Dr D recorded the planned procedure as a laparoscopy,[3] cystectomy,[4]

[1] A growth attached to the wall of the uterus.
[2] A substance in the blood that may be a sign of a condition or disease. A high level of CA 125 may indicate ovarian cancer.
[3] A surgical procedure to examine the organs in the abdomen.
[4] Removal of a cyst.

dilation and curettage (D&C),[5] polypectomy,[6] and a left-sided salpingo-oophorectomy.[7] Dr D also documented that Ms B should be asked if she would like a Mirena intrauterine device (IUD) inserted during the surgery. Dr D did not include a right salpingectomy[8] on the documented plan.

11. Gynaecology registrar Dr C obtained Ms B's written consent for the surgery, which was to occur the following day under the care of consultant obstetrician and gynaecologist Dr A.

12. The consent form detailed the surgery as: 'Diagnostic laparoscopy +/- ovarian cystectomy +/- [left sided] salpingo-oophorectomy + hysteroscopy D & C and polypectomy + insertion of mirena.' The risks of surgery listed on the form included infection, bleeding requiring a blood transfusion, damage to the bowel, bladder, uterus, vessels and surrounding structures, Asherman's syndrome,[9] uterine perforation, venous thromboembolism (VTE),[10] and ongoing abdominal pain. The consent form was signed by Ms B and Dr C. Dr A was listed as the consultant responsible for Ms B's care, as he was to perform the surgery. Dr C also documented in the clinical notes that Ms B had been '[c]onsented for acute operation for tomorrow'.

**21 February 2019**

*Preoperative discussions and consent*

13. Dr A first met Ms B on the morning of the surgery.

14. A clinical note made by Dr C on the morning of the surgery reflects that Ms B was anxious about the surgery. The note also stated: '[Ms B] understands [the] plan is for laparoscopy, removal of ovary if torted,[11] send for histology …' Dr A made a further note below this entry, which states: 'Surgery: with salpingo[-]oophorectomy and salpingectomy right, + [hysteroscopy] and D + C … patient agreed to this …' This entry is the first mention of the right salpingectomy in the clinical records.

15. In relation to the right salpingectomy being added to the surgical plan on the morning of 21 February, Dr A said that he discussed the procedure (including the right-sided salpingectomy) with Ms B in the preoperative holding area. He said that during their conversation, it was evident that Ms B was very anxious and afraid of her future cancer risk in light of her family history of cancer. Dr A told HDC:

> 'As her main concern was to reduce her risk of cancer, I offered her prophylactic right salpingectomy to reduce the future risk for ovarian cancer as well as the removal of the abnormal ovary and tube on the left. We discussed that the removal of both fallopian tubes reduces the risk for serious ovarian cancer originating in her fallopian tubes. We

[5] A procedure used to remove tissue from the uterus.
[6] Removal of a polyp.
[7] Removal of the left-sided ovary and fallopian tube.
[8] Removal of the right-sided fallopian tube.
[9] Occurs when scar tissue forms inside the uterus and/or the cervix.
[10] Blood clots in the veins.
[11] Twisted.

> discussed that this would impact her future fertility and she was clear that she did not desire any more children. This desire was also supported by the fact that she wanted an insertion of a Mirena IUD contraceptive device. [Ms B] was [in her forties].'

16. In relation to the risk of malignancy, Dr A said that although the RMI was low and suggested a benign ovarian cyst, the ultrasound features (of an ovarian mass with blood flow) and positive family history as well as a simultaneous breast lump, 'were non-reassuring features'.

17. Dr A said that although his usual practice is to discuss all the risks, benefits, and consequences of planned procedures, and to document the discussion, he accepts that he gained only verbal consent during the preoperative discussion with Ms B. Dr A said that the clinical notes highlight that an informed consent discussion occurred with Ms B in relation to the right salpingectomy, in particular an entry that states: '[Ms B] concerned re: cancer risk as well +/- proceed.' Dr A said that he discussed the effect of the right salpingectomy on Ms B's fertility. He said that he is sure that this discussion occurred, because if there had been a desire for fertility preservation, he would have removed only the left ovary and would have left both fallopian tubes in situ. It is unclear exactly what Dr A discussed with Ms B in relation to the right salpingectomy, and it was not added to the written consent form.

18. Health NZ told HDC that although the consent form does not state 'right salpingectomy', 'the clinical staff state that it is indicated in the clinical record that this surgical treatment plan was discussed with [Ms B] on 21 February 2021'.

19. Dr A accepted that the consent form documentation was inadequate and did not reflect the preoperative discussion he had with Ms B. He said that he cannot understand why he did not amend the consent form to reflect the discussion and the right salpingectomy. Dr A told HDC:

> 'In retrospect, my documentation should have been better with more detailed description of what was discussed. I feel bad for [Ms B], and I do wish to apologise to her that I did not fully recognize the degree of stress that she was in at that time of our discussion. Although I was sure she fully understood the long-term consequences of the procedure we discussed, clearly, she did not, and I apologize immensely. I have always strived to communicate well with my patients and respect their intentions.'

20. Dr A said that he now recognises that a conversation about the removal of both fallopian tubes in the acute setting, 'should not be done'. He stated that when someone is fearing for their life or in pain, they are most likely not in a mental state to process all the information given to them. He told HDC:

> 'I was also driven by the immense fear [Ms B] showed during the pre-operative visit and did not take into consideration that she might not have understood all information when I discussed the procedure with her.'

21. Health NZ told HDC that it agrees that the informed consent for Ms B's surgery was 'inadequate and did not reflect the pre-operative discussion as documented in the clinical inpatient notes'. Health NZ stated: 'We apologise that our practice was not adequate on this occasion, and we have stressed the importance of this for the future.'

*Surgery*

22. The surgery was completed without incident and included a left salpingo-oophorectomy, a right salpingectomy, peritoneal washings, hysteroscopy, D&C, and the insertion of a Mirena. The clinical notes document that a left ovarian cyst was found with no evidence of torsion.[12] There was no evidence of necrosis[13] in the left-hand ovary. The operation note indicated that the right ovary and right fallopian tube were normal. The left ovary was noted to be increased in size, but the left fallopian tube was normal.

23. Health NZ said that the procedure undertaken was 'in keeping with suspected complex ovarian mass torsion on [the] background of family history of ovarian and breast cancer and that this surgery would usually include removal of both [fallopian] tubes'.

*Postoperative discussion*

24. Ms B told HDC that Dr D spoke to her after the surgery. Ms B remembers Dr D telling her that the surgery had gone well and that they had removed her left ovary and fallopian tube. Ms B said that she asked about her right side and was told that it had been unaffected. There is no clinical record of this discussion.

**22 February 2019**

25. At 9.00am on 22 February, Dr A and obstetrician and gynaecology registrar Dr E saw Ms B. The clinical notes record: 'Surgery explained & photos shown. Questions answered … Feeling ok but some abdominal pain.' There are no details of what exactly was discussed, but further clinical notes state: '[Impression]: Day 1 post laparoscopic L BSO, R salpingectomy, H,[14] D+C, insertion of mirena.' Dr A said that he and Dr E explained the procedure to Ms B. Dr A stated: '[I was] under the full impression that [Ms B] had understood that the right ovary was unaffected, and that I had removed both fallopian tubes.' Dr E cannot recall any of the details that were discussed with Ms B, 'nor whether specifics of the right fallopian tube were discussed'.

**23 February 2019**

26. During a consultant ward round at 1.20pm on 23 February, Ms B was seen again by Dr D, who documented: '[D]ay 2 post op laparoscopic + LSO[15] + [right] salpingectomy + hysteroscopy + mirena.' It is unclear from the clinical records what exactly was discussed with Ms B during this review, and Dr D cannot recall exactly what was said to Ms B about the surgery during the review.

[12] Twisting.
[13] Dead tissue.
[14] Hysteroscopy.
[15] Left salpingo-oophorectomy.

**24 February 2019**

27. Ms B was seen again by Dr D on a consultant ward round. The clinical notes state the details of Ms B's operation (including the right salpingectomy), and that the plan was to discharge Ms B to a friend's house. Dr D cannot recall exactly what was said to Ms B about the surgery during this review.

28. The discharge summary dated 24 February 2019 documented the operation as: 'Hysteroscopy, D&C, insertion of mirena, laparoscopic left salpingo[-]oophorectomy, right salpingectomy.' The discharge letter was addressed to Ms B and her GP.

29. Regarding postoperative care, Dr A said:

> 'In further regard to post operative care and communication, I note that [Dr D] also visited [Ms B] on postoperative day 2 and explained the surgery as well. And finally, [Ms B] was given a discharge summary that stated bilateral salpingectomy. Despite all of this, [Ms B] clearly did not comprehend or understand the details of her operative care which is unfortunate. There is evidence, that chronic stress has negative impact on brain and cognitive function (Lupien et al., 2018). Clearly, [Ms B] was under immense stress and did not recognize, or did not fully understand what I was explaining and discussing with her pre and postoperatively.'

**Subsequent events**

30. Ms B said that in February 2020 she went to her GP with new abdominal pain and was referred for an ultrasound. She said that when she was talking to the technician during the scan, she asked about the impact on fertility of having only one ovary, and the technician advised that it appeared that she had only one ovary and no fallopian tubes. Upon further investigation, Ms B's GP confirmed with her that both fallopian tubes and the left ovary had been removed during the February 2019 surgery.

31. Ms B said that she was concerned that her right fallopian tube had been removed without her knowledge and that she was not informed after the surgery that it had been removed. Ms B said that she feels that this series of events has taken away her chance of becoming a parent.

**Relevant standards**

32. At the time of these events, the district health board (now Health NZ) had an 'Informed Consent for Health Care Procedures' policy, which staff were expected to follow when obtaining informed consent for procedures.

33. The policy states:

> 'Informed consent is required before any health care procedure is undertaken, unless the patient is not competent to make an informed choice and therefore is unable to give that consent. Consent may be verbal or written. Verbal consent to health care procedures must be documented in the health record. Although informed consent for a health care procedure may be given verbally, it **must** be written consent that is

> granted in the following circumstances: … 3. The consumer will be under general anesthetic … Written consent is to be signed on an approved [DHB] Informed Consent Form, which is to be attached to the consumer's current health record. It must be completed and signed before the corresponding health care procedure begins.'

34. The policy stipulates that, in general, the clinician who performs the procedure is the one to gain consent from the patient. Under the policy, if written consent is being obtained, then the member of the healthcare team responsible for gaining consent must sign and date the form to declare that the informed consent process has been completed.

35. Health NZ told HDC that it also follows the Surgical Safety Checklist Policy. The process requires that consent is checked during the 'Sign in — anaesthetic led' stage of the procedure, and again separately at the 'Time out — Surgeon led' stage of the procedure. Health NZ said that at this stage, consent is checked and the procedure is confirmed. Health NZ stated: 'If at any point the consent is considered to be inadequate or incomplete a time out is called to clarify and ensure that the correct consent has been obtained.'

**Responses to provisional opinion**

36. Ms B was given an opportunity to comment on the 'summary of events' section of the provisional report. She said that she did not have much else to say but would like to add that moving forward, 'simple diagrams be used instead of using technical terms'. Ms B said that this would have helped her, as she was so anxious at the time of surgery.

37. Health NZ and Dr A were also given the opportunity to respond to the provisional opinion.

*Health NZ*

38. Health NZ told HDC: 'We have no specific comment or concern regarding your provisional report. We accept the recommendations that relate to Health New Zealand and will commence implementation of these immediately.'

39. Health NZ told HDC that its gynaecology morbidity and mortality (M&M) meetings have not yet commenced, as the team were 'waiting for the implementation of the [relevant] clinical audit tool to help identify the cases'. Health NZ said that the tool went live on 1 June 2024, so it is expected that these will commence shortly. Health NZ stated:

> 'Most events related to the gynaecology team have, however, been linked with obstetrics and we can confirm that these continue to be discussed at the established monthly obstetric M&M meeting.'

*Dr A*

40. Dr A told HDC: 'I agree with the report and accept the follow up actions recommended. I really feel sorry for [Ms B].'

## Opinion

### Introduction

41. On 20 February 2019, Ms B saw Dr D in the gynaecology clinic following a referral from her GP for ongoing abdominal pain. Dr D admitted Ms B to hospital for surgery (to occur the following day) and Ms B was consented for a laparoscopy, cystectomy, dilation and curettage (D&C), polypectomy, left-sided salpingo-oophorectomy, and insertion of a Mirena IUD. The consent form did not include a right salpingectomy, and on the information available to me, it appears that the right salpingectomy was not part of the surgical plan until the following morning, when Dr A met Ms B preoperatively.

42. As part of my assessment of this complaint, I obtained independent clinical advice from obstetrician and gynaecologist Dr Emily Liu.

43. Dr Liu noted that Ms B presented with a complex ovarian cyst on ultrasound, and clinical symptoms of pain, but she had an RMI score of 10. Dr Liu advised that in light of this information, the surgical plan devised and consented for by Dr D was appropriate. Accordingly, the focus of my opinion will be on the consenting process on 21 February and the information about the right salpingectomy provided to Ms B preoperatively and postoperatively.

## Dr A — breach

### Information provided for right salpingectomy

44. Dr A said that on the morning of 21 February 2021, due to Ms B's concerns about the risk of cancer, he changed the surgical plan to include a right salpingectomy. On the previous day, Dr D had given Ms B an RMI score of 10 (low risk of malignancy).

45. Dr Liu advised that most serious ovarian cancers are understood to originate in the fallopian tubes, and a prophylactic (preventative) salpingectomy may reduce the risk of developing ovarian cancer. She said that in Ms B's case, performing a right salpingectomy at the same time as the left salpingo-oophorectomy was a reasonable option to consider. I accept this advice.

46. However, Dr Liu advised:

> '[T]his must be done with proper informed consent prior to the surgery with the pros and cons clearly explained and documented, particularly addressing the loss of natural reproductive potential given that [Ms B] was of reproductive age. I note from [Ms B's complaint] that loss of fertility was her main concern. It would appear to me that the implication of prophylactic salpingectomy was not appropriately discussed with [Ms B] prior to the procedure.'

47. Ms B is clear that she did not consent to having her right fallopian tube removed and that she was unaware that it was part of the surgical plan. On the other hand, although Dr A accepts that the consent form documentation was inadequate, he is sure that he discussed the planned operation (including a right salpingectomy) with Ms B in the preoperative

holding area. Health NZ said that this is supported by the clinical notes from 21 February, which state that the surgical plan included a right salpingectomy and that the 'patient agreed to this'.

48. In terms of what was discussed, Dr A said that he offered Ms B the right salpingectomy to 'reduce the future risk for ovarian cancer'. He said that he discussed with Ms B that the removal of both fallopian tubes would reduce the risk for serious ovarian cancer originating in the fallopian tubes, but that this 'would impact her future fertility'. Dr A stated that Ms B was clear that she did not desire any more children and that the desire was 'supported by the fact that she wanted an insertion of a Mirena IUD contraceptive device'. Dr A said that he is sure that he discussed fertility because if there had been a desire for fertility preservation, he would have removed only the left ovary and would have left both fallopian tubes in situ.

49. Dr A stated that his usual process is to discuss all the risks, benefits, and consequences of planned procedures and to document the discussion, but that on this occasion, he obtained only Ms B's verbal consent.

50. I note that there is no documentation in the clinical notes of any discussion with Ms B about the change in surgical plan, or the risks associated with the right salpingectomy. The clinical notes state only that the surgery was to include a right salpingectomy.

51. On the evidence, I have identified some issues with the informed consent process undertaken by Dr A. First, as accepted by Dr A, the surgical plan was changed in the preoperative holding bay while Ms B was already exhibiting signs of acute stress and anxiety related to the procedure. I accept that it may have been clinically appropriate to consider the removal of Ms B's right fallopian tube despite her RMI of 10, and that there is some evidence in the clinical record that the change in plan was discussed. However, I consider it inappropriate that such a significant change was put to Ms B at that time. Dr A had not discussed Ms B's surgery or priorities with her previously, and it was noted clearly that Ms B was experiencing high levels of distress.

52. I also note that Ms B told HDC that she does not recall being advised of the plan to remove her right fallopian tube. It is my view that Ms B's surprise at the subsequent ultrasound finding that her right fallopian tube was not present suggests that Ms B was unaware that her right fallopian tube had been removed. Although I am unable to make a finding on what exactly was discussed with Ms B about the change in surgical plan, it is evident that Ms B was not informed about the right salpingectomy adequately.

53. Dr A said that his usual process is to explain the risks, benefits, and consequences of the planned procedure and that he discussed the impact on fertility with Ms B. He told HDC that if he had considered that there was any desire for fertility preservation, he would have left both fallopian tubes in situ. However, I can find no evidence in the clinical notes or on the written consent form that this was discussed with Ms B. Ms B does not recall such a conversation taking place. I am critical of Dr A in this regard and find that Dr A did not

provide adequate information to Ms B to facilitate an appropriate informed consent process.

**Written consent to procedure**

54. The written consent form completed on 20 February did not include the right salpingectomy. Following the change in surgical plan, Dr A did not update the written consent form to include the right salpingectomy.

55. The hospital's Informed Consent policy states that informed consent must be in written form when the patient is to be under general anaesthetic. Dr Liu advised:

> 'As [Ms B] was undergoing general anaesthetics for the procedure, according to the [DHB's] informed consent policy, a signed written consent on an approved Informed Consent Form must be done. A new written consent should have been done by the operating surgeons … with right salpingectomy added to the procedure. In my opinion, [Ms B] was not adequately informed of the right salpingectomy prior to the procedure and the consenting process was not in accordance with the [DHB's] informed consent policy or accepted clinical practice.'

56. Dr Liu advised that the accepted clinical practice would have been for written consent to be completed on the day of surgery at the time that the decision was made to perform a right salpingectomy. She said that this would necessitate a new written consent form, or an addition to the existing consent, signed by both Dr A and Ms B, with a discussion of the implications of the surgery documented.

57. I agree with Dr Liu's advice. Dr A did not obtain Ms B's informed consent for the right salpingectomy procedure adequately. As the consultant in charge of Ms B's care, as stated in the consent form, ultimately Dr A was responsible for obtaining Ms B's informed consent in this case. I am very critical of Dr A in this regard.

**Conclusion**

58. Right 6(2) of the Code of Health and Disability Services Consumers' Rights (the Code) stipulates that before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

59. As the operating surgeon, Dr A held responsibility for ensuring that the informed consent process was adequate. There is conflicting evidence regarding the information Ms B received about the right salpingectomy. Regardless of whether Ms B was verbally informed of the right salpingectomy, the environment in which this option was put to her was inappropriate. It affected her understanding of the change in the surgical plan and the effect on her fertility. In addition, the signed consent form did not include the right salpingectomy. I find that the risks, benefits, or options related to the right salpingectomy were not explained to Ms B appropriately, in particular in relation to the impact on fertility. Dr Liu's advice supports this view, and she considers that the inadequate informed consent obtained represents a severe departure from the accepted standards. I agree.

60. Accordingly, I find that Dr A breached Right 6(2) of the Code for failing to provide appropriate information about the right salpingectomy. In addition, it is my view that Ms B did not make a sufficiently informed choice and did not give her informed consent to the right salpingectomy, and I therefore also find Dr A in breach of Right 7(1) of the Code.

**Postoperative discussions — other comment**

61. Ms B raised concerns that she was not advised postoperatively that her right fallopian tube had been removed.

62. As discussed above, I have been unable to make a finding on what exactly was discussed with Ms B preoperatively regarding the right salpingectomy, but Ms B could not recall the change in surgical plan and the impact of this on her fertility. However, it is also evident that at that time Dr A considered that he had explained the right salpingectomy to Ms B adequately prior to the surgery and that subsequently he was unaware that she did not know that her right fallopian tube had been removed.

63. The clinical notes from all three consultant reviews correctly identify that the right salpingectomy was part of the procedure. Dr A's notes from 22 February also state that Dr A explained the surgery to Ms B and showed her photos from the procedure. Dr A said that he and Dr E explained the procedure to Ms B. He stated: '[I was] under the full impression that [Ms B] had understood that the right ovary was unaffected, and that I had removed both fallopian tubes.'

64. On the evidence, I accept that it is more likely than not that during this conversation, Dr A communicated to Ms B that her right fallopian tube had been removed. However, it is also likely that because Dr A believed that Ms B was aware that her right fallopian tube had been removed, he did not explain this to her further, and this is likely where the breakdown in communication occurred.

65. I encourage Dr A to reflect on my comments in this regard.

## Health NZ — adverse comment

66. As a provider of healthcare services, Health NZ had a responsibility to provide services to Ms B that complied with the Code. As noted above, the failure to obtain informed consent from Ms B was the responsibility of Dr A as the operating surgeon.

67. Dr Liu advised that the Informed Consent policy in place at the time of the events was adequate. I accept this advice and am not critical of Health NZ in this regard.

68. Also in place at the time was the Surgical Safety Checklist policy, which all surgical staff were expected to follow. The process requires that consent is checked during the 'Sign in — anaesthetic led' stage of the process, and again separately at the 'Time out — Surgeon led' stage of the process. Health NZ said that at these points, consent is checked and the procedure that is to be carried out is confirmed. Health NZ said '[i]f at any point the consent is considered to be inadequate or incomplete a time out is called to clarify and ensure that the correct consent has been obtained'.

69. Dr Liu advised that it would appear that the sign-in and time-out consent checks likely did not take place for Ms B's surgery. She advised: '[T]he lack of written consent was not picked up prior to the commencement of surgery, suggesting that the inadequate processes in theatre involve the hospital more generally.'

70. I agree. I also note Health NZ's acknowledgement that the informed consent 'practice was not adequate on this occasion'. While I consider that the responsibility for informed consent sits with Dr A, I am concerned that either the Surgical Safety Checklist was not followed in Ms B's surgery, or the lack of written consent for the right salpingectomy was not identified. In my view, this indicates a systemic issue that is not solely attributable to Dr A. I encourage Health NZ to reflect on my comments and those of Dr Liu.

## Changes made since events

71. Dr A said that since these events, he ensures that 'all discussions of irreversible procedures such as bilateral salpingectomy or tubal litigation will be performed in a stress-free environment with adequate time between obtaining informed consent and surgery at least 24 hours and the patient is not admitted to hospital'.

72. Health NZ said that the service has not been running consistent gynaecology Morbidity and Mortality (M&M) reviews, which 'will be rectified with bi-monthly meetings to discuss such cases'.

73. Health NZ stated that consultants have discussed Ms B's case and will provide education to the department on 'ensuring that we have documented patient consent correctly and that the correct processes are followed in theatre to reaffirm this'.

74. Health NZ also said that recently it employed two clinical nurse specialists, who review all postoperative patients, which has ensured that patients are followed up in a timely manner.

## Recommendations

75. I recommend that Dr A:

a) Provide a written apology to Ms B 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 B.

b) Successfully complete HDC's three online modules for health and disability service providers and provide a copy of the completion certificate to HDC, along with a written reflection of his learnings, within six months of the date of this report.

76. I recommend that Health NZ:

a) Audit a sample of 30 clinical records for the six months prior to the date of this report, for compliance with its informed consent policy, specifically:

i. Whether the pre-procedure and surgical consultation discussions of treatment options, risks, and decisions are documented.

ii. Whether the surgical procedure recorded in the signed consent form is the same as the surgery completed.

Health NZ is to provide HDC with a report on the outcome of the audit within six months of the date of this report. Where the audit identifies a variance from Health NZ's informed consent policy, it should advise HDC of the steps it has taken to correct the variance.

b) Use an anonymised version of this report to conduct a training session for surgical staff on informed consent processes. This training is to include a refresher on the Surgical Safety Checklist Policy and the Informed Consent Policy. Evidence of this training is to be provided to HDC within six months of the date of this report.

c) Advise HDC of the regularity of its gynaecology M&M meetings since these events and confirm whether it has been conducting bi-weekly M&Ms where possible. Health NZ is to report back to HDC within three months of the date of this report.

## Follow-up actions

77. A copy of this report with details identifying the parties removed, expect the advisor on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr A's name.

78. A copy of this report with details identifying the parties removed, except the advisor 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 obstetrician and gynaecologist Dr Emily Liu:

'I have been asked to provide an opinion to the Commissioner on case number 21HDC01573. I have read the Guidelines for Independent Advisors and I agree to follow the guidelines. I am not aware of any conflicts of interest.

I am a Consultant Gynaecologist and Fertility Specialist, currently practising in both public and private sectors. My public work is with Te Whatu Ora Te Toka Tumai Auckland. I have been a fellow of the Royal Australian and New Zealand College of Obstetrics and Gynaecology (FRANZCOG) from 2013 and hold Subspecialist Certification in Reproductive Endocrinology and Infertility (CREI).

I have reviewed documentation provided to me in relation to the case. I have been asked by the Commissioner to provide comments on the following.

**[DHB]:**

1. **Whether [Ms B] was adequately informed by [DHB] staff of the right salpingectomy prior to the procedure in accordance with the [DHB's] informed consent policy and accepted clinical practice.**

   When [Ms B] was first assessed in the Gynaecology Clinic by Consultant [Dr D] following the GP referral, the procedure planned and discussed was diagnostic laparoscopy +/ovarian cystectomy +/- left salpingo-oophorectomy + hysteroscopy D&C and polypectomy. The signed informed consent completed by Registrar Dr C states "diagnostic laparoscopy +/- ovarian cystectomy +/- left salpingo-oophorectomy + hysteroscopy D&C and polypectomy + Mirena insertion". There was no discussion of right salpingectomy with [Ms B] on the day of her admission to [the DHB].

   Surgery was conducted the next day by [Dr A], supported by Registrar [Dr E]. [Ms B] was seen by [Dr A] prior to surgery in the pre-operative area. The clinical notes written by [Dr E] indicated that [Ms B] "understands plan is for laparoscopy, removal of ovary if torted, send for histology (patient) concerned re cancer risk as well +/- proceed". An additional note was added by [Dr A] below [Dr E's] note "surgery: with salpingoophorectomy left + salpingectomy right, +H+D+C -> patient agreed to this." The proposed procedure was different from the initial procedure planned. However, I note that the written consent signed by [Ms B] was not changed.

   I have reviewed the [DHB's] informed consent policy, in particular the section on Verbal or Written Consent. The policy states:

   *Informed consent is required before any health care procedure is undertaken, unless the patient is not competent to make an informed choice and therefore is unable to give that consent.*

*Consent may be verbal or written.*

*Verbal consent to health care procedures must be documented in the health record.*

*Although informed consent for a health care procedure may be given verbally, it **must** be written consent that is granted in the following circumstances:*

- *The consumer is to participate in any research, or*
- *The procedure is experimental, or*
- *The consumer will be under general anaesthetic, or*
- *There is a significant risk of adverse effects on the consumer.*

*Written consent is to be signed on an approved [DHB] Informed Consent Form, which is to be attached to the consumer's current health record. It must be completed and signed before the corresponding health care procedure begins.*

As [Ms B] was undergoing general anaesthetics for the procedure, according to the [DHB's] informed consent policy, a signed written consent on an approved Informed Consent Form must be done. A new written consent should have been done by the operating surgeons, either [Dr A] or [Dr E], with right salpingectomy added to the procedure. In my opinion, [Ms B] was not adequately informed of the right salpingectomy prior to the procedure (please also refer to my comments on this in the section below) and the consenting process was not in accordance with the [DHB] informed consent policy or accepted clinical practice.

2. **Whether it was reasonable from [Ms B's] clinical presentation for [DHB] staff to proceed to including a right salpingectomy or whether other options should have been considered.**

[Ms B] presented with a complex ovarian cyst on ultrasound scan and clinical symptoms of pain. The clinical notes from [Dr D] noted that there is family history of breast cancer, no ovarian cancer and no bowel cancer. [Dr D] used RMI (Risk of Malignancy Index) for Ovarian Cancer to assess the risk of the ovarian cyst to be malignant prior to surgery. RMI combines three pre-surgical features, serum CA125, menopausal status and ultrasound score. RMI score greater than 200 indicates high risk for the cyst to be malignant. RMI score between 25 to 200 indicates intermediate risk. RMI score for [Ms B] was 10. [Dr D] noted that the ovarian cyst was most likely benign and the procedure initially recommended by [Dr D] did not include right salpingectomy. I would agree that the surgical decision was appropriate.

Most serous ovarian cancers are now understood to originate in the fallopian tubes. Prophylactic salpingectomy may reduce the risk of developing ovarian cancer. In my opinion, in [Ms B's] case, performing right salpingectomy at the same time of the left salpingo-oophorectomy was a reasonable option to consider. However, this must be done with proper informed consent prior to the surgery with the pros and

cons clearly explained and documented, particularly addressing the loss of natural reproductive potential given that [Ms B] was of reproductive age. I note from the Referral to HDC by [the] Advocate for [Ms B], that loss of fertility was her main concern. It would appear to me that the implication of prophylactic salpingectomy was not appropriately discussed with [Ms B] prior to the procedure.

3. **Whether the communication between staff about the procedure and what had been consented was adequate.**

   I believe the communication between [Dr D] (Consultant who decided on the procedure initially proposed) with [Dr C] (Registrar who consented [Ms B] for the procedure) was adequate. From the clinical notes, on the day of [Ms B's] presentation and admission to [the DHB], [Dr D] wrote that [Dr D] "will discuss with on call consultant" who will be performing the procedure. On the day of the surgery, a right salpingectomy was added to the procedure. There was discrepancy of the notes from the Registrar [Dr E] and the Consultant [Dr A]. Based on the clinical notes provided, I am unable to comment on the communication between staff beyond what was documented.

4. **Whether the [DHB's] informed consent policy is adequate.**

   I have reviewed the [DHB's] informed consent policy. In my opinion, the policy is adequate.

5. **Any other matters in this case that you consider warrant comment.**

   I have no other comment on this case.

**[Dr A]:**

6. **Whether [Dr A] had adequately informed [Ms B] of the right salpingectomy prior to the procedure in accordance with the [DHB's] informed consent policy and accepted clinical practice.**

   As outlined in point 1 in the section above in relation to [the DHB], written consent signed by [Ms B] should have been done on the day of the surgery when the decision for right salpingectomy was added to the procedure. This was stated in the [DHB's] informed consent policy. The accepted clinical practice would be to either sign a new written consent or to add the procedure to the existing consent with initials/signatures by both [Ms B] and [Dr A] and to clearly document in the clinical notes the discussion of the implications on prophylactic salpingectomy.

7. **Whether it was reasonable from [Ms B's] clinical presentation for [Dr A] to proceed to including a right salpingectomy or whether other options should have been considered.**

   Please also refer to point 2 in the section above in relation to [the DHB]. In my opinion, based on [Ms B's] clinical presentation and a low RMI score suggesting likely benign ovarian cyst, salpingectomy of the contralateral fallopian tube (in this situation, a right salpingectomy) is not part of the standard management for ovarian

cyst. Prophylactic salpingectomy is a reasonable option to consider in appropriate situations when natural fertility is no longer desired, but it must be done with appropriate informed consent with the implications clearly outlined to the patients and the discussion documented.

**8. Any other matters that you consider warrant comment.**

I have no other comment on this case.'

The following further advice was received from Dr Liu on 3 May 2024:

'After reviewing the additional documents provided, the only change I would make to my previous response would be that the clinical notes dated 21/2/2019 of the pre-operative discussion were not written by [Dr E]. From [Dr E's] statement, [Dr E] was unaware [of having been] present at the pre-operative review and the clinical notes were written by another RMO whose details are not legible.

In my opinion, the inadequate informed consent is a severe departure from accepted clinical practice. It breaches the patient's right to know the risks, benefits and alternatives of any medical intervention that is going to be performed on them. The inadequate written consent signed by the patient preoperatively in this case is attributable to the operating surgeon [Dr A]. However, I note from the response provided by Te Whatu Ora that [the hospital] has the Surgical Safety Checklist Policy to ensure the correct consenting process has been followed. It would appear that the sign-in and time-out likely did not take place for [Ms B's] surgery, as the lack of written consent was not picked up prior to the commencement of surgery, suggesting that the inadequate processes in theatre involve the hospital more generally.

**Dr Emily Liu**
**Gynaecologist & Fertility Subspecialist**
**MBChB MRMed FRANZCOG CREI**'