Obstetrics and Gynaecology Consultant, Dr B

Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral (formerly MidCentral District Health Board)

A Report by the

Health and Disability Commissioner

(Case 20HDC01873)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a woman by an obstetrics and gynaecology consultant at Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral (formerly MidCentral District Health Board (MCDHB))[1] on 5 August 2020, relating to the removal of her uterus, ovaries and fallopian tubes. In particular, the report considers the adequacy of the informed consent process in relation to the removal of the woman's ovaries, and the type of incision used for the surgery. At the pre-admission appointment, the woman had agreed to the removal of her uterus and fallopian tubes using a bikini incision, and she had understood that her ovaries would be retained. However, around 30 minutes prior to the surgery, the woman was informed of the clinical recommendation to remove both her ovaries, and for a midline incision to be used.

Findings

2. The Commissioner considered that in this case the consenting process was inadequate. She noted that because of the very late stage at which the woman was informed about the clinical recommendation to remove both her ovaries using a midline incision, the woman felt under pressure to go along with that plan. It was not appropriate to introduce such changes to the woman's surgery so late in the process when there was insufficient time for her to make a considered decision to proceed with the surgery. The informed consent process should have taken place in an environment that enabled the woman to communicate openly, honestly and effectively with her healthcare providers. The Commissioner found that the consultant responsible for the woman's care breached Right 5(2) and Right 7(1) of the Code.

3. The Commissioner made adverse comment about MCDHB, and found that gaps in its system contributed to the breaches in care identified. In particular, she was critical that MCDHB staff failed to call the consultant for the woman's pre-admission appointment as required, and that the clinical records from that appointment were unsigned, meaning that the clinician who saw the woman at that time could not be identified.

Recommendations

4. The Commissioner recommended that the consultant provide a written apology to the woman for his breaches of the Code. The Commissioner also made several recommendations to Te Whatu Ora, including that it apologise to the woman for the system issues identified; provide an update to HDC on its review of theatre bookings and pre-admission processes; and share this case anonymously with relevant surgical staff for educational purposes.

[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 MCDHB now refer to Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral.

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Complaint and investigation

5. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided to her by a consultant obstetrician and gynaecologist, Dr B, at MCDHB. The following issues were identified for investigation:

- *Whether MidCentral District Health Board (MCDHB) provided Mrs A with an appropriate standard of care between November 2019 and August 2020 (inclusive).*
- *Whether Dr B provided Mrs A with an appropriate standard of care between November 2019 and August 2020 (inclusive).*

6. The parties directly involved in the investigation were:

Mrs A	Consumer/complainant
Dr B	Obstetrics and gynaecology consultant/provider
MCDHB	Provider

7. Further information was received from:

Mr A	Consumer's husband
Dr C	Obstetrics and gynaecology registrar
Dr D	Obstetrics and gynaecology registrar

The Nationwide Health and Disability Advocacy Service

8. Independent advice was obtained from a consultant obstetrician and gynaecologist, Professor Cynthia Farquhar (Appendix A).

Information gathered during investigation

9. This report concerns the care provided to Mrs A by MCDHB and obstetrics and gynaecology consultant Dr B[2] when Mrs A underwent elective surgery to remove her uterus (a hysterectomy) and her fallopian tubes and ovaries (a bilateral salpingo-oophorectomy) in August 2020.

Background

10. Mrs A (aged in her fifties at the time of events) went through menopause at the age of 50 years and took hormone replacement therapy[3] to help with managing the associated symptoms. In 2018, Mrs A had her post-menopausal bleeding investigated and a Mirena

[2] Dr B is a fellow of both the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and the Royal College of Obstetricians and Gynaecologists (RCOG).
[3] Mrs A was taking Progynova, oestradiol and Provera.

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intrauterine device (IUD)[4] inserted. A biopsy of the lining of her uterus (an endometrial biopsy) was taken, which subsequently was reported as normal.

Appointment 17 December 2019

11. On 17 December 2019, Mrs A was seen by a registrar for Dr B in the outpatient clinic at MCDHB. Mrs A expressed concerns regarding her persistent bleeding. An endometrial sample was taken, and Mrs A was informed that if the test results came back normal she could stop her hormone replacement therapy and continue using the Mirena IUD. The sample results were reported as being normal. A letter was addressed to Mrs A and her GP detailing this appointment.

Appointment 25 February 2020

12. On 6 January 2020, Mrs A was referred by her GP to the Obstetrics and Gynaecology service at MCDHB as her bleeding persisted. The referral letter noted that Mrs A had restarted hormone replacement medications due to the ongoing bleeding, and was keen to pursue a hysterectomy.

13. On 25 February 2020, Mrs A was seen by registrar Dr C in the Obstetrics and Gynaecology Clinic. Dr C found that Mrs A had an enlarged uterine fibroid,[5] and also noted Mrs A's bleeding and hot flushes.

14. Dr C discussed Mrs A's case with Dr B, who recommended a hysteroscopy (a visual examination of the cervix and interior of the uterus). Dr C noted that if the hysteroscopy showed no evidence of malignancy (cancer), they would likely proceed with a total abdominal hysterectomy (removal of both the uterus and cervix), but that a total laparoscopic hysterectomy[6] could also be possible. Dr C told HDC:

> "I did not discuss hysterectomy (the definitive procedure to control the symptoms) nor the options around this in any detail at this clinic visit [with Mrs A] … This is because the outcome of this particular clinic visit was to arrange a hysteroscopy (which was discussed in detail), the outcome of which would influence future management."

15. A letter was addressed to Mrs A and her GP detailing this appointment.

16. Dr B told HDC that following his discussion with Dr C about Mrs A's symptoms, he "was concerned that [Mrs A] had a uterine sarcoma, which is a relatively rare type of aggressive uterine cancer appearing mainly in fibroids".

[4] Mrs A had a contraceptive device inserted to reduce bleeding.
[5] Fibroids are benign/non-cancerous tumours that form inside the wall of the uterus.
[6] Where the surgeon uses a laparoscope, inserted through the vagina or other small incisions in the abdomen, to better see the uterus and cervix. Laparoscopic hysterectomy is less invasive than abdominal hysterectomy, which requires a larger incision in the lower abdomen.

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Hysteroscopy 13 March 2020

17. On 13 March 2020, an obstetrics and gynaecology consultant and an obstetrics and gynaecology registrar, Dr D, performed Mrs A's hysteroscopy. Mrs A's Mirena IUD was also removed. Dr D told HDC: "The communication that we had had from [Dr B] at this time was that hysterectomy was already planned, independent of whether the histology was benign or malignant." It was documented that there was poor visualisation of the lining of the uterus, but there was "no obvious endometrial abnormality". The endometrium was not resampled, "since already sampled twice (both benign) since May 2018".

Surgical booking form

18. After being informed that the hysteroscopy had been undertaken, on 16 March 2020 Dr B completed a surgical booking form for Mrs A outlining the following procedures: total abdominal hysterectomy, bilateral salpingectomy (removal of the fallopian tubes), and a potential removal of the ovaries (documented as "± conservation ovaries"). Dr B selected "specialist to see at pre-admit" on the booking form as he wanted to discuss the surgery and risks with Mrs A and to sign the consent forms at the pre-admission clinic appointment.

19. Dr B told HDC that the main purpose of the booking form is to book a place in the waiting list. Dr B said that he documented "± conservation ovaries" in the booking form so that Mrs A could have the final decision about whether to have her ovaries removed following discussion about this, and that at the time of booking the surgery his intention was to offer Mrs A a bilateral ovarian removal at the pre-admission clinic.

20. MCDHB told HDC that there was no documentation to indicate whether Mrs A was provided with any written information about the procedure (the abdominal hysterectomy and bilateral salpingectomy) at the time of going onto the surgery waitlist or at any stage while waiting for the surgery. In addition, Dr B told HDC that neither the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) nor MCDHB have a specific information leaflet to provide to patients about ovary removal (oophorectomy).

Surgical pre-admission clinic appointment 8 July 2020

21. On 8 July 2020, Mrs A was seen at the surgical pre-admission clinic at MCDHB. There was no documentation of attempts to call Dr B, although the box was clearly ticked on the surgical booking form that he wished to see Mrs A at the pre-admission clinic. Dr B similarly told HDC that he did not see Mrs A at this pre-admission clinic appointment because he "was not called to see her on the day". MCDHB also confirmed that Dr B was not called to the pre-admission clinic to see Mrs A.

22. It is not known who saw Mrs A at the pre-admission clinic, as the handwritten clinical notes for this appointment were unsigned and unnamed.[7] The handwriting in the pre-admission form (created at the pre-admission clinic) is also different to that which is seen in the booking form completed by Dr B. The notes state that the planned operation was an

[7] MCDHB told HDC that a junior doctor (the house officer on call) usually completes the pre-admission clinic and associated documentation.

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abdominal hysterectomy, that the fallopian tubes would be removed, and that Mrs A's ovaries would remain.[8] No consent forms were completed at this time.

23. In a letter to MCDHB from the Nationwide Health and Disability Advocacy Service on behalf of Mrs A, it is noted that at this appointment Mrs A had agreed to have a hysterectomy with a bikini incision,[9] and for her ovaries to remain in situ. The letter also noted Mrs A's understanding at that time that the hysterectomy would deal with her ongoing issues with bleeding, and that the decision to leave the ovaries meant that the hot flushes "would in time abate and cease". There is no documentation in the pre-admission form concerning a discussion about hot flushes.

24. The pre-admission form also did not include any details about what kind of incision would be used. In addition, although Dr B told HDC that he had intended to discuss the removal of both ovaries with Mrs A at this clinic, that discussion did not take place as he was not in attendance.

Surgery 5 August 2020

Informed consent process

25. On 5 August 2020 — the morning of the surgery — Mrs A was seen at approximately 7.30am by Dr D, who completed the consent process. Mrs A signed the consent form for a "[t]otal abdominal hysterectomy [and] bilateral salpingo-oophorectomy" (removal of both ovaries and both fallopian tubes). This differs from the surgery information noted at Mrs A's pre-admission appointment, when the recorded plan was to remove only her uterus and fallopian tubes, and to retain the ovaries. The pre-admission record accords with what Mrs A told HDC she thought would occur on the day of surgery, in relation to the conservation of her ovaries.

26. Dr D told HDC:

> "[Dr B's] booking form states that [Mrs A] would have her ovaries conserved and it would appear that this decision was altered on the day of surgery. This is certainly not something that I would take it upon myself to change."

27. Dr D cannot recall how she became aware of the decision that Mrs A's ovaries were to be removed. Dr D also cannot recall whether she was aware at that time that Mrs A believed she would be retaining her ovaries, and that the incision would be along her bikini line.

28. Dr D recorded the risks for surgery on the consent form as follows: "bleeding, infection, extension of incision/midline incision, injury surrounding structures, risk incomplete resection or repeat procedure required." MCDHB stated that a midline incision was noted as a possible risk of the surgery.

[8] Documented as: "TAH [total abdominal hysterectomy] + BS [bilateral salpingectomy] — for conservation of ovaries."
[9] An informal term for an incision near the top of the pubic area.

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29. Mrs A said that at this point she understood that the incision would be on her bikini line. Dr D told HDC that she does not recall what discussions she had with Mrs A about the incision line, and there is no documentation of any such discussions.

30. Dr D told HDC that on the day of surgery she did not specifically discuss with Mrs A whether her hot flushes would remain after the removal of her ovaries, and there is no documentation of any such discussion with Mrs A at this point.

31. It is disputed whether, following Dr D's review, Mrs A spoke with Dr B prior to the surgery. In response to the provisional report, Mr and Mrs A said that Mrs A did not see or speak to Dr B at all before the surgery. They said that Mrs A saw and spoke to only Dr D before the procedure on the day of surgery. However, Dr B told HDC that he "definitely saw [Mrs A before the surgery] and discussed her surgery and advantages of bilateral removal of ovaries".

32. MCDHB told HDC that Dr B "would have seen [Mrs A] at approximately 7.45am, prior to the commencement of his morning theatre list". Dr B told HDC that prior to the surgery he explained to Mrs A that as her uterus and fibroids were large, they would likely need a midline incision to allow better access and make the surgery "safer and easier". Dr B stated:

> "[It would have been] very difficult and unsafe to operate on [Mrs A] via a transverse abdominal incision (Bikini line) due to the relatively poor access this incision provides in comparison to the midline one."

33. Dr B also said that it was at this time that he first discussed with Mrs A the removal of both her ovaries, including the risks and benefits of that procedure, and his view that removal of the ovaries would be "unlikely to make a difference in [Mrs A's] symptoms of severe hot flushes". However, no such discussions were documented in the clinical notes.

34. In relation to whether Dr B was aware of any discussions about ovary removal Mrs A had had with other clinicians prior to the surgery, Dr B told HDC that he did not know what other clinicians had told her, although he believed Mrs A had been "thoroughly consented" by Dr D. Dr B said that he was not aware of what Mrs A's expectations were on the day of surgery, including her expectation that her ovaries would remain and that the incision would be on her bikini line.

35. Mrs A told HDC that she had only about half an hour to consider whether she wanted her ovaries removed. She said that she felt that the surgery plan had been changed without her having time to consider the proposed changes, including that the incision was to be more invasive than what had been discussed at the pre-admission clinic. Mrs A explained that she felt too shocked to say anything at the time, and "felt coerced to go along with the new plan".

36. Mrs A was also under the impression that after the surgery, she would no longer experience hot flushes. Mrs A said that she was never informed that she might continue to experience

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hot flushes after the surgery, and that possibly she would have to continue to take hormone replacement therapy medication as well.

37. Mrs A's husband, Mr A, was present in the pre-operation room with his wife. Mr A told HDC that in both the pre-operation clinic appointments and initially on the day of the surgery, they were advised that Mrs A would get to keep her ovaries and that there would be a bikini line incision. Mr A said that five minutes before they wheeled Mrs A into surgery, a doctor advised that there would be a bigger incision, and they would be taking out her ovaries. Mr A stated that the doctor did not provide any reasons for the change in incision and the recommendation made to remove Mrs A's ovaries. Mr A said that he did not say anything, because he "didn't know what was going on". The identity of the doctor who Mr A said advised them of this is unclear.

MCDHB Informed Consent Policy

38. The MCDHB Informed Consent Policy (the Policy) states that the primary responsibility for obtaining informed consent lies with the person responsible for the procedure. The Policy requires that patients are to be provided with sufficient information to enable them to make an informed decision, and this information is to be presented in a manner that enables the person to understand what they are consenting to. The Policy also requires that patients are given sufficient time to absorb the information, and discuss the information with others if desired.

Surgery

39. Mrs A entered the theatre at 8.15am. Dr B was the operating surgeon and Dr D was an assisting surgeon. During the surgery, Mrs A had her uterus, fallopian tubes, ovaries and cervix removed via a mid-line incision. The procedure and postoperative period was uncomplicated. Mrs A was discharged on 7 August 2020 with a follow-up telephone appointment scheduled for six weeks' time.

40. The histology results[10] came back negative — that is, there was no evidence of pre-cancerous or cancerous changes.

Subsequent events

41. On 17 September 2020, Mrs A had a follow-up discussion with Dr B about her recovery. Dr B noted: "[S]he is all well and the wounds have healed well." Mrs A raised concerns about hot flushes she was experiencing and the removal of her ovaries. Dr B told HDC that at this appointment he "explained [to Mrs A] that after the change (menopause) ovaries are considered minimally functioning organs and the removal or keeping them will unlikely change the symptoms she was already experiencing over [the] last few years". Dr B recommended that Mrs A take evening primrose oil if she wanted an over-the-counter option, or speak with her GP for oestrogen-only hormonal medication to help with her hot flushes. Dr B told HDC that he acknowledges that most over-the-counter remedies are not very effective, but that in his experience most patients prefer over-the-counter medications

[10] Testing was carried out on the fibroid in the womb, and on the fallopian tubes, ovaries and cervix.

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rather than hormone replacement therapy due to its associated risks, in particular the risk associated with breast cancer.

Further information

42. A RANZCOG statement[11] at the time of these events notes:

> "In postmenopausal women, there is no consensus about whether ovaries should be removed or retained and decisions should be made following patient consultation on an individualised basis."

43. Dr B told HDC that he acted within the capacity of the consent form signed by Mrs A. He stated: "[Mrs A] consented to both ovaries being removed as per the consent form, and I always do what's in the consent form."

44. Dr B apologised to Mrs A for her experience, and also for not being able to meet with her at the pre-admission clinic appointment as planned. He told HDC that had he been aware that Mrs A was unhappy preoperatively, he would have postponed the surgery. Dr B said that on reflection, he now understands that Mrs A did not have time to consider the changes proposed on the morning of the surgery. Dr B explained that it is his usual practice to obtain informed consent at the pre-admission clinic appointment, which is a few weeks prior to the surgery date. He noted that at this pre-admission clinic appointment he usually ensures that the patient has read the information leaflet, he explains the surgery with the use of illustrations, and he discusses all the risks.

45. Dr B stated that the reason he recommended that Mrs A's ovaries be removed is because "she was most likely suffering from ovarian failure as manifested by severe hot flushes", and that at this stage he believed her ovaries had minimal function or were even functionless, with a malignant potential. Dr B further noted:

> "Unfortunately it seems that [Mrs A] was under the impression that she will stop having hot flushes after surgery. This is not true as hot flushes happen with ovarian failure, and removing the ovaries doesn't correct the situation."

46. There is no evidence that the above information was conveyed to Mrs A at any time prior to the day of surgery.

47. MCDHB apologised to Mrs A for her experience, and acknowledged that this case has identified a need to review and improve the processes around theatre bookings and the pre-admission processes.

[11] "Managing the adnexae at the time of hysterectomy for benign gynaecological disease" (2017).

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Responses to provisional opinion

48. Mr and Mrs A were given the opportunity to respond to the "information gathered" section of the provisional report. Where appropriate, changes have been made to this section in consideration of those comments.

49. Dr B was given the opportunity to respond to relevant sections of the provisional opinion. He stated: "While I am naturally disappointed to have been found in breach of the code, I understand the reasons for your decision."

50. MCDHB was given the opportunity to respond to the provisional opinion. It acknowledged the proposed findings and had no further comment to add.

Opinion: Introduction

51. This case highlights the importance of patients having adequate information and sufficient time to provide informed consent for surgical procedures. It also highlights the importance of communication between hospital staff, and between clinicians and the consumer.

52. To assist my assessment of the care provided to Mrs A, I sought independent advice from a consultant obstetrician and gynaecologist, Professor Cynthia Farquhar.

Opinion: Dr B — breach

Informed consent

53. Following a hysteroscopy in March 2020, Mrs A was placed on a surgical waitlist, she attended a pre-admission clinic in July 2020, and she had surgery on 5 August 2020. At the pre-admission clinic appointment, a junior doctor (it is unclear who, as the pre-admission documentation is unsigned) documented that the planned operation was a total abdominal hysterectomy and bilateral salpingectomy, and that the ovaries would not be removed. Dr B was not called to the pre-admission clinic, despite his documented request for this to occur at the time he completed the booking form. MCDHB told HDC that usually a junior doctor completes the pre-admission clinic documentation.

54. Mr and Mrs A told HDC that at pre-admission they were advised by the doctor that the surgical incision would be on the bikini line, and that by keeping the ovaries, Mrs A's hot flushes would in time abate and cease. However, these details were not documented at pre-admission.

55. On 5 August 2020, Mrs A was seen at approximately 7.30am by Dr D, who completed the consent form for a total abdominal hysterectomy, bilateral salpingectomy, and removal of

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both ovaries. Up until that point, the documented plan (and Mrs A's understanding) was to keep Mrs A's ovaries. Mr A, who was present with Mrs A at her preoperative appointments and on the day of surgery, also said that at all times up until then they had been advised that Mrs A would be keeping her ovaries and that there would be a bikini incision. This is not contradicted by the clinical records or Dr D's recollections.

56. Dr D could not recall the details of the discussion she had with Mrs A when completing the consent form, but said that she did not specifically mention whether Mrs A's hot flushes would remain after the removal of her ovaries.

57. It is disputed whether Dr B saw Mrs A before her surgery. Dr B told HDC that he "definitely saw her", and Mr and Mrs A are equally adamant that they did not see him. There is no record of any discussion if it did occur. Dr B said that he explained to Mrs A preoperatively that they would likely need a midline incision to allow better access, as he thought her uterus and fibroids were quite large. Dr B said that he also explained that a midline cut gives better exposure and "would make the surgery safer and easier". He stated that he "explained [to Mrs A] on [the] day of surgery that removal of [her] ovaries [would be] unlikely to make a difference in her symptoms of severe hot flushes, which have been there for several years, hence [his] offer to remove them". Mr A did note that five minutes before Mrs A was wheeled into the operating theatre, a doctor (unidentified) advised them that there would be a bigger incision and that the ovaries would be removed also. Mrs A was subsequently taken into theatre at 8.15am.

58. Mrs A told HDC that she had only about half an hour to consider whether she wanted her ovaries removed, and was surprised to be informed that the incision and surgery would be more invasive than discussed at the pre-admission clinic. She stated that she felt too shocked to say anything at the time, and felt "coerced to go along with the new plan".

59. Although Dr B told HDC that he discussed the risks and benefits of removing the ovaries, and explained his reasons for the midline incision, Mr and Mrs A both maintain that the risks, benefits and reasons were not discussed, and there is no documentation to support that they were.

Discussion

60. Up until less than an hour before her surgery, Mrs A was given to understand that her ovaries would be retained, and the incision would be along the bikini line. Dr B told HDC that on reflection, he understands that Mrs A did not have time to consider the changes proposed (addition of ovary removal and a midline incision) on the morning of the surgery. His usual practice was to obtain informed consent at the pre-admission clinic appointment, but in this case, Mrs A was asked to provide informed consent on the morning she presented for the surgery.

61. This case raises significant issues, primarily in relation to three provisions of the Code of Health and Disability Services Consumers' Rights (the Code):

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a) Right 5(2): Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively.

b) Right 6(2): 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.

c) Right 7(1): Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.[12]

62. These rights are also reflected in MCDHB's Informed Consent Policy, as discussed further below (relevant excerpts are included at Appendix B). The purpose of the Policy is to ensure that "[c]onsumers have sufficient information about a proposed treatment or procedure, specific to their individual situation, to allow them to evaluate the options without pressure and to agree or not agree to that treatment or procedure being carried out". The Policy states:

> "[W]hen obtaining consent the following principles must be observed … Presentation of the information in a manner which enables the person to understand; sufficient time to be available for the person to absorb the information, and discuss it with others if desired."

63. The Policy also sets out that the "primary responsibility for obtaining informed consent lies with the person responsible for the procedure".

64. As the person responsible for Mrs A's procedure, Dr B was responsible for obtaining her informed consent. That remains the case whether or not he spoke to Mrs A prior to the surgery, and for that reason I do not find it necessary to make a factual finding around whether Dr B did have a discussion with Mr and Mrs A preoperatively. My independent advisor, Professor Farquhar, considered that the correct informed consent process was not followed, as Mrs A did not have an opportunity to discuss with Dr B the benefits and harms of removal of both ovaries, or sufficient time to weigh up the change to the surgery. Professor Farquhar considered that this amounted to a moderate departure from the relevant standards.

65. Dr B told HDC that it was always his plan to discuss the surgery, including potential ovary removal, and sign consent forms at the pre-admission clinic with Mrs A. This would have been appropriate, and it is unfortunate for Mrs A that this did not occur. Dr B said that he does not know what other clinicians told Mrs A, and he did not know what Mrs A's expectations were on the day of surgery. While I do not hold Dr B responsible for the error whereby he was not notified about the pre-admission clinic, given the importance of the pre-admission clinic in Dr B's informed consent process for Mrs A, I do hold him responsible for his omission to take all reasonable steps to find out what occurred and what was

[12] Except where any enactment, or the common law, or any other provision of this Code provides otherwise.

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discussed during the appointment. The failure to take such steps contributed to Dr B's lack of understanding about Mrs A's expectations on the day.

66. It appears that Dr B was reassured by his belief that Mrs A had been "thoroughly consented" by Dr D, and the fact that Mrs A had signed the consent form for bilateral ovary removal, which Dr B cites as a key reason for why he proceeded with the surgery. However, I consider that at such a late stage in the process, Mrs A did not have adequate time to consider the new recommendation to have her ovaries removed and her incision line changed, and it was Dr B's responsibility to ensure that she was not put in that position. MCDHB's Informed Consent Policy stated that consumers should be allowed to evaluate their options without pressure and to agree or not agree to that treatment or procedure being carried out. At the time that Mrs A was informed about the recommended addition of bilateral oophorectomy to her surgery, there was a significant degree of time pressure, as the surgery was scheduled to take place within half an hour. Therefore, it was inappropriate to expect Mrs A to give free and fully considered informed consent for the removal of her ovaries on the morning of surgery. For the same reason, it was also not appropriate that Mrs A was informed for the first time only minutes before surgery that a midline incision was the preferred option.

67. I note that Professor Farquhar advised that the majority of her peers would recognise the difficulty that Dr B had on the morning of the surgery, in that he had the pressure of the theatre list about to start, and he had not had the opportunity at pre-admission to discuss with Mrs A the recommendation to remove her ovaries.

68. While I acknowledge that Dr B was not responsible for the fact that he was not called to attend the pre-admission clinic with Mrs A as he had planned, I consider that on the morning of surgery, if not before, he should have recognised that it was not appropriate to introduce a major change to the planned surgery (from what was documented at pre-admission) less than one hour before the surgery was due to commence.

Conclusion

69. Considering the above discussion and Professor Farquhar's advice that the informed consent process for Mrs A departed moderately from accepted standards, I am critical that the consenting process in this case was inadequate. Because of the very late stage at which Mrs A was informed about the recommendation to have her ovaries removed and to have a midline incision, she felt under pressure to go along with this. Furthermore, while it is difficult to know what Dr D or Dr B may have discussed with Mrs A concerning the risks and benefits of ovary removal and a midline incision (due to the lack of documentation), even if the necessary discussions *did* take place at that time, the imminence of the surgery left insufficient time for an appropriate and unpressured informed consent process to take place. Mrs A also had a right to an environment that enabled her to communicate openly, honestly, and effectively with her healthcare providers.

70. Accordingly, as the clinician responsible for Mrs A's care, I find that Dr B breached Right 5(2) and Right 7(1) of the Code.

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Other comments

Clinical need for ovary removal

71. I will now address whether there was a clinical need for Mrs A's ovaries to be removed. In doing so, I reiterate that my discussion in this respect does not change the requirement for clinicians to ensure that a fully informed consent process has taken place prior to the provision of any healthcare procedures.

72. Dr B stated that he recommended the removal of Mrs A's ovaries because he believed that Mrs A was probably suffering from ovarian failure with malignant potential, and that Mrs A's ovaries had minimal function. He also felt that the removal of her ovaries was unlikely to affect her symptoms of hot flushes. However, I note that at that time there was no known ovarian malignancy present.

73. Professor Farquhar advised that most of her colleagues would consider that there was no clinical need to remove Mrs A's ovaries, and would have proceeded with the hysterectomy and bilateral salpingectomy (as consented to at pre-admission), but not the removal of the ovaries.

74. RANZCOG's position at the time of these events stated:

> "In postmenopausal women, there is no consensus about whether ovaries should be removed or retained and decisions should be made following patient consultation on an individualised basis."

75. In the context of RANZCOG's position that there is a lack of consensus about ovary removal in post-menopausal women, and that Dr B had both a clinical rationale, and the intention of acting on Mrs A's choice regarding ovary removal, I am not critical that Dr B recommended the oophorectomy. However, as discussed above, the primary issue is that Mrs A was not in a position to make that informed choice and give her informed consent.

Opinion: MidCentral District Health Board — adverse comment

MCDHB systems to support staff in obtaining informed consent

76. As highlighted by Professor Farquhar, communication between the surgical booking system and the pre-admission clinic was likely at the centre of the failure to obtain informed consent from Mrs A.

Inadequate pre-admission process

77. On 16 March 2020, Dr B completed a surgical booking form for Mrs A outlining the following procedures: total abdominal hysterectomy, bilateral salpingectomy, and "± conservation ovaries". Dr B selected "specialist to see at pre-admit" on the booking form as he wanted to "discuss [the] surgery and risks and sign consent forms" with Mrs A at the pre-admission appointment. Dr B said that at the time of booking the surgery, his intention was to offer to

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remove both Mrs A's ovaries and to discuss this with her at the pre-admission clinic so that she could have the final decision on this.

78. In any event, Dr B was not called to see Mrs A at the pre-admission clinic, and Mrs A was seen by another doctor, who cannot be identified as the relevant notes were unsigned. That doctor did not complete the consent forms with Mrs A at the time, but documented that Mrs A's ovaries were to be conserved. However, there is no record of what was discussed with Mrs A at the time regarding the decision to retain her ovaries. As a result, it is unclear how the decision to keep her ovaries was reached, including to what degree it was Mrs A's expressed preference following discussion on the risks and benefits, or a recommendation by the doctor. Mr and Mrs A also told HDC that they understood from the pre-admission discussion that a bikini incision would be used, but again there is a lack of documentation regarding this in the pre-admission notes.

79. Professor Farquhar advised:

> "In the information we have received from MCDHB there is no explanation for why no call was made for [Dr B] to come to the pre-admission clinic and discuss the surgical procedure with [Mrs A] [and this] has led to a poor informed consent process and a patient who felt coerced on the day of her surgery."

80. Professor Farquhar considered this failure to be a moderate departure from accepted standards.

Discussion

81. I have found that Mrs A's consenting process was inadequate, and that Dr B was responsible for this. However, it appears that gaps in MCDHB's system contributed to the breaches in care identified.

82. While Dr B retained clinical responsibility for ensuring that the informed consent process was carried out appropriately prior to performing the surgery, in my view he should have been able to rely on MCDHB's system to support that process. However, MCDHB staff failed to call Dr B at pre-admission as required, and it appears that at no time between pre-admission and the date of surgery was appropriate action taken by any staff to remedy this error.

83. I accept Professor Farquhar's advice and am critical that the above omission meant that Dr B was not called to Mrs A's pre-admission clinic, which was a significant contributing factor to the poor informed consent process that later transpired. I am also critical that the handwritten notes from that clinic are unsigned and unnamed, meaning that the clinician who saw Mrs A at pre-admission cannot be identified. I take this opportunity to remind staff of the importance of signing all clinical documentation for tracking and accountability purposes.

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Changes made

84. Dr B told HDC that he conducted an audit of the consent process and consent form, and presented this to MCDHB. He said that he is hopeful that as a result of the audit, they will have a procedure-specific consent form where all possible risks and complications are written into it. Dr B explained that the current hospital consent form is generic, and has a small space on which to write all possible risks and complications, and frequently this leads to incomplete documentation. He said that he no longer sees patients in the pre-admission clinic, and instead he has allocated a time slot in his gynaecology clinic to see either one or two of his preoperative patients. Dr B also said that he advised his medical lead that if a patient is not booked in to see him at pre-admission, he will not operate. I commend Dr B for these changes.

85. MCDHB has initiated a review of the theatre bookings and pre-admission processes with the aim to ensure a safe pathway for patients and staff through the gynaecology outpatient clinic, theatre booking process, pre-admission clinic, and operating theatre. MCDHB identified that the most important part of this review is to make sure that "gynaecology consultants can meet with patients in the pre-admission clinic to ensure informed consent discussions occur prior to the day of surgery, allowing the patients enough time to process information and ask questions". MCDHB advised that there is now a plan in place to bring women back to the gynaecology clinic if they require another conversation prior to their surgery. In relation to Dr B's comments about the generic consent form, MCDHB advised that it had implemented a specific consent form for the insertion of a Mirena IUD in its outpatient clinic, and it would like to expand this to procedures performed in theatres.

Recommendations

86. I recommend that Dr B provide a written apology to Mrs A for his breaches of the Code. The apology is to be provided to HDC within three weeks of the date of this report, for forwarding to Mrs A.

87. I recommend that Te Whatu Ora:

a) Provide a written apology to Mrs A for the systems issues that contributed to the breaches in care identified. The apology is to be provided to HDC within three weeks of the date of this report, for forwarding to Mrs A.

b) Provide HDC with an update on its review of theatre bookings and pre-admission processes (including an update on whether any further procedure-specific consent forms have been developed for procedures performed in theatre), within two months of the date of this report.

c) Share this case anonymously with relevant surgical staff to highlight the importance of the following:

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i. obtaining informed consent, specifically providing information to patients in a way they can understand, with enough time for them to consider the information; and
ii. adequate documentation and communication between clinicians at all stages of the preoperative process, including from the initial theatre booking form, to pre-admission and the day of surgery.

Te Whatu Ora should report back to HDC on the steps taken to achieve this, within five months of the date of this report.

Follow-up actions

88. A copy of this report with details identifying the parties removed, except MCDHB/Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral and the expert who advised on this case will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.

89. A copy of this report with details identifying the parties removed, except MCDHB/Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral and the expert who advised on this case, will be sent to the Health Quality & Safety Commission, and will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from consultant obstetrician and gynaecologist Professor Cynthia Farquhar:

"**Complaint: MidCentral District Health Board and [Dr B]**
HDC ref: 20HDC01873

The HDC has provided the correspondence and copy of the clinical records as well as a summary of the case. I have made this summary from my own reading of the documents provided to me.

Description of the case

[Mrs A], [in her fifties], had postmenopausal bleeding investigated in 2018 by MidCentral District Health Board (MCDHB). An endometrial biopsy was taken and was subsequently reported as normal. A Mirena was inserted. She was known to have fibroids.

On 17 December 2019 [Mrs A] was seen by [a registrar] in the outpatient clinic at MCDHB with persistent bleeding. She was taking hormone treatment at that time. [Mrs A's] case was discussed with the consultant gynaecologist, [Dr B] and a sample was taken which was reported as normal.

On 6 January 2020 [Mrs A] was referred again by her GP as bleeding was continuing.

On 25 February 2020 [Mrs A] was seen by [Dr C], registrar. She was noted to have an enlarged fibroid uterus. Bleeding and hot flushes were also noted. Discussed with [Dr B], further hysteroscopy arranged. The words 'Likely TAH[1] (or TLH[2])' are handwritten in the notes. There was no mention of removing the ovaries during this consultation. A similar statement is in the dictated letter to the GP. The patient did not appear to receive a copy of the correspondence.

13 March 2020. A hysteroscopy was performed but no sample taken. Poor visualisation. There was no documentation of any follow up or plans following the hysteroscopy.

16 March 2020. [Dr B] completed a surgical booking form. I did not find a letter or communication from any medical staff to the GP or [Mrs A] informing her that she was being placed on an operating list. On the booking form the procedure was written down as total abdominal hysterectomy, bilateral salpingectomy, +/- removal of the ovaries. The option to see the specialist at the pre-admit clinic was selected on the booking

[1] Total abdominal hysterectomy.
[2] Total laparoscopic hysterectomy, using a laparoscope inserted into the abdominal wall through a small incision.

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form. It is not clear if she was given written information about the procedure at the time of going onto the waiting list or at any stage while waiting for surgery.

8 July 2020. [Mrs A] was seen at the surgical pre-admission clinic at MCDHB. There was no documentation of attempts to call [Dr B] although the box is clearly ticked that he wished to see her. The handwritten notes (unsigned) state that the operation was 'TAH+BS — conservation of the ovaries'. [Mrs A] writes to the HDC that this appointment was with [Dr B] and that she was to have a partial hysterectomy, bikini incision and that her ovaries would not be removed. MCDHB have informed the HDC that this was not [Dr B] and that it was likely to be a junior doctor but note that the checklist was not completed or signed.

5 August 2020 was the scheduled day of surgery. [Mrs A] was seen early in the morning (approximately 7.30am) by the registrar [Dr D], who completed the consent for a total abdominal hysterectomy and a bilateral salpingo-oophorectomy. It is not clear when [Dr D] received instructions to add bilateral oophorectomy to the procedure. [Dr D] states that she does not recall the details and that she would not have initiated this change. 'This is not something that I would take upon myself to change'. It is not clear if [Mrs A] expressed reluctance at this time. She signed the consent form. [Dr B] saw the patient at approximately 7.45am and explained that a mid-line incision would be required because of the size of the fibroids and he also recommended removal of the ovaries. The procedure and post-operative period was uncomplicated. A discussion with [Dr B] on the 17th September highlighted [Mrs A's] concerns with hot flushes and the decision to remove the ovaries.

In summary: A hysterectomy was booked by [Dr B] on the 16th March 2020 which left open the decision about whether or not to remove the ovaries. There appears to be no record to the GP or patient about being placed on the waiting list at this time. [Dr B] has written in a letter to the HDC that he planned to discuss the decision about removing the ovaries at the preadmission clinic but the preadmission staff did not call him in spite of the option on the checklist being correctly ticked. There is some confusion here as [Mrs A] has written that she saw [Dr B] in the preadmission clinic. MCDHB have written that she probably saw a junior doctor. The notes from the preadmission clinic are unsigned. In her communication to the HDC [Mrs A] stated that she was expecting the ovaries to be conserved following the visit to the preadmission clinic and the discussion with the staff there.

When she was seen on the morning of the surgery (5th August 2020) she was asked by the registrar, [Dr D] to consent to removal of the ovaries and she signed the consent form. She was seen by [Dr B] shortly after signing and he also recommended removal of the ovaries. We do not know if she expressed concerns to either [Dr D] or [Dr B]. She does not appear to have received any written information about the procedure. It would seem that there was no discussion or communication between [Dr B] and [Mrs A] about the removal of the ovaries from the time of booking until the morning of the

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surgery. If there was earlier communication it was either not documented or was not in the documents provided.

The issues for [Mrs A] (as in the HDC letter of 25 September 2020) were 'the plan for her surgery was changed without giving her time to consider' and that 'the surgery was more invasive' than discussed at the preadmission clinic. She also felt that in subsequent communications that '[Dr B's] manner was dismissive and she felt coerced to go along with the new plan'.

Please comment on

1. The care provided by [Dr B], including but not limited to:

a. Whether a bilateral salpingo-oophorectomy was clinically indicated?

There has been a change in practice over the past 30 years about the removal of the ovaries at the time of a hysterectomy in order to reduce the risk of developing ovarian cancer. It used to be common to remove both ovaries in post-menopausal women. However there has been increasing recognition that the ovaries do have a role in long term health. Indications for removal include increased risk of breast or ovarian cancer, pathology that may recur (such as endometriosis), or a concern that a malignant condition such as endometrial cancer was present (and then the ovaries are usually removed). In [Mrs A's] case [Dr B] has explained that he was concerned about the size of the fibroids and the possibility of a sarcomatous change within the fibroids. Yet the possible diagnosis of a sarcoma was not investigated prior to the hysterectomy. She was not on the high suspicion of cancer pathway. She did not have any additional imaging. She waited 4 months for surgery.

The long term effects of removing the ovaries are now well studied. In the correspondence from MCDHB, the phrase 'functionless organs with malignant potential' is used more than once. The term 'functionless' is no longer correct and there is a substantial body of evidence that the postmenopausal ovary is physiologically active and continues to produce both estradiol (albeit low levels) and testosterone.

A brief summary of the evidence from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists statement (2017) 'Managing the adnexae[3] at the time of hysterectomy for benign gynaecological disease' is copied here.

- A modelling study concluded that 'women younger than 65 years of age clearly benefit from ovarian conservation, and at no age is there a clear benefit from prophylactic oophorectomy'.
- A subsequent observational study of nearly 30000 women enrolled in the Nurses' Health study, (median follow-up of 24 years), concluded that, 'compared

[3] Refers to the ovaries, fallopian tubes, and ligaments that hold the reproductive organs in place.

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with ovarian conservation, bilateral oophorectomy at the time of hysterectomy for benign disease is associated with a decreased risk of breast and ovarian cancer but an increased risk of all-cause mortality, and fatal and nonfatal coronary heart disease.'

- A further prospective cohort study of over 24,000 women, with a shorter duration of follow-up (median 7.6 years), concluded that, whilst oophorectomy at the time of hysterectomy decreased the risk of ovarian cancer compared to hysterectomy alone, it was not associated with an increased risk of coronary heart disease, hip fracture or death.
- All references to these studies are in the RANZCOG statement.

The RANZCOG consensus statement concludes 'In postmenopausal women, there is no consensus about whether ovaries should be removed or retained and decisions should be made following patient consultation on an individualised basis' and they recommend 'Consider the potential risks and benefits before performing BSO[4] in women younger than 65 years of age.'

[Dr B] may have planned to have that discussion at the pre-admission clinic although his view of the ovary as 'functionless' suggests he was unaware of the potential beneficial role of the ovary in postmenopausal health.

b. Whether [Dr B] followed MCDHB's informed consent policies and processes

I have been provided with a copy of the MCDHB's consent policies and processes. In section 5.3 of the MCDHB policy and also Right 6 of the Code of Rights 'every patient is entitled to, at a minimum', … 'an assessment of expected risks, side effects, benefit' and further into the document also under section 5.3 also 'sufficient time to be available for the person to absorb the information, and discuss it with others if desired.'

I have reached the conclusion that the correct process has not been followed as [Mrs A] never had an opportunity to discuss the benefits and harms of removal of both ovaries with [Dr B]. His correspondence indicates that that would have been his usual practice if he had been called to the pre-admission clinic as he requested when completing the booking form.

c. Whether [Mrs A] was given sufficient information and time by [Dr B] for her to make an informed choice and give informed consent.

Partly covered in the point above.

Section 5.3 of the MCDHB policy also states 'sufficient time to be available for the person to absorb the information, and discuss it with others if desired'.

[4] Bilateral salpingo-oophorectomy.

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[Mrs A] arrived at the hospital on the day of surgery expecting to sign a consent form to have a hysterectomy and bilateral salpingectomy only and then had to consider the additional removal of the ovaries. There was not the time for her to weigh this up and I consider that this was insufficient.

a. What is the standard of care/accepted practice?

The standard of care is in the MCDHB policy and Right 6 about informed consent in the Code of Rights. Please see section 5.3 of the MCDHB policy on informed consent for the detail as provided by the MCDHB to the HDC. A brief summary would be that patients must receive 'an assessment of expected risks, side effects, benefit' and that there should be 'sufficient time to be available etc'.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure (mild/moderate or severe) do you consider this to be?

I consider that there has been a failure in [Mrs A] receiving informed consent and that this is a moderate departure. [Mrs A] felt both coerced and also dismissed when she raised concerns later. MCDHB has suggested that as she was already taking hormone treatment (as she was having hot flushes) removing her ovaries was of little additional consequence and 'the presence or absence of ovaries won't differ in her symptoms'.

c. How would it be viewed by your peers?

The majority of my peers would recognise the difficulty that [Dr B] had on the morning of surgery. He hadn't been able to discuss the recommendation to remove the ovaries with her (and he was not responsible for not being called to preadmission clinic). He also had the pressure of the theatre list about to start. However, I think that most of my colleagues would also think that there was no clinical need to remove the ovaries and they would have proceeded with the hysterectomy and bilateral salpingectomy but not the removal of the ovaries. It is not clear if [Mrs A] expressed reluctance at this time.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

Communication between the surgical booking system and the preadmission clinic is probably at the centre of this failure to provide informed consent. The system needs to be reviewed and a new approach developed. Communication to patients about their surgery when the booking is made could also be improved and I could not see any documentation. I accept that [Dr B] thought he would explain the operation at the time of the pre-admission clinic. And perhaps a phone call was made to the patient but I have no record of that.

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2. The care provided by [Dr D], including whether [Dr D] followed the correct informed consent policies and processes.

[Dr D] followed the MCDHB practice of signing the consent form. She does not recall when or who instructed her to add removal of the ovaries to the consent form.

a. What is the standard of care/accepted practice?

MCDHB informed consent policy under section 3 describes consent being obtained by another health professional familiar with the treatment or procedure. The treating practitioner retains the legal responsibility for ensuring the patient has received the necessary information to enable the patient to give informed consent.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure (mild/moderate or severe) do you consider this to be?

There is no significant departure although there is no explanation about when she was instructed to make the change.

c. How would it be viewed by your peers?

This would not be considered a departure by my peers.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

Better communication and documentation of all instructions and decisions between medical staff.

3. The adequacy of the pre-admission process at MCDHB, in particular for providing information for [Mrs A].

a. What is the standard of care/accepted practice?

I have not been provided with the policy for pre-admissions but this is a service typically led by anaesthetists with nursing staff support. The booking form clearly asks if 'specialist to see at pre-admit'. In the information we have received from MCDHB there is no explanation for why no call was made for [Dr B] to come to the preadmission clinic and discuss the surgical procedure with [Mrs A].

b. If there has been a departure from the standard of care or accepted practice, how significant a departure (mild/moderate or severe) do you consider this to be?

Moderate departure as it has led to a poor informed consent process and patient who felt coerced on the day of her surgery.

c. How would it be viewed by your peers?

They would agree with this assessment and feel let down by the system of the booking form request.

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d. Recommendations for improvement that may help to prevent a similar occurrence in future.

The booking form system and the preadmission processes need review to ensure surgeons and patients can meet up to finalise the surgical procedure and get proper informed consent.

4. The adequacy of the informed consent policies and processes at MCDHB

a. What is the standard of care/accepted practice?

From no 1. The standard of care is in the MCDHB policy and Right 6 about informed consent in the Code of Rights. Please see section 5.3 of the MCDHB policy on informed consent for the detail as provided by the MCDHB to the HDC. A brief summary would be that patients must receive 'an assessment of expected risks, side effects, benefit' and that there should be 'sufficient time to be available etc'.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure (mild/moderate or severe) do you consider this to be?

I consider that this is a moderate departure.

c. How would it be viewed by your peers?

From no 1. Above. The majority of my peers would recognise the difficulty that [Dr B] had on the morning of surgery. He hadn't been able to discuss the recommendation to remove the ovaries with her (and he was not responsible for not being called to preadmission clinic). He also had the pressure of the theatre list about to start. However, I think that most of my colleagues would also think that there was no clinical need to remove the ovaries and they would have proceeded with the hysterectomy and bilateral salpingectomy but not the removal of the ovaries.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

From No 1. Above. Communication between the surgical booking system and the preadmission clinic is probably at the centre of this failure in informed consent. That failure needs to be reviewed and a new approach developed. Communication to patients about their surgery when the booking is made could also be improved. The direct placement of a patient onto a waiting list without talking or communicating with the patient again following the hysteroscopy might have avoided this also. I accept that [Dr B] thought he would do this at the time of the pre-admission clinic. I also acknowledge that perhaps a phone call was made to the patient but I have no record of that.

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

During the postoperative period, the suggestion of seeing her GP for hormone treatment or treating with evening primrose oil was made. I consider evening primrose

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oil to be a poor recommendation as it is not considered to be an effective treatment for hot flushes.

The use of language may be important in this complaint. The description of the ovaries as 'functionless organs with malignant potential' was not helpful and also the implication that as [Mrs A] was already having hot flushes and on hormone treatment, the removal of the ovaries was not an additional burden. Clearly, there was an opportunity for improved communication about [Mrs A's] misunderstanding about hot flushes improving following the hysterectomy. Some of these communications may have led to [Mrs A] feeling dismissed.

Yours sincerely

Cynthia Farquhar
Professor Cynthia Farquhar

Reference: Royal Australian and New Zealand College of Obstetrics and Gynaecology (2017) 'Managing the adnexae at the time of hysterectomy for benign gynaecological disease'."

The following further advice was obtained from Professor Farquhar:

"**Complaint: MidCentral District Health Board and [Dr B]**

HDC ref: 20HDC01873

I have been asked to review the responses and:

1. Consider whether any information provided changes:
   a. your original advice
   b. any departures from the expected standard of care. If you change the level of departure please explain why.
2. Consider if you have any further comments or recommendations to make.

I have read it and I am satisfied with the response from MidCentral DHB. There are no changes required on the basis of what I have read.

However, the response from [Dr B] repeats his view that the removal of the ovaries was justified even while acknowledging that the evidence is conflicted (and therefore benefits and harms needed to be discussed), and he continues to use the misleading term 'functionless' when he talks about postmenopausal ovaries. [Mrs A] did not have the opportunity to discuss the risks and benefits of the procedure. The only sense of apology is where he says 'Sorry that she is not happy'. Those six words are an inadequate apology.

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In the subsequent telephone conversation with the patient's husband on the 13th January 2022 it would seem that [Mrs A] was also concerned about the scar being midline instead of lower transverse (bikini line) as well as mentioning that [Mrs A] 'was too shocked to say anything'. I did not deal with this in my response as it was not raised in the initial letter. The change in the plan about the incision is another part of the complaint about information provided prior to surgery and the consent process. MidCentral DHB has covered the consent processes and their plan to improve it in their reply.

Yours sincerely

Cynthia Farquhar

Reference: Royal Australian and New Zealand College of Obstetrics and Gynaecology (2017) 'Managing the adnexae at the time of hysterectomy for benign gynaecological disease'."

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Appendix B: Relevant Standards

MidCentral District Health Board — Informed Consent Policy — issued 29 October 2018

The MidCentral District Health Board publication "Informed Consent" states the following:

"**1. PURPOSE**

To ensure:

- The proper processes relating to informed consent are followed so that all treatment provided is lawful.
- Consumers have sufficient information about a proposed treatment or procedure, specific to their individual situation, to allow them to evaluate the options without pressure and to agree or not agree to that treatment or procedure being carried out.
- An environment in which people have control over their own lives, accept responsibility for their health, have the opportunity to have an advocate, in which the partnership between the health care user and the health professional is based on trust.
- The informed consent process is properly recorded and documented, and that written consent is obtained from the patient in the circumstances set out in this Policy.
- Relevant legislation is complied with, and risk to MidCentral Health and its employees is minimised.
- The provision of principles and guidelines for health professionals within MidCentral Health with responsibility for obtaining informed consent.

…

3. ROLES & RESPONSIBILITIES

Primary responsibility for obtaining informed consent lies with the person responsible for the procedure. In cases where this is impractical, the information may be imparted by a health professional sufficiently familiar with the treatment or procedure and with adequate knowledge of the risks and benefits of that treatment or procedure. The patient must be informed that this person will not be carrying out the treatment.

The person obtaining the patient's consent will be legally and ethically responsible for his or her actions in obtaining the consent. However, the treating practitioner retains the legal responsibility for ensuring the patient has received the necessary information to enable the patient to give informed consent.

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1. POLICY

5.1 Overview

There are three key elements to informed consent:

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- That the patient is competent, or has the necessary capacity, to make the decision to undergo, or to refuse, treatment; and
- That the patient is provided with sufficient information to enable the patient to make an informed decision about the proposed treatment; and
- That the patient's consent is given voluntarily.

Where one of these three elements is absent the individual cannot give a legally valid consent to medical treatment.

Informed consent shall be obtained from the patient, or if the patient is not competent to give informed consent, a person legally able to give consent to the proposed treatment on the patient's behalf, prior to any treatment being carried out on a MidCentral Health patient. No undue influence or pressure is to be used to obtain consent.

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5.3 Informed Decision

In order to give a valid legal consent or refusal to treatment, a patient must have access to all the information that is required to enable the patient to make a fully informed choice. Under the Code of Health and Disability Services Consumers' Rights ('the Code of Rights') patients have the right to all the information that a reasonable patient in the patient's circumstances would expect to receive. This will include all the information the patient would find material to making a decision about the proposed treatment.

Prior to providing treatment, the health professional undertaking the treatment must be satisfied that they have made every endeavour to ensure that the patient or person legally entitled to consent on the patient's behalf fully understands what is being proposed.

Under Right 6 of the Code of Rights every patient is entitled to, at a minimum, the following information:

- An explanation of his or her condition;
- The nature and purpose of the treatment, including a description of the treatment proposed;
- An assessment of the expected risks, side effects, benefits;
- All relevant treatment options available, including an assessment of the expected risks, side effects, benefits, and costs of each option;
- The timeframe within which such treatment will occur;
- Any proposed participation in teaching or research, including whether the research requires and has received ethical approval;
- Any other information required by legal, professional, ethical, and other relevant standards;
- The result of tests;

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- The results of procedures.

The treating health professional has a duty to provide the patient with any further information that is relevant to the decision a reasonable patient would make in deciding whether to undergo the proposed treatment.

Patients also have the right to:

Honest and accurate answers to any questions asked, including questions relating to:

- The services being provided;
- The identity and qualifications of the health professionals providing the services;
- The recommendation of the health professional;
- How to obtain an opinion from another health professional; and
- The results of research.
- Receive a written summary of the information given if they request it.

Patients should also be informed that they may refuse treatment or withdraw consent at any time. If a patient refuses treatment or withdraws consent he or she must be informed of the consequences of not accepting the proposed treatment or withdrawing consent to further treatment.

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Providing information in an appropriate manner and environment

When obtaining consent the following principles must be observed:

- Privacy for the person concerned;
- The right for the person to have a support person present;
- Presentation of the information in a manner which enables the person to understand;
- Sufficient time to be available for the person to absorb the information, and discuss it with others if desired.

Information may be given verbally, in writing, by video or other means of communication.

Verbal information is acceptable for treatments where there is a low level of risk. However, the patient has the right to receive written information concerning their treatment if they request it.

MidCentral Health is committed to the development of treatment information sheets. Group Managers will negotiate with Clinical Staff regarding the resources required and the timeframe for completion.

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7. Definitions

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Informed Consent

Informed consent may be defined as the process whereby someone who has the capacity/competence to consent, having been given sufficient information, arrives at a reasoned decision freely as to whether or not to agree to a proposed therapy or procedure.

Consent may be given orally or in writing depending upon a number of issues. Informed Consent is not the act of filling out forms. It is a process of the exchange of information so that an informed decision can be made by that person. A signature on a consent form is not in itself conclusive evidence of informed consent and is no guarantee that the person has understood the information provided."

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