Te Whatu Ora Te Toka Tumai Auckland
(formerly known as Auckland District Health Board)

Obstetrician and Gynaecologist, Dr B

A Report by the
Health and Disability Commissioner

(Case 20HDC01421)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. A woman underwent surgery for endometriosis on 5 September 2019. The surgery was carried out by an obstetrician and gynaecologist at Te Whatu Ora Te Toka Tumai Auckland. This report examines the consenting process, and the events leading up to the use of a procedure during the surgery to which the woman had not consented. The report also examines the woman's concerns about the outcome of the surgery and the circumstances in which a Mirena IUCD was replaced during the surgery.

Findings

2. The Commissioner found that the woman had clearly communicated that she did not want ablation, and that on the day of the procedure she did not receive an explanation that ablation might still be required in some circumstances. Because the woman needed this information to enable her to make an informed choice and give informed consent, the Commissioner found that the obstetrician and gynaecologist breached Right 6(2) of the Code, and that because the woman did not give informed consent to the procedure, the obstetrician and gynaecologist also breached Right 7(1) of the Code.

3. The Commissioner raised concerns about Te Whatu Ora Te Toka Tumai Auckland in relation to informed consent, and also about the clinical documentation and note taking by another obstetrician and gynaecologist.

Recommendations

4. The Commissioner recommended that the obstetrician and gynaecologist apologise to the woman and complete HDC's online modules for health and disability service providers.

5. The Commissioner recommended that Te Whatu Ora Te Toka Tumai Auckland audit a sample of its clinical records to ascertain compliance with its informed consent policy, take steps to correct any variance from the policy, and use this report as a basis for staff training.

Complaint and investigation

6. On 7 August 2020, the Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided by Dr B at Te Whatu Ora Te Toka Tumai Auckland (formerly known as Auckland District Health Board (ADHB)).[1] The following issues were identified for investigation:

[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 ADHB now refer to Te Whatu Ora Te Toka Tumai Auckland.

- *Whether Auckland District Health Board provided Ms A with an appropriate standard of care between June and September 2019.*
- *Whether Dr B provided Ms A with an appropriate standard of care in September 2019, including whether Ms A gave informed consent to the ablation procedure performed on 5 September 2019.*

7. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Te Whatu Ora Te Toka Tumai Auckland	Provider/district health board
Dr B	Provider

8. Further information was received from Dr C, a gynaecologist, and Dr D, an obstetrician and gynaecologist. Registrar Dr E is also mentioned in this report.

9. Independent advice was obtained from Dr Colin Conaghan, an obstetrician and gynaecologist (Appendix A).

Information gathered during investigation

Background

10. Ms A was in her mid-twenties at the time of the events described in this report. Ms A had suffered pain during menstruation for some years, and in March 2019 underwent a diagnostic laparoscopic[2] procedure and insertion of a Mirena intrauterine contraceptive device (IUCD).[3] During the procedure, it was found that Ms A was suffering endometriosis.[4]

11. Ms A signed a consent form before the procedure. The form described the procedure as 'Laparoscopy +/- treatment [of] endometriosis or adhesions & insertion of Mirena IUCD …'

12. In response to the first provisional opinion, Ms A told HDC that when she signed the consent form for the March surgery, she did not have prior knowledge of different surgical treatment options, and therefore did not specify the specific type of surgical treatment on the form. However, for her second surgery in September 2019 (as discussed below) she was more informed and had sought advice on the most effective surgical options.

13. Ms A met with a consultant obstetrician and gynaecologist, Dr D, in late June 2019 to discuss surgical options for treating the endometriosis. Ms A told HDC that they discussed removal

[2] Also known as keyhole surgery — the inside of the abdomen and pelvis is accessed via small incisions; the surgery is carried out through the incisions with the aid of a camera.
[3] A Mirena is used for both contraception and the treatment of heavy menstrual bleeding and associated symptoms.
[4] A condition in which tissue that normally lines the uterus grows outside the uterus, often causing pain and menstrual irregularities.

of the endometriosis lesions by excision surgery only.[5] Ms A was clear in her evidence that having taken into account her own research, she communicated clearly that she did not consent to ablation.

14. Surgery was planned for 5 September 2019. On the day of her surgery, Ms A was seen by registrar Dr E, who discussed the intended procedure with her. The intended procedure is described on the consent form completed by Dr E as '… Laparoscopy + excision of endometriosis +/- replacement of Mirena IUCD'. Several risks of the procedure are also itemised on the form.

15. On 5 September 2019, Ms A underwent laparoscopic surgery to remove the endometriosis from her pelvic sidewall and to replace her Mirena IUCD. The surgery was performed by Dr B, an obstetrician and gynaecologist, because Dr D was unwell that day. Dr E assisted Dr B and completed the consenting process on Dr B's behalf.

16. In addition to the excision of the endometriosis from the pelvic sidewall, Dr B removed a small endometriosis lesion from the Pouch of Douglas[6] using ablation.[7]

17. Following the surgery, Ms A continued to have pain. She told HDC that she is disappointed with the treatment she received, which has not improved her symptoms.

18. On 23 March 2020, Ms A sought a private second opinion from Dr C, a consultant gynaecologist. Dr C's report narrates Ms A's significant history, and states:

a) Ms A's uterus was perhaps too small for the Mirena to sit comfortably within;

b) It would be a good idea for Ms A to undergo further surgery to excise the remaining endometriosis that was ablated;

c) Ms A might want to consider having her Mirena removed and a Jaydess[8] placed instead to make sure there was no obvious mechanical contribution from the Mirena towards her pain.

Ms A's complaint

Decision to perform ablation

19. Ms A told HDC that she explicitly asked Dr D to ensure that the surgery was excision of the endometriosis, and she is unhappy that Dr B performed an ablation procedure contrary to her express wishes.

20. Dr D told HDC that during one of his appointments with Ms A, he told her that his approach was to excise endometriotic disease. He also said that Ms A wanted only excision surgery, and she was pleased that he intended to excise rather than ablate her endometriotic lesions.

[5] The surgical cutting away of the endometriosis lesions.
[6] A small pouch of tissue between the uterus and the rectum.
[7] Ablation is the surgical destruction of tissue. It is distinct from excision in that excision involves cutting away affected tissue, whereas ablation destroys the tissue by, for example, burning or freezing.
[8] An IUCD similar to a Mirena. The Jaydess is smaller and is not used for the treatment of heavy menstrual bleeding.

Dr D told HDC that during this discussion, he also discussed 'the risks associated with the procedure, including … injury to surrounding structures including bowel, bladder, major vessels, and ureter'. Dr D did not document that Ms A had withdrawn her consent for ablation.

21. In response to the first provisional opinion, Ms A told HDC:

> '[I]t is my right to take into account medical research and consent to excision as treatment of endometriosis while withdrawing consent for ablation which I communicated clearly before and after the procedure …'

22. Ms A told HDC that on the day of surgery, she had 'reiterated her refusal of ablation during the consenting process with [Dr E]' and that she 'checked this on the form and explicitly discussed that [she] did not consent to ablation'. This was not documented in the clinical notes.

23. Dr E told HDC:

> '[A]t no time was explicit refusal for ablative treatment brought up during [Ms A's] surgical consent discussion with me. Had explicit refusal for ablative treatment been raised, I would not only have clearly documented this in [Ms A's] clinical record and her surgical consent form, but would have also alerted the operating consultant [Dr B] to the patient's request.'

24. Dr E also told HDC that she obtained Ms A's written consent for the procedure as documented on the surgical booking form and Dr D's clinic letter (both of which had been written by Dr D) — that is, for 'Laparoscopy + excision of endometriosis +/- replacement of Mirena IUCD'. She also said that she discussed with Ms A only the planned procedure of excision along with the surgical risks.

25. Dr B told HDC that she met Ms A prior to the surgery and 'noted consent had been obtained [by Dr E], [and] there were no further questions asked as per the clinical notes'. Dr B stated: 'I do not recall any other concerns from [Ms A] at this stage.'

26. Dr B told HDC that currently when consenting patients for endometriosis surgery she ensures that the consent reads 'surgical treatment to endometriosis' and that 'discussion about both excision and ablation takes place and are listed on the consent form'.

27. In response to the first provisional opinion, Dr B stated:

> 'I accept that this patient chose to receive excision surgery to remove the endometriosis. I was aware of that. This was her preference, rather than have the operation proceed by way of ablation. I respected that and 99% of the operation proceeded by way of excision in accordance with her wishes. When I found a small "pea" sized lesion which [was] close to the bowel I removed this by way of ablation. [Ms A] made no mention of any concern regarding this when she was seen, prior to surgery,

> nor did she post operatively immediately after surgery while still in hospital not on the 2 occasions she was seen back in an outpatient clinic.'

28. Dr B also stated in response to the first provisional opinion that if Ms A had expressed a prohibition on having ablation, she would understand that reconsenting was would have been required. Dr B said: '[E]xcision was her preference and this was respected save for a very small exception which was clinically justified.' Dr B also submitted that choosing one option over another for the surgery does not operate as a blanket prohibition on the alternative in any circumstances.

29. Ms A said that she spoke to Dr B in follow-up appointments and raised her disappointment with the ablation having been carried out. Ms A said that she felt dismissed and was referred to a pain psychologist even though she had already been seeing one. She also felt that Dr B was not open to learning more about the differences between excision and ablation and why someone would feel uncomfortable being treated by ablation rather than excision.

30. Dr B told HDC that postoperatively Ms A did not raise any concerns with her about ablation or Mirena insertion.

31. Dr B said that treatment of endometriosis can involve a combination of surgical techniques, including excision and ablation, and that these techniques are well recognised and effective.

32. Te Whatu Ora told HDC:

> '[T]he judgement about the best approach is made by the surgeon at the time of surgery when they can see the disease and assess the risks and benefits of excision or ablation. The RANZCOG[9] guidelines for endometriosis produced in 2021 do not recommend excision of endometriosis over ablation. We will continue to follow this recommendation of the RANZCOG Guidelines.'

33. Te Whatu Ora said that a RANZCOG pamphlet, 'The Laparoscopic Treatment of Endometriosis — A Guide for Women', was provided to Ms A. The pamphlet states:

> '**Operative laparoscopy**
>
> …
>
> A variety of techniques may be used, including:
>
> - Excisional surgery (removal of patches using small cutting instruments)
> - Cautery (cutting and burning of tissue using an electrical probe)
> - Laser surgery, for excision or cautery.
>
> The surgical techniques depend on your surgeon's preference, the location of the endometriosis, and the reasons for surgery.'

[9] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

34. In response to the first provisional opinion, Ms A told HDC that RANZCOG guidelines do not take into consideration her clear communication that she did not consent to ablation as a treatment for endometriosis.

Problems with Mirena

35. Ms A told HDC that she had her Mirena IUCD replaced because it fell out during the surgery. She said that she has had ongoing issues and pain caused by the Mirena.

36. Dr C's report noted that the Mirena might be too large for Ms A's uterus and suggested trying a Jaydess device instead (see footnote 8).

37. Dr B told HDC that the Mirena did not fall out during the surgery — it was removed intentionally to allow a uterine manipulator to be placed, so that the surgery could be performed correctly. A new Mirena then had to be inserted following the surgery. Dr B said that Ms A's uterine cavity had been assessed — both in theatre and on ultrasounds — as being of sufficient size to fit a Mirena. Te Whatu Ora said that the Mirena was required, rather than a Jaydess, as only the Mirena was used to treat pelvic pain and endometriosis.

38. Dr E told HDC that during the consenting process on 5 September 2019, she discussed with Ms A that removal and replacement of the Mirena would typically be indicated due to the use of the uterine manipulator.

39. Several documents record that the Mirena was inserted in March 2019 to try to reduce Ms A's endometriosis symptoms. The documents include a note of a gynaecology clinic appointment with a registrar on 19 February 2019 which records that the Mirena was part of a plan of pain management for Ms A, and that Ms A was keen to go ahead with it.

40. A clinical psychology record dated 28 May 2019 notes that the Mirena inserted in March 2019 was 'taking some time to achieve results'.

41. A nurse assessment in Ms A's clinical notes states that on 25 August 2019, Ms A attended a medical appointment for abdominal pain. The record notes that the Mirena was inserted in March 2019 to manage Ms A's endometriosis symptoms, and a concern that the device may have become dislodged is noted.

42. Several documents mention the replacement of the Mirena on 5 September 2019. The anaesthetic assessment carried out on 9 July 2019 notes the intended surgery as including '+- replacement mirena'. Similarly, the waitlist referral form completed by Dr D on 18 June 2019 records the planned procedure as 'Lap excision +/- replacement Mirena'. The operation note records: '[U]terine manipulator placed following removal of Mirena IUCD … a new Mirena inserted as per manufacturer's instructions, following sounding of the uterus to 8cm.'

43. Later records indicate that Ms A suspected that the Mirena could be contributing to her pelvic pain. A nursing assessment during a hospital admission for pelvic pain on 5 August 2020 noted that Ms A reported that it felt as if 'her Mirena ha[d] dislodged following [a] forceful bowel movement'.

44. In response to the first provisional opinion, Ms A told HDC that she was never advised that the Mirena would be removed intentionally and replaced during the surgery, and she was under the impression that it would be replaced only if it fell out. Ms A reiterated that she believes that the Mirena was a major cause of her pain, and that her assertion that it was causing her pain was dismissed by doctors.

Ongoing pain

45. Ms A told HDC that she has had ongoing pain caused by endometriosis, with no improvement from physiotherapy or psychology. She said that she is disappointed with the treatment she received, which has not improved her symptoms.

46. Dr D told HDC that he had extensive discussions with Ms A about the risks associated with the procedure, including the risk that surgery might not fully resolve her pain.

47. Te Whatu Ora provided HDC with a pamphlet called 'The Laparoscopic Treatment of Endometriosis — A Guide for Women', which is given to patients who are considering laparoscopic treatment of endometriosis. The pamphlet states:

> 'RESULTS OF LAPAROSCOPIC TREATMENT
>
> - Improvement in pain: About eight women out of 10 with pelvic pain report a reduction in pain. The improvement is greater in women whose endometriosis was moderate to severe. About one or two women in 10 report a return of pain in the year after surgery, even though the operation to remove endometriosis was successful.'

48. It is recorded in Ms A's clinical notes that this pamphlet was given to her on 18 June 2019. In the same note, Dr D recorded his discussion with Ms A about the 'risk of surgery not relieving pain'.

49. In response to the first provisional opinion, Ms A told HDC that there are limited options for those with endometriosis, and, based on her discussions with clinicians and her research, excision surgery was her best option for relieving her symptoms.

Further information

50. Ms A told HDC that she still suffers from endometriosis, but in May 2023 she had surgery overseas with a specialist endometriosis surgeon that has significantly reduced her pain and symptoms. She no longer has a Mirena.

51. Ms A said that the most distressing part of her treatment experience in New Zealand was that she felt dismissed when she tried to speak to Dr B about her concerns following the 5 September 2019 surgery, and it was frustrating to be ignored. Ms A feels that since she has been overseas, she has had a much better experience, and she does not want her experience in New Zealand to happen to other patients.

Responses to provisional opinions

52. Ms A, Dr B, Te Whatu Ora, Dr D, and Dr E were given the opportunity to respond to the relevant sections of the first and second provisional opinions. Where appropriate, their comments have been incorporated into this opinion. Dr D did not wish to comment on the second provisional opinion. In addition, I note the following:

Ms A

53. Ms A also told HDC:

> 'I am disappointed that although I advocated for myself to get the best possible treatment, I still received a treatment that I did not consent to. I am concerned that if nothing is done, future patients will have similar experiences, especially those that are unable to advocate for themselves or have the support they need to manage their endometriosis symptoms.'

Dr B

54. Dr B questioned how it was possible to obtain adequate consent in anticipation of events that are unknown and possibly unforeseeable at the time of consenting. She stated:

> 'Do I record on the consent "proceed to any other treatment required" or must I proceed to discuss a list of possible eventualities potentially leading to patient confusion to the extent that they no longer have any confidence or understanding about which procedure they are consenting for.
>
> … [A]m I to understand there is no role for clinical judgement and that I must always wait till post operatively to discuss and re consent for e.g. biopsy of your abnormal looking appendix, right and not left ovarian cyst. When I know that a second operation and anaesthetic is detrimental even to fit patients, expensive for the health service to say nothing of precious surgical resource and waiting list times in public.'

Relevant policy

55. Te Whatu Ora Te Toka Tumai Auckland's policy on informed consent dated 2 May 2018[10] was the version in effect at the time of the events covered by this report. Relevant extracts from the policy are reproduced below:

> '**What is informed consent?**
>
> Informed consent assumes three key elements:
>
> - Effective communication with the patient (Right 5)
> - Provision of all necessary information to the patient (Right 6) and

[10] Informed Consent, 2 May 2018, Unique Identifier PP01/PCR/007.

- The patient's freely given and competent consent (Right 7)

Informed consent process applies to the provision of all health services.

Informed consent is not filling out forms, but rather the exchange of information. The patient must be able to make an informed decision about healthcare options, including the option of refusing the service.

…

Documentation of consent

Right 7 states:

…

6. Where informed consent to a health care procedure is required, it must be in writing if:

a) The consumer is to participate in any research; or
b) The procedure is experimental; or
c) The consumer will be under general anaesthetic; or
d) There is a significant risk of adverse effects on the consumer

7. Every consumer has the right to refuse services and to withdraw consent to services

…

Right to refuse

Under section 11 of the New Zealand Bill of Rights Act 1990 (see Legislation) and Right 7 (7) of the Code,[11] every competent person has the right to refuse or withdraw consent to services.

…

11. Declining services and withdrawing consent

Should a competent patient decline an option of services or withdraw consent, that choice cannot be overruled and must be respected, with no change in the standard of care provided.'

[11] The Code of Health and Disability Services Consumers' Rights.

56. The Medical Council of New Zealand's 2019 statement on informed consent[12] states:

> '…
>
> **The key principles of informed consent**
>
> …
>
> **Consent is an interactive process, not a one-off event**
>
> c. Obtaining consent is a process of shared decision-making where you help the patient understand their medical condition and the options for treating (or not treating) that condition. It is more than signing forms and completing paperwork. Take the time to ask questions so that you understand what matters to your patient, and what their concerns, wishes, goals and values are.
>
> …
>
> **Documenting discussions during the consent process**
>
> 13. You must keep clear and accurate patient records that note:
>
> a. the information that was discussed
>
> b. any specific risks that were highlighted
>
> c. any request or concerns expressed
>
> d. any decisions made and the reasons for them.
>
> …
>
> **Your responsibilities**
>
> 21. The doctor undertaking the treatment or procedure is responsible for the overall informed consent process. If you are the doctor treating the patient, you need to check that the patient is clear about their decision to have treatment before you go ahead with it.'

[12] Medical Council of New Zealand, 'Informed Consent: Helping patients make informed decisions about their care', September 2019.

Opinion: Dr B

Decision to perform ablation — breach

Background

57. Dr B was the operating surgeon and held ultimate responsibility for the informed consent process with Ms A. This investigation considered whether Dr B, during the consent process, complied with the relevant law and standards[13] to enable Ms A to provide informed consent for her procedure.

58. The MCNZ 2019 informed consent statement sets out that '[c]onsent is an interactive process, not a one-off event'.[14] It states that the process involves shared decision-making to help the patient understand their condition and their options in relation to it. The statement emphasises that effective communication is critical and 'what matters to your patient' should be established. It is also noted that '[i]f you are worried that your patient is making a decision that is not in their best interests, you should explain your concerns clearly to them and outline the possible consequences of their decision'. The 2019 statement advises, in part, that doctors must give patients the information they need to make a fully informed decision, and reasonable time to make that decision. Further, doctors must keep clear and accurate records noting the information discussed; any specific risks highlighted; any request or concerns expressed; and any decisions made and the reasons for them.

59. Te Whatu Ora Te Toka Tumai Auckland's policy on informed consent states:

> 'Informed consent is not filling out forms, but rather the exchange of information. The patient must be able to make an informed decision about healthcare options, including the option of refusing the service.'

60. The policy makes it clear that every patient has the right to refuse services, and, where an option for services has been declined, this 'choice cannot be overruled and must be respected'.

Independent advice

61. To assist me in this investigation, I obtained independent advice from an obstetrician and gynaecologist, Dr Colin Conaghan. Dr Conaghan advised that while undertaking the laparoscopic excision and cautery for Ms A, Dr B exercised appropriate skill and varied the surgical procedure to stay within safe surgical boundaries whilst optimising the best outcome for the patient and minimising complications. He considers that Dr D provided

[13] Including The Code of Health and Disability Services Consumers' Rights 1996 (the Code) https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/; the Medical Council of New Zealand (MCNZ) Informed Consent statement (September 2019); and Te Whatu Ora Te Toka Tumai Auckland's Informed Consent policy dated 2 May 2018.

[14] MCNZ's September 2019 informed consent statement was applicable at the time of Ms A's surgery. At the time of her preoperative appointments, MCNZ's 2011 informed consent statement applied. The statements are very similar in terms of the key principles set out in paragraph 56.

adequate information to Ms A prior to the surgery, and appropriately confirmed the benefits and risks of her preferred procedure.

62. Dr Conaghan advised that generally the surgical procedure will be adapted to meet the requirements of the disease being dealt with, and to maintain safe surgery for the patient. He advised that in a case such as Ms A's, it would be inappropriate for a surgeon to undertake excision on bowel where excision would run a high risk of perforation.

63. Regarding the mention on the consent form of excision only, and the absence of any mention of ablation, Dr Conaghan advised that this left very little flexibility for Dr B to vary the procedure. Dr Conaghan was critical of the description of the surgical procedure included on Ms A's consent form and said that the wording should have been couched in more general terms, for example, 'surgical treatment of endometriosis'. However, he considered this to represent a mild departure from the standard of care, with no clinical significance.

64. Dr Conaghan advised that overall, Dr B did not depart from the standard of care. Dr Conaghan commented:

> 'As events would transpire [Dr B] exercised appropriate surgical care and skill in avoiding excision in close proximity to the bowel, a procedure which might have left the patient with a surgical perforation of the colon. [Dr B] exercised her clinical skill in opting for a procedure which would achieve the goal of managing the endometriosis and avoiding the potential complication of perforation. This is a skill which comes from experience and we ask our surgical colleagues to exercise appropriate judgement in such situations.'

65. Dr Conaghan's advice appropriately focuses on the surgical skill and care exercised. Dr Conaghan did not specifically identify a departure from the standard of care in relation to informed consent, in particular Dr B's decision to utilise ablation as a surgical technique during Ms A's procedure. However, I also note that Dr Conaghan has not clearly delineated the facts in relation to the consenting process on the day of surgery. Indeed, he suggested that had cautery not been consented to, then this procedure should not have been performed.

66. Dr B submitted that it is not appropriate for me to depart from Dr Conaghan's advice. Dr B referred to the New Zealand High Court decision *The Partners of Waikanae Health Centre v The Health and Disability Commissioner*[15] and the finding that the (then) Commissioner required clearly articulated reasons to depart from its own independent advice to avoid the criticism that his decision lacked any adequate evidential foundation.

67. In response, I note that in relation to informed consent, Dr Conaghan's advice was sought on whether the consenting process met accepted practice, but he was not asked to comment on whether or not informed consent was obtained. Although Dr Conaghan's

[15] CIV2020-485-544 [2021] NZHC 1488 (paragraph 76(c)).

opinion on this point provides useful context, the determination on whether informed consent was obtained is primarily a finding of fact, for which expert advice is not necessary.

68. Furthermore, in *Stubbs v The Health and Disability Commissioner*, the High Court commented on the difference between departing from expert advice on a purely medical issue, and informed consent:

> 'If, however, a Commissioner disagreed, on a purely medical issue with an independent medical expert, then the Courts would be likely to look very carefully at the justification for doing so. Such a decision could be said to be without any factual/scientific foundation. However, this complaint was about informed consent.
>
> What would a properly informed patient expect in the circumstances from his health care provider? While there are medical issues tied up with this issue of informed consent in this case a judgment as to what the patient would expect is something the Commissioner is well if not uniquely qualified to express.'[16]

69. I accept that but for the issue of consent, Dr B's care would otherwise have met accepted standards. However, for the reasons outlined below, I consider that Dr B departed from accepted standards by utilising ablation during Ms A's procedure when this had not been explained to her adequately, and where consent had not been obtained.

Use of ablation

70. Dr D and Ms A both recall that excision and ablation were discussed, and that Ms A expressed that she wanted to undergo excision, and not ablation. Ms A had carried out her own considerable research into the surgical options for treatment of endometriosis. The result of her being in possession of that information led her to opt for excision surgery only. Although Dr D bears some degree of responsibility for failing to record his discussions with Ms A (discussed separately below) on the day of the surgery, it was Dr B's responsibility to engage in an exchange of information with Ms A to ensure that Ms A was able to make an informed choice about her options.

71. Dr B told HDC that her senior registrar, Dr E, had obtained consent prior to the surgery. Dr E described the procedure in narrow terms — '… Laparoscopy + excision of endometriosis +/- replacement of Mirena IUCD' — which is consistent with Ms A's understanding of the procedure to be undertaken and surgical technique to be used. The wording appears to have been lifted verbatim from Dr D's clinic letter and surgery booking form.

72. Ms A said that she communicated to Dr E that she refused ablation. In contrast, Dr E said that there was no discussion about ablation at that time, but she discussed only the procedure documented on the consent form — that is, excision of endometriosis. There is no documentation of this discussion beyond the consent form.

73. There is also no documented evidence of what was discussed between Dr B and Dr E about Ms A's concern about ablation. Nevertheless, Dr B accepts that prior to the surgery she was

[16] CIV2009-485-2146, HC Wellington, 8 February 2010, (paragraph 53).

aware that Ms A wanted to receive excision surgery, not ablation. Dr B submitted that this had not been communicated as a refusal of ablation, but as a preference for excision.

74. That Dr B was aware that Ms A wanted excision not ablation, and that the consent form specified excision only, imposed an obligation on Dr B as the operating surgeon to discuss with Ms A any risks associated with not having ablation, and also that ablation might need to be used, if it was anticipated that ablation would be clinically appropriate in some circumstances to maintain safe surgery.

75. In this respect, Dr B considers that Ms A received sufficient information for her to understand the nature of her condition and the surgical procedure being contemplated, including that the procedure might be adapted to maintain safe surgery. However, there is no evidence that Dr B or Dr E communicated to Ms A that this could mean that ablation might still be used in some circumstances, and there is also no evidence that Ms A was advised of the risks or consequences associated with her express wish not to have ablation. I do not accept Dr B's submission that this was a preference, where choosing one option over another (ie, excision over ablation) did not operate as a prohibition on the alternative in any circumstances. In fact, I am satisfied that the weight of evidence shows that Ms A consented to excision surgery only.

Mitigating factors

76. Te Whatu Ora submitted that Dr B 'unwittingly … used a particular surgical technique, against the express wish of the patient. However, … in the circumstances of this case, a breach finding against [Dr B] is disproportionate.' Te Whatu Ora asked me to take into account several factors in this respect, as follows:

a) Dr B stepped in at short notice and was not aware of the previous discussions between Ms A and Dr D;

b) While it is concerning that preoperative discussion on the day did not highlight Ms A's wish not to undergo ablation, in the absence of information to the contrary, it was reasonable for Dr B to assume that consent for endometriosis surgery would include all techniques covered by standard accepted surgical practice; and

c) It is not standard practice to obtain express consent for particular surgical techniques commonly used in an operation. Absence of express consent for a technique should not be a barrier to using it, except when a patient explicitly declines it.

77. I am sympathetic to Dr B's predicament of having to step into undertaking Ms A's operation at short notice, and that (beyond the consent form) there were no notes of the previous discussion with Dr D. Nevertheless, in the circumstances, responsibility for ensuring proper informed consent and shared decision-making fell to Dr B as the operating surgeon.

78. On the second and third issues, I agree with Te Whatu Ora that it is unreasonable to expect surgeons to itemise every potential clinical technique. I have also considered Dr B's submission that a finding that informed consent was not obtained in this case would lead to unreasonable burdens on clinicians and health services. However, as I have concluded above, on the basis of Dr B's evidence she was aware that Ms A had opted for excision over

ablation, and that the consent form specified excision only, the consequences of that choice should have been discussed with Ms A.

Conclusion

79. Right 6(2)[17] of 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.

80. Ms A was informed about the various surgical treatments of endometriosis, and she chose excision surgery. Ms A clearly communicated that she did not want ablation. Dr B was aware that Ms A wanted excision surgery, and the consent form was expressed in restrictive terms. The MCNZ 2019 informed consent statement places the responsibility for completing the consent process on the doctor undertaking the treatment or procedure, so accordingly the overall responsibility remained with Dr B. The MCNZ 2019 informed consent statement also requires the clinician to take the time to ask questions so that they understand what matters to the patient, and what their concerns, wishes, goals and values are.

81. Dr B had an obligation to ascertain why Ms A wanted excision only, and, with the knowledge that Ms A did not want ablation, it was vital to explain to Ms A that in some circumstances ablation may be the safest technique, there was a possibility that it might need to be utilised, and the consequences and/or risks of not using it. Had this conversation occurred, Ms A would have had an opportunity to make an informed choice. That is, this is information that a reasonable person in Ms A's circumstances would expect to receive.

82. Te Whatu Ora and Dr Conaghan approach the issue from a different perspective — that the only safe way to have removed the lesion on Ms A's bowel was by ablation, and ablation is recognised as a safe and effective way to treat endometriosis. However, this perspective does not consider a consumer's right to choose when fully informed.

83. I have also considered the mitigating factors submitted by Dr B and Te Whatu Ora. While I agree that it is not standard practice to obtain express consent for particular surgical techniques, this situation was different. Ms A had communicated that she did not want a particular technique (ablation) used, and therefore Dr B had a responsibility to ensure that this concern was addressed adequately in the consenting process.

84. Accordingly, I find that Dr B did not provide Ms A with this information, and therefore breached Right 6(2) of the Code.

85. It follows that as Ms A did not make an informed choice, she did not give informed consent to the procedure, and therefore I also find that Dr B breached Right 7(1) of the Code.

[17] Right 6(2) of the Code states: '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.'

Discussion post-surgery — educative comment

86. Although there is no record of the discussions in the patient notes, Ms A told HDC that when she tried to raise her concerns about the ablation procedure with Dr B after the surgery, she felt dismissed. It is concerning that if this discussion did occur, Dr B did not record it in the patient notes and does not appear to have addressed Ms A's central complaint regarding consent to ablation. I ask Dr B to reflect on Ms A's comments, and I remind Dr B of the importance of effective communication.

Problems with Mirena — no breach

87. Ms A told HDC that her original Mirena fell out during the surgery and had to be replaced, and that it caused her ongoing issues and pain. Dr C noted that the Mirena could be too large for Ms A's uterus and should be replaced with a smaller Jaydess device. Dr B told HDC that the Mirena was the only appropriate device to treat Ms A's condition, and Ms A's uterus had been assessed as being of sufficient size to fit a Mirena. Dr B said that the Mirena was removed and replaced intentionally to permit the use of a uterine manipulator during the surgery.

88. The clinical notes show that the original Mirena inserted in March 2019 was intended to reduce Ms A's pelvic pain symptoms. The notes documented prior to the surgery also show an intention to replace the Mirena, if necessary, on 5 September 2019. In every instance, the procedure is recorded as an excision of endometriosis '+/-' the replacement of the Mirena. Dr E also said that she discussed the likely removal and replacement of the Mirena with Ms A.

89. Dr Conaghan advised HDC that the introduction of the intrauterine manipulator during the 5 September surgery necessitated the removal of the Mirena. He also said that Mirena IUCDs are commonly used for the long-term management of endometriosis, and it is standard practice to recommend the insertion of a Mirena for any patient who is to undergo endometriosis surgery. Dr Conaghan made no criticisms of the procedure, or the introduction of the Mirena itself, and I accept his advice in this respect.

90. Although the Mirena was inserted in an attempt to reduce Ms A's pain, unfortunately it appears not to have had that effect, and Ms A suspects that it may have caused her new and distressing symptoms. Although I can make no finding on whether the Mirena was causing Ms A's pain, there was no failure by Dr B or any other clinician in either recommending the use of a Mirena, or the care and skill used in fitting the device, either in March or September 2019.

91. In addition, there is no evidence that the Mirena was too large for Ms A's uterus, and although a Jaydess device is smaller, the Jaydess is not recognised as effective in the treatment of pelvic pain, and so would not have been an appropriate alternative. I am not critical of this aspect of the care provided to Ms A by Dr B.

92. I have considered Ms A's comment in her response to the first provisional opinion that she was not aware that the Mirena would be removed intentionally during the surgery. I note that prior to the surgery, Ms A already had a Mirena in place, and there had been no clinical

decision to cease the use of a Mirena. The possibility of replacement was also recorded on the consent form that was signed by Ms A. For these reasons I do not consider that there has been a breach of the Code.

Ongoing pain — no breach

93. The consent procedure was started by Dr D and completed by Dr E on the day of Ms A's surgery on 5 September 2019. Dr D had discussions with Ms A about the intended surgical procedure and advised her of the risks. A record of a discussion on 18 June 2019 notes that Dr D advised Ms A of the risk that surgery might not resolve her pain. The printed material Ms A was given also warns of the risk that surgery may not resolve pain caused by endometriosis.

94. Ms A has since undergone physiotherapy and psychology treatments, which unfortunately have been unsuccessful in dealing with the ongoing pain.

95. Dr Conaghan did not identify a departure from the standard of care in this respect, and noted that the procedures carried out, including the surgical procedures and the use of the Mirena IUCD, are appropriate methods to treat endometriosis. I accept Dr Conaghan's advice in this respect.

96. Clearly it is frustrating for Ms A to have suffered from the pain caused by endometriosis for a considerable time, and to have had several clinical interventions with results that have not been acceptable to her. Whilst recognising that frustration, I am satisfied that Ms A was made aware of, and understood, the risk that the interventions might be wholly or partially ineffective. For these reasons I do not consider that there has been a breach of the Code.

Opinion: Te Whatu Ora Te Toka Tumai Auckland — adverse comment

97. Dr Conaghan did not identify any departures from the standard of care by Te Whatu Ora. My review of the care provided did not identify any systemic concerns, and I find that Te Whatu Ora did not breach the Code.

98. However, I remain concerned by Te Whatu Ora's response to HDC, which states:

> '[T]he judgement about the best approach is made by the surgeon at the time of surgery when they can see the disease and assess the risks and benefits of excision or ablation. The RANZCOG guidelines for endometriosis produced in 2021 do not recommend excision of endometriosis over ablation. We will continue to follow this recommendation of the RANZCOG Guidelines.'

99. Te Whatu Ora considers that the surgical approach taken by Dr B was entirely appropriate.

100. The appropriateness of the surgical option is not at issue here. Rather, the concern is that having had the surgical approaches discussed with her, Ms A expressly indicated that she

did not want ablation — as was her right. As discussed above in more detail, the ablation procedure performed on Ms A was not consented to, and therefore was a breach of Right 7(1) of the Code. I remind Te Whatu Ora that in the exercise of clinical judgement, a surgeon must ensure that a patient has been fully informed about, and consented to, a particular treatment option.

101. Te Whatu Ora Te Toka Tumai Auckland's policy on informed consent was appropriate with respect to a patient's right to refuse consent, but in this case it was not followed. I therefore make no criticism of Te Whatu Ora Te Toka Tumai Auckland's informed consent policy.

102. In response to my first provisional opinion, Te Whatu Ora told HDC:

> 'Te [Whatu Ora] is cognisant of our obligations to patients with respect to informed consent, including under Right 7.7. We recognise that in our earlier response we focused on the exercise of appropriate clinical judgement, rather than the issue of lack of consent and a patient's right to decline treatment. We accept the adverse comments made in relation to our organisation and your recommendations.'

Opinion: Dr D — adverse comment

103. This complaint is not primarily about Dr D. However, I have noted that the discussion about Ms A's refusal of consent to ablation does not appear to have been documented, and the patient notes provided to me do not mention any discussion about the differences between excision and ablation, and the risks and advantages of each.

104. I am concerned that the discussions between Dr D and Ms A regarding her refusal of ablation (described by Ms A as 'withdrawal of consent') do not appear to be recorded anywhere. I consider it vital that where a consumer has specifically declined a treatment option, that information is documented clearly, so that other clinicians can access the information easily. I remind Dr D of the importance of accurate and comprehensive clinical documentation, and I will send this report to him for his review.

105. In response to my first provisional opinion, Dr D told HDC:

> 'I am very much aware of the importance of accurate and comprehensive clinical documentation and this matter has been a useful reminder for me to specifically document where a patient declines a particular treatment option. I will ensure that I do so in the future.'

106. In response to my first provisional opinion, Te Whatu Ora told HDC that it also recognises that when a patient explicitly declines a treatment, it is incumbent on the health professional who receives the information to document it in the patient record. In this case, that responsibility fell on Dr D.

Changes made

107. In response to the first provisional opinion, Te Whatu Ora noted that it had updated its informed consent policy since Ms A's complaint.

108. Te Whatu Ora also said that its Gynaecology team facilitated a session in June 2023, as part of its monthly Aspiring to Excellence education series, which focused on informed consent. Te Whatu Ora also said that it has communicated the need for a robust conversation and documentation of consent, and that its theatre staff have been vigilant in scrutinising consent forms.

Recommendations

109. I recommend that Dr B:

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

b) Successfully complete HDC's three online modules for health and disability service providers and provide a copy of the completion certificate to HDC within three months of the date of this report.

110. I recommend that Te Whatu Ora Te Toka Tumai Auckland:

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

   i. whether the pre-procedure or surgical consultation discussion of treatment options, risks, any requests/concerns raised, and decisions made are documented;

   ii. whether the particular surgical procedure recorded in the signed consent form is aligned with the documented pre-procedure or surgical consultation discussion; and

   iii. whether, if the signed consent form records the particular surgical procedure, only the stated procedure has been performed.

   Te Whatu Ora is to provide HDC with a report on the outcome of the audit within six months of the date of this report.

b) Where the above audit identifies a variance from Te Whatu Ora Te Toka Tumai Auckland's informed consent policy, Te Whatu Ora Te Toka Tumai Auckland should, within one year of the date of this report:

   i. report to HDC on the steps it has taken to correct the variance;

ii. once the steps have been implemented, conduct a further audit in terms of subparagraph a) above; and

iii. report to HDC on the results of that audit.

Follow-up actions

111. A copy of this report with details identifying the parties removed, except Te Whatu Ora Te Toka Tumai Auckland and the advisor on this case, will be sent to the Medical Council of New Zealand and it will be advised of Dr B's name.

112. A copy of this report with details identifying the parties removed, except Te Whatu Ora Te Toka Tumai Auckland and 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 expert advice was obtained from Dr Colin Conaghan, an obstetrician and gynaecologist:

'Thank you for asking me to provide expert advice to the Health and Disability Commissioner regarding the care provided by Auckland District Health Board to [Ms A].

I can confirm that I have no personal or professional conflict in this case.

My qualifications and experience

1. I confirm I am registered with the Medical Council of New Zealand in the vocational scope of practice of Obstetrics and Gynaecology. I am a Fellow of the Royal College of Obstetricians and Gynaecologists (FRCOG) (1997) and a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) (1988).

2. I am a practising obstetrician and gynaecologist in Christchurch New Zealand. For 19 years I worked as a Senior Medical Officer in obstetrics and gynaecology at the Christchurch Women's Hospital for the Canterbury District Health Board. I currently work fulltime in private practice in the area of obstetrics and gynaecology. I am a visiting clinical lecturer for the Otago Medical School, lecturing in the area of obstetrics.

3. I am on the RANZCOG expert witness register.

Documents provided

1. Letter of complaint dated 7 August 2020
2. The Auckland District Health Board's response dated 29 September 2020
3. Clinical records from Auckland District Health Board covering the period of 25 June 2019 to 5 September 2019. Including
   a. Consent form dated 5 September 2019
   b. Laparoscopic Treatment Pamphlet
   c. Endometriosis Pamphlet

Background

1. [Ms A] was referred to the waiting list office in a document dated 18.6.19 with a diagnosis of endometriosis and a planned procedure of lap excision +/- replacement Mirena. It is noted at the bottom of the page that the patient has a Mirena in place. The document is signed [Dr D].

2. A consent is identified dated 5 September 2019 and signed by the registrar identifying the procedure as laparoscopy plus excision of endometriosis +/-

replacement of Mirena IUCD. A number of risks have been identified and itemised and the document has been signed by patient and registrar.

3. A handwritten surgical letter dated 5 September 2019 by the attending registrar [Dr E].

4. A typed report identified as Operation Note: Gynaecology, on [Ms A] identifying those clinicians present and laid out with operation details, indications for surgery, surgical findings and the procedure along with post operative management. The document is signed [Dr E] Registrar Obstetrics and Gynaecology.

5. Incorporated into the Auckland District Health Board clinical notes is a note identified by date as 6.9.19 and SMO review [Dr B]. The document is identified as 1030 hours and is a review of the surgical procedure and progress to date. A plan is identified regarding discharge and follow up.

Expert Advice

Item 1 Whether the consenting process for [Ms A's] endometriosis surgery was consistent with accepted practice. Please advise whether there was adequate information provided regarding the benefits and risk of the different excision techniques.

6. The consenting process for [Ms A's] endometriosis surgery commenced in the outpatient setting with [Dr D]. At the time that the referral to the waiting list office dated 18.6.19 was undertaken we are led to believe that the Royal Australian and New Zealand College of Obstetrician & Gynaecologists documentation regarding laparoscopy and endometriosis were provided to the patient.

7. Taking specifically the laparoscopic treatment of endometriosis document identified as a Guide for Women there is a subsection identified as 'Operative Laparoscopy'.

8. The operation procedure in the above document is written in a language that is clearly understandable by the public/patients. It identifies the various surgical procedures starting initially with:

   Excisional surgery

   Cautery

   Laser surgery.

   Perhaps the most important part of this section of the document is the comment that:

   "The surgical techniques depend on your surgeon's preferences, the location of the endometriosis, and the reason for surgery. The procedures can remove patches, nodules and endometriosis, and cut adhesions."

There are further useful comments in this subsection.

9. **Conclusion**

The documentation is consistent with accepted practice. Sufficient information has been given for [Ms A] to understand the nature of her condition and the surgical procedure being contemplated. As per the guideline document identified as RANZCOG "The Laparoscopic Treatment of Endometriosis" the key point here is that the surgical procedure will be adapted to meet the requirements of the disease being dealt with at the time of surgery and to maintain safe surgery for the patient, minimising any potential complications that might occur.

It would be inappropriate for an appropriately trained surgeon to undertake ablation on deeply infiltrating endometriosis where excision offers the best chance of cure. Equally it would be inappropriate for excision to be undertaken on endometriosis on bowel where excision will inevitably run a high risk of perforation.

10. The surgical procedure will need to be adapted to the circumstances identified at the time of surgery.

11. In reference to the letter of complaint [Ms A] indicates that laparoscopic excision of endometriosis was the procedure consented to and that laparoscopic diathermy had not been consented to or discussed. The dilemma the surgeon would then find themselves in if being confined to the surgical consent would be to leave endometriosis in situ as he/she has not given consent to undertake cauterisation of the lesion and if one was to pursue laparoscopic excision then a high risk of bowel perforation and subsequent sequalae might ensue. Those complications could potentially include, laparotomy, repair of bowel perforation with a possibility of defunctioning colostomy.

These complications had been discussed in the consent form, and are identified on the consent form.

12. The surgeon undertaking the laparoscopic excision and cautery for [Ms A] exercised appropriate skill and varied the surgical procedure to stay within safe surgical boundaries whilst optimising the best outcome for the patient and minimising complications.

13. [Dr D] in the Auckland District Health Board response of 29 September 2020 confirms that he discussed endometriosis surgery with [Ms A] on 18.6.19 and that a full consultation took place. [Dr D] confirms that a surgical discussion took place and that the appropriate information documents (enclosed in the HDC pack to myself) was supplied. The usual practice of endometriosis excision was explained.

Adequate information was provided to [Ms A] prior to the surgical procedure carried out on 5.9.19. Appropriate documentation from the Royal Australian and New Zealand College of O & G was provided for her perusal. [Dr D] confirms that

the benefits and risks of her preferred procedure as laparoscopic excision of endometriosis has been explained.

An appropriate standard of care has been delivered by [Dr D] and [Dr B].

My colleagues would view the pre operative consenting process to be adequate and comprehensive with the documentation supplied. There has been no deviation from an appropriate standard of care.

Item 2 Whether the ablation technique ought to be discussed and recorded separately in the consent documentation prior to an ablation being performed.

14. The surgical procedure has been discussed in great detail both preoperatively in the outpatient setting with appropriate documentation provided.

    The documentation provided, particularly that identified as RANZCOG "The Laparoscopic Treatment of Endometriosis" identifies ablation along with excision as appropriate surgical procedures undertaken for the management of endometriosis.

15. The surgical consent identified the surgical procedure as laparoscopic excision of endometriosis +/- replacement of Mirena. This is a very specific surgical procedure although flexibility has been indicated regarding the replacement of the Mirena.

16. **Conclusion**

    The surgical consent has been specifically identified as laparoscopic excision of endometriosis +/- replacement of Mirena leaving very little flexibility for the surgeon to vary the procedure. As events would transpire [Dr B] exercised appropriate surgical care and skill in avoiding excision in close proximity to the bowel, a procedure which might have left the patient with a surgical perforation of the colon. [Dr B] exercised her clinical skill in opting for a procedure which would achieve the goal of managing the endometriosis and avoiding the potential complication of perforation. This is a skill which comes from experience and we ask our surgical colleagues to exercise appropriate judgement in such situations.

17. The referral to the Waiting List Office for surgery on [Ms A] might have been more appropriately identified as "Surgical treatment of endometriosis +/- replacement of Mirena". Whether one wishes to place on the consent form as a matter of record that such surgical procedures might include laparoscopic excision, laparoscopic cautery or laparoscopic laser is unnecessary in my opinion.

18. There should be a full discussion regarding the types of surgical procedures that might be carried out under the heading of "Surgical treatment of endometriosis", for example the RANZCOG document provided to patients. Such a document could be utilised within the outpatient setting where the formal discussion has taken place and the additional patient information supplied to the patient to take on her departure from the clinic. This is an entirely appropriate venue for the patient to ask questions and seek guidance regarding how the procedure might be performed.

It has been perceived by [Ms A] as "cautery" had not been consented to, then this procedure should not have been performed. The consent document specifying "Laparoscopic excision" is too specific and lacked flexibility and treatment modalities. As noted elsewhere it would be entirely appropriate to be less specific with the surgical description, thereby giving flexibility to the surgeon without obscuring the intention of the surgery. As noted prior, laparoscopic surgical treatment of endometriosis would be an appropriate title for the surgical procedure.

19. **The standard of care delivered to [Ms A] has been of an appropriate standard and acceptable practice. There has been a mild departure from an appropriate standard of care in the description of the surgical procedure to be undertaken. My colleagues and I would see this deviation as being of no clinical significance.**

    I would recommend less specific surgery titles be used and a more broad terminology confirming the "intention" of the surgery i.e. in this particular case the treatment of the endometriosis.

Item 3 Whether [Ms A's] surgery on 5 September 2019 adhered to the expected standard of care.

20. There is both a handwritten letter and a typed report which is well laid out.

21. With respect to the surgical report the note identified as 5.9.19 and identified as "Operation Note Gynaecology" identifies the surgical procedure by subheading: operation, surgeons present, anaesthetist, indications, procedure and post operative directions. This document is a well written, clearly laid out document with each subheading well described. The surgical procedure itself is easy to follow and identifies for the reader exactly how the procedure took place. Attention to detail is excellent.

22. **The standard of care exercised at the time of surgery and documented in the surgical letter of 5 September 2019 meets an appropriate and acceptable standard. There has been no departure from an appropriate standard of care, or accepted practice.**

    The surgical letter would be viewed by my colleagues and myself as an excellent record of events of 5 September 2019 and reflects an appropriate level of surgical skill delivered to [Ms A]. There are no further recommendations.

Item 4 Following the surgery, was there a clinical need for further surgery? Please outline any reasons further surgery may have been indicated.

23. The surgical summary identified in the operation note 5 September 2019 identifies that all areas of endometriosis have been identified and managed.

24. During the course of the surgical procedure a device identified as the Rumi uterine manipulator was introduced into the uterus to facilitate manipulation of the uterus. The introduction of this device necessitated the removal of the Mirena IUCD.

25. Subsequent to the surgery being completed a new Mirena IUCD was introduced and there are comments made attesting to the examination of the uterus. The manufacturer's identification documentation regarding the device inserted has been appended to the notes and viewed by myself.

26. On the basis of the current surgical findings and management, together with the long term management provided by the Mirena, there is no indication for further surgery at this time.

27. **An appropriate standard of care has been delivered and there is no departure from accepted practice. The post operative management with the introduction of Mirena meets the appropriate standard and would be viewed by my colleagues as preferred management in this situation. There are no further recommendations.**

Item 5 Whether it was clinically appropriate to replace the Mirena in [Ms A's] uterus.

28. The consenting document identifies that the replacement of the Mirena may be required.

29. The surgeon has used a Rumi uterine manipulator and as such has elected that the Mirena should be removed and a new device put in place at the completion of the procedure.

30. **Conclusion**

    Surgeons introducing equipment into the uterine cavity would normally remove any IUCD which might be present with a view to replacing this at the conclusion of the procedure. The need for replacement of the Mirena was considered early in the procedure and is noted on the surgical referral waiting list form dated 18.6.19.

    The replacement of the Mirena IUCD has also been identified on the consent documentation completed prior to surgery.

    It was clinically appropriate to remove the Mirena and replace this with a similar device upon completion of the procedure.

31. **An appropriate standard of care and accepted practice has been delivered. There has been no deviation from an appropriate standard.**

    The practice carried out by [Dr B] at the time of surgery would be considered by my colleagues as appropriate and normal practice. There are no recommendations.

Item 6 Whether it was clinically appropriate to consider and use alternative IUCDs.

32. I am unable to find any documentation within the current material provided regarding [Ms A's] care that alternative IUCDs had been considered.

33. The Mirena IUS has internationally been used for the long term management of endometriosis.

34. In 2021 it would be considered standard practice to recommend the insertion of a Mirena IUCD for any patient undergoing endometriosis surgery.

35. **An appropriate standard of care has been delivered. There has been no deviation from normal practice. My peers would consider the introduction of a Mirena IUS for the long term management of endometriosis as an appropriate standard of care. There are no recommendations.**

Item 7 Any there any other matters in this care that you would consider warrant comment.

36. [Ms A] has identified the cauterisation of endometriosis as being a deviation from the consenting document and I note her comments and concerns.

37. It is noted however that [Ms A] was presented with the RANZCOG document "The Laparoscopic Treatment of Endometriosis" — a Guide for Women. Perusal of this document would have identified that the surgical procedure and findings at the time of operation may require a variation of the surgical treatment which falls outside the specifics of the "planned procedure or consent document".

38. While complications have been extensively identified on the consent form it is implicit within the consent that whilst the primary procedure will be laparoscopic excision it is understood by the surgeon, and should be understood by the patient, that the surgeon will exercise appropriate skill and expertise in the delivery of that care. If it was deemed that laparoscopic excision was an unsafe or unwise procedure then an alternative procedure will be offered without first waking the patient to gain consent.

39. A level of trust in the delivery of treatment is inherent when a patient presents for surgical management.

40. In our HDC documentation we focus specifically on whether an appropriate standard of care delivered with appropriate skill has been undertaken.

41. At no time during the pre operative assessment or surgical procedure has there been any deviation from what is an appropriate standard. The skill exercised by [Dr D] in the outpatient clinic with his presentation of appropriate literature and full discussion regarding the procedure is documented. The surgical skill and judgment exercised by [Dr B] and [Dr E] meets all standards.

42. If there is one area that I might criticise, it would be the specificity of the surgical procedure to be performed. Specifying the procedure as laparoscopic excision and giving no flexibility to the surgeon to act with care and skill has tied the surgeon down to an unacceptable degree. If one was to adhere to the documentation exclusively then the endometriosis in the vicinity of the bowel would not have been ablated but left in situ. This would be considered by my peers as an inappropriate course of action.

43. [Dr B] exercised appropriate clinical judgement in treating this area with the appropriate surgical modality which achieved both destruction of disease and minimised any potential complications for [Ms A]. [Dr D] and [Dr B] might consider the possibility of being a little less specific with their treatment of endometriosis and a suggestion might be made that their surgical consent should simply read **laparoscopic surgical treatment of endometriosis**, thereby giving the surgeon flexibility in using appropriate skill and management of the disease found at the time of surgery. Such a title on a consent document does not obviate the need to discuss the various surgical modalities that might be utilised during surgery in the pre operative consultation process. Aspects of that discussion should be fully documented.

Footnote

44. I thank you for the documentation that HDC have supplied. If I may be so bold as to indicate that the surgical operation note written by [Dr E] was such an excellently laid and comprehensive document that this has made my task of assessing and imagining the situation at the time of surgery so much easier. Poor documentation, often not typed, nor well laid out has been a common feature in the past and this is such a pleasant deviation from that level of care.

45. May I ask for your support re, a letter from HDC to indicate how pleasing it was to read a well laid out and documented surgical procedure. [Dr E] is not subject to complaint in this case and encouragement of good practice would be appropriate for a trainee embarking on a career in obstetrics and gynaecology.'