Capital & Coast District Health Board Obstetrician & Gynaecologist, Dr B

A Report by the Health and Disability Commissioner

(Case 18HDC00131)



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Executive summary

- This report concerns the care provided to a woman by Capital & Coast District Health Board (CCDHB) and an obstetrician and gynaecologist (O&G) during the woman's preassessment and surgical treatment for endometriosis. The report highlights the need for ensuring that a consumer's right to decide to refuse treatment is upheld, and that staff understand the relevance of consent issues and escalate pertinent consent information.
- The woman required surgery for suspected endometriosis, and told the O&G that she did not want ablation used to treat any endometriosis found. The woman repeated her refusal for ablation at the pre-assessment clinic, and this was documented in her clinical notes. On the day of surgery, a registrar obtained written consent for surgery, but did not read the pre-assessment notes that recorded the refusal of ablation. When the O&G performed the surgery, endometriosis was found and removed using ablation.

Findings

- The Commissioner considered that staff lacked clarity and guidance on the relevance of consent discussions, the escalation of pertinent information about consent, and the reading of preoperative assessment notes, and found CCDHB in breach of Right 4(1) of the Code.
- The Commissioner found the O&G in breach of Right 7(7) of the Code for using ablation to treat the woman's endometriosis when she had specifically refused consent for this. Furthermore, the Commissioner was critical that he did not read the notes sufficiently to obtain the information he needed before commencing the surgery, and found him in breach of Right 4(1) of the Code. The Commissioner was also critical of the O&G's record-keeping in relation to the information given to the woman, pertinent discussions about consent, and concerns raised by the woman postoperatively, and found the O&G in breach of Right 4(2) of the Code.

Recommendations

- The Commissioner recommended that CCDHB report back to HDC on its corrective actions taken following this complaint; review staff training on informed consent; confirm the process for escalating important consent information at pre-assessment; clarify the expectation that an operating surgeon is responsible for reading the preoperative assessments; and provide a written apology.
- The Commissioner recommended that the O&G apologise to the woman and report back to HDC with his reflection on the changes he has made to his practice.
- 7. The Commissioner also recommended that the registrar apologise to the woman.

Complaint and investigation

- 8. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided by Capital & Coast District Health Board (CCDHB). The following issues were identified for investigation:
 - Whether Capital & Coast District Health Board provided Mrs A with an appropriate standard of care between October 2015 and November 2015.
 - Whether Dr B provided Mrs A with an appropriate standard of care between July 2015 and January 2016.
- 9. The parties directly involved in the investigation were:

Mrs A Complainant

Mr A Complainant's husband

Dr B Provider/obstetrician and gynaecologist

CCDHB Provider

10. Further information was received from:

Dr C House officer/CCDHB
Dr D Registrar/CCDHB

Information gathered during investigation

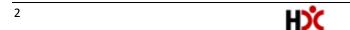
Background

- A general practitioner (GP) referred Mrs A, then aged in her thirties, to a private obstetrician and gynaecologist, Dr B, for assessment and management of worsening pain caused by menstruation (dysmenorrhoea).
- 12. Mrs A is a health professional. She said that she researched the various treatment options for her condition and decided that she did not want to have ablation (cutting and burning of tissue using an electrical probe) performed on her.

Clinic appointments with Dr B

- 13. Mrs A first consulted Dr B on 25 February 2015. Dr B noted Mrs A's history of worsening dysmenorrhoea for which she required pain relief.
- Dr B's clinic letter to the GP recorded that he suspected that Mrs A had endometriosis, and that he had discussed the treatment options with Mrs A, including insertion of a

¹ The presence of uterine tissue (the lining of the womb) on other organs inside the body. Endometriosis is more likely to be found in the lower abdomen or pelvis, but can appear anywhere in the body. Women with endometriosis often have lower abdominal pain and pain with periods.



Mirena² intrauterine device (IUD) or a laparoscopy³ with excision of pelvic endometriosis +/- (with or without) insertion of a Mirena. Dr B recorded that he had explained to Mrs A the risks and benefits of both treatment options and provided her with information leaflets. There was no documentation of any discussion about the use of ablation in the surgery, or the risks and benefits of this technique.

- The information leaflet provided to Mrs A states that operative laparoscopy is undertaken 15. to remove endometriosis either by excision (removal of patches using small cutting instruments) or ablation, or by using both techniques.
- Mrs A told HDC that at her first appointment with Dr B, he discussed surgery in passing as 16. a treatment option after other options had been tried. She said that there was no detailed discussion about surgery and whether this would involve ablation or excision. Mrs A stated that had Dr B discussed ablation at this appointment, she would have recalled this, and would not have returned for further consultations when it was clear that the Mirena was unsuccessful.
- On 20 May 2015, Mrs A saw Dr B for the insertion of a Mirena IUD. Following insertion of 17. the Mirena, Mrs A had ongoing abdominal discomfort, nausea, and vomiting. On 17 June 2015, Dr B removed the Mirena at Mrs A's request and arranged a follow-up appointment.

Discussion about surgical options

- On 29 July 2015, Mrs A, accompanied by her husband, Mr A, saw Dr B to discuss further 18. treatment options to manage her ongoing symptoms of menorrhagia⁴ with dysmenorrhoea.
- Dr B's reporting letter to the GP states: 19.

"We discussed various options. After careful consideration [Mrs A] has opted to undergo an operative laparoscopy with excision of pelvic endometriosis. This procedure including risks was discussed and information leaflets⁵ given to peruse."

- It is recorded that the surgery would be performed at a public hospital. 20.
- Mrs A told HDC that she asked Dr B whether he would treat any endometriosis with 21. ablation or excision, because she understood that excision was the gold standard for treatment. She said that Dr B responded that ablation was not performed at CCDHB. Mrs A said that she stated clearly at this appointment that she did not want to have ablation to treat any endometriosis found during the surgery. She said that she was provided with a treatment information leaflet about laparoscopy.
- Mr A recalls that following the removal of the Mirena, Dr B discussed a range of options. 22. Mr A said that Mrs A told Dr B about her understanding of the literature about

⁵ Dr B provided HDC with a copy of the treatment information pamphlet. It does not mention that the doctor will make a decision about the use of ablation or excision during the operation.



² A hormonal IUD that is inserted into the uterus for long-term contraception and to reduce heavy periods.

³ Examination of the organs inside the abdomen.

⁴ Menstrual periods with abnormally heavy or prolonged bleeding.

endometriosis and her opinion that ablation was a risky treatment. She was clear to Dr B that she was not interested in ablation to treat endometriosis, and she gave him her reasons for her decision.

- 23. Mr A recalls that Dr B said that ablation was not performed at CCDHB, but it was unclear whether Dr B was referring to his practice, or to his peers at CCDHB. Mr A said that both he and Mrs A were reassured that ablation was a procedure that would not be performed.
- Dr B told HDC that he met with Mrs A on four occasions prior to the surgery, and discussed the surgical plan in detail. Dr B stated:

"I do not recall [Mrs A] saying that she only wished to be treated by excisional treatment ... It would be unusual for me to proceed with excision alone. I therefore believe that if [Mrs A] had told me that she was opposed to ablation that would have led to a detailed discussion and have been recorded in the notes."

- There is no documentation in Mrs A's clinical records of a discussion about ablation or her refusal to have ablation during the surgery.
- Dr B cannot recall specific details of his conversations with Mrs A. He told HDC that he routinely performs ablation in his practice, and he would not have told Mrs A that he does not perform ablation at CCDHB. He said that his usual practice is to tell patients that although excision of endometriosis is his treatment of choice, ablation may need to be performed in specific cases.
- 27. Dr B stated that he informs patients that there is no way of knowing whether ablation will be required until after the laparoscopic surgery has commenced, because the exact location of the endometriosis lesions becomes apparent only during the surgery. He said that each lesion is evaluated and a decision made on whether to use excision or ablation based on the proximity of the lesion to major blood vessels.

Referral to CCDHB for surgery

- 28. On 29 July 2015, Dr B referred Mrs A to CCDHB for laparoscopic excision of pelvic endometriosis. CCDHB triaged Mrs A, and on 21 August 2015 placed her on the surgical waiting list with an estimated waiting time of up to four months.
- 29. CCDHB told HDC that Dr B was the lead clinician in Mrs A's care.

Preoperative assessments

on 20 October 2015, Mrs A attended gynaecology and anaesthetic pre-assessments⁶ at the public hospital. She was seen by an obstetrics and gynaecology house officer, Dr C, and an anaesthetist.

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⁶ Also referred to as "preoperative assessment" or "pre-assessment clinic".

- 31. CCDHB told HDC that the purpose of pre-assessments is to "check to ensure fitness for surgery and to be given information to help prepare for treatment, recovery and discharge".
- Dr C advised HDC that her understanding of the purpose of a pre-assessment is to ensure that the patient is fit for an anaesthetic and to address any treatable risks prior to surgery. A secondary role is to ensure that the patient has an understanding of general preoperative and postoperative information. Dr C said that there is an expectation that house officers will complete a written consent form during the pre-assessment appointment.
- Mrs A told HDC that she asked Dr C to confirm that any endometriosis found would be treated by excision and not ablation, and told Dr C that she would rather any endometriosis remain than to be treated by ablation. Mrs A recalls being told by Dr C that the planned treatment was excision, and that this was recorded in her clinical notes.
- Mrs A also told HDC that Dr C told her that she would have access to photographs taken during the surgery, and said that she would seek advice about whether Mrs A should continue taking her usual medication, Provera. Mrs A said that she was concerned that she was not given any advice about taking Provera at the pre-assessment or at a later date.
- Dr C stated that although she cannot recall the details of the consultation with Mrs A, it is unlikely that she told Mrs A with "absolute certainty" that she would undergo endometriosis excision rather than ablation, because she (Dr C) was not performing the surgery.
- Dr C said that in this situation, she would record the patient's wishes and inform the patient that there would be an opportunity to discuss the procedure with the operating doctor on the day of surgery, when the patient would be asked to sign the consent form. Dr C told HDC that she cannot recall whether she conveyed Mrs A's refusal of ablation to Dr B or his registrar, Dr D.
- 37. The preoperative assessment form recorded:

"For laparoscopy + excision of endometriosis."

"Fit for O.T [operating theatre]."

- 38. The "investigations and management plan" section of the form recorded:
 - "1 Bloods
 - 2 D/W Reg re: Provera should it be stopped? Hasn't helped pelvic pain significantly. Pt wants to know if it will affect outcome/success of surgery.
 - 3 Consent on day wants excision. Not ablation. If endo[metriosis] is found."

⁷ A medication used to treat endometriosis.



- 39. Dr C told HDC that Mrs A's refusal of ablation varied from the standard procedure, and therefore she did not complete the consent form for treatment. Dr C said that she understood that completing the consent form in the pre-assessment clinic was one part of the three essential steps involved in the consent process, along with discussions taking place with more senior doctors in outpatient clinics, and a final "safety check" on the day of surgery.
- obtaining photographs of the surgery, but understood at the time of events that photographs taken during surgery were able to be viewed postoperatively by patients, if they wished. Dr C told HDC that she planned to communicate to Mrs A the preoperative recommendations for Provera, and apologised if she did not provide this information to Mrs A.
- Mrs A also attended an anaesthetic pre-assessment as part of the preoperative assessment. She saw the anaesthetist, who documented the proposed operation as "operative laparoscopy: excision endometriosis". There is no record of any discussion about Mrs A's refusal of ablation.
- 42. CCDHB stated that it was appropriate for Dr C to document in the pre-assessment management plan that Mrs A had stated that she did not want ablation, and that this was to be taken into account during the informed consent stage on the day of the surgery.

Signing consent for treatment and procedure form − 5 November 2015

- On 5 November 2015, Mrs A presented to hospital for surgery. Dr D saw Mrs A prior to her surgery to obtain her signature on the consent for treatment and procedure form.
- Dr D told HDC that she does not recall any discussion with Mrs A about her refusal of consent for ablation at the time of obtaining her consent for the surgery. Dr D stated:
 - "I am confident that if I was made aware of [Mrs A's] wishes not to have ablation (as opposed to excision) I would have noted it on the consent form and advised [Dr B]."
- Dr D told HDC that her usual practice is to read the Gynaecology Clinic letters in preparation for the patient's surgery to understand what the patient's concerns are, the reasons for the surgery, and the surgical procedure. She said that occasionally the clinic letters from private clinics were not available on the CCDHB patient records, and she cannot recall whether Mrs A's clinic letters were available.
- ablation during the discussion at the preoperative assessment clinic. Dr D stated that it was not her usual practice to read the preoperative assessment form because the purpose of the preoperative assessment clinic is to assess whether a patient is medically fit for surgery. She said that it was not usual for instructions about consent to be recorded on the

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⁸ The assessment is to determine fitness for a general anaesthetic and to discuss anaesthetic risks.

preoperative assessment form. Therefore, it was not common practice for CCDHB registrars to read this form when a patient reached the preoperative area prior to surgery.

- Dr D stated that if a patient had not already consented to the surgery, it was her usual practice to see the patient in the preoperative area shortly before the surgery to go through the consent form and answer any questions. Dr D said that her practice is to ask the patient to explain in the patient's own words what the surgery involves, to ensure that this is consistent with the surgery booked and the record on the operative list for the day.
- 48. Mrs A told HDC that there was no discussion with Dr D about how the laparoscopy would be performed, except in the very broadest sense, and had the ablation treatment been discussed, she would not have consented.
- Mr A told HDC that he was present on the morning of the surgery when a doctor met with Mrs A prior to the surgery. He recalls that Mrs A checked with the doctor that it was clear that she did not want ablation, and told the doctor that this was recorded in her clinical notes. He recalls that the doctor acknowledged that Mrs A did not want ablation.
- 50. The consent for treatment and procedure form signed by Mrs A and countersigned by Dr D states that the procedure to be performed was "operative laparoscopy + excision endometriosis". It does not mention ablation.

Dr B

Dr B was not present when Mrs A signed the consent for treatment and procedure form. He told HDC that he does not recall whether he read Mrs A's notes prior to the surgery on 5 November 2015, and he did not document any discussion regarding her refusal of ablation at the time. He said that his usual practice is to review the preoperative assessment before surgery and discuss any matters arising from the clinical notes. Dr B stated:

"I sincerely apologise for this oversight and consider this a timely reminder to review and act on the notes appropriately by discussing any matters with the patient directly at the time."

CCDHB

- 52. CCDHB stated that there is no record of Mrs A repeating her refusal of ablation during the consenting process on 5 November 2015. It also said that it was reasonable for Mrs A to have expected the consenting clinician to know that at the preoperative assessment process, she gave instructions about the operative procedure.
- 53. CCDHB also stated:

"The onus is on the clinician at the time of consent to ensure informed consent has fully taken place. It is also reasonable for the clinician at the time of consenting to expect that a patient would raise concerns and questions if they are uncertain or unhappy about the surgery even post earlier discussions at pre-assessment."

Surgery and postoperative care

- Dr B and Dr D performed the surgery, and endometriosis was found. The operation record states: "[E]ndometriosis excised on both pelvic side walls. Diathermy [ablation] to other areas of endometriosis as mentioned in findings."
- Dr B told HDC that during the laparoscopic surgery, significant excisional biopsies were performed. He said that further lesions were found on the pelvic brim⁹ and over the uterovesical peritoneum,¹⁰ and that he used ablation to remove these lesions because of the increased risk of damaging blood vessels or of unnecessary scarring.
- Mrs A told HDC that when she woke from surgery she was told that endometriosis had been found and treated with ablation and excision. She said that she was shocked, upset, and alone, and felt that she was not in a position to complain having just woken up from surgery. Mr A said that his wife contacted him and was upset because ablation had been performed.

Postoperative review 12 January 2016

- Dr B saw Mrs A again on 12 January 2016. Dr B documented that the operation record was discussed.
- 58. Mrs A recalls that she attempted to discuss her concerns about the use of ablation, but she felt that her concerns were dismissed by Dr B. She also said that she was not informed of the option to make a formal complaint.
- Mr A told HDC that a registrar spoke to them for 10–15 minutes and then left to get Dr B. Mr A cannot recall whether Mrs A's concerns about the use of ablation were discussed with Dr B. Mr A recalls that Dr B proposed that Mrs A have a hysterectomy, and they left the appointment to consider the procedure further.
- Dr B told HDC that he was surprised to receive this complaint, as he continued to provide treatment to Mrs A following the laparoscopic surgery. He said that he does not recall Mrs A raising any concerns about the procedure at the postoperative reviews in January and March 2016. He apologised that Mrs A felt dismissed when she raised her concerns with him following the surgery.

CCDHB — further information

- 61. CCDHB told HDC that the preoperative assessment is not the formal consent process. It stated that information gained at preoperative assessment that is pertinent to consent needs to be made known by the clinician, and escalated to the clinician who obtains the signed consent for the surgery.
- 62. CCDHB apologised that the instructions Mrs A gave to Dr C about not wanting ablation did not transpire.

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⁹ The outer edge of the pelvic inlet.

¹⁰ A membrane in the abdominal cavity.

- 63. CCDHB also apologised that the opportunity for photography during surgery was lost. It said that there was no consent for photographs to be taken, no documentation in the clinical notes about Mrs A wanting photographs, and the photographer was unable to find copies of any photographs.
- 64. CCDHB apologised that Dr D and Dr B deviated from Mrs A's instructions that were stated at her preoperative assessment. CCDHB said that both Dr D and Dr B consider that they acted within the realms of the signed consent form. CCDHB told HDC: "We sincerely apologise for any distress that the outcome of this operation caused for [Mrs A] and any sense of mistrust or vulnerability it created for her."

Changes made since these events

Dr B

of Dr B told HDC that he has amended the consent form, which now records: "operative laparoscopy with excision of pelvic endometriosis with +/- ablation". He also stated that he ensures that he reviews the preoperative assessment notes and informs patients that he may consider ablation if this is indicated during the surgery.

CCDHB

- 66. CCDHB told HDC that it has taken a number of corrective actions since these events, including:
 - Clinicians ensure that the purpose of the preoperative assessment is understood by women prior to and at the start of pre-assessment.
 - Implementation of a checking system for actions identified at preoperative assessment clinics to ensure that actions are undertaken and documented.
 - Prior to obtaining an informed consent, the doctor obtaining the consent needs to read the preoperative assessment documentation, including the anaesthetic assessment and gynaecology assessment.
 - The informed consent form for laparoscopic excision of endometriosis now states: "operative laparoscopy with excision of pelvic endometriosis with +/- ablation".
 - Time Out sessions are mandatory as part of all operating schedules, and are being used to ensure that the entire operating team is familiar with the surgical plan, including the postoperative care.

Mrs A — further information

67. Mrs A stated:

"[T]he bottom line is that I did not consent to a treatment that I subsequently had. I had the right to refuse that treatment regardless of the surgeon's preference and my right to choose was taken away from me."

Dr D — comment

Dr D acknowledged the seriousness of Mrs A's concerns and apologised that Mrs A was not treated according to her wishes. Dr D advised that she has made changes to her practice, and now reads the preoperative assessment notes prior to consenting a patient.

Dr B — comment

Or B apologised for not clarifying the note in the preoperative assessment form with Mrs A, and said that had he done so he would have respected her decision not to have ablation performed. Dr B said that it was never his intention to disrespect Mrs A's choices in any way, and that he acted in her best interests. In response to the provisional opinion, Dr B stated that he intended no harm to Mrs A and that he thought he was proceeding in accordance with best practice and her best interests. Dr B stated: "Had I appreciated that [Mrs A] did not consent to ablation, I would not have performed it, regardless of whether I believed it was in her best interests or not."

CCDHB informed consent policy

70. CCDHB's "Informed consent (adults and children)" policy (July 2013) states:

"Obtaining consent — requirements

Timing of consent

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In most cases where written consent is required, treatment options will be discussed with the patient well in advance of the actual treatment being carried out. The consent process may then involve two stages: the provision of information, discussion of options and an initial usually oral decision of the patient, followed by confirmation that the patient wishes to go ahead with the planned treatment. This second stage may occur at any appropriate time before the treatment, including in out-patients, at a preadmission clinic, or when the patient is admitted for treatment. What is important is that the patient has had time to take in and understand the information and options available, and does not feel under any undue pressure to consent.

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Right to refuse medical treatment

The competent patient

A competent adult patient who has the capacity to consent, may refuse to consent to medical treatment even if it results in that patient's injury or death, including an emergency situation. A health professional has no right to proceed in the face of a competent patient's refusal.

...

There is no requirement that a patient's refusal to consent to medication treatment be in writing in order to be valid. Health professionals should, however, endeavor to obtain such a refusal in writing. Full documentation in the patient's clinical record should be completed by the responsible health professional, outlining the exchanges between the health professional and the patient."

Responses to provisional opinion

- Mrs A, Dr B, Dr D, CCDHB, and Dr C were given the opportunity to respond to relevant sections of the provisional opinion. Where appropriate, changes have been incorporated into the report.
- 72. Dr B accepted the recommendations in the provisional opinion.
- 73. Dr D had no comment in response to the provisional opinion.
- 74. CCDHB accepted the recommendations in the provisional opinion. Dr C did not comment on the provisional opinion.

Opinion: Dr B — breach

Introduction

- Mrs A did not wish to undergo ablation. That was her choice to make. Right 7(7) of the Code of Health and Disability Services Consumers' Rights (the Code) states: "Every consumer has the right to refuse services and to withdraw consent to services." This is consistent with the New Zealand Bill of Rights Act 1990, which states: "Everyone has the right to refuse to undergo any medical treatment."
- The principle of informed consent is at the heart of the Code. Pursuant to Right 7(1) of the Code, services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. The informed consent process began when Mrs A first consulted Dr B.
- Dr B, as the treating practitioner, retained overall legal responsibility and accountability for the consent process. Ultimately, he performed a procedure on Mrs A that she had not consented to. Dr B said that it was never his intention to disrespect Mrs A's choices in any way, and that he acted in her best interests. That is not the point. It is the consumer's right to decide and, in the absence of an emergency or certain other legal requirements, clinical judgement regarding best interests does not apply.

Preoperative discussions

On 29 July 2015, Mrs A, accompanied by her husband, saw Dr B and agreed to proceed with laparoscopic surgery to remove endometriosis. Mrs A is a health professional, had researched her treatment options, and held strong views on ablation as a treatment. She says that she asked Dr B about the surgical methods he used to treat endometriosis and was told that he does not perform ablation at CCDHB. Mrs A said that she expressly

refused consent to the use of ablation during the surgery to remove endometriosis. Mr A was also present on 29 July 2015, and his evidence supports her account.

- In contrast, Dr B said that he would not have told Mrs A that he does not perform ablation at CCDHB, because he routinely performs this in his practice. He said that he does not recall Mrs A stating that she was opposed to ablation and, because it would be unusual to perform excision alone, if she had done so he would have had a detailed discussion with her and recorded this in the notes. He said that his standard practice is to discuss with patients that ablation may need to be performed, and tell them that there is no way of knowing whether ablation is required until the surgery has commenced. Dr B recorded that he discussed various options with Mrs A and she decided to proceed with "excision of pelvic endometriosis", and that the "procedure including risks were discussed". However, he made no record of having discussed ablation with her.
- It is not clear precisely what Dr B told Mrs A during the clinic appointments, owing to the discrepancies between accounts and the paucity of documentation. However, it is clear to me that Mrs A was not aware that Dr B still intended to perform ablation if he considered it was required. In light of her experience as a health professional and her strongly held views on this issue, I find it likely that she would have raised those views in her consultations. Her evidence is supported by her husband's account and the preoperative assessment on 20 October 2015, which records Mrs A's refusal for ablation. Accordingly, I accept Mrs A's account that she discussed with Dr B her views about ablation and made it clear that she did not want ablation.
- I also accept Mrs A's account that she was not aware that ablation could still be used in her surgery. Dr B did not tell Mrs A that he still intended to use ablation in addition to excision during her surgery. Had he explained in full the planned procedure, and that excision and/or ablation might be used, Mrs A would have had an opportunity to express her views, and to refuse consent.
- 82. Concerns about ablation were clearly significant to Mrs A, and she had researched its use. I accept her account that she told Dr B that she did not want ablation; however, it appears that he did not pay attention to her concerns, and he did not respect her refusal.

Review of records prior to surgery

- Dr B did not meet with Mrs A prior to the surgery. He does not recall whether he read the preoperative assessment form, which states: "Consent on day wants excision. Not ablation. If endo[metriosis] is found." Dr B does not recall reading Mrs A's clinical notes prior to her surgery on 5 November 2015.
- As I have stated previously, a surgeon needs to read the notes to the extent necessary to satisfy himself or herself that s/he has all of the information that s/he, as the operating

surgeon, needs to know.¹¹ I expect that this would include recently prepared documents, completed for the purposes of the surgery. Furthermore, as stated in a previous opinion:¹²

"The onus is on the clinician to ask the relevant questions, examine the patient, and keep proper records. Only then is the clinician in a position to properly consider all the risks, review all available information, and then and only then, proceed to perform surgery."

- In my view, Dr B did not read Mrs A's notes sufficiently to obtain the information he needed before commencing her surgery. This was a failure to provide services with reasonable care and skill.
- Dr B's failure to read Mrs A's notes sufficiently had significant implications for Mrs A. Dr B acknowledged that had he been aware of Mrs A's views, his approach to her surgery would have been different.

Record-keeping — breach

- The Medical Council of New Zealand's statement on "Maintenance and Retention of Patient Records" (2008) includes:
 - "(a) You must keep clear and accurate patient records that report:
 - · relevant clinical findings
 - decisions made
 - information given to patients
 - any drugs or other treatment prescribed.
 - (b) Make these records at the same time as the events you are recording or as soon as possible afterwards."
- In my view, Dr B's record-keeping was poor. He failed to record in the clinical notes the information he provided to Mrs A, and her refusal of consent for ablation. Consequently, the clinicians who reviewed the clinical notes during the ongoing consenting process were unaware that Mrs A did not consent to the use of ablation, and did not clarify this with Mrs A.
- Furthermore, Dr B did not accurately record the procedure he intended to perform, being excision and/or ablation rather than excision alone. The consent for treatment and procedure form states that the procedure to be performed was "operative laparoscopy + excision endometriosis". It does not mention ablation. Had Dr B recorded the procedure accurately, other staff would have been alerted to the need to discuss ablation specifically with Mrs A as part of the consenting process.
- 90. I am also concerned that Dr B made no record of the concerns raised by Mrs A at the postoperative review.



¹¹ See Opinion 11HDC00531, available at www.hdc.org.nz.

¹² Opinion 09HDC01505, page 23.

The importance of record-keeping cannot be overstated. It is the primary tool for 91. continuity of care and managing patients. Dr B's lack of documentation resulted in junior doctors involved in Mrs A's care lacking key information, as they were not aware of Mrs A's views on ablation, or that Dr B might intend to use that technique.

Conclusions

- Whether Dr B's use of ablation and excision to treat the endometriosis was clinically 92. appropriate is not the issue. Mrs A had a right to refuse consent to the use of ablation, and she expressed this to Dr B during her appointments with him and at the preoperative assessment visit. Dr B failed to pay sufficient attention when Mrs A told him that she did not want to have ablation performed. It was Mrs A's right to make an informed choice about the procedure she was to undergo, and not to be treated with ablation when she had refused it. By treating the endometriosis with ablation when Mrs A had refused consent to ablation, Dr B breached Right 7(7) of the Code.
- Dr B did not read Mrs A's notes sufficiently to obtain the information he needed before 93. commencing her surgery. This was a failure to provide services with reasonable care and skill and, accordingly, a breach of Right 4(1) of the Code.
- 94. I am critical of the standard of Dr B's record-keeping in relation to information given to Mrs A, the pertinent discussions about consent, and the concerns raised by Mrs A postoperatively. Dr B failed to comply with professional and legal standards and, accordingly, also breached Right 4(2) of the Code. 13

Opinion: Capital & Coast DHB — breach

Lack of consensus on consent at the pre-assessment clinic

- Dr C saw Mrs A on 20 October 2015 for a preoperative assessment. Mrs A asked Dr C to 95. confirm that any endometriosis found would be treated by excision and not ablation, and said that she would rather any endometriosis remain than be treated by ablation. Dr C recorded Mrs A's refusal of ablation in the preoperative assessment form. Dr C told HDC that she understood that the preoperative assessment was one part of the consenting process, and that further consenting discussions would take place, including a final check on the day of surgery.
- CCDHB told HDC that a preoperative assessment appointment is separate from the 96. consent for surgery. It said that it is a "check to ensure fitness for surgery and to be given information to help prepare for treatment, recovery and discharge".
- On the day of surgery, Dr D saw Mrs A to obtain written consent. Dr D told HDC that it was not usual for instructions about consent to be documented on the pre-assessment form.

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¹³ Right 4(2) of the Code states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

Dr D did not read the pre-assessment form, and said that it was not common practice for her or her registrar colleagues to do so, because she understood that the purpose of the pre-assessment was to assess whether a patient was fit for surgery. Dr B stated that his usual practice was to review the preoperative assessment, but he cannot recall whether he reviewed Mrs A's notes prior to surgery. Dr C, Dr D, Dr B, and CCDHB all had different views about the relevance of consent discussions at the pre-assessment. The variation in practice is problematic. It reflects the lack of consensus and suggests a problem at a systems level. It led to a misunderstanding between the doctors, and a subsequent failure by both Dr D and Dr B to read the preoperative assessment, which recorded Mrs A's refusal for ablation. Had Dr D and Dr B clearly understood that the preoperative assessment could hold information relevant to consent, they may have been alerted to review this documentation during the course of officially recording consent on the day of surgery.

- I disagree with CCDHB's statement that the preoperative assessment is separate from consent for surgery. The preoperative assessment is not necessarily separate to the consent process should pertinent consent information be obtained. The provision of the required information and the obtaining of informed consent are not a single event. The process commenced on 29 July 2015 and continued throughout each contact Mrs A had with the system, including on 20 October 2015 and 5 November 2015.
- 99. Although I consider that Dr D and Dr B were individually responsible for reading the clinical notes and obtaining consent (or noting the refusal of consent) on the day of surgery, I am critical of CCDHB that staff were not clear about the relevance of consent discussions at the preoperative clinic.

Processes for escalating matters of concern

- Dr C was the only doctor who recorded Mrs A's refusal for ablation when she saw her in the preoperative assessment clinic. It was Dr C's understanding that on the day of surgery Mrs A's refusal would be discussed with the responsible clinician prior to the signing of the consent for treatment and procedure form. However, Dr D advised that she does not recall Dr C informing her about Mrs A's refusal for ablation.
- 101. CCDHB stated that the clinician performing the pre-assessment should escalate consent issues to the clinician obtaining formal consent, prior to the upcoming surgery.
- 102. CCDHB's informed consent policy required staff to document a patient's refusal of consent, which Dr C did believing such information would be reviewed and discussed by senior doctors. However, CCDHB's informed consent policy did not specify any requirement to escalate concerns beyond documenting the refusal. There is no guidance for staff on the appropriate steps to escalate pertinent information to the responsible clinician.
- 103. If CCDHB intended pertinent consent issues to be escalated, it should have made that clear to staff, and also made clear its expectations for how such escalation would be achieved,

for example by verbally communicating such issues to senior doctors or entering an alert on the patient's record.

Overall I am critical of the lack of clarity and guidance for staff around CCDHB's expectations for escalating information pertinent to consent and in relation to reading the preoperative assessment. However, again, Dr B was the operating surgeon and was therefore ultimately responsible for obtaining consent (or noting the refusal of consent).

Conclusions

- 105. While aspects of the care provided to Mrs A by CCDHB were adequate, I am concerned that aspects of the care she was provided were suboptimal. In particular:
 - Staff were not clear about the relevance of consent discussions at the preoperative clinic.
 - The informed consent policy did not specify any requirement to escalate concerns beyond documenting the refusal.
 - There was no guidance for staff on the appropriate steps to escalate information pertinent to consent to the responsible clinician.
 - There was a lack of clarity and guidance for staff around reading the preoperative assessment.
- For these reasons, I find that CCDHB did not provide services with reasonable care and skill, and breached Right 4(1) of the Code. 14

Opinion: Dr D — adverse comment

- Dr D saw Mrs A prior to her surgery on 5 November 2016 to obtain her signed consent for the procedure. Dr D does not recall having any discussions with Dr C or Mrs A about Mrs A's refusal of ablation. Dr D also has no recollection of whether she read Mrs A's clinical notes, and said that it is not her usual practice to read the preoperative assessment notes.
- 108. It was reasonable for Mrs A not to have reiterated her refusal of ablation when she met with Dr D. Mrs A had already told Dr B and Dr C, and expected the system to be aware of her refusal.
- As Dr D failed to read the preoperative assessment notes, she was not aware that Mrs A had previously refused ablation as a treatment. I am critical that Dr D did not read the notes prior to obtaining Mrs A's signature, and I do not accept that it is acceptable practice not to read pre-assessment records. The purpose of the pre-assessment is to determine whether a patient is medically fit for the particular surgery to be performed. In order to

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¹⁴ Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

obtain Mrs A's consent to the proposed treatment, Dr D needed to ensure that she was aware of any relevant medical information documented in the clinical record, particularly information obtained during the preoperative assessment and any previous discussions about treatment.

- In addition to not reading the notes, Dr D did not explain to Mrs A that the proposed treatment involved ablation. Dr D said that her usual practice is to go through the consent form with the patient and ask the patient to explain what the surgery involves, to reconcile this with the surgery planned. However, this is of little efficacy given that the procedure was not recorded accurately on the consent form. Dr D recorded that the procedure to be performed was "operative laparoscopy + excision endometriosis", with no mention of the potential for ablation.
- 111. Mrs A stated that she remembers a broad discussion about how the laparoscopy would be performed, and said that had ablation been discussed specifically, she would not have consented to it.
- 112. I am critical of Dr D's failure to inform Mrs A adequately about the procedure, including the use of ablation. If she had discussed ablation, Mrs A would likely have reiterated her refusal.

Recommendations

Dr B

- 113. I recommend that Dr B:
 - a) Provide a written apology to Mrs A for breaching the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A.
 - b) Provide a written report to HDC on the changes he has made to his practice as a result of this complaint, within three months of the date of this report.

Dr D

I recommend that Dr D provide a written letter of apology for the deficiencies in care identified in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A.

CCDHB

- 115. I recommend that CCDHB:
 - a) Provide a written apology to Mrs A within three weeks of the date of this report. The apology is to be sent to HDC for forwarding to Mrs A.

- b) Confirm to HDC the process for clinicians to follow at pre-assessment when important consent information obtained should be escalated to the clinician obtaining signed consent.
- c) Provide an update to HDC on the corrective actions taken as a result of this complaint, and report back to HDC within three months of the date of this report.
- d) Provide HDC with a review of training provided to staff in relation to informed consent, and evidence that all medical staff in the Women's Health Service have been trained in informed consent, within three months of the date of this report.
- e) Clarify the expectation that an operating surgeon is responsible for reading the preoperative assessments, and report back to HDC within three weeks of the date of this report.

Follow-up actions

- A copy of this report with details identifying the parties removed, except CCDHB, will be sent to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and the Medical Council of New Zealand, which has been advised of Dr B's name.
- A copy of this report with details identifying the parties removed, except CCDHB, will be sent to the Health Quality & Safety Commission and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.