

**A District Health Board
Obstetrician & Gynaecologist, Dr B**

**A Report by the
Health and Disability Commissioner**

(Case 14HDC00307)



Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of Contents

Executive summary.....	1
Complaint and investigation	2
Information gathered during investigation.....	3
Opinion: Dr B	12
Opinion: The district health board	15
Recommendations.....	16
Follow-up actions.....	17
Appendix A — Independent obstetric and gynaecological advice	18

Executive summary

1. Mrs A, 46 years old at the time of these events, had suffered from epilepsy¹ since childhood, and also experienced menstrual problems. In August 2010 she had an endometrial ablation² and a uterine cyst removed but, after an initial improvement, her symptoms returned.
2. On 11 November 2011, Mrs A had an ultrasound at the gynaecology clinic of a public hospital. The ultrasound indicated adenomyosis,³ the treatment for which was discussed with Mrs A as being a hysterectomy.⁴ At that stage, Mrs A chose not to undergo a hysterectomy.
3. On 11 May 2012, Mrs A attended a further appointment at the gynaecology clinic. Again the possibility of a hysterectomy was discussed with her, but again she chose not to undergo a hysterectomy.
4. On 11 December 2012, Mrs A was seen at the gynaecology clinic by obstetrician and gynaecologist Dr B. Dr B explained adenomyosis to Mrs A, and discussed the possibility of undergoing a hysterectomy. He recorded that having thought about the possibility of having a hysterectomy over the previous year, Mrs A had decided to undergo the procedure. Mrs A signed a consent form for the procedure “total abdominal hysterectomy” (TAH).
5. Also during the consultation on 11 December 2012, Dr B diagnosed Mrs A with catamenial epilepsy,⁵ and said that he would have explained to Mrs A what that was. Mrs A told HDC that she recalls that she and Dr B discussed that there was a relationship between her epileptic seizures and her menstrual cycle, but said that she was not told at any stage that she had been diagnosed with catamenial epilepsy. It is not recorded in the clinical notes that Mrs A’s diagnosis of catamenial epilepsy was discussed with her.
6. On 21 March 2013, Mrs A presented to the public hospital for her surgery. While Mrs A was on the operating table, anaesthetist Dr F had a conversation with Dr B. There are differing recollections as to what was said between Dr B and Dr F. However, following the conversation, Dr B approached Mrs A on the operating table and sought her consent to the removal of her ovaries.
7. Mrs A signed her consent to undergo a bilateral oophorectomy.⁶ The consent form records “Total abdominal hysterectomy”, next to which has been added “+ Bilateral

¹ A neurological disorder marked by sudden recurrent episodes of sensory disturbance, loss of consciousness, or convulsions, associated with abnormal electrical activity in the brain.

² Endometrial ablation is a medical procedure that is used to remove or destroy the endometrial lining of the uterus. This technique is most often employed for women who suffer from excessive or prolonged bleeding during their menstrual cycle but cannot, or do not wish to, undergo a hysterectomy.

³ Adenomyosis occurs when endometrial tissue, which normally lines the uterus, exists within, and grows into, the muscular wall of the uterus.

⁴ A hysterectomy is the surgical removal of the uterus.

⁵ Catamenial epilepsy is a subset of epilepsy, which includes women whose seizures are exacerbated by their menstrual cycle. Women with catamenial epilepsy are unusually sensitive to hormonal changes.

⁶ A bilateral salpingo-oophorectomy is the removal of both fallopian tubes and ovaries.

Oophorectomy” (BSO). The addition has been initialled by Mrs A and Dr B. With regard to giving consent to the BSO, Mrs A told HDC that she felt “immensely pressured” to make a decision.

Findings

8. The manner in which Mrs A’s consent was obtained for the BSO was not appropriate. The operating theatre was not an appropriate environment for the informed consent process to take place, and did not allow for effective communication between Mrs A and Dr B. Accordingly, Dr B breached Right 5(2)⁷ of the Code.
 9. Furthermore, Mrs A was not given sufficient time to consider whether she wished to have a BSO, and was not in a position to give informed consent to the removal of her ovaries. Accordingly, Dr B breached Right 7(1)⁸ of the Code.
 10. The clinical care provided to Mrs A by Dr B was within accepted standards. However, adverse comment is made that Dr B did not appear to have communicated clearly to Mrs A that he had diagnosed her with catamenial epilepsy.
 11. The district health board was not found in breach of the Code.
 12. Adverse comment is made with regard to the failure by clinicians in the operating theatre to advocate appropriately on behalf of Mrs A.
-

Complaint and investigation

13. The Health and Disability Commissioner received a complaint from Mrs A regarding the care provided to her at a public hospital. The following issues were identified for investigation:
 - *Whether the district health board provided an appropriate standard of care to Mrs A between January 2012 and March 2013.*
 - *Whether Dr B provided an appropriate standard of care to Mrs A between January 2012 and March 2013.*
14. An investigation was commenced on 12 June 2014. The parties directly involved in the investigation were:

Mrs A	Complainant/consumer
Dr B	Obstetrician and gynaecologist
RN C	Registered nurse
Dr D	Neurologist

⁷ Right 5(2) states: “Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively.”

⁸ Right 7(1) states: “Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.”

Dr E	Registrar
The DHB	Provider

15. Other parties mentioned in this report are:

Dr F	Anaesthetist
Mr G	Anaesthetic technician
RN H	Registered nurse
Dr I	Gynaecology registrar

16. Independent expert advice was obtained from an obstetrician and gynaecologist, Dr John Short (**Appendix A**).

Information gathered during investigation

Background

17. Mrs A, 46 years old at the time of these events, had suffered from epilepsy since childhood. She told HDC that when she was 11 years old she was given a diagnosis of temporal lobe epilepsy.⁹ At the time of these events, Mrs A had not experienced a tonic clonic seizure¹⁰ for approximately 20 years. She had trialled a number of medications to treat her epilepsy, with variable effects.
18. Mrs A also experienced menstrual problems, including heavy painful menstruation. In August 2010, she had an endometrial ablation¹¹ and a uterine cyst removed but, after an initial improvement, her symptoms returned.

Neurology appointment — 13 July 2011

19. In the middle of 2011, Mrs A became concerned regarding increased intensity in her seizure activity. On 13 July 2011, Mrs A was seen in the public hospital's neurology clinic by a registered nurse (RN), RN H. At that time, Mrs A was taking levetiracetam.¹² RN H documented that Mrs A told her that her seizure activity usually presented as visual disturbances, which occurred weekly but were worse pre-menstrually, at which time she had visual disturbances daily for about 7–10 days. Mrs A reported increased tiredness and speech disturbances, and headaches with associated nausea, all of which tended to increase pre-menstrually. She told RN H that in the previous 18 months she had had a change in her menstrual cycle, with heavy bleeding, longer periods and increased pain. RN H increased Mrs A's dose of levetiracetam in consultation with Mrs A's neurologist, and asked her to keep a record

⁹ Characterised by recurring seizures that stem from the medial or lateral temporal lobes of the brain.

¹⁰ A type of generalised seizure that affects the entire brain. Tonic clonic seizures are the seizure type most commonly associated with epilepsy and seizures in general.

¹¹ Endometrial ablation is a medical procedure that is used to remove or destroy the endometrial lining of the uterus. This technique is most often employed for women who suffer from excessive or prolonged bleeding during their menstrual cycle but cannot, or do not wish to, undergo a hysterectomy.

¹² An anticonvulsant medication used to treat epilepsy.

of the frequency of her seizures. RN H arranged to review Mrs A in six weeks' time for follow-up regarding the increase in medication.

Neurology appointment — 6 September 2011

20. On 6 September 2011, Mrs A attended an appointment at the neurology clinic with RN H in order to review the efficacy of the increase in levetiracetam. Following the appointment, RN H recorded in a clinic letter to Mrs A's general practitioner (GP), that since the increase in medication Mrs A's seizures had not been as intense as previously. RN H recorded that Mrs A had experienced improvement in her visual disturbances. Mrs A reported that since the 11 July 2011 appointment, she had experienced seven episodes of visual disturbances, which RN H noted did not appear to coincide with Mrs A's menstrual cycle.¹³ Mrs A told RN H that she was happy to continue with her current dose of levetiracetam.

Obstetrics/gynaecology appointment — 11 November 2011

21. On 11 November 2011, Mrs A attended an appointment with an obstetric and gynaecology registrar, Dr I, at the gynaecology clinic, with regard to having pelvic pain related to her menstrual cycle. Mrs A had an ultrasound scan, which Dr I noted showed a thin endometrium,¹⁴ and that the appearance of her uterus was possibly consistent with adenomyosis.¹⁵ Dr I discussed Mrs A's management options with her, in particular having a hysterectomy.¹⁶ At that stage, Mrs A chose not to undergo a hysterectomy. Dr I provided Mrs A with written information about hysterectomies and arranged for her to return for review after she had considered her options.

Neurology appointment — 20 January 2012

22. On 20 January 2012, Mrs A attended an appointment at the neurology clinic with RN H for a review of her neurological symptoms. In a clinic letter to Mrs A's GP, RN H recorded that Mrs A had experienced a decrease in headaches, but that her visual disturbances had not decreased, and usually occurred around the time of her menstruation. RN H noted that Mrs A had experienced a recent episode of abdominal cramping, and recorded: "I am aware that she is under Gynaecology with regard to this who have recently suggested a hysterectomy to her. She is going to meet them again before she makes a decision about this."
23. With regard to Mrs A's ongoing visual disturbances, RN H again increased Mrs A's levetiracetam in consultation with Mrs A's neurologist, and arranged to review her in a few months' time to ascertain whether this had been successful.

Neurology appointment — 20 April 2012

24. On 20 April 2012, Mrs A attended an appointment at the neurology clinic with RN H to review the efficacy of the increase in levetiracetam with regard to Mrs A's visual disturbances. In a clinic letter to Mrs A's GP, RN H stated that Mrs A's visual

¹³ Mrs A told HDC that at this time she was in the early stages of peri-menopause, so both her menstrual cycle and her epilepsy were "chaotic with no real pattern to either events".

¹⁴ The inner mucous membrane of the uterus.

¹⁵ Occurs when endometrial tissue, which normally lines the uterus, exists within, and grows into, the muscular wall of the uterus.

¹⁶ A hysterectomy is the surgical removal of the uterus.

disturbances had decreased, and her headaches were “virtually non-existent”. RN H noted that Mrs A was happy to remain on her current dose of levetiracetam. RN H arranged to see Mrs A for review in approximately six months’ time.

Obstetrics/gynaecology appointment — 11 May 2012

25. On 11 May 2012, Mrs A attended an appointment with an obstetric and gynaecology registrar at the gynaecology clinic. The registrar recorded that she discussed with Mrs A the possibility of a hysterectomy; however, at that time, Mrs A felt that her previous two menstrual cycles had been tolerable, and so chose not to undergo a hysterectomy. The registrar arranged for Mrs A to return to the clinic once she had considered her options, with a view to booking a hysterectomy, or discharging Mrs A from the gynaecology clinic.

Neurology appointment — 19 October 2012

26. On 19 October 2012, Mrs A attended an appointment at the neurology clinic with RN H, in order to review the ongoing efficacy of levetiracetam. RN H recorded that over the previous couple of months Mrs A’s gynaecological problems had returned, her periods were non-existent, she felt bloated, and she was experiencing pain associated with visual disturbances. Mrs A told RN H that her visual disturbances tended to cluster around when she was supposed to be menstruating. RN H increased Mrs A’s dose of levetiracetam in consultation with Mrs A’s neurologist, and arranged to see her again in approximately five months’ time.

Consent to total abdominal hysterectomy — 11 December 2012

27. On 11 December 2012, Mrs A was seen at the gynaecology clinic by obstetrician and gynaecologist Dr B. In a clinic letter to Mrs A’s GP, Dr B recorded that he explained adenomyosis to Mrs A, and told her that “the cure for it was a hysterectomy”. He recorded that over the previous year Mrs A had thought about the possibility of having a hysterectomy, and had decided to undergo the procedure. He recorded: “The operation and its complications were explained to her.”
28. Mrs A stated that during the discussion with Dr B she was told that it was advisable for her to undergo a total abdominal hysterectomy¹⁷ (TAH) rather than a vaginal hysterectomy.¹⁸ She stated that she informed Dr B that she wished to retain both ovaries, and that they were to be removed only if he detected ovarian disease during the surgery. Mrs A told HDC that they both agreed to this plan, and that Dr B told her that it would be best for her to retain her ovaries because she was still quite young to undergo menopause, which would result from removal of her ovaries.
29. There is no documentation regarding a discussion about the removal of Mrs A’s ovaries, including the risks and benefits, at the 11 December 2012 consultation. Dr B

¹⁷ A total abdominal hysterectomy is the removal of the uterus and cervix through an abdominal incision.

¹⁸ During a vaginal hysterectomy, the surgeon detaches the uterus from the ovaries, fallopian tubes and upper vagina, as well as from the blood vessels and connective tissue that support it. The uterus is then removed through the vagina.

told HDC that this is because he does “not routinely offer oophorectomy¹⁹ to women under the age of 45 years when undergoing hysterectomy”.²⁰

30. In response to the provisional opinion, Dr B told HDC that “a clear instruction to preserve ovaries if at all possible is a clinically significant conversation that [he] does not recall and would have recorded in the notes if it had taken place ...”.
31. On 11 December 2012, Mrs A signed a “Request for Treatment/Procedure(s)” form, which stated that she requested that the procedure “total abdominal hysterectomy” be performed.

Diagnosis of catamenial epilepsy

32. Dr B told HDC that during the consultation on 11 December 2012, he also diagnosed Mrs A with catamenial epilepsy,²¹ and said he would have explained to Mrs A what that was. However, it is not recorded in the clinical notes that Mrs A’s diagnosis of catamenial epilepsy was discussed with her. Dr B recorded:

“[Follow-up appointment] (with) [abnormal uterine bleeding] + [heavy menstrual bleeding] + catamenial epilepsy and dysmenorrhoea. Requests [total abdominal hysterectomy]. Procedure and complications explained.”

33. Mrs A told HDC that the frequency of her epileptic seizures had always appeared to increase “pre-menstrually”, but that she was not told at any stage that she had been diagnosed with catamenial epilepsy.

Total abdominal hysterectomy and bilateral salpingo-oophorectomy — 21 March 2013

34. On 21 March 2013, Mrs A underwent a TAH and bilateral salpingo-oophorectomy²² (BSO) at the public hospital. Dr B was the surgeon, and his registrar was Dr E. The anaesthetist was Dr F. RN C was working as a staff nurse/operating theatre nurse in a team with an anaesthetic nurse and a scrub nurse. Mr G was the anaesthetic technician.
35. The recollections regarding what occurred in theatre²³ on 21 March 2013 differ between the relevant parties as follows.

Mrs A

36. Mrs A stated:

¹⁹ The surgical removal of one or both ovaries.

²⁰ Mrs A was 46 years old at the time of this consultation.

²¹ Catamenial epilepsy is a subset of epilepsy, which includes women whose seizures are exacerbated by their menstrual cycle. Women with catamenial epilepsy are unusually sensitive to hormonal changes.

²² A bilateral salpingo-oophorectomy is the removal of both fallopian tubes and ovaries.

²³ Prior to entering theatre, Mrs A was given the following medications: 8.35am, 150mg ranitidine (reduces the risk of stomach acid secretion and risk of aspiration of stomach contents while under general anaesthetic); 9.05am, 1.5g paracetamol. The procedure was undertaken at approximately 9.35am.

“[W]hilst [I was] prepped and on the operating table surrounded by the team the anaesthetist [Dr F], called [Dr B] over to where she was away from the operating table. I overheard her say to [Dr B], something about taking the ovaries as well ‘... because of her epilepsy’. [Dr B] returned to the operating table with the consent form that I had previously signed asking me if I would consent to having my ovaries removed. I was extremely emotional and nervous. I remember having the pen in my hand while [Dr B] was holding the clip board and by this stage I was crying and distraught. I wasn’t sure whether to sign to have my ovaries removed or not ...”

37. Mrs A told HDC that she recalls a nurse speaking to her and asking her if she wanted more time to consider her decision. She stated that the nurse rubbed her arm and attempted to comfort her. Mrs A recalls telling the nurse that she could not discuss the decision with her husband as he had already gone home to wait until her surgery was completed. Mrs A told HDC that she believes that the nurse was “trying to advocate on her behalf under very stressful circumstances ...”.
38. Mrs A signed her consent to undergo a BSO. She is unable to recall the details of her conversation with Dr B, but the consent form records “Total abdominal hysterectomy”, next to which has been added “+ Bilateral Oophorectomy”. The addition has been initialled by Mrs A and Dr B.
39. With regard to giving consent to the BSO, Mrs A stated that she “felt pressured to make a quick decision and sign on the dotted line. I signed, giving my permission to have both my ovaries removed; a decision I regretted and still regret to this day.” She further stated: “I have never felt so alone, so distraught and immensely pressured to make a major life changing decision that ultimately threw me into immediate surgical menopause; a procedure that once undertaken, could not be corrected; my ovaries could not be put back.”

RN C

40. RN C told HDC that she has over 13 years’ experience in operating theatre nursing. She stated that she was present in the operating theatre when Dr B and Dr F were preparing for Mrs A’s surgery. RN C said that she was the circulating nurse in a team with an anaesthetic nurse and a scrub nurse. Her role as circulating nurse included helping position and prepare Mrs A for surgery.
41. RN C said that the anaesthetic nurse brought Mrs A into theatre, and she was guided to the operating bed and prepared for the process of undergoing a general anaesthetic.
42. RN C stated that she and the anaesthetic nurse performed a “sign in” procedure, which included ensuring that they had the correct patient and the correct operation, and that the consent forms were written correctly. RN C noted that Mrs A had consented to a TAH. RN C stated that Mrs A appeared to be anxious during sign-in.²⁴

²⁴ In response to the provisional opinion, Mrs A confirmed that she was anxious prior to her surgery, and considers that feeling anxious prior to surgery is “normal”. However, Mrs A stated that she was “particularly anxious as [she] was being cut open for the third time in the same place”.

43. RN C stated that after the sign-in process, she noticed a conversation between Dr B and Dr F. After the conversation, Dr B came towards Mrs A and began to discuss her epilepsy condition and removing her ovaries. RN C told HDC that she recalls that Dr B told Mrs A that removing her ovaries would cause early surgical menopause, and that it would improve her epilepsy. RN C told HDC that Dr B “went on to give [Mrs A] some statistical facts. I cannot recall what these facts were.”
44. RN C stated: “[Mrs A] appeared more anxious and tearful as [Dr B] continued to explain the reasons for removing her ovaries.” RN C said that Dr B and Mrs A had a brief discussion while RN C held Mrs A’s hand, and that Mrs A appeared overwhelmed with the information and unsure what to do.
45. RN C said that, in her role as Mrs A’s advocate, she recalls expressing to Mrs A a few options such as, “If she was unsure, would she like more time to think about this new information?” RN C said that she also explained to Mrs A that if she was unsure of what decision to make, she did not have to go through with the surgery, and that Mrs A replied that she wanted to discuss the matter with her family. RN C said that she offered to find Mrs A’s family and bring them into the theatre department for the discussion, but Mrs A said that her family had already left the hospital.
46. RN C said that she suggested that they delay the surgery while Mrs A had time to think,²⁵ but Mrs A made the decision to sign the consent form to which Dr B had added “+ Bilateral Oophorectomy”.
47. RN C stated that Mrs A signed the consent form while she was on the operating table. RN C added to the Intraoperative Record: “[T]earful — discussed further surgery pre-op — overwhelmed with informed consent.”

Dr F

48. Following the procedure, Dr F wrote to Mrs A in response to Mrs A’s concerns about the way in which her consent for BSO was obtained. In the letter, Dr F apologised to Mrs A if her (Dr F’s) actions caused Mrs A added anxiety or stress. Dr F stated that she would not have suggested that the surgeon perform any particular operation, and she would have merely wanted clarification as to what surgery was to be carried out. She stated: “Any discussion about the procedure and the process of obtaining informed consent for any procedure is the responsibility of the surgeon involved.”
49. Dr F further stated in her letter:

“It is not unusual for the anaesthetist to discuss the surgery with the surgeon, to clarify the surgeon’s plan.”

Dr B

50. Dr B told HDC that he cannot recall the exact sequence of events prior to Mrs A’s surgery, the details of what transpired in the operating theatre, or the conversation that

²⁵ In response to the provisional opinion, Mrs A told HDC that she does not recall RN C giving her the option that she did not have to go through with the surgery, or that she could delay the surgery. She stated: “[S]he may have but I was laying on a gurney prepped for surgery and immensely distressed and feeling like I was being pressured and hurried.”

took place. He stated that when the consent for removal of ovaries was countersigned, he would have mentioned the risk of surgical menopause if the ovaries were removed, and the possible need for hormone replacement should Mrs A suffer menopausal symptoms. He stated: “[A]t the time I must have weighed the benefit of removing her ovaries to improve her seizures, and would have explained this to [Mrs A].”

51. Dr B explained to HDC the reasons he believes may have influenced his decision to suggest removal of Mrs A’s ovaries. He stated:

“[I]n women with catamenial epilepsy there may be improvement in seizure control after menopause ... Removal of the ovaries during hysterectomy is a recognised modality of treatment for catamenial epilepsy ...”

Dr E

52. Dr E told HDC that she recalls Dr F approaching Dr B prior to Mrs A’s surgery. Dr E stated that she was not a part of the conversation between Dr F and Dr B, but that she recalls hearing Dr F mention that Mrs A suffered from epilepsy that might be related to her periods.
53. Dr E confirmed that following a discussion with Dr F, Dr B approached the operating table and discussed with Mrs A the possibility of a BSO in order to reduce her seizures. Dr E told HDC that she does not recall Mrs A being tearful at this time.

Mr G

54. Anaesthetic technician Mr G stated that he was unable to recall Mrs A or any incident surrounding her operational consent procedure.

Postoperative assessment and follow-up

55. On 24 March 2013, Dr E assessed Mrs A during her ward round. Dr E certified six weeks off work for Mrs A, and discharged her with a plan for follow-up.
56. On 14 May 2013, Mrs A attended a follow-up appointment with Dr E as an outpatient, at which time Mrs A had returned to work. The histology of her uterus confirmed that the cause of her heavy painful periods was adenomyosis, and that her ovaries were normal. Dr E discussed hormone replacement therapy for menopausal symptoms, and recommended that Mrs A discuss the matter further with her GP.
57. Mrs A stated that she felt that she should have been seen by Dr B following her procedure, in order to address what occurred on the day of the surgery and the manner in which it took place.

The DHB’s response to the investigation

DHB policy

58. The relevant DHB policy was the “Informed Consent (Adults and Children)” policy (15 July 2010). That policy provides as follows:

“Responsibility for seeking consent

- The health professional who is performing the treatment has a duty of care to the patient to ensure the patient has given informed consent prior to treatment proceeding. This duty of care cannot be delegated.
- Anyone involved in the care or treatment of a patient, who believes the patient is not being adequately informed, should convey this to the person responsible. This should occur prior to the treatment or procedure being performed.

Timing of consent

- In many instances it would be appropriate for a health professional to initiate treatment immediately after discussing it with the patient. For example, taking a routine blood test or performing a particular physiotherapy technique as part of an ongoing episode of care.
- Where the proposed treatment carries significant risks, or where written consent is required, the health professional must consider whether the patient has had sufficient chance to take in the information necessary for the patient to make an informed choice and given informed consent. Consent should be obtained a reasonable time prior to the treatment in order to allow for the patient to consider the information and make an informed choice.
- For consent to be legally valid the patient must not feel under undue pressure or that they must proceed with the treatment or cannot change their mind. In most circumstances consent should be sought before the patient has been prepared for the treatment (i.e. consent should not in normal circumstances be obtained after the patient is on the theatre trolley). Normally consent should be obtained before a pre-med or any medication which may impair the patient's judgement is given. However, the affect of medication is a matter of clinical judgement as some medication may improve the person's capacity to consent (e.g. analgesics for a patient in severe pain)."

Informed consent

59. The DHB stated that Mrs A was placed in an unacceptable and distressing situation when asked to consent for the additional surgical procedure for removal of her ovaries while she was already on the operating table for a hysterectomy, and about to be anaesthetised.
60. The DHB stated that the circumstances contravened usual practice and were contrary to the DHB's "Informed Consent (Adults and Children)" policy (above). The DHB stated that it is not clear why there is no documentation of discussions with Mrs A regarding the option of oophorectomy prior to her being on the operating table.
61. The DHB advised HDC that it has taken steps to educate staff about the consent policy, and plans to audit consents for abdominal hysterectomy. The DHB advised that "a pre-operative discussion and surgical plan for ovarian conservation or oophorectomy is to be documented when consenting for hysterectomy".

Postoperative follow-up

62. With regard to Mrs A's postoperative follow-up, the DHB stated that "it is regrettable that [Mrs A] was given the wrong expectations that she would see [Dr B] at the scheduled post-operative clinic visit".

63. The DHB stated that unless there is a specific identified need, Dr B allocates a number of patients to be seen by his registrar. The DHB noted that Dr B would have been happy to meet Mrs A, but was not alerted to any concerns or outstanding issues.
64. The DHB stated: “[W]e are seeing if we can ensure the appointment letters could be modified to state that patients may signal at that appointment if there are any concerns that specifically warrant the consultant’s attention to please advise the team on the day.”

Dr B’s response to the investigation

65. In response to this investigation, Dr B told HDC:

“Consent to the removal of ovaries should have occurred at the consultation with me on 11 December 2012 and not in the operating room. I do not recall a situation like this arising previously in my practice. I will be very careful to avoid any similar event in the future.”

66. Dr B also told HDC:

“I have reviewed again the New Zealand Medical Council and [the DHB’s] guidelines on consent procedure, and have requested from the Medical Protection Society any material they have on the consent process and issues arising out of it. I will be reviewing this and taking all this information into account in my future practice.”

67. He further stated:

“I have definitely learned from this experience and will take all of these matters into account in my future practice. Should a similar situation arise in the future I would reconsider the proposed surgery and reschedule a clinic appointment to discuss any additional procedures. This would give the patient time to consider the additional information and the options available, and allow me time to consult with any related speciality.

I would again like to apologise to [Mrs A] for the effects removal of her ovaries have had on her quality of life, and regret the way things happened.”

Dr B’s response to the provisional opinion²⁶

68. Dr B stated that he did not “endeavor to make excuses for what occurred or dispute [Mrs A’s] account of the events on 21 March 2013”.
69. Dr B told HDC: “[Dr F] queried whether or not the surgery was intended to include BSO ... in the circumstances of that day [I] responded to [Dr F’s] query by raising the issue with [Mrs A].”²⁷ Dr B told HDC that he was “trying to do the right thing”, and

²⁶ Responses to the provisional opinion from other parties have been incorporated into the “facts gathered” section of the report.

²⁷ Prior to receiving the provisional opinion, Dr B told HDC that he had no recollection of a conversation with Dr F. However, in response to the provisional opinion, Dr B acknowledged that he did not “endeavor to make excuses for what occurred or dispute [Mrs A’s] account of the events on 21 March 2013”.

that at that time he had “no recollection of any preference expressed by [Mrs A] that she retain her ovaries”.

70. Dr B told HDC that he would have been present when RN C discussed with Mrs A options regarding postponing the surgery or discussing her options with her family. He said that these discussions “would have formed part of the context within which he decided to accept [Mrs A’s] consent to the BSO”.
 71. Dr B told HDC that following these events he has attended workshops in order to improve his interactions and communication with patients.
-

Opinion: Dr B

Preliminary matters

72. On 21 March 2013, Mrs A presented to the public hospital for her surgery. While Mrs A was on the operating table, Dr F had a conversation with Dr B, following which Dr B sought Mrs A’s consent to the removal of her ovaries.
73. There are differing recollections as to what was said between Dr B and Dr F immediately prior to Dr B seeking Mrs A’s consent to a BSO. I do not consider that there is sufficient evidence to make a finding as to what was discussed between Dr F and Dr B prior to Mrs A’s surgery on 21 March 2013. Furthermore, regardless of what was discussed between Dr F and Dr B, it is my view that the responsibility for obtaining informed consent rests with the responsible clinician, in this case Dr B.

Informed consent — Breach

74. For clarity, I note that I have no concerns with the clinical appropriateness of the BSO procedure performed for Mrs A, and no such concerns have been raised by my expert advisor, obstetrician and gynaecologist Dr John Short. My primary concern is with the manner in which Mrs A’s consent for the BSO was obtained, which is discussed below.
75. Mrs A had considered whether to have a hysterectomy for around a year before deciding to proceed. During that period, Mrs A had clearly signalled a wish to carefully consider her options before consenting to surgery. On 11 December 2012, during a consultation with Dr B, Mrs A signed a “Request for Treatment/Procedure(s)” form for a TAH. I consider that Mrs A’s consent to the TAH was obtained appropriately.
76. The consent form did not contain any reference to an oophorectomy.
77. Mrs A said that she and Dr B discussed her wish to retain her ovaries unless disease was discovered during the surgery. Dr B does not recall having this conversation with Mrs A, and there is no record of such a discussion in the clinical records. There is also no documented discussion with Mrs A regarding the potential risks or benefits of removal of her ovaries. While I am unable to make a finding as to whether Dr B had a

discussion with Mrs A on 11 December 2012 regarding retaining or removing Mrs A's ovaries, there is no dispute that on 11 December 2012 Mrs A did not consent to the removal of her ovaries.

78. On 21 March 2013, Mrs A presented to the public hospital for her surgery. She stated that after she had been brought into the operating theatre and was on the operating table, Dr F called Dr B over to her and said something about taking out Mrs A's ovaries. Dr B then returned to speak to Mrs A and presented to her the consent form that she had signed previously, and asked whether she would consent to have her ovaries removed.
79. Informed consent under the Code is a process with three essential elements: effective communication between the parties (Right 5); the provision of all necessary information to the consumer (Right 6); and the consumer's freely given and competent consent (Right 7).
80. Mrs A cannot recall the details of her conversation with Dr B. Dr B said that he would have mentioned to Mrs A the risks associated with removal of her ovaries, but this is not documented. RN C told HDC that she recalls Dr B telling Mrs A that removing her ovaries would cause early surgical menopause, and that it would improve her epilepsy. RN C also recalls Dr B telling Mrs A "some statistical facts". While all the parties recall that Dr B had a discussion with Mrs A about her epilepsy and the removal of her ovaries, none can recall Dr B's discussion with Mrs A in any detail. RN C recalled, however, that Dr B's discussion with Mrs A was brief. Mrs A and Dr B signed an amendment to the consent form which stated "+Bilateral Oophorectomy".
81. I find that Mrs A was provided with some information about the proposed BSO prior to the procedure commencing. However, given the lack of documentation and the limited recall of the parties, I am unable to make a finding as to whether Mrs A was provided with all the necessary information she required pursuant to Right 6 of the Code.
82. However, I do have concerns about the effectiveness of Dr B's communication with Mrs A. In my view, the operating theatre was not an appropriate environment for Dr B to provide information to Mrs A about the proposed BSO and to seek her consent to that procedure, in that it did not allow for effective communication between the parties.
83. Mrs A stated that she felt alone, distraught and immensely pressured to make a major life-changing decision. RN C told HDC that Mrs A was anxious and unsure what to do, and documented on the Intraoperative Record that Mrs A was tearful and "overwhelmed with informed consent". Furthermore, Mrs A's family was not available to support her while she made the decision.
84. As previously stated by this Office,²⁸ except in an emergency, it is not good practice to provide information within a short timeframe prior to the procedure for which consent is sought:

²⁸ Opinion 08HDC20258 (11 November 2009), with regard to information provided on the evening before the relevant procedure.

“... particularly in cases where the procedure is not urgent, as this does not allow adequate time for reflection. Furthermore, if the patient has already chosen a particular procedure, he or she may be less attentive to the information provided.”

85. The DHB policy provides that where written consent to a proposed treatment is required, the health professional must consider whether the patient has had sufficient chance to take in the information necessary to make an informed choice and give informed consent. It is stated in the policy: “Consent should be obtained a reasonable time prior to the treatment in order to allow for the patient to consider the information and make an informed choice.” Specifically, it is stated: “In most circumstances consent should be sought before the patient has been prepared for the treatment (i.e. consent should not in normal circumstances be obtained after the patient is on the theatre trolley).”
86. The DHB stated that Mrs A was placed in an unacceptable and distressing situation when asked to consent for the additional surgical procedure for removal of her ovaries while she was already on the operating table for a hysterectomy, and I agree.
87. Regardless of what Dr F said to Dr B, it was Dr B’s responsibility to ensure that the surgical plan was clear, and that appropriate informed consent was obtained. Dr Short advised that Dr B “clearly made a gross error of judgement and is guilty of a severe departure from expected standards of care in the manner of the timing and manner of obtaining surgical consent, regardless of the potential benefits of removing the ovaries”.
88. I acknowledge that Dr B has accepted that consent to the removal of Mrs A’s ovaries should have occurred on 11 December 2012 rather than in the operating room on 21 March 2013.
89. In my view, the manner in which Mrs A’s consent was obtained for the BSO was not appropriate. Pursuant to Right 5(2) of the Code, Mrs A had the right to an environment that enabled her and Dr B to communicate openly, honestly, and effectively. In my view, the operating theatre was not an appropriate environment for the informed consent process for the BSO to take place, and did not allow for effective communication between Mrs A and Dr B. Accordingly, Dr B breached Right 5(2) of the Code.
90. Furthermore, Mrs A was not given sufficient time to consider whether she wished to have a BSO, and was not in a position to give informed consent to the removal of her ovaries. Accordingly, in my view, Dr B also breached Right 7(1) of the Code.

Communication regarding diagnosis of catamenial epilepsy — Adverse comment

91. On 11 December 2012, Mrs A attended a consultation with Dr B at the public hospital gynaecology clinic. Dr B told HDC that he diagnosed Mrs A with catamenial epilepsy, and a note referring to the diagnosis is recorded in Mrs A’s clinical notes. Dr B told HDC that he believes he would have explained to Mrs A what catamenial epilepsy means.

92. Mrs A told HDC that she recalls that she and Dr B discussed her epilepsy and the apparent increase in seizures pre-menstrually; however, she stated that she was not told at any stage that she had been diagnosed with catamenial epilepsy.
93. I accept that, given Mrs A's recollection, Dr B discussed with Mrs A that there was a relationship between her epileptic seizures and her menstrual cycle. However, I am concerned that Dr B does not appear to have clearly communicated to Mrs A that he had diagnosed catamenial epilepsy. It is my view that Dr B's communication in this respect was suboptimal. However, given that a conversation about the relationship between Mrs A's epileptic seizures and her menstrual cycle clearly occurred, I do not find that Dr B breached the Code in relation to his communication regarding the diagnosis of catamenial epilepsy.

Clinical care — No breach

94. In the period leading up to her surgery on 21 May 2013, Mrs A was reviewed on a number of occasions at the gynaecology clinic. She was seen by two registrars and Dr B. My expert advisor, obstetrician and gynaecologist Dr John Short, advised that the clinical care provided by Dr B and the registrars prior to 21 March 2013 was appropriate and well within the accepted standards of care. Dr Short further advised that he would not have expected Dr B to consult Mrs A's neurologist in relation to her care.
95. On 21 March 2013, Mrs A underwent a TAH and BSO. Dr Short advised that the surgery appeared to be challenging and, although the clinical records are very brief, the surgery appears to have been performed appropriately.
96. Guided by Dr Short's advice, I find that the clinical care Dr B provided to Mrs A was within accepted standards, and he did not breach the Code in this respect.

Opinion: The district health board

Informed consent — No breach

97. In addition to any direct liability for a breach of the Code, employers are vicariously liable under Section 72(2) of the Health and Disability Commissioner Act 1994 (the Act) for any breach of the Code by an employee. Under Section 72(5) of the Act it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the act or omission of employees that breached the Code.
98. At the time of these events, the DHB had a comprehensive policy in place, "Informed Consent (Adults and Children)", which sets out in detail the obligations of providers involved in obtaining informed consent. The policy states that the health professional performing the treatment, in this case Dr B, has a duty of care to the patient to ensure that the patient has given informed consent prior to treatment proceeding. The policy also states that a patient should be given sufficient time to consider the information provided, and to make an informed choice and give informed consent. Dr B did not comply with the policy.

99. In my view, the DHB's expectations in respect of informed consent were clear, and it took all reasonable steps to prevent Dr B's breaches of the Code. In my view, Dr B's failure to communicate effectively with Mrs A or to obtain her informed consent to the BSO was an individual clinical failing by Dr B, and I do not consider that the DHB breached the Code.
100. The DHB has acknowledged that Dr B's actions were inappropriate. The DHB has also taken steps to educate staff about the consent policy, and plans to audit consents for abdominal hysterectomy. The DHB confirmed that a definitive plan regarding ovarian conservation or oophorectomy is to be documented at the time a patient consents to a hysterectomy. Dr Short advised that these steps are reasonable in the circumstances, and I agree.

Advocating for the patient — Adverse comment

101. RN C stated that Mrs A was anxious and tearful when Dr B asked for Mrs A's consent to the removal of her ovaries while she was on the operating table. RN C documented that Mrs A was overwhelmed with the informed consent process.
102. The DHB's "Informed Consent (Adults and Children)" policy states: "Anyone involved in the care or treatment of a patient, who believes the patient is not being adequately informed, should convey this to the person responsible. This should occur prior to the treatment or procedure being performed."
103. I note that RN C advised HDC that she recalls telling Mrs A that she did not have to go through with the surgery if Mrs A was unsure of what decision to make in respect of the removal of her ovaries, and that RN C suggested that the surgery be delayed.
104. I am concerned that, given Mrs A's obvious distress, no one in the operating theatre conveyed to Dr B any concerns about the appropriateness of him seeking to obtain Mrs A's consent to the removal of her ovaries in these circumstances. This was contrary to the DHB's policy. I have previously commented on the need for clinicians to advocate on behalf of patients,²⁹ and for institutional providers to normalise a culture where such actions are accepted and expected. I am concerned that none of the clinicians in the operating theatre advocated effectively for Mrs A in this case.

Recommendations

105. In response to a recommendation in the provisional opinion, Dr B provided a letter of apology to Mrs A for his breaches of the Code, which has been forwarded to Mrs A.
106. I also recommend that Dr B undertake further training on informed consent processes, arranged by the Medical Council of New Zealand. Dr B is to provide evidence of attendance at such a course within three months of the date of this opinion.
107. I recommend that within six months of the date of this opinion, the DHB:

²⁹ Opinion 09HDC01592 (31 January 2012) and 13HDC00515 (30 June 2014), available at www.hdc.org.nz.

- a) Review staff training with regard to the DHB's informed consent policy and provide HDC with evidence of this review.
 - b) Supply HDC with the outcome of its audit of consents for abdominal hysterectomy.
 - c) Audit compliance with the requirement that a definitive plan regarding ovarian conservation or oophorectomy is documented at the time a patient consents to a hysterectomy, and provide HDC with evidence of this audit.
-

Follow-up actions

108. • A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand and the Royal Australasian College of Obstetricians and Gynaecologists, and each will be advised of Dr B's name.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent obstetric and gynaecological advice

The following independent expert advice was provided to the Commissioner by Dr John Short:

“I have been asked to provide an opinion to the Commissioner on case number 14/00307. I have read and agree to follow the Commissioner’s Guidelines for Independent Advisors.

I am a specialist Obstetrician and Gynaecologist, vocationally registered in New Zealand since 2007. I have worked as a senior medical officer in Obstetrics and Gynaecology at Christchurch Women’s Hospital since 2006.

I have been asked to provide advice to the Commissioner regarding the care provided to [Mrs A] by [the] DHB and [Dr B], Obstetrician and Gynaecologist at the public hospital. More specifically I have been asked to comment on the following:

- The appropriateness of the clinical care provided by [Dr B] to [Mrs A] prior to her TAH and BSO on 21 March 2013
- The appropriateness of the clinical care provided by [Dr B] to [Mrs A] on 21 March 2013
- The appropriateness of the relevant DHB policies provided
- Whether [Dr B] should have consulted a neurologist or other appropriate clinician regarding [Mrs A’s] care/treatment plan, and if so:
 - a. who/what type of clinician should have been consulted; and
 - b. at what stage(s) should [Dr B] have consulted another clinician

This report is based upon information provided by the HDC, including copies of clinical records, DHB policies/procedures and responses from the DHB, [Dr B] and others.

Background/Key points

[Mrs A] had a long history of seizures, which are variously described in the records. Over the years it appears that multiple medications had been prescribed but good seizure control was elusive. I particularly note a statement ([in 2009]) ‘she has an unusual seizure syndrome’. In April 2010, it is documented for the first time that irregular periods were affecting seizure frequency. In June 2011, it is recorded for the first time that she had visual disturbances pre-menstrually. In the same letter (from the epilepsy nurse) this is rated as her third problem, following tiredness and headaches. It is also noted that the symptom diary did not support the report of premenstrual headaches. The same letter also, for the first time, challenges the diagnosis of epilepsy and raises the possibility of migraine.

In July 2011 there is further elaboration, again from the epilepsy nurse, regarding the pre-menstrual symptoms. In particular it is stated that visual disturbances are worse pre-menstrually but occur at other times. Further comment is also made regarding heavy and painful periods.

By January 2012 there appears to have been some success in reducing [Mrs A's] headaches and the intensity of the visual disturbances. In April 2012 it is reported that visual disturbances were also less frequent. It is recorded on 4/5/12 that [Mrs A] was happy 'not to do anything at the moment (regards further management)'.

On review in October 2012, it appears that the more severe visual disturbances had ceased but that there were on-going gynaecological issues coincident with associated visual disturbances. It is noted that she is awaiting gynaecological review at the time (see later). A further letter, from May 2013, describes the symptom pattern following the hysterectomy which appears somewhat variable.

The gynaecological notes begin in August 2010 with the report of the left salpingectomy and endometrial ablation (for heavy and painful periods). This appears to have been uncomplicated. At follow up in November 2010 it appears that the surgery was successful and that [Mrs A] had recovered well and was discharged from on-going review.

In May 2011, [Mrs A] was re-referred by her GP to the gynaecologist at the public hospital with a recurrence of heavy and painful periods. She was subsequently seen by [Dr I], gynaecology registrar, who made a presumptive diagnosis of adenomyosis (based on an ultrasound report). 'Surgery' was proposed although the exact procedure is not stated. One presumes a hysterectomy was intended. [Mrs A] was not ready to make this decision at that time [and] went away to consider the option. At subsequent review in May 2012 the same conclusion was reached and further review was arranged. Upon review by [Dr B], in December 2012, a decision was made to proceed with the hysterectomy.

Throughout the gynaecological correspondence the only mention of epilepsy or other symptoms described above is in [Dr I's] letter of 11 November 2011. However, there is no reference to premenstrual symptoms. Catamenial epilepsy is mentioned in a handwritten note dated 11/12/12.

This surgery was performed on 21/03/2013. The planned procedure was a total abdominal hysterectomy (removal of uterus, including cervix, through an abdominal incision). The actual procedure performed was a total abdominal hysterectomy and bilateral salpingo-oophorectomy (as above plus removal of ovaries and fallopian tubes).

It appears that on the day of surgery a discussion took place between [Dr B] and his anaesthetist, [Dr F]. Accounts vary, but it was possibly suggested by [Dr F] that due to [Mrs A's] premenstrual symptoms, labelled as 'catamenial epilepsy', [Dr B] should consider removing both ovaries at the time of hysterectomy. [Dr B] appears to have agreed and held a brief discussion with [Mrs A] on this subject, whilst she was lying on the operating table waiting to be anaesthetised for her surgery. She signed an amended consent form.

The surgery itself appears to have been reasonably complicated with excessive bleeding and some difficulties encountered with fibrous/scar tissue. Postoperatively there also appear to be some issues, particularly with haematuria (bloodstained urine). However, there was no injury identified and [Mrs A] went on to make a good recovery. Upon review in May 2013, she appears to have recovered well and had no ongoing gynaecological issues other than the need for ongoing hormone replacement therapy.

Opinion/Comment

With regard to the commissioner's specific questions:

— *The appropriateness of the clinical care provided by [Dr B] to [Mrs A] prior to her TAH and BSO on 21 March 2013*

It is my opinion that the care provided by [Dr B] and his registrars prior to 21 March 2013 was appropriate and well within expected standards of care.

— *The appropriateness of the clinical care provided by [Dr B] to [Mrs A] on 21 March 2013*

The surgery performed by [Dr B] appears to have been challenging and whilst the notes are very brief it appears to have been performed appropriately and I have no reason to be concerned in this regard.

The decision to change the procedure and the manner in which 'consent' was obtained was entirely inappropriate. This is clarified later in my report.

— *The appropriateness of the relevant DHB policies provided*

These appear to be comprehensive, clear and entirely appropriate. However that does not mean they were widely circulated or that staff were aware of them.

— *Whether [Dr B] should have consulted a neurologist or other appropriate clinician regarding [Mrs A's] care/treatment plan, and if so:*

a) who/what type of clinician should have been consulted

b) at what stage(s) should [Dr B] have consulted another clinician

I don't think it was entirely necessary for [Dr B] to consult another clinician regarding [Mrs A's] care or treatment. Consulting another clinician on the day of surgery would be unrealistic and would not alter the fact that changing the procedure at this time was inappropriate. Had [Dr B] consulted a neurologist prior to the surgery, ie sometime between 11/11/2011 and 20/03/2013, I would not be critical. However, I also do not think it was strictly necessary. For this consultation to be worthwhile or even considered, the gynaecology team would need to recognise the potential for [Mrs A's] epilepsy/migraines to have a gynaecological influence and for the alternative treatment (oophorectomy) to be potentially beneficial. They obviously did not recognise this, therefore the issue is largely irrelevant. I must also emphasise that I would not be critical of [Dr B] or his team for failing to identify this potential connection as I consider it somewhat dubious and [Mrs A] herself has minimised its significance in subsequent correspondence. Had [Dr B] considered it relevant and or important prior to the

surgery then it would have been reasonable, but in my view not essential, to consult a neurologist.

The key issue in this case is clearly whether the manner in which consent for bilateral oophorectomy was appropriate. [The] DHB has provided a comprehensive policy on consent which covers all the important points. This policy was clearly not followed by [Dr B]. In particular, [Mrs A] was not provided sufficient information to make an informed decision and she was not provided with sufficient time to duly consider the suggestion. One could also argue that, given the circumstances at the time, her capacity to provide consent was impaired. She was clearly anxious about her surgery and under considerable emotional stress as a result. I also have no doubt that she would have felt coerced into making a hasty and ill-informed decision. This is not to say that consideration of oophorectomy in this situation is in itself inappropriate. This decision is ultimately the woman's to make and it is the doctor's duty to provide her with time and information to allow her to measure the relative benefits and risks and to make a decision she is comfortable with.

[Redacted as not relevant to the care provided to [Mrs A] by [Dr B].]

Regardless of what was said to [Dr B] by [Dr F], it remains his responsibility to ensure the surgical plan is clear and that appropriately informed consent is obtained. Therefore, even if [Dr F] did suggest the oophorectomy, the responsibility for this decision still lies with [Dr B]. He clearly made a gross error of judgement and is guilty of a severe departure from expected standards of care in the matter of the timing and manner of obtaining surgical consent, regardless of the potential benefits of removing the ovaries. He is also guilty of contravening the policies of his employer. In mitigation, the standard of care provided was otherwise acceptable and he has expressed significant regret and already offered sincere apologies to [Mrs A].

It is also noteworthy that the DHB has taken this matter seriously. They acknowledge the inappropriateness of the actions described above and offer apologies. They have also taken steps to educate staff on their consent policy and indicated plans for an audit of consent for abdominal hysterectomy. They have also stated that the gynaecology department has unanimously agreed that a definitive plan regarding ovarian conservation or oophorectomy is to be documented when consenting for hysterectomy. Despite my earlier comments, this is a reasonable step given the obvious confusion on the matter.

Summary

[Mrs A] was in the care of [Dr B] and had agreed to undergo surgery. Regardless of his reasons, [Dr B] made an inappropriate change to his surgical plan and did not allow sufficient time or information for [Mrs A] to provide informed consent for this. This amounts to a severe departure from expected standards of care. The DHB has an appropriate policy on consent. However it is not clear if staff were aware of or had received any education on this policy. It is my opinion that the positive actions of [Dr B], in acknowledging his error and apologising, and the DHB, through the subsequent steps they have taken in response to [Mrs A's] complaint, should be taken into consideration.”