Obstetrician and Gynaecologist, Dr A
Gynaecology Clinic

A Report by the
Deputy Health and Disability Commissioner

(Case 20HDC01996)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report discusses the care provided to a woman by an obstetrician and gynaecologist and a private gynaecology clinic. In 2020, the woman underwent surgery for the management of heavy menstrual bleeding causing anaemia. The surgery included a total bilateral hysterectomy and a bilateral salpingo oophorectomy. During the procedure, the woman suffered an injury to the bladder wall.

2. The report considers the adequacy of the information provided to the woman to allow her to provide her informed consent to the surgery, in particular information about the surgical risk of injury to the bladder wall and that the removal of her ovaries would render her menopausal.

Findings

3. The Deputy Commissioner found the obstetrician and gynaecologist in breach of Right 6(1) for failing to inform the woman of the risk of injury to the bladder, prior to her undergoing the procedure. As the obstetrician and gynaecologist did not provide adequate information to the woman to allow her to make an informed choice about the proposed treatment, the Deputy Commissioner also found that the obstetrician and gynaecologist breached Right 7(1) of the Code.

4. The private gynaecology clinic was not found to have breached the Code.

Recommendations

5. The obstetrician and gynaecologist provided a written apology to the woman in response to the provisional decision. The Deputy Commissioner also recommended that the obstetrician and gynaecologist review the Medical Council statement on 'Informed Consent: Helping patients make informed decisions about their care' (2021) and provide a reflection to HDC; complete the online learning modules at hdc.org.nz regarding informed consent; and complete an audit of his clinical documentation looking at recording of consent discussions.

Introduction

6. This report is the opinion of Rose Wall, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

7. The report discusses the care provided to Mrs B by Dr A at the clinic.

8. The following issues were identified for investigation:

- *Whether Dr A provided Mrs B with an appropriate standard of care from 2019 to 2020 (inclusive).*

- *Whether the clinic provided Mrs B with an appropriate standard of care from 2019 to 2020 (inclusive).*

Dr A

9. Dr A is a specialist obstetrician and gynaecologist who is a visiting consultant at a private clinic (the clinic). He is vocationally registered with the Medical Council of New Zealand in the scope of obstetrics and gynaecology and is a member of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG). Dr A works as an individual private gynaecologist at the clinic on a cost-sharing basis.[1]

10. The parties directly involved in the investigation were:

Dr A	Provider/obstetrician and gynaecologist
Mrs B	Consumer
Gynaecology clinic	Provider/clinic

11. Further information was received from Mrs B's general practice, the private hospital where the surgery took place, Te Whatu Ora|Health New Zealand, and the Accident Compensation Corporation (ACC).

12. Independent advice was obtained from Dr Richard Dover, a consultant gynaecologist (Appendix A).

Information gathered during investigation

13. At the time of the events, Mrs B was in her fifties, and had a history of anaemia[2] secondary to heavy menstrual bleeding for a few years. In 2019, Mrs B's general practitioner (GP) referred her to Dr A to manage her symptoms.

14. Dr A examined Mrs B at the clinic on 22 May 2019 and found multiple fibroids[3] in her uterus, and adenomyosis.[4] A conservative approach was discussed, which entailed blood tests, the insertion of a Mirena,[5] and the option of hormonal medication. Dr A's clinical notes record that endometrial ablation (surgery to destroy the uterine lining) was also considered, and it was noted that this could result in ongoing pelvic discomfort.

[1] He is not an employee of the clinic, but he uses the practice for 'nursing, administrative and IT support' once a week and pays a percentage of his income to the clinic for this purpose.
[2] Anaemia occurs when there are insufficient healthy red blood cells to carry oxygen to the body's organs. Symptoms include feeling cold, tired, and weak.
[3] Non-cancerous tumours.
[4] Adenomyosis occurs when the tissue that normally lines the uterus grows into the muscular wall of the uterus. This displaced tissue continues to act normally by thickening, breaking down, and bleeding during each menstrual cycle.
[5] A hormone-releasing intrauterine device that helps with heavy menstrual bleeding.

15. On 4 July 2019, Dr A wrote to Mrs B regarding her recent period, which her GP had reported had been extremely uncomfortable. Her blood tests indicated normal iron levels and hormonal markers. Dr A recommended a Mirena be inserted to manage her periods, and again advised that endometrial ablation was unlikely to help because it could cause persistent pelvic discomfort. It is unclear whether the Mirena was inserted.

16. On 14 August 2019, Mrs B presented to Dr A at the clinic. Dr A prescribed Provera[6] tablets to help control the heavy bleeding.

17. Dr A next consulted with Mrs B on 12 February 2020. She had been experiencing excessive menstrual bleeding since December 2019 and had had a recent iron infusion. Dr A recommended that Mrs B take high doses of Provera to stop the bleeding and advised that she would require a total hysterectomy and salpingo oophorectomy (removal of the ovaries and fallopian tubes) for long-term benefit.

18. Dr A told HDC that prior to any surgery, usually he discusses the procedure in detail, often draws diagrams to explain the surgery, and provides the consumer with a brochure. This discussion would include complications of hysterectomies such as intraoperative bleeding, infection, blood transfusion, deep vein thrombosis,[7] and possible injury to the bowel and urinary system. Dr A stated that this would have taken place with Mrs B during the consultation on 12 February 2020. The clinical record from 12 February 2020 does not record any such discussion, but Dr A provided HDC with a hand-drawn diagram of Mrs B's procedure.

19. On 26 February 2020 Mrs B signed the private hospital's consent form for her procedure. The form states that she had been informed of the risks of the procedure and that she might require further treatment if any complications arose. The form does not document the specific risks and complications of the procedure that were discussed.

20. On 6 March 2020, Mrs B underwent a total bilateral hysterectomy[8] and a bilateral salpingo oophorectomy at the private hospital. The procedure was performed by Dr A.

21. Dr A reported that the procedure was successful, and care was taken to ensure that the bladder and ureters[9] were out of the operating field. There was some excessive bleeding from the vaginal vault,[10] which was managed and oversewn.[11] Mrs B's urine was clear, and her blood tests 24 hours post-surgery indicated normal renal function.

22. Post-surgery on 6 March, the post-anaesthesia care unit nurses observed Mrs B to be in 'obvious pain' at the incision site and noted this in Mrs B's clinical record. The pain was

[6] Medication to manage abnormal uterine bleeding.
[7] A blood clot that develops in a deep vein in the body.
[8] The surgical removal of the uterus.
[9] Tubular structures that connect the kidney to the urinary bladder.
[10] The expanded region of the vaginal canal at the internal end of the vagina.
[11] Where the two edges are sewn together with close vertical stitches that pass over and draw the two edges together.

treated by IV analgesia,[12] but Mrs B continued to report that her pain was 'unmanageable', which is also noted in her clinical record. It is unclear whether Dr A was advised of Mrs B's pain, and there is no documentation of the actions taken to manage her pain further.

23. Mrs B was discharged from the private hospital on 9 March 2020. Dr A told HDC that Mrs B would have been given a brochure with symptoms to look out for and his contact details. A copy of the brochure has not been provided to HDC and there is no evidence other than Dr A's recollection that the brochure was provided to Mrs B. On discharge, Mrs B scheduled two follow-up appointments at the clinic, one with Dr A's nurses on 13 March, and the other with Dr A on 22 April.

24. Mrs B said that in the two days following her discharge, she developed extreme pain and bloating in her abdomen. Initially, Mrs B told HDC that she made multiple phone calls to Dr A at the clinic in the weekend following her surgery (10 and 11 March), but later clarified that these calls were likely made in the week after her surgery (12 to 16 March). Mrs B told HDC that she was unable to speak with Dr A, and instead she spoke with the clinic receptionist and nurses, who advised that it was 'just pain from the operation' and it would settle.

25. The clinic's timeline of contact with Mrs B records the first contact on 13 March when Dr A's nurse checked the wound and provided further pain relief as scheduled. The first phone call from Mrs B was noted on 16 March, when the nurse recommended that Mrs B present to her GP as there were no specialists at the clinic. A second phone call occurred on 18 March. These calls are reflected in the clinic's clinical records.

26. Mrs B said that by 18 March her stomach was grossly swollen and causing extreme pain. She stated that she contacted the clinic and was advised by the nurse to present to her GP. Mrs B saw the GP later that day and the GP contacted the clinic to advise Dr A's nurse of her concerns of a possible vault haematoma.[13] Dr A was unavailable to speak with the GP as he was in surgery at the time. He said that later his nurse told him about this discussion, and this was the first time he was advised of Mrs B's condition post-surgery.

27. Given the GP's concerns, Dr A asked his nurse to arrange a pelvic ultrasound scan for Mrs B, which was undertaken on 18 March.

28. The radiologist reported: '[N]o discrete vault hematoma or drainable pelvic collection, but generalized intra-abdominal free fluid is present.' The radiologist advised Dr A that a 'nick to the bladder' had been identified. It was recommended that Mrs B present to a public hospital (Hospital 1) for treatment.

29. Dr A told HDC that he did not identify an injury to the bladder during the surgery, and the clinical notes state that the bladder and uterus were 'out of the operating field'. He hypothesised that potentially the injury was caused by a suture going through the bladder

[12] Tramadol and morphine and ketamine.
[13] Localised bleeding outside of blood vessels.

when he tried to control the vaginal vault bleeding. He said that it would not be until the suture dissolved that the complication would become evident.

30. Mrs B presented to Hospital 1 at 6.30pm on 18 March 2020 and was admitted to the Gynaecology ward at 8.08pm. A CT scan on 19 March confirmed a small bladder wall defect.

31. On consultation with the Urology team, the clinicians decided to fit Mrs B with an indwelling catheter[14] to allow her bladder to rest and heal from the bladder wall defect. The catheter was inserted on 19 March at 11.20am and was to remain in place for two weeks.

32. Dr A visited Mrs B at Hospital 1 on 19 March. He recalls discussing the complication and stating that the leak was small, and he was hopeful that it would settle with catheterisation. Dr A also told HDC that he apologised to Mrs B. However, Mrs B told HDC that he did not offer an apology.

33. On 20 March, Mrs B developed signs of sepsis,[15] with tachycardia[16] and spiking temperatures around 38°C. Her abdomen became distended, and her abdominal pain worsened. She was treated with antibiotics[17] and pain relief medication. The Gynaecology clinicians consulted with the Urology team at another public hospital (Hospital 2), and Mrs B was accepted for transfer. The transfer occurred that day.

34. Mrs B continued on IV antibiotics at Hospital 2 for two days. The initial plan was to drain abdominal fluid, but imaging indicated that no significant fluid was present. Mrs B showed no fever for over 24 hours.

35. On 22 March, Mrs B was discharged from Hospital 2. Her discharge plan included an indwelling catheter remaining in place, a prescription for antibiotics and pain relief, and a scheduled cystogram (an X-ray of the bladder) at Hospital 1 10–12 days later. This is consistent with the intended discharge plan from Hospital 1 before Mrs B developed symptoms of sepsis and was transferred to Hospital 2.

36. On 23 March, Mrs B presented to the Emergency Department at Hospital 1 due to discomfort from her catheter. Potential infective causes were investigated and ruled out with a urine dipstick and blood tests, and the catheter position was adjusted. Mrs B was discharged on 24 March to the care of her GP.

37. By 29 March Mrs B had developed severe pain due to fluid in the pelvis, and she presented to Hospital 2 and was admitted under the Urology team for six days. During this time, a PICC line[18] was inserted and she was prescribed a three-week course of intravenous antibiotics,[19]

[14] A tube inserted into the bladder for the collection of urine.
[15] An extreme reaction to an infection.
[16] A rapid heart rate.
[17] Cefuroxime and metronidazole.
[18] A peripherally inserted central catheter, which is used to access the large veins in the chest. This facilitated Mrs B's long course of IV antibiotics.
[19] Cefuroxime and amoxicillin.

to be followed by three weeks of oral antibiotics. Mrs B was discharged from Hospital 2 on 3 April with a referral for district nurse care and daily blood tests.

38. On 9 April, Mrs B became incontinent. She said that she spent the following day speaking to Hospital 2 and it was recommended that she present to Hospital 1.

39. Mrs B presented to the Emergency Department at Hospital 1 on 11 April 2020 at 8.09am with a two-day history of urinary incontinence and passing urine beyond the catheter. Mrs B's care was discussed with the Gynaecology consultant and Urology registrar at Hospital 2 due to concern about a possible fistula.[20] As there was no current evidence of acute infection, Mrs B was discharged at 12.14pm on 11 April with a referral to outpatient Urology services.

40. Dr A told HDC that he received a call from an Emergency Department specialist on 11 April at the time of Mrs B's presentation to Hospital 1 and was advised of her condition and that the potential cause was a blocked catheter. He recalls discussing whether Mrs B's care could be managed on the Urology ward, but as it was the Easter holidays, the specialist stated that she would be managed as an outpatient.

41. On 14 April 2020 Mrs B presented to Hospital 2 on the advice of her GP for a suspected vesicovaginal fistula[21] and was admitted to the Urology ward. Mrs B stated that during this admission, a 'camera and dye test' found that her bladder was not fixed, and a further procedure was required. Investigations also confirmed the fistula. However, prior to this she had to complete her course of antibiotics to clear her infection. Her catheter was changed, and IV antibiotics were continued until her discharge on 16 April.

42. Mrs B told HDC that on 22 April 2020 she had a scheduled telephone consultation follow-up appointment with Dr A. She stated that Dr A asked for copies of her discharge information from Hospital 2, and on 24 April advised her that he would meet with the Urology services to discuss her condition. However, Mrs B said that she did not hear from Dr A following this discussion. Dr A's clinical notes do not contain a record of this telephone consultation, and he did not comment on this appointment in his response to HDC.

43. On 7 May and 21 May 2020, Mrs B had her catheter changed by a Urology specialist. She told HDC that the pain of this was 'outstanding'. On 28 May she underwent a CT scan, which confirmed that she was able to undergo the procedure to repair her fistula.

44. The procedure was completed by the Urology specialist on 11 June 2020 at the private hospital. Mrs B said that the procedure was successful, and she was 'at last' able to 'get rid of the catheter'.

[20] An abnormal connection between two body parts.
[21] Mrs B had developed an abnormal opening between the bladder wall and the vagina.

Responses to provisional opinion

45. Mrs B was given the opportunity to comment on the 'information gathered' section of the provisional report and had no further comments to make.

46. Dr A and the clinic were given the opportunity to comment on relevant sections of the provisional opinion. The clinic had no further comment to make.

47. Dr A stated:

> 'I would like to take this opportunity to again apologise to [Mrs B] for the upset and distress she has experienced. I very much wish she had not suffered from a complication and her post-operative course had been different for her. I do hope that she has fully recovered … [Mrs B's] complaint and this investigation process has been a salutary lesson for me and it has highlighted the importance of the informed consent process I undertake to ensure my patients are provided with all the relevant information to enable them to make an informed decision on their care.'

48. Dr A told HDC that he has taken on board the comments of the Deputy Commissioner and of HDC's advisor, and he accepts that his documentation could have been better. He said that he now ensures that he records the discussions he has with patients relating to consent, including all issues discussed, specific risks/complications for the surgery to be performed, and general complications of the surgery, and he records that the patient has been provided with the relevant brochure for the surgery. In addition, Dr A said that he is considering using consent forms tailored for the procedure/surgery to be performed, which will include the specific risks for the procedure/surgery to be undertaken along with more general risks associated with surgery.

49. Dr A agreed to undertake the recommendations and provided HDC with an apology, which has been forwarded to Mrs B.

Relevant standards

50. The Medical Council of New Zealand's guideline 'Informed Consent: Helping patients make informed decisions about their care' (2019) states:

> 'To help the patient decide whether they want a treatment, they first need to be given information, such as the risks and benefits of their treatment options.'[22]

51. The guideline also states that clinicians must keep 'clear and accurate patient records' that note the information that was discussed and the specific risks that were highlighted. Whilst not every aspect of a consultation can be noted in a patient's record, enough information

[22] Medical Council of New Zealand, 'Informed Consent: Helping patients make informed decisions about their care' (2019) p 1.

must be recorded to provide an accurate summary of the clinician's discussion with the patient.

52. The RANZCOG statement on 'Consent and the provision of information to patients in New Zealand regarding proposed treatment' (2019)[23] refers to the HDC Code of Health and Disability Services Consumers' Rights (the Code), stating:

> '[E]very patient must be provided with information that a reasonable patient, in that patient's circumstances, would expect to receive, including … an explanation of the options available, including expected side-effects, risks, benefits …'[24]

53. The statement also notes that doctors should keep clear, contemporaneous notes of the advice and information provided to the patient, 'including the specific risks that have been discussed'.[25]

Opinion: Dr A — breach

Introduction

54. The issues Mrs B raises in her complaint are twofold. Mrs B's first concern relates to the adequacy of the information provided to her preoperatively, and whether she was given sufficient information about the surgical risk of injury to the bladder wall to enable her to provide informed consent to the surgery. Her complaint highlights the importance of the informed consent process, and, in particular, consumers being given all the relevant information to enable them to make an informed decision on their care.

55. Mrs B's second concern relates to the complications she developed postoperatively and the surrounding communication, diagnosis, and management. From Mrs B's perspective it brought into question the adequacy of the hysterectomy surgery performed by Dr A and whether she would have experienced her complications had Dr A provided appropriate post-surgical care.

Informed consent — breach

56. Right 6(1) of the Code states that 'every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including … an assessment of the expected risks [and] side effects'. As to whether a reasonable consumer would expect to be told of a rare risk requires the probability of that risk to be weighed against the magnitude of the potential harm. Accordingly, if the potential harm is

[23] https://ranzcog.edu.au/wp-content/uploads/2022/05/Consent-and-Provision-of-Information-to-Patients-in-New-Zealand-Regarding-Proposed-Treatment.pdf.
[24] RANZCOG statement at p 4.
[25] Above at p 6.

serious, a reasonable consumer may expect to be told of it, even though the likelihood of it occurring is less than one percent.[26] Of course, each case must turn on its own facts.

57. Right 7(1) of the Code states that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. Right 7(1) interacts closely with Right 6(1), as to make an informed choice and give informed consent, a consumer must have received the information that a reasonable consumer in their circumstances would expect to receive.

58. Consultant gynaecologist Dr Richard Dover provided independent advice on the care Dr A provided to Mrs B. Whilst he acknowledged Dr A's statement that formal consent for the hysterectomy was obtained (in that Mrs B signed the written consent form), Dr Dover highlighted that there are no written notes relating to the consent discussion, either about the issues that were discussed, or confirming that Mrs B was given a copy of the brochure on discharge.

59. Dr Dover advised that specific complications for a hysterectomy that should be discussed with a consumer as part of an informed consent discussion would include the possibility of bladder, ureteric, and bowel injury, as well as (in Mrs B's case) discussing that the removal of Mrs B's ovaries would render her menopausal. Dr Dover advised that Dr A should have covered these specific complications with Mrs B in addition to general complications of surgery. I agree that Mrs B should have been made aware of this information.

60. I acknowledge Dr A's statement that it is his usual process to discuss complications (as noted above by Dr Dover) with patients and offer them the RANZCOG pamphlet on the risks of a hysterectomy. However, I also note that Mrs B does not recall having had the risks explained to her by Dr A; Dr A did not document any discussion with Mrs B about the risks associated with the procedure; and there is no evidence to suggest that Dr A provided Mrs B with the abovementioned RANZCOG pamphlet. In addition, while I accept that Mrs B signed the written consent form, this form also did not detail the risks specific to Mrs B that were associated with the planned procedures.

61. As advised by Dr Dover, as part of the informed consent process undertaken prior to Mrs B's hysterectomy and bilateral salpingo oophorectomy, Mrs B should have been informed about the risk of injury to the bladder. This is also outlined in the relevant guidance on informed consent from the Medical Council and RANZCOG, which both state that for a patient to make an informed decision on their treatment, they need to be given information in advance about the potential risks and benefits. On the evidence before me, and on the balance of probabilities, I consider that this did not occur. Accordingly, I find that Dr A breached Right 6(1) of the Code.

62. I also consider that because Dr A did not provide adequate information to Mrs B, she could not make an informed choice about the proposed surgery. Accordingly, I find that Dr A breached Right 7(1) of the Code.

[26] Paterson R and Skegg P (eds), *Health Law in New Zealand*, Thomson Reuters NZ Ltd (2015) p 47, f/n 114.

Procedure — no breach

63. Mrs B also raised concern about Dr A's surgical skill, given the injury she sustained to the bladder wall. Dr Dover advised that an injury to the bladder wall is a low (less than 1%) but recognised risk of this procedure. While I acknowledge that the injury had a significant impact on Mrs B's postoperative recovery, it does not of itself indicate that the surgery was performed without due care and skill.

64. Dr Dover's review of this matter concluded that there is no evidence to suggest that Dr A did not undertake the procedure with reasonable care and skill. Dr Dover advised that whilst the documentation records some bleeding on the posterior wall of the vagina, this is not uncommon and there is clear documentation suggesting that the site of the bleeding was repaired, and the bladder was clear of the surgical field. On this basis, Dr Dover considered that there was no departure from accepted practice. I accept this advice, and I am satisfied that Dr A performed the procedure with reasonable care and skill.

Postoperative care — no breach

65. Mrs B also raised concerns about the adequacy of Dr A's follow-up care.

66. Whilst Dr Dover recognised that Mrs B had a complicated recovery, he advised that following the diagnosis of the complication, Mrs B was under the care of gynaecologists and urologists at Hospital 1. Accordingly, he considered that it was reasonable that Dr A was no longer responsible for Mrs B's ongoing care. I accept this advice.

67. I am satisfied that the standard of postoperative care Dr A provided to Mrs B met accepted standards. In reaching this conclusion, I accept Dr Dover's advice that Dr A's care was reasonable because Mrs B was in fact under the care of public hospital urologists and gynaecologists at the time.

Opinion: Clinic — other comment

68. Dr A advised HDC that he was acting in a private capacity when providing care to Mrs B, and thus the clinic played no role in the matter. Notwithstanding this, I am conscious that Dr A's business agreement with the clinic included the use of administrative and nursing staff who undertook work for him, including screening telephone calls and conducting Mrs B's initial follow-up appointment. Given this information, I consider that the clinic had a role in Mrs B's care, particularly in relation to the management of her postoperative communications when Mrs B reported concerns.

69. Dr Dover advised that primarily aftercare is done through the consumer's GP with specialist input through nursing staff telephone calls and an in-person review at approximately six weeks post-operation. Applying this standard, Dr Dover considered that the format of Mrs B's aftercare plan was in accordance with accepted practice.

70. The issue is the variance between the clinic's documented notes and Mrs B's recollection. Mrs B reported that she developed pain in the weekend following her procedure (10 and 11 March) and made multiple attempts to contact Dr A during this time. She stated that she was unable to speak with him and instead was advised by the clinic reception and nursing staff that the pain was normal. In contrast, the clinic stated that the first telephone contact from Mrs B was on 16 March.

71. As a result of the variance between the clinic's documented notes and Mrs B's recollection, Dr Dover advised that it was difficult to determine the true course of communication over this period and therefore when Mrs B's concerns were first raised. Given this, HDC obtained further information from Mrs B, who stated that 'it was probably the next week when the phone calls were made' (12 to 16 March).

72. I agree with Dr Dover that on the information provided it is difficult to determine the true course of communication and therefore when Mrs B's clinical concerns were first raised. In considering this issue, I gave thought to Mrs B's report and the degree of urgency she states she expressed to the clinic. This is balanced against the timely and appropriate actions taken by Dr A when he became aware of Mrs B's postoperative concerns.

73. Given the disparities in documentation and the differing recollections of the parties involved, I am unable to make a factual finding on when Mrs B reported her postoperative concerns to the clinic and Dr A. Notwithstanding this, I consider it relevant to remind the clinic of the importance of timely and detailed communication with the treating specialist[27] when a patient has called with concerns. It was reasonable for Mrs B to attempt to contact Dr A through the clinic, given that this was where the consultations took place. As this was her only avenue for communication with Dr A, it was essential that her concerns were passed on to him by the clinic staff in a timely manner. This case serves as a salient reminder for the clinic.

Recommendations

74. In my provisional opinion, I recommended that Dr A provide a written apology to Mrs B for the criticisms identified in the report. Dr A provided his apology to HDC, and this has been forwarded to Mrs B.

75. I recommend that Dr A:

a) Review the Medical Council statement on 'Informed Consent: Helping patients make informed decisions about their care' (2021) and provide a reflection to HDC within three months of the date of this report.

[27] This applies to situations where the treating specialist has entered into a business arrangement similar to that of Dr A and the clinic.

b) Complete the online learning modules at hdc.org.nz regarding informed consent, and report back to HDC within six months of the date of this report.

c) Complete an audit of his clinical documentation, looking at recording of consent discussions for the period of one year prior to the date of this report. A copy of the results of the audit should be provided to HDC within six months of the date of this report.

Follow-up actions

76. A copy of this report with details identifying the parties removed, except the advisor on this case, will be sent to the Medical Council of New Zealand and the Royal Australian and New Zealand College of Obstetrician and Gynaecologists, and they will be advised of Dr A's name.

77. A copy of this report with details identifying the parties removed, except the advisor on this case, will be placed on the HDC website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from obstetrician and gynaecologist Dr Richard Dover:

'**Re: Complaint C20HDC01996**

Thank you for your letter of instruction dated 18 October 2021 in which you have requested that I provide my opinion on the care provided by [Dr A] to [Mrs B] in relation to a total abdominal hysterectomy.

My qualifications and experience

I can confirm I am registered with the Medical Council of New Zealand in the vocational scope of practice of obstetrics and gynaecology. I am a Fellow of the Royal College of Obstetricians and Gynaecologists and a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG).

I am a full time practising private gynaecologist working out of Oxford Women's Health based in the Forte Hospital complex in Christchurch. I am currently the Clinical Director of this unit.

I have been based in New Zealand for over 20 years, initially working in private practice and through the CDHB. I have been employed solely on a private basis for the last 14 years.

In the past I have served two terms on the RANZCOG New Zealand committee and have been an examiner for the RANZCOG final exam for over 12 years.

I have been involved in practice visits for both the Medical Council and the Royal College.

Documentation considered and relied upon

I have considered the following information that has been provided to me by your office.

An overview of the case
I have set out below my understanding of the case.

A complaint was made by [Mrs B] to the Health and Disability Commissioner. This related to a complication that she sustained during a total abdominal hysterectomy.

There seem to be two key issues relating to this complaint.

The first relates to the level of pre operative counselling and the degree to which any of the potential complications of the surgery were discussed and documented.

The second issue relates to the development of the complication and issues surrounding communication, diagnosis and management of this.

With regard to the timeline of the incident, I have looked at three separate strands of documentation.

Clinic notes/letters
[Mrs B] came to see [Dr A] on 22 May 2020. The history is well documented and a management plan was established.

On 4 July 2020 [Dr A] wrote to [Mrs B], having been informed by her GP that her most recent period was extremely uncomfortable. He pointed out that the hormonal markers were within the normal range and as such it would be likely that she would *"continue with menstrual cycles for the next year or so."*

On 14 August 2020 [Mrs B] attended for a follow up visit. It appeared that her previous period had been a little lighter and that she would like to follow a conservative approach.

On 12 February 2021 [Mrs B] went for a further follow up visit. At that point she had had excessive bleeding since December and felt rather drained. This was to the extent that she had required an iron infusion.

It is documented, and had indeed been noted before, that she had an enlarged 16 week gestation sized uterus. Some options were discussed, including high dose Provera and the fact that hysterectomy would be a definitive solution.

At the time of that visit formal consent for the surgical procedure was taken. I am assuming that the enclosed diagram was drawn at that time.

I have no written notes relating to that appointment that may contain issues that were discussed with [Mrs B]. There is certainly no documentation relating to that visit that talks about the issues that were discussed nor does it specifically state that she was given a copy of the College hysterectomy pamphlet.

On the current form the operation is written as total abdominal hysterectomy and bilateral salpingo-oophorectomy and washings. I am uncertain as to the necessity for the washings but it makes it very clear that the uterus, tubes and ovaries are to be removed.

Further down the form is an area for admitting doctor's instructions where clinicians often write issues that were specifically discussed at the time of consenting. This area is completely blank.

From a documentation point of view there is therefore no evidence at all that any complications of surgery were discussed. These would relate to the general

complications of any operation such as bleeding, infection and the development of blood clots.

They would also relate to the specific complications of hysterectomy including bladder, ureteric and bowel injury.

Lastly, there is absolutely no mention made of the fact that removing the ovaries will render her menopausal, the symptoms that may develop as a result of this and any implications this may have for her ongoing health, or indeed measures that could be taken to address this.

The surgery took place on 6 March 2020 and there is a typed operation note that was clearly written in retrospect as it details the post operative course during the hospital stay. The operation note does mention that the vaginal vault was quite broad and that there was some bleeding from the posterior aspect of this, which was over sewn. It is specifically stated that *"care was taken to ensure that the bladder and ureters were out of the operating field."* It also comments on the presence of mild haematuria at the end but this is not uncommon following abdominal hysterectomy where the retractors can sometimes put pressure on the bladder causing some haematuria. I note that this resolved afterwards.

There is no documentation in the operation notes about antibiotic prophylaxis, thromboprophylaxis, or the time at which the catheter would be removed.

Following [Mrs B's] discharge she was seen by one of the nursing team on 13 March. The notes described she was feeling well, the dressing was taken down, her bowels had opened and the results were given. There is certainly nothing concerning or untoward about the documentation there.

On 16 March it is documented that [Mrs B] called the practice. It is documented that it was *"to chat about analgesia."* It does allude to some irritation on passing urine and a suggestion was made about organising a urine test or some Ural sachets.

On 18 March [Mrs B] called again. This was the 12th post operative day. At this point she had been dry retching since the previous day and felt that her pain had increased. Her Tramadol was almost finished. It was explained to her that [Dr A] was in surgery and indeed there were no other doctors available. The nursing member suggested that she obtain an appointment with her GP for an assessment, a script for analgesia and perhaps an investigation to see if there was any infection in the urine. It is clearly documented that the nursing member would contact the patient that afternoon to see how she got on.

Shortly after that there was a call from the GP explaining that [Mrs B] had a soft abdomen but significant abdominal pain. The urine dipstick was negative but she had been given antibiotics until the MSU report came back. It was suggested that the nursing member would inform [Dr A] with perhaps a view to him reviewing the patient that day or the following day.

The next note states that having been informed of this [Dr A] suggested an ultrasound scan to rule out a vault haematoma and a form for this was sent out to the patient.

The next consultation note relates to 23 March where a courtesy call was made to [Mrs B] who had been admitted to [Hospital 1] for two nights. She had also had a night in [Hospital 2] and it seems that the catheter was to remain in situ for two, with a District Nurse attending. It is documented that [Dr A] had visited her.

I am also aware that at this time it appears that there was a COVID Level 4 lockdown and some of the follow up may have been altered as a result of this.

The next thread of correspondence relates to the patient complaint
It is clear that the surgical procedure appeared to go well and from the patient's perspective there were no complaints about her hospital stay and her condition at the time of her discharge.

It was made clear that she was to have follow up by one of the nursing team on Friday and a follow up with the surgeon on 22 April.

The patient states that on the weekend of 10th & 11th of March she developed some pain with swelling and bloating. She phoned the surgery and spoke to a nurse. Her complaint suggests that she was told that her pain was *"just from the operation and would settle."* She states she was never able to speak to [Dr A] only his nurse and could not *"get past his secretary."*

On 18 March [Mrs B] says she was so swollen that she was in tears with the pain. She was *"unable to get past his nurse."* She confirms the nurse advised her to make an appointment with her own doctor and from there her family GP was involved.

[Mrs B] alludes to the fact that it was the GP who advised her to go for the ultrasound scan and she was admitted to [Hospital 1].

The remainder of her complaint deals with her admission and what sounds like a complex and difficult process involving admissions, PIC lines and corrective surgery.

I reviewed the hospital notes that were enclosed and they relate to [Mrs B] returning from theatre and documentation on the first day somewhere between 20:00 and 22:25 that the indwelling catheter was draining clear, pale yellow urine.

Over the coming night two separate notes indicate a good diuresis.

The following morning [Mrs B] was seen by [Dr A] who explained the operation and it was noticed that the urine was clear. Later in the day she was reviewed by the anaesthetist and the urine output was good. This is certainly documented later in the day at midday.

At 14:05 on the first day after this operation she had a small amount of vaginal bleeding. Following discussion with [Dr A], which appeared to be by text, a decision was made to withhold the Clexane.

Later that day the catheter was working and draining well, with a note being made it was to be removed the following day.

At 0200 on the morning of the 8th March it is documented that the urine was draining well, although slightly concentrated amounts. There was no evidence of any haematuria and at 0900 it was documented that she had passed urine since the catheter was removed. No comment was made on the colour or volume, although the following day it is documented that she had passed a good amount of clear urine.

[Dr A's] response to the complaint
In his response he comments that "*prior to any surgery I usually discuss the procedure in detail and tend to draw diagrams to explain the surgery*." He goes on to discuss the complications that he usually discusses and also comments that "*I also usually hand out the College brochure that gives further details*."

[Dr A] details the operation and describes some bleeding from the posterior wall that was over sewn but again it reiterates that the bladder and ureters were "*out of the operating field*."

[Dr A] then discusses the follow up for the patients and the hand outs that would have been given to [Mrs B] by [the private hospital] and describes the follow up protocol that he uses in his rooms, detailing the follow up by the practice nurses and then a six week follow up by himself.

[Dr A] describes that all of the patients are given the contact details and that he "*tends to rely on the assessment of my nurses*." He expects his nurses to "*inform me if there are concerns and if so I will contact the patient*."

On the 18th March it was suggested that she should see her GP. [The GP] later called the practice nurse with her findings. [Dr A] was informed about this and asked the nurse to organise an urgent scan of the pelvis.

After the scan was done the Radiologist called [Dr A] with the findings and [Mrs B] was then asked to be admitted to [Hospital 1].

[Dr A] states clearly that he informed the on call consultant and house surgeon to arrange for further imaging. It does not specify what speciality but I am assuming this was the on call Gynaecology team.

[Dr A] then documents seeing [Mrs B] the following day, apologising to her and noting that the *"Urologists were contacted and a conservative management plan was suggested."*

On 23 March one of the nursing team contacted [Mrs B] and it seemed that she was feeling better and that the catheter was draining.

Some time later on 11 April a call came through from [the Emergency specialist] who informed [Dr A] that [Mrs B] had been admitted and was passing urine past the catheter.

There was further correspondence from [Dr A] relating to the events of 18 March. He goes on to say that [Mrs B] was under the care of [the urologist]. He states that over the next few weeks whenever he saw [the urologist] he would get an update regarding [Mrs B].

Comment about specific issues

It does seem that [Dr A] had been involved in [Mrs B's] care over several months and a diagnosis of an enlarged uterus with heavy bleeding that may or may not have been peri menopausal was identified. It did seem that the symptoms waxed and waned but that ultimately she underwent an abdominal hysterectomy. There could have been a number of potential options offered to her at this stage but in the absence of seeing a formal ultrasound scan or talking to the patient I cannot comment on these any further. I think it is, however, reasonable that the procedure that was undertaken was appropriate and would deal definitively with her problems.

It had previously been documented that her hormones were within the normal range and again without having seen these it is difficult to comment, but it does appear that it was presumed that her symptoms could continue for some considerable time and that she was some way from the menopause.

I have read the operation notes that were typed but also the handwritten ones at the time of surgery. They are far from comprehensive but they do not necessarily raise any issues. Bleeding from the posterior wall is not uncommon and additional sutures are often required to deal with this. As it is in the mid line ureteric injury would be very unlikely and it is certainly documented that the bladder was thought to be well clear.

There do appear to be two significant areas that require further scrutiny.

From the documentation that I have been provided with there is no record of what took place or what was discussed at the consenting appointment.

I have no reason to doubt [Dr A's] assertation covered the issues that he has described in his response to [Mrs B's] complaint but there is no documentation in any of the paperwork that I have been sent through that confirms this.

With regard to that appointment I have no indication of how long it lasted for. In most cases a follow up appointment lasts between 15–20 minutes. This would mean that during that time a number of separate items would have had to be undertaken.

An assessment of the patient would have to have been made, a full discussion of all of the options with pros and cons would also have been needed. Consent for the

procedure, including specific and general complications, would also have needed to have been performed.

As mentioned beforehand [Dr A] should have covered the general complications of surgery, specific complications and clearly should have touched on the fact that removing [Mrs B's] ovaries would render her menopausal.

It seems that the surgical stay in hospital proceeded smoothly and that the problems only began following discharge. Clearly there does seem to be a disconnect between the statements in [Mrs B's] complaint through to HDC and the documentation provided by the nursing staff at that time.

Matters clearly came to a head on 18 March and when [Mrs B] phoned through [Dr A] was not available, he was out of the building and committed to a surgical procedure. There was clearly no way that he could have attended and I think it is unfortunate that one of his colleagues was not around to see her on his behalf.

The advice given by the nursing member was appropriate in that clearly [Mrs B] needed to be seen. It appears that as soon as [Dr A] was available he organised further investigations and indeed admission through to the hospital.

From that point on it is clear that a complicated post operative course unfolds but from the documentation provided it is unclear as to who was clinically responsible for [Mrs B's] ongoing follow up.

[Dr A], having been aware of the issue, arranged admission to the hospital. Their follow up and management is not recorded in the notes.

[Dr A] also states that [Mrs B] was under the care of [the urologist] and he would periodically enquire about her progress, suggesting that there was some ongoing supervision from the Urologist.

It is unclear from the documentation given as to who was responsible and it seems that if having diagnosed the complication [Dr A] had admitted her under the care of public gynaecologists or urologists then it seems reasonable that he was no longer responsible for her ongoing care from that point. Any issues that developed after that should not be addressed to him.

In response to the specific questions you have asked

It is easier to answer question 1 and 2 together.

I have already commented that at the time that consent is being obtained there should be a discussion with regard to the general risks of surgery that would include bleeding, thrombosis and infection. They should also include specific complications of the procedure involved and in relation to hysterectomy this would be, amongst others, the risk of injury to the bladder and the ureter. If the ovaries are being removed in someone who is still menstruating then there should also be an expectation that there should be

a discussion regarding the onset of the menopause and the management strategies that could be taken to reduce that.

The risk of injury to the bladder is difficult to quantify and a review of the literature does not really give any consistent answer. My personal figure that I quote is 1:500 but talking to my colleagues there is a consensus that it should be quoted as less than 1%. I would expect the risks and complications to be discussed verbally with the patient and there should be some written documentation in the notes confirming the points that have been raised. A number of complications of surgery are covered in The Royal College handout and it would be reasonable to expect that should be given and documented as such.

From review of the notes that I have been given there is no documentation at all about any of the above points. This of course does not mean that the discussion did not take place, merely that there is no documentation relating to it. I certainly think that this would be viewed as a significant departure from the norm and that most colleagues would view this as a sub optimal level of documentation and practice.

Point number 3 — Reasonable skill and care

There is certainly nothing that is written in the notes that suggests that anything other than reasonable skill and care was taken during the procedure. There is documentation about some bleeding on the posterior wall of the vagina which is not uncommon and clear documentation suggesting that at the time this was repaired that the bladder was clear of the surgical field. I am certainly comfortable there has been no departure from standard care of accepted practice and that our peers would feel comfortable with the surgical care and operation notes that were provided.

Point number 4 — The level of after care

This is also difficult as there is no accepted standard of after care following hysterectomy. From talking to my colleagues who work publicly they confirm that there is no follow up through the public gynaecology service and all follow up is done through the patient's GP. My practice is to see the patients after a week and at six weeks but a number of my colleagues rely on a nursing phone call at one week and a phone call with themselves at two weeks, followed by an in person review at six weeks.

I think this makes it clear that the format of the after care is well within the standard of care or accepted practice. The issue, I think from the documentation, is that there is a degree of variance from the documented notes from the nursing staff and those submitted by [Mrs B].

With the information that has been provided it would be very difficult to work out where the true nature of the clinical course lay between those two apparently contradictory statements.

It seems that when [Dr A] was aware that there was a significant problem an appropriate response was generated, contact with the GP was made and when he was

aware that there was an abnormality on the scan that an appropriate referral was made to the hospital.

I think, therefore, that on balance it is fair to say that the standard of after care was acceptable.

Point 5 relates to clinical documentation

I think that as discussed above the level of documentation regarding the consenting appointment was inadequate and there was certainly no confirmation of the documentation of the risks that were discussed. There may of course have been other documentation or clinical notes but these were not made available to me.

Point 6 relates to any other matters

I think in this case this does relate to the patient's journey once the complication was diagnosed.

Whilst there was clearly inadequate documentation about the risks of surgery it does seem that when the complication was diagnosed an appropriate referral was made.

It is also clear that the journey from that point was difficult and complicated with what sounds like a number of operations and interventions. It is, however, unclear from the notes that were sent through to me who was responsible for [Mrs B's] care at this point.

There is no documentation about who was taking the clinical lead and from the notes and the conversations with [the urologist] it is implied that the Urology team were involved with providing [Mrs B's] care. As such I think that the complicated nature of the post operative course has not helped the situation but I think on balance it is unfair to blame [Dr A] for that aspect of the outcome.

Conclusion

In my opinion, for the reasons referred to above, [Mrs B] received an adequate degree of surgical care and post operative follow up. It is, however, clear from the information provided that there appears to be some omissions from the consenting process and these have been detailed above.

With kind regards and best wishes,

Yours sincerely

Richard Dover
Consultant Gynaecologist & Medical Director
BM, MRCPI, FRCOG, FRANZCOG'