District Health Board (now Te Whatu Ora)

Obstetrician & Gynaecologist, Dr C

A Report by the

Deputy Health and Disability Commissioner

(Case 19HDC01509)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

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Executive summary

1. This report highlights the importance of the informed consent process, and the consequences for the consumer if the consent process is incomplete. Informed consent 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).

2. The report considers the information provided to a woman before she underwent a morcellation procedure to remove her uterus, fallopian tubes, and ovaries (a total laparoscopic hysterectomy and bilateral salpingo-oophorectomy) on 5 April 2017, and the events prior to her diagnosis with cancer in December 2018.

3. Prior to the procedure, the woman had an ultrasound scan and an endometrial pipelle biopsy, which showed a pre-cancerous condition associated with abnormally thick tissue on the inside of the endometrium (complex atypical endometrial hyperplasia (CAH)).

4. The consultant who performed the woman's surgery in 2017 was an overseas-trained specialist who was working for six months as a locum obstetrician and gynaecologist at the DHB. The consultant discussed various surgical complications with the woman, but did not inform the woman adequately about the disadvantages of morcellation as compared to open surgery; in particular, the consultant did not tell the woman about the difficulty in making an accurate pathological diagnosis following morcellation.

Findings

5. The Deputy Commissioner found that a reasonable consumer in the woman's circumstances would have expected to receive an explanation about the risks and benefits of morcellation in order to make an informed choice. By failing to do so, the consultant breached Right 6(1) of the Code. It follows that the woman was not able to make an informed choice and give informed consent, and, accordingly, the consultant also breached Right 7(1) of the Code.

6. The Deputy Commissioner made adverse comment about the DHB's lack of policy or guidelines regarding morcellation, or adequate processes to ensure that the consultant, a locum specialist, was aware of the RANZCOG guideline. The Deputy Commissioner also made adverse comment about the DHB's processes for the management of an urgent GP referral.

Recommendations

7. The Deputy Commissioner recommended that the DHB provide a written apology to the woman; institute a policy or guideline regarding the use of morcellation; put in place adequate processes to ensure that locum specialists/consultants are orientated adequately to the expected processes at the DHB; and review its system for waitlist bookings and consider whether an appropriate safety-net should be put in place.

8. The Deputy Commissioner recommended that the consultant apologise to the woman for the breaches of the Code identified in this report.

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Other comments

9. The Deputy Commissioner noted that her expert advisor, gynaecological oncologist Associate Professor Peter Sykes, expressed concern that access to gynaecological services throughout New Zealand is limited by resources, and this leads to delays in the management of women with possible or suspected malignancy, and that such delays may lead to poorer outcomes and increased inequality for women with gynaecological cancer. The Deputy Commissioner will bring these concerns to the attention of RANZCOG, the Ministry of Health, Te Whatu Ora — Health New Zealand, and Te Aka Whai Ora — Māori Health Authority, and recommend that they review Dr Sykes' suggestions and report the outcome to HDC.

10. In addition, the expert advisor expressed concern that the RANZCOG guideline does not specifically mention CAH as a contraindication to morcellation, and the Deputy Commissioner will draw these comments to the attention of RANZCOG for its consideration. The Deputy Commissioner noted that the RANZCOG guideline "Tissue Extraction at Minimally Invasive Procedures" is under review, and she recommended that RANZCOG consider Dr Sykes' suggestions about the use of morcellation when CAH is present, and report the outcome of its review of the guideline to HDC.

Complaint and investigation

11. The Health and Disability Commissioner (HDC) received a complaint from Dr B about the services provided to his daughter, Ms A,[1] at a district health board (now Te Whatu Ora — Health New Zealand).[2] The following issues were identified for investigation:

- *Whether the district health board provided Ms A with an appropriate standard of care in 2017 and 2018.*
- *Whether Dr C provided Ms A with an appropriate standard of care in 2017.*

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

13. The parties directly involved in the investigation were:

Ms A	Consumer
Dr B	Complainant/consumer's father
Dr C	Provider/locum obstetrician & gynaecologist
District Health Board	Provider

[1] Ms A supported the complaint.
[2] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, resulting in all district health boards being disestablished and Te Whatu Ora — Health New Zealand being established in their place.

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14. Further information was received from:

ACC	
Dr D	Provider/obstetrician & gynaecologist
Dr E	Provider/general practitioner (GP)

15. Gynaecologist Dr F is also mentioned in this report.

16. Independent expert advice was obtained from a gynaecological oncologist, Associate Professor Peter Sykes (Appendix A).

Information gathered during investigation

17. This opinion relates to the procedure involved in surgically removing Ms A's uterus, fallopian tubes, and ovaries (a total laparoscopic hysterectomy [3] and bilateral salpingo-oophorectomy[4]) on 5 April 2017, and her diagnosis of cancer in December 2018.

18. On 20 December 2016, Ms A (then aged in her fifties) saw her GP, Dr E, because she had experienced vaginal bleeding for six weeks. Dr E undertook a cervical smear and ordered an ultrasound scan (USS) of Ms A's uterus. Dr E prescribed medication[5] to try to control the bleeding.

19. On 24 December 2016, Dr E referred Ms A to the DHB Gynaecology Clinic. He noted in the referral that her general health was good and that previously she had had normal cervical smears (which had been undertaken on 26 November 2015 and 20 December 2016).

20. The referral was triaged as urgent (to be seen within six weeks) and Ms A's abnormal perimenopausal[6] bleeding was noted. The triage decision notes that it would be preferable to review Ms A after her USS.

21. On 27 February 2017 (close to nine weeks after the GP referral), a USS of Ms A's pelvis was performed at the hospital. The scan showed an enlarged uterus with numerous fibroids[7] but no adnexal masses.[8]

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[3] A total laparoscopic hysterectomy is the surgical removal of the uterus (womb) using an operating telescope inserted through the abdominal wall. The technique is minimally invasive — the surgeon makes only small cuts in the abdomen to minimise or lessen injury to the body.

[4] A bilateral salpingo-oophorectomy is the surgical removal of both fallopian tubes and both ovaries.

[5] Primolut (norethisterone). Norethisterone is used for endometriosis, heavy menstrual periods, irregular periods, and premenstrual syndrome.

[6] Around menopause.

[7] Non-cancerous growths in the uterus.

[8] An adnexal mass is a growth that occurs in or near the uterus, ovaries, fallopian tubes, and the connecting tissues. Usually the mass is benign, but sometimes it can be cancerous.

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Review in Gynaecology Outpatient Clinic 1 March 2017

22. On 1 March 2017, locum obstetrician & gynaecologist Dr C reviewed Ms A in the Gynaecology Outpatient Clinic. Dr C noted that since November 2016, Ms A had experienced a very significant change in her bleeding pattern, which had become heavy and occurred daily. The norethisterone medication prescribed by Ms A's GP two months earlier had helped to reduce the bleeding, and Ms A was otherwise well.

23. Dr C reviewed the USS from 27 February 2017 and noted that Ms A's uterus was enlarged and contained multiple fibroids. The largest measured 6cm, and several others had not been measured. The lining of the uterus[9] was thicker than normal[10] and the ovaries were not seen. On physical examination, Ms A's uterus was enlarged, and estimated to be the same size as that of a pregnant woman at 16–18 weeks' gestation, with an abnormal shape, and multiple fibroids were palpable. Her cervix appeared to be normal. An endometrial pipelle biopsy[11] was taken.

24. Dr C and Ms A discussed treatment options to manage the bleeding, including continuing with norethisterone treatment or the insertion of a progesterone-releasing intrauterine device (IUD). Dr C arranged for follow-up two weeks later to review the histology and consider the insertion of an IUD. She also discussed endometrial ablation (a procedure to remove a thin layer of the lining of the uterus) and a hysterectomy (removal of the uterus).

25. The histology of the endometrial pipelle biopsy showed a pre-cancerous condition associated with abnormally thick tissue on the inside of the endometrium (complex atypical endometrial hyperplasia (CAH)[12]). There was no evidence of adenocarcinoma[13] in the material that was examined.

Review 14 March 2017

26. Ms A was reviewed in the Gynaecology Clinic on 14 March 2017.

27. Dr C subsequently recorded in her operation note made after the surgery on 5 April 2017 (see below) that during the 14 March 2017 consultation she discussed the histology with Ms A and told her that there was a possibility of it becoming an adenocarcinoma, and that she (Dr C) recommended a hysterectomy. The operation note states:

> "We reviewed that the patient could have a malignancy of the uterus, should have all surgery by a Gynae Oncologist with further staging but this is not necessarily recommended for her situation. We reviewed the risks and indications of the procedure

[9] Endometrium.

[10] It measured 6mm. Among postmenopausal women with vaginal bleeding, an endometrial thickness ≤ 5mm is generally considered normal, while thicknesses > 5mm are considered abnormal.

[11] A biopsy taken by inserting a thin straw-like tube (pipelle) through the vagina and cervix into the uterus.

[12] CAH is an overgrowth of abnormal cells. The condition is considered to be pre-cancerous because if left untreated it may turn into uterine or endometrial cancer.

[13] Adenocarcinoma is a type of cancer that starts in mucus-producing glandular cells.

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at length in the office and then again today they reviewed and the patient gave informed consent to proceed."

28. Dr C recorded in the clinical notes that she had discussed in detail with Ms A the plan for a total laparoscopic hysterectomy and bilateral salpingo-oophorectomy. The risks of surgery were discussed, including bleeding. Blood transfusion was discussed, and Ms A told Dr C that she had recently converted to being a Jehovah's Witness and would consider whether to decline blood products. Further potential complications were discussed, including the risk of infection and damage to pelvic structures, such as the bowel, bladder, blood vessels, and nerves. The potential need for a laparotomy[14] to remove the uterus was also discussed. In response to the provisional opinion, Dr C said that sometimes an enlarged uterus can be delivered vaginally intact after total laparoscopic hysterectomy, but whether this will be possible cannot always be predicted preoperatively. She said that it is her practice to discuss with the patient the fact that the manner in which the uterus is removed will need to be an intraoperative decision. However, she noted that there is no record of this discussion, and she does not have a clear recollection of this conversation with Ms A.

29. Ms A told HDC that Dr C explained that she would "put a camera down", and showed her a picture of the parts that were to be removed. Ms A said that Dr C told her that she had a very large uterus, but did not discuss morcellation.[15] Ms A stated that she was not told about the potential risks of morcellation with regard to histology after the surgery.[16] She said that there was no discussion about removing the uterus whole, and that this would require a larger incision. Dr C said that based on Ms A's account, she must not have gone into enough detail about how the surgical approach could potentially affect the assessment of the pathology.

30. Similarly, the DHB told HDC that there was no specific discussion regarding removal of the uterus intact as opposed to removal of the uterus through a small incision via morcellation.

31. Dr C said that she explained that sometimes CAH can be seen with adenocarcinoma also present, and that there was a possibility that this diagnosis might be made on the final histology. She noted that an intervening hysteroscopy (examination of the inside of the uterus) was not needed. She said that she also noted that if there was a postoperative diagnosis of malignancy, particularly if it was invasive or aggressive cancer, then further surgery or further treatment might be required. Ms A signed the consent form for the surgery.

32. Dr C responded to HDC's request for information at the outset of this investigation, contributing to the DHB's response dated 18 September 2020. HDC requested additional

[14] A laparotomy is a surgical incision (cut) in the abdominal cavity (also referred to as "open" surgery). This surgery is more invasive than a laparoscopy, as the cut in the abdomen is much larger, but sometimes it is required to provide increased access for the surgery.

[15] Morcellation is the process of cutting fibroid or uterine tissue into smaller pieces to allow removal, usually during laparoscopic surgery with minimally invasive incisions.

[16] Morcellation can shred undiagnosed cancerous tissue, creating a risk of spreading the tissue in the abdominal cavity.

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information from Dr C regarding the specific information she gave to Ms A about morcellation and the possible effect it could have on the histology of the uterus.

Preoperative anaesthetic review

33. On 21 March 2017, Ms A was seen by an anaesthetist for a preoperative review. Ms A was noted to be a Jehovah's Witness, and that she declined blood products and a transfusion of whole blood, but she consented to receive specific blood component fractions.[17]

Surgery 5 April 2017

34. On 5 April 2017, Ms A underwent a total laparoscopic hysterectomy and bilateral salpingo-oophorectomy. Dr C's operation note states that there was an enlarged fibroid uterus and some mild adhesions, but the structures within the abdomen, fallopian tubes, and ovaries all appeared normal.

35. The operation note describes that a laparoscopic catch-bag was placed into Ms A's abdomen through the umbilicus (navel). The left fallopian tube and ovary were dissected and placed into the catch-bag, followed by the enlarged uterus. The umbilical incision was extended to 4cm, the uterus was morcellated, and the bag was removed through the extended umbilical wound. There was no spillage of the uterine contents into the abdomen because the morcellation occurred within the laparoscopic catch-bag. Dr C completed a pathology request form for the histology of the material removed during the surgery.

36. There were no reported complications, and Ms A had a relatively uneventful postoperative course. She was discharged on 7 April 2017.

37. The DHB noted that the pathology request form completed by Dr C did not record Ms A's history of the pre-cancerous condition CAH. The DHB said that this would be regarded as essential information for the pathologist, and it accepts that it was a significant shortcoming not to include it. The DHB stated that it is departmental policy to fill in laboratory request forms with adequate clinical information. It told HDC that the clarification of theatre specimen labelling is a part of sign-out.[18]

38. The histology report of 19 April 2017 states that the specimen was received on 5 April 2017 with no clinical information other than a description of the procedure performed. The laboratory requested further information, and on 9 April 2017 Dr C emailed that Ms A had had menorrhagia (heavy bleeding during menstruation) and fibroids, and her preoperative endometrial biopsy had shown CAH.

39. The histology report of the material removed during the surgery states that only one piece of tissue could be identified as coming from the uterine cavity. Microscopic examination

[17] The blood in the body is called "whole blood", and it has four major components: platelets, red blood cells, white blood cells, and plasma. Substances taken out of these four components are called "minor fractions".
[18] Sign-out is a check completed before a patient is removed from the operating room. The aim is to facilitate the transfer of important information to the teams responsible for the care of the patient after surgery.

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showed extension of the CAH into the fallopian tube. The fallopian tube was otherwise normal and the cervix was normal. There was no evidence of malignancy.

40. On 27 April 2017, Dr C wrote to Ms A informing her that the histology report showed that there was no evidence of cancer. Dr C wrote that she hoped that Ms A was feeling well in her recovery, and that she was looking forward to seeing her at her postoperative appointment.

41. Ms A was scheduled to attend a postoperative appointment on 24 May 2017, but she did not attend. That day, Dr C wrote to her noting that the appointment had been missed. Dr C confirmed that the histology did not show evidence of malignancy, and recommended ongoing follow-up with her GP, Dr E, rather than scheduling a further appointment through the outpatient clinic. Dr C wrote that she would like to schedule a further appointment in the outpatient clinic if Ms A's recovery was not going well or she had abdominal pain or vaginal bleeding, or Ms A could request an appointment herself.

Diagnosis of cancer

42. Ms A consulted Dr E on 26 November 2018 because she had vaginal bleeding and abdominal discomfort. On examination, Dr E found abnormal masses in Ms A's vagina. He sent an urgent referral to the Gynaecology Clinic stating that he suspected cancer.

43. The DHB said that the referral was triaged and identified as a case of high suspicion of cancer. This placed Ms A onto the fast-track cancer triaging pathway with a view to being seen within two weeks.

44. On 6 December 2018, a registrar saw Ms A in the Gynaecology Clinic. It was noted that she had a history of abnormal bleeding and discomfort since October 2018, and that a vaginal vault smear[19] undertaken on 28 November 2018 had been normal. Vaginal examination was limited because of Ms A's level of discomfort and her high BMI, but it was noted that there were hard solid lesions in the vagina and a solid mass at the posterior fourchette.[20] It was decided to perform an urgent examination under anaesthetic (EUA) and obtain a biopsy of the vaginal mass. As Ms A was known to be a Jehovah's Witness, a preoperative review with an anaesthetist was arranged.

45. A booking form to place Ms A on the surgical waiting list was completed. The form stated that the EUA should be performed "urgently", and that it could be done on any consultant list (i.e., in the next available operating space).

46. The DHB stated that the Clinical Priority Assessment Criteria (CPAC) score was 90 because there was a high probability of malignancy. The DHB told HDC:

> "It appears that the booking co-ordinator originally arranged for [Ms A] to have her EUA performed by [Dr F] in February 2019. It seems the two month timeframe between

[19] A sample of cells taken from the top of the vagina when a woman has had a hysterectomy (removal of the cervix).

[20] The posterior fourchette is a fork-shaped fold of skin at the bottom of the entrance to the vagina.

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assessment and proposed surgery prompted [Ms A's] father to make contact with the hospital with a view to expediting her surgery."

47. Subsequently, the DHB stated:

"I have re-checked with the booking clerk as to whether [Ms A] was ever given a surgery date for an EUA on [Dr F's] operating list in February 2019. There is no record at all on the computer or in the booking diary of a date being given."

48. On 9 December 2018, Ms A's father, Dr B, telephoned the on-call registrar. The DHB stated that initially Dr B said that he was Ms A's GP, and he asked questions about her care and requested clinical details. He said that he was concerned about her pain and suggested that a C-reactive protein (CRP) test and white blood cell count be taken to check for inflammation. The registrar told Dr B that there was a concern regarding malignancy, and that the most relevant investigation was a biopsy of the vaginal lesions. The registrar said that Ms A was on the fast-track cancer pathway, but did not have a date for the EUA. At some point, Dr B said that he was in fact Ms A's father and not her GP. The DHB said that the registrar was concerned about broken confidentiality and that inappropriate information had been shared.

49. On 10 December 2018, Ms A presented acutely to the Emergency Department with lower abdominal pain, vaginal bleeding, and lethargy. It was noted that she wanted to expedite her hospital treatment. The Emergency Department consulted the Gynaecology Department but was advised that no further treatment was required and she was discharged home.

50. On 14 December 2018, Dr B contacted gynaecologist Dr F through the hospital switchboard. The DHB said that Dr B had assumed that Dr F had performed Ms A's hysterectomy. He believed that Ms A had been given a date for an EUA in February 2019 on Dr F's operating list. Dr F was not on call and was not in the hospital when she received the telephone call from Dr B. She did not think it appropriate to discuss clinical details, and there was no detailed discussion.

51. The DHB said that Dr F was concerned about the nature of the telephone call and wanted to explore this further. She did not know any clinical details relating to Ms A, so she reviewed Ms A's records and then realised that the hysterectomy had been performed by Dr C in April 2017.

52. Dr F emailed her gynaecology colleagues asking whether the EUA should be expedited, given that February was some time away. Dr F also asked whether a further clinic appointment should be arranged for Ms A.

53. On 15 December 2018, obstetrician and gynaecologist Dr D responded to Dr F indicating that his expectation was that the EUA would be performed prior to the Christmas break. He told Dr F that he had an operating list on 19 December 2018 and he would perform the EUA on that list if it could not be done sooner.

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EUA 19 December 2018

54. On 19 December 2018, Dr D performed an EUA and a vaginoscopy (examination of the inside of the vagina). He told HDC that there was vaginal thickening across the vaginal vault, which was firm with limited mobility and was suspicious for malignancy. There was also a 2cm circular area of raised firm tissue in the lower posterior vaginal wall, with a slightly dark colour, which was also suspicious for malignancy. Biopsies were taken from those two areas.

55. The histology confirmed that the tissue showed evidence of invasive endometrial adenocarcinoma consistent with recurrent endometrial cancer, which had not been identified previously.

56. On 21 December 2018, Ms A underwent an MRI of the pelvis and a CT scan of the chest, abdomen, and pelvis, and the findings were suspicious for vaginal vault recurrence of tumour with possible lymph node involvement.

Multidisciplinary review

57. On 3 January 2019, the imaging and histology of the vaginal vault biopsy were reviewed at a multidisciplinary meeting, and it was confirmed that there was recurrent endometrial cancer at the vaginal vault. The recommendations were for palliative radiotherapy or, if radiation was not technically possible, then chemotherapy could be considered, with a referral to Medical Oncology. It was decided that surgery would not be offered. A referral was made to Radiation Oncology.

Further treatment

58. Dr D arranged for Ms A to be followed up in his Gynaecology Clinic scheduled for 23 January 2019. This was intended to be an opportunity to review treatment options and to answer any questions or address any concerns that Ms A might have. However, Ms A did not attend the appointment.

59. Ms A's care was transferred to a gynaecological oncologist in another region.

Adverse event review

60. The DHB conducted an adverse event review (the review), which found that the decision to perform the hysterectomy laparoscopically was consistent with standards in 2017. It noted that it can be difficult for a pathologist to look for evidence of tissue invasion in a specimen that is in small pieces (as a result of morcellation), rather than being intact. However, it was not expected that morcellation would be a critical aspect of the diagnosis.

61. The review notes that subsequently it was recommended by the gynaecological oncologist that the uterus should always be removed intact when CAH is the indication for the hysterectomy, because 25–30% of cases will be found to have evidence of cancer when they are examined histologically. The review states that the DHB Gynaecology Department has now changed its process, and will always remove the uterus intact in such cases.

62. With regard to the booking of the urgent EUA in early December 2018, the review found that because of the time of year, a number of specialists were on leave, and the next

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available appointment was likely to be February 2019. However, the booking records show that no formal booking was made for Ms A to have her surgery in February 2019. There was further communication over ensuing days, and ultimately the EUA was performed on 19 December 2018.

63. The waiting list booking form for the EUA did not stipulate a timeframe — it simply stated "Urgent", and there is no section on the form to specify a timeframe. However, a National Prioritisation form (electronic) was also filled out and printed to accompany the booking form, which provided a timeframe of four weeks.

64. The review states that the usual booking process is that when a request for a waiting list procedure is made, that request goes to the booking coordinator. The request is reviewed, specifically looking at the timeframe as indicated and which doctor is to perform the procedure. The booking coordinator then reviews the electronic booking system and finds the next available space. If what is requested is not available, the patient's procedure is "pencilled in" and the booking coordinator contacts the requesting consultant to advise this. The consultant will then review preceding waiting lists and postpone other less urgent patients' procedures, to ensure that the patient with the highest clinical priority is treated first.

65. The review states that Ms A rang the booking coordinator to follow up on her waiting list booking. The booking coordinator explained that the first available appointment was in February. Although the booking coordinator considered that this might be changed once she had spoken to the consultant, she did not wish to give Ms A incorrect information, so she did not mention that possibility. Between the "pencilled in" booking being made and the booking coordinator asking the consultant to review the surgical list for reprioritisation, Dr B attempted to expedite the EUA. After the DHB consultants became aware of the triage issue, Ms A was prioritised and had her biopsy completed four days later on 19 December 2018. The review states that the process in place to manage any mismatch between waiting list booking requests and availability requires a person — i.e., the booking coordinator — to manage this actively, and there is no appropriate safety-net.

Further information relating to Dr C

66. At the time of these events, Dr C was a locum specialist (consultant) at the DHB's Obstetrics & Gynaecology Department. Dr C no longer works in New Zealand. Dr C expressed to Ms A her sincere sympathy for the outcome.

67. Dr C stated that Ms A's uterus was enlarged, and generally that size of uterus cannot be extracted intact from the abdomen using laparoscopic surgery, so the alternative is morcellation. Once Ms A's total hysterectomy had been completed, the uterine specimen was collected within a large laparoscopic bag, to avoid spillage of uterine tissue in the abdomen. This allowed Ms A to avoid a laparotomy incision.

68. Dr C said that the preoperative information about CAH would not have been a contraindication to this approach to hysterectomy or to morcellation contained in a catch

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bag. She said that the laparoscopic approach is supported, even in women who are known to have malignancy.[21]

69. Dr C stated that Ms A's preoperative histology diagnosis of CAH is noted on Ms A's operative record, booking form, and histology report. She said that she assumed that there was also a form that accompanied the surgical specimen. As noted in paragraph 35 of this report, the pathology request form Dr C completed at the conclusion of the laparoscopic surgery did not record the essential clinical information relating to Ms A's history of the pre-cancerous condition CAH, but that information was provided a few days later.

70. Dr C acknowledged that if Ms A's uterus had been intact, her original hysterectomy specimen may have had a more accurate pathological diagnosis. Dr C said that she told Ms A that the possibility of malignancy was not ruled out by her endometrial biopsy being free of cancer. Dr C stated that this was the reason that contained extraction of the specimen was done so carefully. She noted that Ms A's blood loss risks would have been minimised by a laparoscopy, which was a factor that was considered because of Ms A's possible refusal of blood products.

Further information relating to DHB

71. The DHB told HDC that its Obstetrics & Gynaecology Department did not have a policy on morcellation at the time of these events, other than to avoid it in cases of malignancy or suspected malignancy. However, the policy has now been extended to include CAH.

72. The DHB said that it follows the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) guidelines on morcellation (see Appendix B). However, it no longer uses powered morcellation[22] because of the risk of injury to internal organs, and, where possible, morcellation is performed within a contained extraction bag to prevent dissemination. The DHB said that while Dr C was a locum specialist, she was "nominally supervised" by the head of department, but that consultant is no longer employed by the DHB.

73. The DHB stated that locum specialists are supported clinically by all specialists in the department, but direct supervision of all procedures is not possible. Locum specialists are directed to the RANZCOG website for clinical guidance, but the DHB has no formal documentation or process to ensure compliance. However, the risks of morcellation with respect to cancer spread had received considerable publicity, and the DHB said that it would have expected Dr C to have been fully aware of those risks at the time.

74. The DHB stated that when Ms A re-presented to hospital in December 2018 with symptoms of recurrent endometrial cancer, the hospital was experiencing a significant shortage of gynaecology consultants, and it was just prior to the Christmas break, which is a time of high

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[21] Dr C supported this by reference to the Gynecologic Oncology Group LAP2 trial. https://pubmed.ncbi.nlm.nih.gov/19805679/. She did not refer to the RANZCOG guideline.

[22] Laparoscopic power morcellators are medical devices used during laparoscopic surgery to cut tissue into smaller pieces.

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annual leave. As such, availability of operating lists was limited, and they were significantly booked.

75. The DHB said that it appears that there was a miscommunication about the waiting time for an urgent EUA. The usual booking clerk was on leave at the time, and a less experienced staff member was covering for her. The restricted availability of operating lists and the clerk's limited experience may have been factors in the informal conversations between the clerk and the consumer about timeframes for an EUA procedure.

Responses to provisional opinion

76. All parties were given an opportunity to respond to the provisional opinion. The responses have been incorporated into the "information gathered" section as appropriate.

77. The DHB stated that it had no comment to make on the provisional report, and accepted the proposed recommendations and follow-up actions.

78. Dr B said that he telephoned the Obstetrics & Gynaecology registrar at the DHB in September 2019 and subsequently on another two or three occasions. He stated that on the initial occasion, he introduced himself as a retired doctor and father of the patient, and affirmed Ms A's consent for him to ask for help for her. Dr B said that he told the registrar that he was not Ms A's GP. He said that by December 2019 he had spoken to clinicians seven times, including the Obstetrics & Gynaecology registrar, the consultant surgeon, and the anaesthetist.

79. Dr C said that Ms A's uterus was enlarged and could not be removed from her abdomen intact with laparoscopic surgery without morcellation. She said that there are times when an enlarged uterus can be delivered vaginally intact after total laparoscopic hysterectomy, but whether this will be possible cannot always be predicted preoperatively. She still considers that the laparoscopic approach was preferable in Ms A's case.

Opinion: Dr C — breach

Use of morcellation — no breach

80. In 2017, Dr C, an overseas-trained specialist, was working for six months as a locum obstetrician and gynaecologist at the DHB. She was the consultant responsible for Ms A's surgery on 5 April 2017.

81. To assist in my assessment of the standard of care provided to Ms A, I sought independent advice from gynaecological oncologist Dr Peter Sykes. Dr Sykes advised that a significant proportion (20–40%) of women with CAH, such as Ms A, will have a diagnosis of endometrial cancer following a hysterectomy. He noted the importance of histological examination following a hysterectomy in such circumstances, and said that the whole uterus and cervix are required for histological assessment. Dr Sykes noted that morcellation can result in an inability to undertake adequate histological examination.

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82. The DHB did not have a policy in place regarding morcellation, but it followed the RANZCOG guideline, which states that malignancy or a suspicion of malignancy is a contraindication for morcellation. Similarly, Dr Sykes stated: "[M]orcellation therefore is not recommended if malignancy is suspected or a significant possibility."

83. Dr Sykes advised that the minimum expected preoperative assessment would be a pelvic ultrasound — as was performed — to exclude a large uterine tumour or ovarian masses. Ms A's ultrasound examination and pipelle biopsy did not indicate that cancer was present, but Dr C was aware of the potential for malignancy in patients with CAH, as she told Ms A that the possibility of malignancy could not be ruled out by her endometrial biopsy being free of cancer.

84. Dr C has stated that she considered that the preoperative diagnosis of CAH was not a contraindication to contained morcellation. She also said that the laparoscopic approach is supported by research, even in women who are known to have malignancy. However, the research referred to does not mention the effect of morcellation on histological examination of the uterus, and Dr C did not refer to the RANZCOG guideline in support of this view.

85. Dr Sykes advised that in this case, utilising morcellation was a deviation from ideal practice, as it resulted in an inability to undertake adequate histological examination. The uterine cavity was identified in only one piece of tissue, and no evidence of malignancy was seen. He considers that this may have resulted in a misdiagnosis of the presence of endometrial cancer.

86. However, Dr Sykes also noted that the RANZCOG guideline does not explicitly state that morcellation is contraindicated in the presence of CAH, although it does say that malignancy should be excluded. He considers that with the lack of clear RANZCOG guidelines, some gynaecologists would believe the risk–benefit calculation to be in favour of minimally invasive surgery, even if that meant that morcellation was required. Dr Sykes stated that laparoscopic hysterectomy is associated with less blood loss and a shorter hospital stay compared with open hysterectomy, and noted that, as Ms A would not accept a blood transfusion, there were clear advantages to minimally invasive surgery in the absence of malignancy.

87. Dr Sykes noted that it is possible that the cancer arose from endometriosis in another genital or pelvic site, and it is unlikely that the morcellation led to the dissemination of the cancer.

88. I accept the advice that although not ideal in hindsight, in the circumstances, it was not unreasonable to have proposed minimally invasive surgery and morcellation. My primary concern lies with the information provided to Ms A about the risks associated with that technique, as discussed below.

Information provided — breach

89. In response to the provisional opinion, Dr C said that Ms A's uterus was enlarged and could not be removed from her abdomen intact with laparoscopic surgery without morcellation. She said that there are times when an enlarged uterus can be delivered vaginally intact after

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total laparoscopic hysterectomy, but whether this will be possible cannot always be predicted preoperatively.

90. Dr C stated that it is her usual practice to discuss with the patient the fact that the manner in which the uterus is removed will need to be an intraoperative decision. However, this information is not recorded, and she stated in her response that she does not have a clear recollection of the conversation with Ms A.

91. Dr C discussed various surgical complications with Ms A, but, according to Ms A and the DHB, Dr C did not discuss the risks and benefits of removing the uterus intact rather than utilising morcellation to extract it in small pieces — in particular, she did not tell Ms A about the difficulty in making an accurate pathological diagnosis following morcellation. The clinical records and operation note do not refer to this risk having been discussed. Dr C acknowledged that based on Ms A's account she must not have gone into enough detail about how the surgical approach could potentially affect the assessment of the pathology.

92. I find that Dr C did not adequately inform Ms A about the disadvantages of morcellation.

93. Dr Sykes advised that the failure to conduct a preoperative discussion of the risks and benefits of morcellation as compared to open surgery was a significant deviation from accepted practice. Similarly, the RANZCOG guidelines state: "Patients must be engaged in the discussion of the method of tissue extraction. This discussion should include the risks and benefits of alternative management options."

94. Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code) states:

> "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including— (a) an explanation of his or her condition; and (b) an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option …"

95. In my view, a reasonable consumer in Ms A's circumstances would have expected to receive an explanation about the risks and benefits of morcellation in order to be able to make an informed choice. By failing to do so, Dr C breached Right 6(1) of the Code. It follows that Ms A was not able to make an informed choice and give informed consent, and, accordingly, I find that Dr C also breached Right 7(1) of the Code.[23]

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[23] Right 7(1) states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent …"

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Opinion: District Health Board (Te Whatu Ora — Health NZ) — adverse comment

Introduction

96. As a healthcare provider, the DHB was responsible for providing services in accordance with the Code. I consider that the primary issues in this case are individual failures, which I discuss above in relation to Dr C. However, I also consider that there were aspects of the care provided by the DHB that warrant comment.

Guidance for staff on use of morcellation

97. At the time of these events, the DHB had no specific policy for dealing with morcellation other than that it should be avoided in cases of malignancy or suspected malignancy. Instead, the DHB relied on its staff referring to the RANZCOG guideline.

98. Dr C, who was a locum specialist, said that the preoperative knowledge that Ms A had CAH would not have been a contraindication to the laparoscopic hysterectomy or to contained morcellation. She also said that the laparoscopic approach is supported even in women who are known to have malignancy. However, she did not refer to the RANZCOG guideline to support this view.

99. With regard to the use of morcellation, the RANZCOG guideline states: “Morcellation of a fibroid or uterus should only be performed in the absence of a suspicion of malignancy.” It also states: “Patients must be engaged in the discussion of the method of tissue extraction. This discussion should include the risks and benefits of alternative management options.”

100. The histology from the biopsy sample taken showed no adenocarcinoma, and Dr C told Ms A that the possibility of malignancy had not been ruled out by her endometrial biopsy being free of cancer. A biopsy sample involves testing only a small sample of tissue, and the pathology results did not give rise to a suspicion of malignancy. Dr C acknowledged that if Ms A’s uterus had been intact, her original hysterectomy specimen may have had a more accurate pathological diagnosis.

101. Dr Sykes said that 20–40% of women with CAH will be diagnosed with endometrial cancer following a hysterectomy, and he noted the importance of the histological examination following the hysterectomy in such circumstances. He advised that the whole uterus and cervix are required for histological assessment. He stated:

> “[F]or a patient likely to require morcellation, standard practice would include exclusion of malignancy and a pre-operative discussion of the risks and benefits of morcellation as compared to open surgery.”

102. On 14 March 2017, Dr C discussed various complications, but the DHB said that there was no specific discussion regarding the removal of the uterus intact, rather than utilising morcellation in order to extract it in small pieces. Similarly, Ms A told HDC that Dr C did not discuss morcellation with her. Dr C does not recall the details of the conversation, but, based

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upon Ms A's account, she acknowledged that she must not have gone into enough detail about how the surgical approach could potentially affect the assessment of the pathology.

103. Dr Sykes advised that the failure to exclude malignancy, and the failure to conduct a preoperative discussion of the risks and benefits of morcellation as compared to open surgery, was a significant deviation from accepted practice. I agree and consider that the primary responsibility for this lies with Dr C as the treating clinician. However, the DHB did retain some responsibility for ensuring that Dr C, as an overseas-trained locum doctor with limited clinical experience at the DHB, was aware of its expectations for accepted practice in New Zealand. The DHB stated that locum specialists are directed to the RANZCOG website for clinical guidance, but the DHB has no formal documentation or process to ensure that the locum has reviewed the website and is aware of the clinical guidance offered. The guidance is titled "Tissue Extraction at Minimally Invasive Procedures", which may not obviously relate to morcellation. However, the DHB stated that the risks of morcellation with respect to cancer spread had received considerable publicity at the time of these events, and it would have expected Dr C to have been fully aware of those risks at the time, and therefore taken this into account in her discussions with Ms A.

104. The Medical Council of New Zealand (MCNZ) Standard "Orientation, induction and supervision best practice guidelines" (January 2011) states:

> "The new IMG [(International Medical Graduate)] will need to access different information at different times, and you cannot meet all those information needs immediately. A key aspect of providing a good orientation and induction experience is to make sure that the IMG knows how to find information."

105. Dr Sykes commented that "[a]voidance of future occurrences such as this comes down to education". Dr Sykes suggested that hospitals could introduce guidelines on morcellation. I agree. In my view, the DHB either should have had a policy or guideline in place regarding morcellation, or should have had adequate processes to ensure that Dr C, as a locum specialist from the USA, was aware of the RANZCOG guideline. This was necessary to ensure that Ms A received services of an appropriate standard.

Booking processes

106. On 26 November 2018, Ms A consulted Dr E because she had vaginal bleeding and abdominal discomfort. Dr E referred Ms A urgently to the Gynaecology Clinic stating that he suspected cancer. Ms A was placed on the fast-track cancer triaging pathway, with a view to her being seen within two weeks.

107. A registrar reviewed Ms A on 6 December 2018 and noted that she had vaginal lesions. It was decided to perform an urgent EUA to obtain a biopsy of the vaginal mass. Initially, Ms A was pencilled in to have the EUA performed by Dr F in February 2019, but the procedure was never actually scheduled for this date. The DHB said that as the EUA was urgent, the process would then have been to arrange to slot Ms A's procedure in at an earlier date.

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108. After contacting the on-call registrar, Ms A's father also contacted Dr F on 14 December 2018 and expressed his concerns about the scheduling of the EUA. Dr F emailed her gynaecology colleagues asking whether the EUA should be expedited, and on 15 December 2018, Dr D responded that his expectation was that the EUA would be performed prior to the Christmas break, and it was placed on his operating list of 19 December 2018. Biopsies taken during the EUA confirmed that Ms A had invasive endometrial adenocarcinoma consistent with recurrent endometrial cancer.

109. I am unable to determine whether Ms A would have received a timely date for her EUA in the absence of her father's intervention. However, I consider that the information from the booking coordinator that the first available appointment was in February 2019 would have been concerning for Ms A and her family. The booking coordinator did not explain the process at the DHB to schedule the procedure sooner. If the information given to Ms A was incorrect or incomplete, it was inappropriate to give it to her.

110. The DHB stated that in December 2018 the hospital was experiencing a significant shortage of gynaecology consultants, and as it was just prior to the Christmas break, the operating list was significantly booked. The DHB said it appears that there was a miscommunication about the waiting time for an urgent EUA, perhaps because the usual booking clerk was on leave and a less experienced staff member was covering for her.

111. I note Dr Sykes' comment that despite the clinician involved being concerned about the presence of malignancy, an appropriate date for the EUA or other investigation was not forthcoming. However, he noted that in the event, an urgent arrangement was made, and he considers that overall the DHB provided satisfactory care. Notwithstanding my expert advisor's views on this matter, I am critical of the management and scheduling of this urgent GP referral.

Other comments

Resources

112. I note the comments made by Dr Sykes regarding his concern that access to gynaecological services throughout New Zealand is limited by resources, including specialist staff, access to outpatient services, operative time, and clerical staff. He said that this not infrequently leads to delays in the management of women with possible or suspected malignancy, and that such delays may lead to poorer outcomes and increased inequality for women with gynaecological cancer. I intend to bring Dr Sykes' concerns to the attention of RANZCOG, the Ministry of Health, Te Whatu Ora — Health New Zealand, and Te Aka Whai Ora — the Māori Health Authority.

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Morcellation

113. I have noted the concerns raised by my expert advisor that the RANZCOG guideline does not specifically mention CAH as a contraindication to morcellation, and I intend to draw Dr Sykes' comments to the attention of RANZCOG for its consideration.

Recommendations

114. I recommend that Te Whatu Ora — Health New Zealand:

a) Provide a written apology to Ms A for the criticisms raised in this opinion. The apology is to be sent to HDC within three weeks of the date of this opinion, for forwarding.

b) Put in place a policy or guideline regarding the use of morcellation, and adequate processes to ensure that locum specialists/consultants are orientated adequately to the expected processes at the DHB. Te Whatu Ora — Health New Zealand is to report to HDC on the policy, and any changes made, within three months of the date of this opinion.

c) Review the system for waitlist bookings to consider whether it is necessary to put in place an appropriate safety-net, and report to HDC on any outcomes from the review, and/or changes made, within six months of the date of this opinion.

115. I recommend that Dr C provide a written apology to Ms A for the breaches of the Code identified in this opinion. The apology is to be sent to HDC, for forwarding, within three weeks of the date of this opinion.

116. I recommend that within six months of the date of this opinion, the Ministry of Health, Te Whatu Ora — Health New Zealand, and Te Aka Whai Ora — the Māori Health Authority review the suggestions made by Dr Sykes in this opinion regarding resource constraints, and report the outcome of this consideration to HDC.

117. I note that currently the RANZCOG guideline "Tissue Extraction at Minimally Invasive Procedures" is under review. I recommend that within six months of the date of this opinion, RANZCOG consider the suggestions made by Dr Sykes about the use of morcellation when CAH is present, and report the outcome of its review of the guideline to HDC.

Follow-up actions

118. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to RANZCOG, the Health Quality and Safety Commission, ACC, the Ministry of Health, Te Whatu Ora — Health New Zealand, and Te Aka Whai Ora — the Māori Health Authority, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from gynaecological oncologist Associate Professor Dr Peter Sykes:

"Your ref C19HDC01509

[Ms A]

My name is Associate Professor Dr Peter Sykes. I am a gynaecologic oncologist and provide an expert opinion in this case based on the information provided by the HDC. I declare prior knowledge of this case as I previously provided a report for ACC however I do not believe there is any conflict of interest.

In brief summary [Ms A] presented to [the public hospital] in January 2017 with abnormal vaginal bleeding. Ultrasound examination revealed a fibroid uterus and endometrial biopsy revealed atypical endometrial hyperplasia. A laparoscopic hysterectomy was performed in April 2017, the uterus was morcellated in a bag to enable removal. Final histology was limited by the morcellation but confirmed Atypical endometrial hyperplasia without malignancy.

A scheduled follow up appointment in May 2017 was not attended, ongoing follow up was recommended with her GP.

In November 2018 the client was referred to [the public hospital] with vaginal bleeding and a vaginal mass. In December she was reviewed in gynaecology clinic and an urgent examination under anaesthetic was recommended, following a number of phone calls from [Ms A's] father this was scheduled on 19/12/18. A diagnosis of disseminated grade 1 endometrioid adenocarcinoma was made involving the vagina pelvis, pelvic and paraaortic nodes.

Response to questions;

Comment on

1 The overall adequacy of the care provided by [the DHB]. In general terms the care provided to [Ms A] was satisfactory and provided with good intent, in that she was investigated and treated for abnormal vaginal bleeding. Subsequently on further presentation with symptoms this was investigated and an appropriate diagnosis was made. There however was a specific deviation from ideal practice in that the uterus was morcellated and this resulted in an inability for adequate histological examination. This may have resulted in a missed diagnosis of endometrial cancer.

There is also a question as to whether appropriately timely arrangements were being made for investigation of symptoms in December 2018. It seems as though, despite the fact that the clinician involved being concerned about the presence of malignancy an appropriate date for examination under anaesthetic or other investigation was not

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forthcoming. It is unclear if an appropriate date would have been given without the intervention of the patient's father. However an urgent date was given.

The DHB overall therefore provided satisfactory care other than the clinical decision of a single practitioner.

2 Whether [Ms A] received adequate follow up after her laparoscopic hysterectomy and BSO in April 17.

Following the hysterectomy [Dr C] wrote to the patient explaining the histology results in Lay terms, but there is no record of this being copied to the GP.

[Ms A] was scheduled for a post operative visit on 24 May 2017. [Dr C] then wrote to the patient and her GP reiterating her results and inviting her to request another appointment if she still had symptoms. She was discharged to her GP for follow-up but no specific instructions were given regarding symptoms and there was no disclosure regarding the limitations of the histological examination.

While in retrospect the lack of instructions regarding presentation with symptoms and lack of discussions regarding the limitations of the histological diagnosis fall short of what would be considered ideal practice, I expect in the view of most of [Dr C's] colleagues the follow up would be considered satisfactory.

3 Whether it was advisable to morcellate the uterus prior to removal during hysterectomy.

It is well documented that for a significant proportion (20–40%) of women with atypical endometrial hyperplasia that a diagnosis of endometrial cancer will be made following hysterectomy. The importance of histological examination following hysterectomy in these circumstances is therefore widely recognised.

The route of hysterectomy for atypical endometrial hyperplasia is unimportant however the whole uterus and cervix is required for histological assessment.

While morcellation of the uterus usefully allows minimally invasive surgery to be performed for women with enlarged uteri, there has been much international recognition of hazards associated with morcellation. These risks are likely to be minimised if the morcellation takes place in a bag (like this patient) without spill. Morcellation in these circumstances is unlikely to worsen prognosis however does make histologic assessment (which is crucial for diagnosis and subsequent management) difficult. Morcellation therefore is not recommended if malignancy is suspected or a significant possibility.

It is interesting that in reviewing RCOG (UK) and RANZCOG Aust/NZ guidelines the use of morcellation in the presence of atypical endometrial hyperplasia is not clearly identified as a contraindication, it is identified that patients should undergo a workup to exclude malignancy. The risks to histological assessment are however identified and it is noted that these risks should be discussed with the patient. The American college guideline clearly states that malignancy is a contraindication to morcellation and that it should be excluded.

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Therefore for a patient likely to require morcellation standard practice would include exclusion of malignancy and a preoperative discussion of the risks and benefits of morcellation as compared to open surgery. It appears that these steps were overlooked and therefore represent a significant deviation from accepted practice.

Avoidance of future occurrences such as this comes down to education. Individual hospitals could introduce guidelines and the HDC could write to RANZCOG suggesting that their guidelines on morcellation are reviewed possibly to include a statement that Atypical endometrial hyperplasia and endometrial cancer should be considered a contraindication to morcellation and that this should not be undertaken without discussion with a gynaecologic oncologist.

It is important to comment in this case that while morcellation may have been responsible for a missed diagnosis of Endometrial cancer it is possible that the cancer arose from endometriosis in another genital or pelvic site. In addition as the morcellation took place in a bag it is unlikely that the morcellation led to the dissemination of the cancer and therefore if the endometrial cancer had been diagnosed there is no assurance the outcome would have differed. If endometrial cancer was diagnosed adjuvant treatment would only have been recommended if there was deep myometrial invasion a high grade tumour or metastatic disease, it would seem most likely that if a cancer had been missed it would have been small low grade and without significant myometrial invasion.

An additional note is that generally laparoscopic hysterectomy is associated with less blood loss and a shorter hospital stay as compared with open hysterectomy. Particularly in mind that [Ms A] would not accept a blood transfusion in the absence of possible malignancy there would have been clear advantages to minimally invasive surgery for the patient.

4 The adequacy of changes made by [the DHB].

The submission made by [Dr D] reflects a detailed and open review of the case. The errors and shortcomings are acknowledged and appropriate measures are taken.

However I have significant concern that in general terms throughout many services in New Zealand that access to gynaecological services are limited by resource. This includes specialist staff, access to outpatients and operative time and clerical staff. This not infrequently leads to delays in management of women with possible or suspected malignancy. Such delays may lead to poorer outcomes and increased inequity for women with gynaecological cancer. I believe if the HDC is able to identify this pattern through this and other cases it should be brought to the attention of [the DHB] and Ministry of Health.

5 Any other matters in this case that amount to departure from accepted practice.

It is important to note that the history of Atypical endometrial hyperplasia was not documented on the pathology form. This was essential information for the pathologist

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and failure to do this a deviation from standard practice and a potential risk to the patient. Such medical clerical errors however are common, review of clinical information on pathology forms should be a part of theatre sign out.

Signed P Sykes 18/6/20"

Addendum

"Having read the supplied information I do not believe my opinion should be altered in any way. It appears that [the DHB] has performed a thorough and appropriate review of this case and done their best to action appropriate changes. While I agree with [Dr C] that minimally invasive surgery offers benefits for women with endometrial cancer I do not believe in normal circumstances any gynaeoncologist or gynaecologic pathologist would support uterine morcellation in patients with atypical endometrial hyperplasia as it is well documented a significant proportion of these women will have endometrial cancer. Morcellation will increase the risk of tumour dissemination as well as inhibit adequate histological examination. I believe it may be appropriate for the HDC to write to the Royal Australia and New Zealand College of O&G and ask them to consider reviewing their guideline. I would be happy to do so at the Commissioner's request."

Addendum 16 March 2022

"I think it is correct to say that general gynaecologists are aware that a proportion of women with a pipelle biopsy revealing CAH actually have endometrial cancer. I also believe most gynaecologists would manage a woman with this in mind. The minimum expected preoperative assessment would be a pelvic ultrasound to exclude a large uterine tumour or ovarian masses. I don't believe many gynaecologists would consider that morcellation would be appropriate in the presence of a known cancer and that in the presence of CAH they would also avoid it. However with the lack of clear (RANZCOG) guidelines I expect that some gynaecologists would believe the risk benefit calculation to be in favour of minimally invasive surgery even if morcellation was required. I am sorry I cannot be more definitive however as you are aware individual practitioners have varied practices and while some would consider morcellation acceptable others would not."

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Appendix B: "Tissue Extraction at Minimally Invasive Procedures"

Australasian Gynaecological Endoscopy and Surgery Society and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists Guideline (March 2017)

"… Gynaecologists recognise that tissue extraction by morcellation may be associated with a number of risks:

1. Patient injury: other tissue, such as bowel, other pelvic organs intended to stay in the body or blood vessels may be inadvertently injured during the morcellation process. The efficiency of electromechanical morcellation poses a specific hazard in this setting.

2. Dissemination: fragments of tissue generated by the morcellation process may disseminate throughout the peritoneal cavity. This has been reported for both benign disease (fibroids, endometriosis) and malignancy where this may have a detrimental effect on prognosis and/or increase the need for adjuvant treatment. Concerns have been expressed that electromechanical morcellators may increase the risk of dissemination by creating a larger volume of smaller fragments.

3. Pathology: the size of the fragments and, at times, the loss of anatomical relationships, may complicate the diagnosis by the pathologist. Concerns have been expressed that electromechanical morcellation may yield a large volume of small and dissociated fragments, which may further complicate analysis.

…

3.1.2 Dissemination The dissemination of both benign and malignant disease cannot be completely prevented if a decision is made to morcellate a specimen. However, appropriate steps may be taken to minimise this risk:

3.1.2.1 Case Selection Patients requiring a hysterectomy or removal of an abdominopelvic mass represent a heterogeneous group, each with inherent risk factors. As such, it is not possible to distil the assessment of any patient to a simple decision matrix. This assessment is inherent to the core knowledge of a specialist in obstetrics and gynaecology.

3.1.2.2 Preoperative Assessment Patients should have an appropriate history and examination performed, specifically to assess the risk of malignancy. Routine preoperative investigations should include a Pap smear and an ultrasound. Further investigations must be targeted to the type of pathology and may include blood tests, such as tumour markers, endometrial sampling and/or extended imaging.

3.1.2.3 Consent Patients must be engaged in the discussion of the risks and benefits of the route of any proposed surgical procedure, including the mechanism of tissue extraction. This discussion should include the risks, benefits and likely outcomes of alternative management options.

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3.1.2.4 Intraoperative Assessment Clinical intraoperative assessment of a pelvic mass is difficult and inaccurate. If gynaecologists unexpectedly encounter suspicious pathology, it may be appropriate to abandon the procedure, seek the advice of a gynaecological oncologist intraoperatively or avoid techniques that may increase the risk of dissemination, such as morcellation. Consider options to minimize the potential risks of tumour spread, such as mini-laparotomy or extraction with an endopouch.

3.2 Pathological assessment The postoperative histopathological diagnosis of a morcellated specimen may be compromised. It is recommended that members seek the opinion of a gynaecological oncologist and specialised pathologist in the diagnosis of any gynaecological malignancy, whether expected or unexpected.

3.3 Specific Consideration: Leiomyosarcoma In April 2014, the United States Food and Drug Administration (FDA) issued an FDA Safety Communication regarding power morcellation in hysterectomy and myomectomy, followed shortly by a Safety Alert on laparoscopic power morcellators from the Australian Therapeutic Goods Administration (TGA). These alerts Tissue Extraction at Minimally Invasive Procedures C-Gyn 33 5 reacted to reports of adverse patient outcomes in patients with fibroids related to the potential for the devices to spread malignant cells in patients with previously undetected malignancy. The specific problem posed by the diagnosis of uterine sarcoma, is that there are no reliable preoperative diagnostic tools to differentiate malignant mesenchymal tumours of the uterus from their benign counterparts. Local gynaecological units are encouraged to develop their own guidelines, based on the availability of local resources and expertise. The incidence of leiomyosarcoma (LMS) has been variably quoted at between 0.02 to 0.3%, depending on the study population. The difficulty in attaining an exact incidence relates to both case capture and the determination of an appropriate denominator. Reported demographic risk factors for LMS include:

- Age (mean age of diagnosis: 60)
- Menopausal status
- African American ethnic background
- Current or prior tamoxifen exposure
- History of pelvic Irradiation
- Hereditary Leiomyomatosis and Renal Cell Carcinoma (HLRCC) syndrome
- Survivors of childhood retinoblastoma

In the clinical assessment, practitioners should be alert to the possibility of malignancy, if:

- Rapidly expanding mass
- Postmenopausal bleeding or variants of abnormal uterine bleeding, in premenopausal women with an unusual pattern

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- Ascites
- Lymphadenopathy
- Evidence of secondary spread

A cervical screening test should be taken and endometrial assessment be performed by imaging and/or endometrial sampling prior to engaging in any invasive procedure if there is a history of abnormal uterine bleeding. Patients should have preoperative imaging by ultrasound or MRI, with reference to local guidelines.

Risk factors for LMS include:

- Large size or large interval growth
- Tissue signal heterogeneity
- Central necrosis
- Ill-defined margins
- Ascites
- Metastases

With the exception of the last two elements, it is recognised that these features have a significant overlap with degenerating fibroids. There are no established tumour markers for LMS, though there may be an elevation in LDH, related to an increased cell turnover.

…

Recommendation 1

Patients must be engaged in the discussion of the method of tissue extraction. This discussion should include the risks and benefits of alternative management options.

Recommendation 2

Morcellation of a fibroid or uterus should only be performed in the absence of a suspicion of malignancy.

Recommendation 3

Practitioner should be credentialed for the use of an electromechanical morcellator by the local credentialing committee.

Conclusion

It is recognised that these measures will not completely preclude the occurrence of an unsuspected malignancy at myomectomy or hysterectomy. If the diagnosis is made postoperatively, early consultation with a gynaecological oncologist is mandatory."

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