Obstetrician and Gynaecologist, Dr B
Private Hospital
District Health Board

A Report by the
Deputy Health and Disability Commissioner

(Case 17HDC00636)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. A woman suffered an extremely unfortunate outcome from an apparently routine thermal ablation procedure, caused by thermal damage during the procedure.

2. This report considers aspects of the care provided to the woman, including the adequacy of the information she was provided, whether the procedure was carried out with reasonable care and skill, and whether her postoperative management was reasonable and in accordance with accepted standards.

Findings

3. The Deputy Commissioner found that aspects of the services provided to the woman by the obstetrician and gynaecologist were inadequate, and breached Right 4(1) of the Code. The Deputy Commissioner considered that the obstetrician and gynaecologist should have proceeded with caution when she encountered difficulties during the ablation procedure, and should have documented the complications that occurred. The Deputy Commissioner also considered that the obstetrician and gynaecologist should have ensured adequate monitoring and follow-up before the woman was discharged, and, when the obstetrician and gynaecologist saw the woman the following day at the public hospital, referred her to the on-call Gynaecology team. The Deputy Commissioner was unable to conclude that information about the very rare risk of thermal injury is information that a reasonable consumer would expect to receive in similar circumstances.

4. The Deputy Commissioner was critical of aspects of the systems in place at the district health board (DHB), in particular the lack of clear guidelines for patients from a private outpatient context being assessed at its facilities.

5. The Deputy Commissioner was satisfied that the care provided by the private hospital, where the thermal ablation procedure was performed, was adequate.

Recommendations

6. In response to the recommendation in the provisional report, Dr B provided a written apology to the woman.

7. The DHB agreed to undertake an audit of its clinicians' private gynaecology patients who are referred or transferred to the public hospital for review, to ensure that they have been referred to and admitted by the acute team in accordance with its updated policy.

Complaint and investigation

8. The Commissioner received a complaint from Ms A about the services provided to her by Dr B. The following issues were identified for investigation:

- *Whether Dr B provided Ms A with an appropriate standard of care between 27 February 2017 and 23 March 2017.*
- *Whether the private hospital provided Ms A with an appropriate standard of care on 21 March 2017 and 22 March 2017.*
- *Whether the district health board provided Ms A with an appropriate standard of care in March 2017.*

9. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Dr B	Provider/obstetrician and gynaecologist
Private hospital	Provider/private hospital
District health board	Provider/DHB

10. Further information was received from:

Dr C	Anaesthetist
Dr D	Obstetrician and gynaecologist

11. Also mentioned in this report:

RN E	Registered nurse
Dr F	Obstetrician and gynaecologist
Dr G	Obstetrician and gynaecologist
Dr H	Specialist gynaecologist

12. Independent expert advice was obtained from an obstetrician and gynaecologist, Dr Celia Devenish (Appendix A).

Information gathered during investigation

13. On 27 February 2017, Ms A consulted obstetrician and gynaecologist Dr B in private rooms regarding treatment for menorrhagia[1] and contraceptive options. Dr B recommended endometrial ablation[2] to control the heavy bleeding, and a Multiload intrauterine contraceptive device[3] (IUCD) for Ms A's contraceptive needs.

Ablation process

14. The ablation process involves the dilation of a woman's cervix, insertion of a wand and a triangular-shaped netted device, and expansion of the netting to fit the size and shape of the uterus. Radiofrequency energy is then delivered through the netting for about 90 seconds to ablate[4] the endometrium.[5] The netted device is then pulled back into the wand, and both are removed from the uterus.

15. The device's "Instructions for Use" state that the safety and effectiveness of the system has not been evaluated in patients "with bicornuate,[6] septate or sub-septate uteri[7]". Under "Other Adverse Events", the instructions state:

> "As with all endometrial ablation procedures, serious injury or death can occur …
>
> [The following adverse events] could occur or have been reported in association with the use of the [device] system: … thermal injury to adjacent tissue … perforation of the uterine wall."

16. Contraindications include the following:

- A patient with a uterine cavity length less than 4cm. The Instructions for Use state: "The minimum length of the electrode array is 4cm. Treatment of a uterine cavity with a length less than 4cm will result in thermal injury to the endocervical canal."
- A patient with a uterine cavity width less than 2.5cm, as determined by the width dial of the disposable device following device deployment.

17. Under the heading "Precautions", the Instructions for Use state:

> "• It has been reported in the literature that patients with a severely anteverted,[8] retroflexed or laterally displaced uterus are at greater risk of uterine wall perforation during any intrauterine manipulation.

[1] Heavy menstrual bleeding.
[2] Removal of a thin layer of tissue in the uterus.
[3] A device inserted into and left in the uterus to prevent effective conception.
[4] Remove or destroy.
[5] The inner lining of the uterus.
[6] A condition in which the uterus has two cavities instead of one.
[7] A condition in which a septum (wall of tissue) divides the inner portion of the uterus at its middle; the septum may extend part-way down the uterus or all the way down.
[8] The uterus is tilted towards the front of the abdomen.

- A false passage can occur during any procedure in which the uterus is instrumented, especially in cases of severe anteverted, retroflexed or laterally displaced uterus. Use caution to ensure that the device is properly positioned in the uterine cavity."

Consent

18. In describing the consenting process, Dr B stated:

> "I explained the device is inserted into the uterus, heats up to ablate the endometrium, and is then removed. I also explained the quoted success rates with satisfaction rates of about 90%. I explained the risks of surgery including infection, bleeding and uterine perforation … I explained that if a perforation had occurred, or a false passage made, the procedure would have to be abandoned and I may have to perform a laparoscopy to check for injury to internal organs … I also explained that if I had any concern with the appearance of the endometrium at the time of hysteroscopy that I would not proceed with the ablation."

19. Dr B told HDC that she supplemented this information by giving Ms A a brochure which lists the risks of the procedure as perforation, bleeding, infection, bradycardia,[9] injury to organs within the abdomen around the uterus, or complications leading to serious injury or death. The brochure states that these problems are very rare, and reported at a rate of less than 0.05%.

20. A written consent form for a hysteroscopy,[10] dilation and curettage,[11] ablation, and insertion of a Multiload IUCD was signed by both Dr B and Ms A, and dated 28 February 2017. The private hospital told HDC that the consent form used was a generic form used by all specialities, with space provided for the specialist to record discussion of risk factors specific to the procedure. Dr B documented on the form the risks of infection, bleeding, and uterine perforation.

21. Ms A stated that she does not recall being informed of the process and risks, as described by Dr B. Ms A said that the brochure she was given describes the procedure as quick, easy, and pain free, and, while it lists the risks, these are detailed as occurring in 0.05% of cases which Ms A said was "all very misleading".

22. Dr B did not specifically discuss the risk of thermal injury. She said that although she did discuss the risk of uterine perforation and the risk of injury to the bowel, she did not go into detail about all the potential ways in which the internal organs could be injured. She said that thermal injury is very rare, and it would not be practicable to go through every potential risk. Dr B stated:

[9] A slow heart rate of less than 60 beats per minute in adults.
[10] Visual examination of the cervix and interior of the uterus.
[11] A procedure in which the cervix is made larger and the inner lining is scraped to remove uterine tissue and contents.

> "I was not aware at that time nor was it widely known that there had been very rare cases of thermal injury in patients with an intact uterus or with a partial penetration of the uterine wall."

23. Further to this, Dr B said that from discussion with the Medical Director at the device manufacturer, it is her understanding that the risk of thermal injury with the device is 1:15,000, and the majority of historical cases relating to thermal injury were associated with an override of the safety mechanism alerting surgeons to uterine perforation. Dr B noted that the requirement is for patients to be informed of the expected risks of treatment, and stated: "A risk of 1/15,000 is not an expected risk." She also noted that the manufacturer's reference guide for the device does not mention thermal injury to surrounding organs as being something that women should be counselled about.

24. Dr B told HDC:

> "[This risk rate] was only obtained or known by me, after direct and explicit inquiry I made with the Medical Director of the device manufacturer … it was not a published rate that would have, at that time, been known by my peers."

25. Dr B said that the consenting process in place at the public hospital for hydrothermal ablation procedures, including this device, does not specifically mention thermal injury to the bladder or bowel. Dr B stated: "[T]herefore in my written consent I believe that I was acting as my peers certainly at [the public hospital] would do in my consenting."

26. Dr B provided a number of informed consent brochures from other hospitals internationally, none of which refer to thermal injury as a potential complication of endometrial ablation.

27. Dr B said that she has spoken widely with her colleagues and others familiar with the procedures, and only one other person was aware of the risk of thermal injury. She stated:

> "Unquestionably, my practice at the time was in keeping with that of my peers with respect to discussion of the risk of internal organ injury associated with perforation of the uterus and the potential need for surgery associated with this."

28. In relation to the preoperative assessment she carried out and any consideration given to performing an ultrasound scan prior to surgery, Dr B noted that Ms A had no past medical history that would warrant an ultrasound scan prior to surgery. Dr B stated: "An ultrasound is not a universal requirement in younger women being worked up for menorrhagia." Dr B also said:

> "[Ms A] was young, very slim and her uterus was easily palpable, she had no other symptoms apart from moderately heavy menstrual bleeding to indicate for example uterine polyp. Had my examination revealed an enlarged uterus or other pathology I would have routinely ordered an ultrasound. I believe my practice was in keeping with international guidelines."

29. Dr B told HDC that a number of international guidelines[12] for menorrhagia do not support undertaking a pelvic ultrasound as part of a general work-up for menstrual disorders. Dr B noted that because the device works by impedance, measurement of the uterine wall thickness is not required prior to ablation.

30. Dr B explained that her usual practice is to perform a hysteroscopy prior to the ablation procedure, "which more effectively examined the uterine cavity than an ultrasound".

Procedure — 21 March 2017

31. On 21 March 2017, Ms A attended the private hospital. Dr B stated that she again discussed the risks and benefits of the surgery with Ms A and completed a written consent, which specifically noted infection, bleeding, and uterine perforation as risks of the procedure.

32. Ms A told HDC that she does not recall discussing the procedure with Dr B, but she does recall talking to another doctor.

33. Ms A was transferred to the operating theatre at 9.24am. Dr B performed a bimanual examination and then carried out a routine hysteroscopy dilation and curettage. Dr B then proceeded with the ablation procedure.

34. On the handwritten operation record completed by Dr B on 21 March 2017, it is recorded that the uterine length at the cornua[13] was 9.5cm and 8.5cm to the septum,[14] and that Ms A had a subseptate uterus. However, an electronic record subsequently completed by Dr B stated that Ms A had an "[a]cutely anteverted, anteflexed[15] uterus that was arcuate[16]". Dr B explained that the typed operation note is always more specific than the handwritten note, and that when completing her typed notes she looked up the definition of an arcuate uterus and felt that "this accurately described [her] hysteroscopic findings, a subseptate uterus did not". Dr B told HDC: "The reason I described the uterus as being arcuate was because of a slight curving towards the cornua."

35. Dr B explained:

> "An arcuate uterine shape is common present in up to 5% of the population and regarded as a normal variant, it is not a contraindication to [ablation with this device] nor is it a relative contraindication."

36. After Dr B had performed the hysteroscopy and confirmed that there was no issue that contraindicated a thermal ablation using the device, she proceeded with the procedure.

[12] For example, the National Institute for Health and Care Excellence, "Heavy menstrual bleeding: assessment and management" (14 March 2018) and the Australian Commission on Safety and Quality in Health Care, "Heavy Menstrual Bleeding Clinical Care Standard" (October 2017).
[13] The entry points of the fallopian tubes into the uterine cavity.
[14] The membrane dividing the uterine cavity.
[15] The uterus tilts forward at the cervix.
[16] A uterine abnormality where the uterine cavity displays a concave contour towards the top of the uterus.

37. Dr B told HDC that she did a pre-test of fully opening the device, which was set at a cavity length of 5.5cm (the cervical length being 3cm). She then inserted the device, but it did not open satisfactorily, so she removed the device to check whether it was functioning correctly. Dr B said that she fully opened the device and depressed it centrally to ascertain how much pressure it would take for the device to follow the contour of the uterus. She found this to be excessive, so she reduced the length of the device to 5cm. She stated that this meant that the device would sit at or just below the lowest part of the septum, in which case the procedure would not stop Ms A's menstruation completely but she would have a "very significant reduction in bleeding".

38. The operation note confirms that Dr B inserted the device with a length of 5.5cm but that it did not open easily, so she withdrew it and reduced the length to 5cm, and "[t]he device was manipulated in routine fashion". Dr B explained that she applied "gentle central depression of the device". She stated:

> "I did not tamper with the device at all and the performance [of the device] was thus unchanged. The device is designed to open and close and be withdrawn into a very narrow sheath, and thus by design needs to be flexible and robust."

39. Dr B provided a further explanation of this part of the process. She stated:

> "I merely gently depressed the central portion momentarily which then immediately resumed its normal shape. The movement was in millimetres and the device was not damaged, bent or changed in any permanent way that could change function.
>
> [The device] is designed to be flexible to expand and contract back into a very narrow sheath many times without being damaged. In seating [this] device there are set safety tolerances. At no time did I breach the safety margins outlined by the device manufacturer and nor did I perform the ablation outside the recommendations."

40. Dr B told HDC that there were no findings that would contraindicate undertaking the procedure on Ms A. Dr B stated: "I always perform a hysteroscopy prior to an ablation in order to assess the endometrial cavity, its integrity and to obtain a thorough sampling of the endometrium." She said that the finding of an arcuate uterus is not a contraindication to the use of the device, and that she allowed for this by reducing the length of the device to 5cm. Dr B stated that she does not believe that this finding was a reason to terminate the procedure. Dr B said that she does not consider that she needed to wake up Ms A to explain that she had a uterine shape regarded as a normal variant and present in 5% of the population, and that this would not be reflective of accepted practice at the time.

41. Dr B also considers that the failure of the device to open initially was not reason to terminate the procedure. She noted that the device had passed the safety check, and stated: "Had the device failed the safety check I would not have proceeded or been able to proceed with the ablation."

42. Dr B submitted that this was not a failed attempt, as she did not deploy the device, she was merely trying to seat it in a satisfactory manner. She stated: "This is routine and if one

is not satisfied following seating manoeuvres then the advice is to remove, check the array and retry which I did." Dr B stated that having discussed this with her colleagues, they confirmed that this is also what they would do.

43. Dr B then re-inserted the device. She said that she used the recommended seating techniques for the device, and applied counter traction to the uterus, and the device opened to a width of 2.7cm (above the minimum recommended width of 2.5cm).

44. Dr B stated that she has performed over 180 endometrial ablations, and that the seating of the device did not feel any different to the other cases. The device passed the cavity check first time and automatically went on to perform the ablation cycle with 74 watts of energy over 55 seconds.

45. The anaesthetist for the procedure, Dr C, told HDC that other than Dr B's comment that there was a partial uterine septum (the uterine cavity is only partially separated)[17] the surgery was uneventful. He said:

> "Specifically, the [endometrial ablation with the device] went as straightforwardly as the many similar procedures that [Dr B] and I have been involved with in the past. From my point of view, the variable tone made by [the machine] was no different to usual, and the duration of the ablation process was no different to usual."

46. After the ablation, Dr B undertook a repeat hysteroscopy. She said that the "uterine cavity immediately filled with fluid indicating no uterine perforation". She noted that about 80–85% of the uterine cavity had a thermal effect, and the cavity distended immediately and easily with fluid. Dr B then inserted a multi-load IUCD.

47. At 10.05am, Ms A was transferred to the recovery room. According to the clinical records, Ms A woke up at 10.17am. On waking she was reported to be "tearful … due to having a very sore throat". Dr C subsequently reviewed Ms A and administered a topical local anaesthetic spray. Ms A was also noted to have 6/10 abdominal pain, and was given morphine and sevredol "[with] some effect" for pain relief. At 11.25am, Ms A was transferred to the ward. She was noted to be feeling well and keen to go home, and Dr B did not review her before she was discharged.

48. The private hospital said that on discharge, Ms A was advised to contact her surgeon directly or seek advice from her general practitioner if she had any concerns. Ms A was given a copy of her operation note and an information sheet on hysteroscopy dilation and curettage procedures. The sheet outlines what to expect following the procedure, including some vaginal bleeding and mild, cramping abdominal pain that could be relieved by paracetamol.

22 March 2017

49. On 22 March 2017, Ms A began to experience what she described as severe, contraction-like pain in her pelvis.

[17] As noted above, this description was later updated by Dr B in the electronic records.

50. The private hospital told HDC that Ms A contacted the hospital reception by telephone requesting the contact details for Dr C. The scrub nurse, RN E, who had been present during the procedure the previous day, was at reception at the time of Ms A's call, and spoke to her. RN E said that Ms A described increasing pain and discomfort, and requested that the hospital contact the anaesthetist. RN E said that she told Ms A that Dr C was not working at the private hospital that day, but agreed to contact him. RN E also suggested that Ms A contact her general practitioner or call an ambulance if the pain was severe, but Ms A declined to do so.

51. RN E said that she contacted Dr C, who agreed to contact Ms A directly. RN E also reported the conversation to the theatre manager.

52. Dr C said that immediately after he received the call from RN E, he contacted Ms A, who described severe "crampy" type pain. Ms A told him that she had contacted her general practitioner, who was faxing a prescription for additional pain relief to her local pharmacy. Dr C said that he explained to Ms A that it was "very unusual to be experiencing such severe pain after the particular combination of procedures that she had undergone, and rather than just taking painkillers, she should be reviewed by [Dr B]".

53. Dr C said that he then contacted Dr B, who told him that she would arrange to review Ms A at the public hospital. Dr C sent a text message to Ms A to advise her to expect a telephone call from Dr B.

54. Dr B telephoned Ms A, who described severe pain that was coming in waves. That day, Dr B was working at the public hospital in a non-clinical capacity, and she arranged for Ms A to attend the public hospital and contact her directly when she arrived, rather than go through the Emergency Department. Dr B stated:

> "I did not anticipate she would require any acute gynaecological intervention or admission, only a consultation. … If I had suspected [Ms A] would need a hospital admission I would certainly have asked her to go through to the emergency department."

55. At the time of these events, the DHB did not have a policy in place relating to assessment of private out-patients. The DHB told HDC that at the time, there was an "unwritten expectation" that a private patient would be admitted under the acute team, but this was not a formally documented policy.

Assessment by Dr B at the public hospital

56. Dr B assessed Ms A in the gynaecology unit. Dr B noted that Ms A's pain was centred on the uterus, and she described it as being typical of period-type pain. Dr B said that Ms A's pain was not constant and severe, and she did not have shoulder tip pain, "ie there were not symptoms in [Ms A's] history that would have been typical of a bowel injury and bowel perforation".

57. Dr B examined Ms A and noted that her abdomen was soft and not tender, with no signs of peritonitis, "ie no tenderness, guarding or rebound". Dr B said that a speculum

examination was difficult because the uterus was anteverted and anteflexed and, as a result, she was unable to see the IUCD strings. She said that at that stage her differential diagnoses were that the IUCD was sitting low in the uterine cavity, or it was embedded in the uterine wall. She considered that the possibility of perforation was unlikely, "given the cavity check passed first time and the cavity had distended promptly and easily in the post ablation hysteroscopy".

58. Dr B decided to conduct a transabdominal and transvaginal ultrasound scan,[18] and asked Obstetrician and Gynaecologist Dr F to assist. Dr F said that she did not record her findings, as this was an informal scan, but her recollection, as provided to the Serious and Sentinel Events (SSE) team within a few weeks of the incident, was as follows:

> "No obvious myometrial defect was detected. Endometrium was thin. A longitudinal echogenic object could be identified, located obliquely at the lower intra-uterine cavity. This was most certainly the vertical arm of the intrauterine contraceptive device (IUCD). The horizontal arm could not be identified within the uterine cavity during the limited time of examination. No pelvic free fluid seen."

59. Dr B said: "[A]t this point my clinical impression was that firstly [Ms A] was tender because of her recent ablation and secondly the cramps could be related to her rejecting the [IUCD]." Dr B's clinical records state: "[On examination] USS [ultrasound scan] — [Dr F] — ? [IUCD] sitting in canal of cervix. No free fluid." It is noted that the speculum examination was painful, and that the IUCD strings were not visible. Dr B recorded her impression as: "Rejecting [IUCD] or [IUCD] within muscle wall." She decided to admit Ms A and remove the IUCD in theatre under general anaesthetic. Dr B stated:

> "At this point I realised that [Ms A] required admission and so asked the ward clerk if she could do this, explaining I had [Ms A] in the treatment room and had not expected her to need admission. On transfer to the ward I requested a set of vital observations to be taken."

60. Dr B said that she also discussed Ms A's case with the on-call gynaecology registrar.

Removal of IUCD

61. An operating theatre became available immediately, so Ms A was taken into theatre at 3.15pm, and her observations were taken when she reached the theatre. Dr B stated that under normal circumstances observations would be done in the ward setting, but in this case there was not enough time.

62. Dr B also stated that she had discussed Ms A's case with the on-call registrar, and had the theatre slot not been available until after 5pm, rather than immediately, she would have called the on-call consultant to provide a detailed handover.

[18] A diagnostic procedure using ultrasound — either through the abdomen (transabdominal) or through the vagina (transvaginal) — to provide images of the uterus.

63. Once in theatre, Dr B attempted to grasp the IUCD but was unsuccessful, so she contacted the on-call obstetrician, Dr G, to assist with the visualisation of the tip of the forceps while Dr B grasped the IUCD. Dr B stated: "I wanted ultrasound guidance during the procedure to assist me in view of [Ms A's] recent surgery."

64. Dr B noted that although Dr G was the on-call obstetrician that day, she "has very significant gynaecological experience". Dr B stated: "[W]ithout doubt, in calling [Dr G], I called the most appropriate clinician available."

65. Dr G said that she checked that Dr B wanted her to attend rather than the on-call gynaecologist. Dr B confirmed that she did want Dr G because of Dr G's experience with ultrasound scanning. Once in theatre and briefed on the situation, Dr G suggested using a pelican retriever, under ultrasound guidance. However, there was a delay in obtaining the correct instrument, and Dr G proceeded with the ultrasound scan using a portable scanner. Dr G told HDC: "While scanning, I noted a lot of free fluid in the abdomen/pelvis and the uterine contour was fuzzy and not well lineated."

66. Dr G said that she raised with Dr B the possibility of uterine perforation, but Dr B considered that the fluid visible was saline that had been inserted during the previous procedure coming out of the fallopian tubes. Dr G stated that the portable ultrasound scanner "is not the best diagnostic tool" and, given that Dr B had extensively viewed the uterine cavity and had not noted a perforation, she considered that Dr B's explanation was reasonable.

67. Dr B stated that at the time of the procedure, she had more information than Dr G. Dr B also said that the quality of the scan images was inferior to the ones Dr F had obtained preoperatively, but they were adequate to be able to see the tip of the forceps.

68. Dr B explained that at that time Ms A was not exhibiting any signs of peritonism,[19] and there was no indication that perforation had occurred. Dr B stated:

> "At the time, I most definitely considered perforation or peritonitis as possible causes of [Ms A's] pain. I undertook a careful abdominal examination and noted no guarding or rebound tenderness. This important observation on examination reasonably excludes peritonitis. Likewise, my questioning of the presence of the contour and any free fluid on the scan performed by [Dr F] using a high-performance GE machine, indicates I was appropriately enquiring into a possible perforation."

69. Further to this, Dr B stated:

> "Fluid surrounding the uterus was only apparent after the hysteroscopy was performed. It is normal for fluid to pass via the fallopian tubes into the pelvis during a hysteroscopy and thus fluid would be expected on ultrasound at this point. If perforation of the uterus has occurred the cavity does not distend well during hysteroscopy and visibility is generally poor due to the presence of blood. In this case

[19] Localised inflammation of the peritoneum (the membrane that forms the abdominal cavity).

> the cavity did distend well, the visibility was good and the [IUCD] was in situ; I had no good reason to make a diagnosis of uterine perforation."

70. Dr G attempted the IUCD removal with the available equipment, but was unsuccessful. Dr G said that she discussed the options with Dr B, which included doing nothing and trying again later, removing the IUCD using hysteroscopy and laparoscopy,[20] or removing it using a pelican retriever. Dr G said that she also queried whether another opinion should be sought, and recommended the option of using a laparoscope to allow visualisation of the outside of the uterus to observe for perforation.

71. Dr B decided to proceed with a pelican retriever, which eventually was located, and the IUCD was removed successfully.

72. Dr G said that she did not document her involvement in the case in the clinical records because she had to return to her duties, and she left Dr B to complete the documentation.

73. At 5.23pm, Ms A was taken to recovery, and then to the gynaecology ward, where she was monitored. Dr B documented on the operation record that Ms A could go home when she was comfortable, either that evening or the following morning. Dr B stated:

> "I talked at length with [Ms A] in recovery explaining the surgery and suggesting and encouraging she stay overnight to rest and recover. [Ms A] remained extremely keen to get home, thus, reluctantly, I said that providing she was clinically well, and ONLY if she was clinically well according to medical staff, she could go home that night."

74. At 11.15pm, Ms A was discharged from hospital with Buscopan for pain relief.

75. The DHB told HDC that Dr B's working diagnosis was pain owing to a misplaced IUCD. The DHB stated that in these circumstances it was reasonable for Ms A to go home, and it was not clinically indicated for her to stay in hospital overnight, but that had there been a suspicion of bowel perforation, it would have been appropriate for her to remain overnight. Furthermore, the DHB stated that the decision to discharge Ms A was in accordance with the relevant guideline, "Discharge criteria following day surgery".

23 March 2017

76. On 23 March 2017, Ms A experienced "more severe pain which just kept getting worse", so she called an ambulance and was taken to the public hospital.

77. At 6.20pm, Ms A was assessed by emergency department medical staff and noted to have a distended abdomen with local peritonism. A chest X-ray showed free air under the diaphragm consistent with intra-abdominal perforation. A CT scan was then ordered, which showed a large volume of free air and a large perforation at the fundus of the uterus.

[20] Examination of the organs inside the abdomen.

78. On 24 March 2017, Ms A was taken to theatre, where a hysterectomy[21] and bilateral salpingectomy[22] were performed, as well as a Hartmann's procedure[23] and an associated stoma.[24] Histological findings revealed that Ms A had suffered a thermal injury at the fundus of the uterus.

79. Dr B noted that the uterine pathology specimen "shows a smooth serosal surface[25] with a tiny area of serosa 4×2 mm that is thermally affected that has slightly lifted". She stated: "This specimen **did not** show a large uterine fundal perforation [emphasis in original]."

Further information from Dr B

80. Dr B stated:

> "I am very aware of the enormous distress this complication and the need for a hysterectomy and stoma has caused [Ms A] and the interruption to her personal and professional life. I could not be more sorry."

81. Dr B told HDC that on learning of the diagnosis, she contacted the pathologist and the medical director of the device manufacturer to try to understand how this could have happened. She obtained permission from Ms A to send the manufacturer's medical director a copy of the pathology report and images.

82. Additionally, Dr B informed the private hospital's clinical director of the incident, and had the machine removed to check for faults. She also notified the DHB of the complication.

83. Dr B said that the manufacturer's guidelines do not state that an arcuate uterus is a contraindication to the procedure, and she specifically asked the manufacturer whether an arcuate uterus is a contraindication to ablation and was told that it was not, but the manufacturer declined to put this in writing.

84. Dr B told HDC that she no longer performs this procedure.

Further information from the DHB

Guidelines

85. The DHB told HDC that at the time of these events the guidelines for "transferring and re-admitting Patients from Private Surgical Hospitals to [the public hospital]" was not explicit regarding admitting patients under the acute team, although this was "custom and practice".

86. The DHB also did not have any policies or guidelines in relation to the documentation of ultrasound scans performed outside the Radiology Department. The DHB said that this is not an issue isolated to its hospitals.

[21] An operation to remove the uterus.
[22] Removal of one or both of the fallopian tubes.
[23] An operation to remove part of the sigmoid colon and/or the rectum.
[24] Diversion of the bowel to an opening in the abdominal wall.
[25] Lining of the uterus.

The DHB's Serious and Sentinel Event (SSE) review

87. Following the incident, the DHB conducted an SSE review, which identified the following key findings:

a) The standard acute review and admission process was not followed, which resulted in an incomplete work-up prior to surgery, and the acute gynaecology team was not informed.

b) The process for informal point-of-care scans is unclear, resulting in poor documentation.

88. The SSE review also identified the following:

- The guidelines for admission of patients from private hospitals did not include outpatient presentations.
- A lithotomy bed[26] was available only in the gynaecology unit, which influenced where Dr B saw Ms A.
- There was a lack of variety of surgical equipment.

89. The review team made a number of recommendations, including the following:

a) A review of admission processes for acute presentation of private outpatients.

b) A refresh of the requirement to document conversations/findings.

c) The establishment of a private space in the emergency department with a lithotomy bed.

d) A review of the requirement for surgical instruments and equipment in operating theatres.

90. The review team met with Ms A on 22 August 2017 to apologise to her for the distress caused by this incident and to discuss the report findings with her.

Changes made by the DHB

91. The DHB advised that the policy covering admission from private surgical hospitals — "Transferring and re-admitting Patients from Private Surgical Hospitals to [the public hospital]" — has now been updated to ensure that patients are admitted under an acute team, which takes over clinical care of the patient.

92. In relation to the recording of informal scan images, the DHB stated: "[The DHB] is investing in a software package that can gather 'informal' scan images from portable machines and attach them to the patient's clinical records." The Q-Path-E Integration was introduced in the emergency department in 2020, and the DHB reported that this is working well.

[26] A bed that facilitates the lithotomy position (supine position of the body with the legs separated, flexed, and supported in raised stirrups).

93. The requirement to document conversations and/or findings relating to a patient has been communicated to staff through departmental operational and educational meetings.

94. The DHB advised that there are sufficient private rooms in the emergency department for gynaecological assessments. If a woman is admitted under the gynaecology team, assessment will take place on the gynaecology unit, where a lithotomy bed is available. The DHB said that it is not practicable to introduce a lithotomy bed in the emergency department.

95. A pelican retriever is now available in acute theatres.

96. The DHB advised that Ms A's case was presented in an anonymised form to an "Audit of Gynaecology Complications" meeting in 2017. The meeting was attended by women's health doctors and "enables the service to monitor procedures and ensure that [the DHB] is practicing within international rates of complications".

97. The DHB also advised that since this incident it has been closely monitoring ablation procedures, and advised that out of the 124 ablation cases performed at the DHB, only one required hospital admission, and this was for an infection.

Further comment

98. The DHB stated that "[it] would like to formally apologise again to [Ms A] for her experience", and offered a further opportunity for Ms A to meet to discuss the case.

Dr D — opinion

99. As part of her response to HDC, Dr B provided an opinion from obstetrician and gynaecologist Dr D. Dr D was part of the DHB's SSE review team.

100. With regard to the consenting process, Dr D stated that he would expect the risk of uterine perforation and bowel injury to be discussed, "but not necessarily the exact range of all possible ways of injuring internal organs". He noted that the DHB had a standard form for preoperative hysteroscopy and ablation, which had been developed by the wider consultant body and approved by the senior management team within the gynaecology department at the DHB, and this did not mention the risk of thermal injury. Additionally, he noted that the device manufacturer does not include the risk of thermal injury in its patient information literature.

101. Dr D stated that although a uterine septum would be a contraindication to surgery, there was no evidence from the operation notes, the pathology report, intra-operative photographs, or the reviewers who undertook the DHB's SSE review that Ms A had a uterine septum.

102. In Dr D's view, the device was used in a manner consistent with the device manufacturer's instructions. He stated:

> "If [the device] does not open within the uterus as expected it would be normal practice to remove the device and confirm that it opens freely outside the uterus

> (normally to a width of more than 4cm). The manufacturers actually recommend in their operator instructions that the device is deployed outside the body prior to use to confirm that it opens correctly … The device is robust and designed to be opened and closed a number of times prior to activation."

103. Dr D also submitted that it was appropriate for Ms A to be seen in the gynaecology unit on 22 March 2017, as the emergency department does not have a private area with a lithotomy bed. He stated:

> "In a busy hospital with overcrowded facilities for assessing patients, it would seem reasonable to examine and assess a patient in the facility most suitable for the intimate examination required … Most patients presenting to ED with a gynaecological problem will [be] triaged to the [gynaecology unit] anyway with only a limited assessment being made in ED."

104. According to Dr D, a laparoscopy on 22 March 2017 would not necessarily have revealed any sign of bowel injury, as thermal injuries can take three to five days to manifest. He noted that Ms A had no peritonism or fever, and that her symptoms, pain, and ultrasound finding were all associated with the possible expulsion of her IUCD rather than perforation.

105. Dr D stated that ideally, a patient who has undergone an acute procedure in the early evening would be kept overnight, but no hospital in the region is able to provide this level of care consistently. He noted that Ms A had normal observations following the operation, and that routine pain relief was effective. He considers that two hours of observation was sufficient.

Action by manufacturer

106. As a result of this incident, the device manufacturer issued the following statement to providers who use the device:

> "As there can be significant variability in patient anatomy, further precautions exist regarding certain uterine positions and anomalies such as the patient involved in the recent adverse event. Patients with a severely anteverted uterus are at greater risk of uterine perforation during any intrauterine manipulation. A false passage can occur during any procedure in which the uterus is instrumented, especially in cases of a severely anteverted uterus. It is therefore important to use caution to ensure that [the device] is properly positioned in the uterine cavity."

107. Furthermore, it noted:

> "Although the patient in the present case [Ms A] was not contraindicated for the use of [the device] … she had anatomic irregularities that increased the likelihood of false tracking and the potential for thermal spread to the uterine serosal surface and adjacent bowel."

Comment from Ms A

108. Ms A stated:

> "This whole situation has been extremely traumatic for me both mentally and physically and the repercussions on my family and home life have been equally traumatic. I was unaware of the risks involved and certainly would not have agreed to this procedure if I knew that the risks would be this extreme and end like this. I hope that no other women in New Zealand or anywhere for that matter, has to go through this experience and believe that the procedure should be withdrawn from being available."

109. Ms A further stated:

> "If I had been given more information from [Dr B], although I appreciate she has not experienced anything of this nature before and so it would be difficult for her to comment, then I would not have put my life at risk in this way. I certainly would not have committed to the procedure if I was fully informed of the risks."

Further comments — Dr B

110. Dr B told HDC that she has spoken to over 20 colleagues who are experts in the use of ablation, and all were "very shocked to know a thermal injury of this nature could occur in this manner. The advice was that it was safe due to the impedance mechanism and safety checks." Dr B said that at the time she was not aware of any cases where thermal injury had occurred using the device, with the exception of one historical case where the safety check was overridden.

111. In response to expert advice referencing the RANZCOG guideline for Hysteroscopy and Hysteroscopic resection, Dr B submitted that this was misleading because "[h]ysteroscopic resection is a fundamentally different procedure to [ablation] using a heated knife".

112. Dr B noted that the RANZCOG patient guideline on hysteroscopy available in 2017 makes no reference to thermal injury as a complication, and that the newer 2018 guideline states that it is not possible for a doctor to outline every side effect or rare complication of a procedure and that a risk of 1:15,000 "is classified by RANZCOG as very rare".

113. Dr B stated:

> "I am not a cavalier clinician. I would never perform a procedure 'at all costs'. I have discontinued operations on a number of occasions where I considered continuing may risk causing potential harm. I did not think this was the case with [Ms A].
>
> …
>
> I performed this procedure completely within the guidelines issued by the manufacturer/distributor and did provide services with a reasonable level of care and skill."

114. In conclusion, Dr B stated:

> "I am very sorry that [Ms A] had the difficulties that she did encounter. I was at all times doing my best for her. With the information that I had at the time, I do not consider it is reasonable to expect that I should have conducted myself differently. Such an opinion is clearly one with the benefit of hindsight. Having said that, as a direct consequence of the experience I have undertaken in this matter … I now have a much lowered threshold coupled with a greater appreciation of the risk (albeit extremely rare) of a patient suffering an injury like [Ms A] has, subsequent to [an] ablation procedure."

Further comments — Dr D

115. Dr B asked Dr D to undertake a further review of this case. Dr D stated:

> "I stand by the comments and opinions expressed in my earlier opinion. I also agree with [Dr B's] statements and her comments on the clinical issues she addresses in her response."

116. In relation to the issue of informed consent, Dr D said that this was more difficult for him to comment on because he was not there, but stated:

> "[A]ssuming what [Dr B] has said (that she was not prompted or asked to relay all possible risks to the patient), then I agree that her approach to that aspect (consent) prior to the procedure, was reasonable and in keeping with the practice that many of our colleagues would follow."

Further comments — Dr H

117. Dr B also sought advice from specialist gynaecologist Dr H.

118. Dr H told HDC: "I have been undertaking [endomentrial ablation with this device] since before 2009 and understand that I have the largest experience of this operation in New Zealand." In relation to undertaking ultrasound prior to a planned [ablation], Dr H stated:

> "[While it is my practice to arrange an ultrasound prior to an endometrial ablation,] I understand that it is common practice not to arrange an ultrasound in the presence of normal clinical examination and know that there are several published guidelines around this."

119. In relation to consent, Dr H said that while it is his practice to discuss the risk of thermal injury, "with a risk of 1/10,000", he notes Dr B's submission that she did not discuss it because of the rarity of the risk, and he understands that this "is an acceptable option by [his] colleagues for very uncommon complications". Further to this, Dr H stated: "Unless of course the patient signals a wish to know of all possible risks, I do not believe it is mandatory for a clinician to refer to all the risks [discussed above]."

120. In relation to the uterine shape, Dr H stated:

> "From the hysteroscopic photographs I believe the uterus was of an arcuate type. In my opinion an arcuate uterus is not a contraindication of use of [ablation with this device]. I would consider it appropriate to proceed if I encountered an anatomical variant as is visible in this patient's hysteroscopic images."

121. In relation to the handling of the device, Dr H noted that the device is "quite robust and can withstand reasonable attempts at manipulation and handling in its placement". He noted that it is relatively commonplace to shorten the cavity length if correct seating cannot be achieved. Furthermore, he stated: "I do not believe that the manual adjustment to alter the contour of this device is likely to have led to the subsequent complication."

122. Dr H said that he would not have proceeded with a cavity width of 2.7cm, but stated:

> "I understand that [Dr B] believed the device to be appropriately and optimally/ideally sited prior to engaging the ablation pedal. … I would also note that [Dr B] deployed the device above the safety guidelines of achieving more than a 2.5cm cavity width setting."

123. Dr H concluded:

> "In my opinion the complication occurred due to partial penetration of the myometrium due to the creation of a 'divot' from one end of the device tip and then electrical/heat injury to the uterine outside surface and closely applied rectum. I believe that acute anteversion of the uterus played a significant part in this and probably more so than the arcuate nature of the uterus."

Further comments — the DHB

124. The DHB said that since this case it has been closely monitoring all endometrial ablation cases performed with this device at the DHB. It advised that since this case it has had one patient who required hospital admission owing to infection.[27]

Responses to provisional opinion

125. Dr B, the DHB, and the private hospital were provided with an opportunity to comment on the provisional opinion. Their responses have been incorporated into this report where relevant.

126. Ms A was provided with a copy of the "information gathered" section of the provisional opinion. Her response has been incorporated into this report where relevant.

[27] This information was provided in 2017.

Opinion: Dr B — breach

Introduction

127. Ms A had an extremely unfortunate outcome from an apparently routine thermal ablation procedure in 2017. I acknowledge the traumatic impact that this has had on her life.

128. This report considers a number of aspects of the care provided to Ms A, including the adequacy of the information she was provided, whether the procedure was carried out with reasonable care and skill, and whether her postoperative management was reasonable and in accordance with accepted standards.

129. Overall, guided by expert advice obtained from obstetrician and gynaecologist Dr Celia Devenish, I consider that aspects of the services Ms A received were not provided with reasonable care and skill. I discuss the reasons for my views in more detail below.

Preoperative information and consent

130. I have considered whether Dr B provided Ms A with sufficient information about the potential risks of thermal ablation for her to be able to make an informed decision about the procedure. In making this assessment, I am required to assess Dr B's actions against those of her peers, that is, whether her consent practices were consistent with those accepted by obstetricians and gynaecologists at the time, and in these circumstances.

131. Dr B said that she explained the procedure to Ms A and told her that the potential risks included infection, bleeding, and uterine perforation. Dr B also provided Ms A with an information brochure for the device that lists the risks of the procedure, including perforation and injury to organs within the abdomen around the uterus, or complications leading to serious injury or death, occurring in less than 0.05% of patients. Ms A signed a consent form on which Dr B noted that uterine perforation had been discussed specifically.

132. Dr B did not specifically discuss the risk of thermal injury, because she understood that thermal injury is very rare. She said that she was not aware at the time that there had been very rare cases of thermal injury in patients with an intact uterus or with a partial penetration of the uterine wall. She stated that it would not be practicable to go through every potential risk.

133. Dr B's understanding from subsequent discussions with the manufacturer is that the risk is 1:15,000, with the majority of historical cases being associated with an override of the safety alarm mechanism. Dr B said that the requirement is for patients to be informed of expected risks of treatment, and submitted that "[a] risk of 1/15,000 is not an expected risk".

134. Dr B said that thermal injury is not listed in the device reference guide as something a patient should be counselled for, nor is it mentioned in the consenting process in place at the DHB. Dr B stated: "[T]herefore in my written consent I believe that I was acting as my peers certainly at the public hospital would do in my consenting."

135. Dr B provided an opinion from obstetrician and gynaecologist Dr D, who was part of the SSE review team that reviewed this incident. Dr D stated that in his opinion, he would expect the risk of uterine perforation and bowel injury to be discussed, "but not necessarily the exact range of all possible ways of injuring internal organs". Dr D noted that the DHB consent form for this type of procedure does not mention the risk of thermal injury, nor is it mentioned in the device's patient information literature. Further, Dr B reiterated her view that discussing such a rare risk such as thermal injury was not consistent with the practice of her peers. Dr B also provided further supporting opinions from colleagues Dr D and Dr H, who agree that counselling a patient for such a rare risk would not be considered mandatory, and that this approach is consistent with the practice of their colleagues.

136. The instructions for use of the device include, as known adverse events, "thermal injury to adjacent tissue … perforation of the uterine wall".

137. Dr Devenish advised: "While thermal damage to adjacent organs is a rare occurrence, outlining potential damage to adjacent organs and the uterus is the expected standard of care." Further, Dr Devenish advised:

> "Uterine perforation, and the associated injuries from, e.g. perforation of the uterus at hysteroscopy D&C, is fundamentally different to procedures when thermal devices, such as [this], are used. In the case of [this device], there is a risk of burns and subsequent organ necrosis. If there is partial penetration of the uterine wall, then heat is easily transferred to adjacent structures, such as bowel, which are in close proximity. The complications that arise in this situation are delayed. Although very rare, they are life threatening."

138. In further advice, after considering Dr B's submissions, Dr Devenish advised:

> "It is the Clinician's responsibility to give information relevant to the context of individual patients, i.e. the small risks of other organ damage and thermal injury has routinely been given to women in our unit undergoing endometrial ablation with [this device]. …
>
> I understand that there may be some variation in information provided by Surgeons. All procedures have capacity for error, whether via the operator, device or systems. I believe patients should be aware of any risks significant to them, when giving consent, especially when there are rare, but serious complications. These are as suggested in patient information available from RANZCOG, as used in DHBs at the time and consistent with [device] on line information. I believe most of my peers would agree with this. I do not believe this was a significant deviation from the expected standard of care, as Clinicians vary in their views on this."

139. Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code) gives consumers the right to be fully informed and to "the information that a reasonable consumer, in that consumer's circumstances, would expect to receive".

140. The issue I have considered is whether a reasonable consumer in Ms A's circumstances would have expected to be told that thermal ablation procedures carry a rare risk of thermal injury.

141. I note that Ms A told HDC: "I was unaware of the risks involved and certainly would not have agreed to this procedure if I knew that the risks would be this extreme and end like this."

142. I note that there appears to be some variation between specialists about discussing the very rare complication of thermal injury. I also note that this is a very rare outcome, and Dr Devenish also acknowledges this. Accordingly, I am unable to conclude that information about a very rare risk of thermal injury is information that a reasonable consumer would expect to receive in similar circumstances.

Hysteroscopy

143. Dr B explained that her usual practice is to perform a hysteroscopy prior to the thermal ablation procedure, "which more effectively examined the uterine cavity than an ultrasound".

144. When performing the hysteroscopy, Dr B identified a new finding relating to Ms A's uterine shape — that Ms A had an acutely anteverted, anteflexed uterus that was arcuate. Dr B told HDC: "The reason I described the uterus as being arcuate was because of a slight curving towards the cornua."

145. Dr B said that the finding of an arcuate uterus is not a contraindication for the use of the device, and that she allowed for it by adjusting the length of the device after the initial attempt to commence the procedure failed. Dr B said that she does not believe this new finding was a reason to terminate the procedure.

146. Further, Dr B stated: "An arcuate uterine shape is common present in up to 5% of the population and regarded as a normal variant, it is not a contraindication to [device] ablation nor is it a relative contraindication." I note that this view is supported by Dr H.

147. On reviewing the hysteroscopic photographs and other evidence, Dr Devenish advised that while Ms A's uterus was "not entirely normal", she agrees that it would not have precluded deployment of the device. I accept this advice and am satisfied that it was reasonable for Dr B to proceed with the procedure at that time. However, I consider that at that point Dr B was on notice that the procedure might not be straightforward, and needed to proceed with caution. I note the statement by the manufacturer:

> "Although the patient in the present case [Ms A] was not contraindicated for the use of [the device] … she had anatomic irregularities that increased the likelihood of false tracking and the potential for thermal spread to the uterine serosal surface and adjacent bowel."

148. I discuss this further below.

Ablation procedure

149. I have considered whether Dr B performed the procedure in a manner consistent with accepted standards, including whether it was appropriate for her to proceed with the procedure at various points in the care pathway.

Ultrasound

150. Prior to recommending thermal ablation, Dr B undertook an assessment and considered Ms A's past medical history. Dr B said that on examination, Ms A did not have any pathology that she considered warranted an ultrasound. Dr B stated:

> "An ultrasound is not a universal requirement in younger women being worked up for menorrhagia … [Ms A] was young, very slim and her uterus was easily palpable, she had no other symptoms apart from moderately heavy menstrual bleeding to indicate for example uterine polyp. Had my examination revealed an enlarged uterus or other pathology I would have routinely ordered an ultrasound. I believe my practice was in keeping with international guidelines."

151. Further, Dr B noted that a number of international guidelines for menorrhagia do not support undertaking a pelvic ultrasound as part of a general work-up for menstrual disorders.

152. In contrast, Dr Devenish advised that although a pipelle sampling of the endometrium had been taken, no ultrasound of the pelvis had been conducted, which is recognised as part of the general work-up for menstrual problems. She stated:

> "I recommend that pelvic ultrasound be completed prior to such procedures to exclude endometrial shape and pathological anomalies and also to confirm uterine wall and endometrial thickness."

153. Overall, while I accept Dr Devenish's advice that an ultrasound would be recommended as part of a general work-up for menstrual problems, I accept that there appears to be some variation in practice, and that the relevant guidelines do not contain a clear requirement for an ultrasound to be undertaken.

Ablation procedure

154. After the hysteroscopy, Dr B proceeded with the ablation procedure. When the initial attempt at the procedure failed, Dr B removed the device, tested it by opening it, and applied pressure to see how much pressure would be required to follow the contour of the uterus. She then altered the length of the device, reinserted it, and successfully commenced the procedure. Dr B said that she did not tamper with the device, and she does not consider that its failure to open initially was reason to terminate the procedure. Dr B noted that the device had passed the safety check. She stated: "Had the device failed the safety check I would not have proceeded or been able to proceed with the ablation."

155. Dr B provided a further explanation of this part of the process. She stated:

> "I merely gently depressed the central portion momentarily which then immediately resumed its normal shape. The movement was in millimetres and the device was not damaged, bent or changed in any permanent way that could change function.
>
> [The device] is designed to be flexible to expand and contract back into a very narrow sheath many times without being damaged. In seating [this] device there are set safety tolerances. At no time did I breach the safety margins outlined by the device manufacturer and nor did I perform the ablation outside the recommendations."

156. I note that Dr H and Dr D both agree that manipulation of the device in this manner was appropriate, and would not have affected its functioning. However, Dr Devenish advised that this was a further opportunity to halt the procedure. She stated: "I believe most specialists would have considered abandoning at this point to review all possible options after discussion with the patient." Dr Devenish does not consider that manually adjusting the contour of the device would be consistent with accepted practice.

157. With regard to the cause of Ms A's thermal injury, Dr Devenish said that it is most likely that the device was inserted into one aspect of the uterine fundus, partially perforating the uterine wall and, therefore, allowing heat to transfer into the pelvic organs.

158. Further, upon reviewing the evidence and Dr B's response again, Dr Devenish noted the presence of a 2cm intramural fundal fibroid that may have simulated a sub-septate or arcuate appearance. In addition, Dr Devenish stated:

> "I believe, as stated in both the Pathologist's report and that from [Dr H], that the device was applied close to or into the fundal myometrium to cause this neo-cavity, adjacent to the intramural fibroid and resulted in intra-abdominal damage."

159. Dr Devenish noted that the device assumes a standard shape of a uterine cavity with minor adjustments possible to width and depth of placement, "[h]ence, the checks prior to deployment, if not in the correct position, the unequal spread of [electromagnetic] waves with distribution through to abdominal organs". I note Dr Devenish's advice, consistent with that of Dr H, that she would not have used the device given the uterine width of 2.7cm. However, as also noted by Dr H, this was within the safety guidelines requiring a minimum cavity width of 2.5cm. Dr Devenish stated:

> "The device's safety mechanisms ideally prevent deployment when the device is malpositioned, but this is not fail-safe, especially if any force is used.
>
> Irrespective of how many cases are performed by a Gynaecologist, there is an increased risk of an adverse event and of thermal injury beyond the endometrium, if the device is not correctly sited or seated with a width, where caution is advised."

160. Dr Devenish noted that in this case, Dr B's manoeuvres to ensure correct placement were not effective, and this was not recognised by Dr B, resulting in the device causing thermal

damage. I note Dr Devenish's comments that "the pattern of charring from ablation described by the Pathologist does not concur with [Dr B's] description of 'having withdrawn the device below or at the level of the septum', as it appears one of the prongs was against or penetrating the fundal myometrium". Dr Devenish considered that the decision to proceed with the ablation procedure was a mild to moderate departure from accepted standards.

161. I accept Dr Devenish's advice. While I accept that the device has a number of safety features aimed at preventing deployment if not placed correctly, this is not fail safe. I also note that the "Instructions for Use" state under "precautions" that patients with a severely anteverted uterus are at greater risk of uterine wall perforation. Dr H advised that in his opinion, Ms A's "acute anteversion of the uterus played a significant part" in her injury.

162. Guided by Dr Devenish's advice, although I accept that there was no clear contraindication to proceeding with the procedure, I consider that there were factors that should have put Dr B on alert that this might not be a straightforward procedure. As noted by Dr Devenish, one of the key points is "whether the uterine cavity was such that made the procedure more difficult than usual. Importantly, what led the device to be malpositioned and yet still deployed with subsequent injury."

163. Further, I note Dr Devenish's advice regarding the documentation:

> "I would expect that the expected standard of practice for a Surgeon, when they reflect on a statement written at the time of surgery, would be to correct this with an addendum to the hospital notes, especially in light of the serious complication that eventuated."

164. Dr Devenish advised that this was a mild deviation from the expected standard of care. I agree that it is important to ensure that clinical records are kept updated with the most accurate clinical information, even if this has to be added retrospectively.

Care provided on 22 March

165. Ms A presented with abdominal pain on 22 March — Day One postoperatively. Dr C first informed Dr B about Ms A's ongoing abdominal pain. Dr B subsequently spoke to Ms A and appropriately arranged for her to be assessed. Because Dr B was working at the public hospital that day, she arranged for Ms A to meet her there. I note that Dr B did not anticipate that Ms A would require admission, so arranged for Ms A to contact her directly on arrival, rather than be admitted through the emergency department.

166. The DHB advised that there was an unwritten expectation that private outpatients would be admitted under the acute team, but at the time it did not have a specific policy that required private outpatients to be admitted that way prior to assessment.

167. On examination of Ms A, Dr B considered that there were no signs of perforation, and her differential diagnoses were that the IUCD was sitting low in the uterine cavity, or it was embedded in the uterine wall. Dr B arranged for a transabdominal and transvaginal

ultrasound to be performed by Dr F, which confirmed Dr B's impression that Ms A's pain was related to a rejection of the IUCD.

168. Dr B then made the decision to admit Ms A and remove the IUCD under anaesthetic in theatre. A theatre became available immediately and, as a result, routine observations were not completed until Ms A arrived in theatre.

169. Dr B asked Dr G, the on-call obstetrician, to assist because of Dr G's expertise in ultrasound. Dr G subsequently raised the possibility of a uterine perforation. However, Dr B did not follow up that possibility because she considered that she had more information than Dr G, including the findings of the ultrasound scan completed by Dr F, which were of a higher quality, and the findings of the postoperative hysteroscopy, which showed no sign of perforation. I note Dr Devenish's advice that following thermal hyperscopic procedures (such as this), "the expected standard is that specialists always consider the potential complications of perforation and or heat spread causing damage to adjacent structures whenever a procedure is performed on a hollow organ".

170. Dr Devenish advised that, in her opinion, perforation or peritonitis should have been considered as a differential diagnosis at the time of this admission, and a second opinion should have been sought from the on-call gynaecologist at that point. She advised that had a laparoscopy been performed at the time of the hysteroscopy, then the nature of Ms A's abdominal and pelvic injuries would have been apparent 24 hours earlier.

171. However, I note Dr B's comments that she did consider perforation and peritonitis as possible causes of Ms A's pain, including noting that there was no guarding or rebound tenderness on abdominal examination, and her questioning of the presence of the contour and any free fluid on the ultrasound scan performed by Dr F.

172. While I note that the approach of seeing private patients, bypassing the acute gynaecology team, was not unusual at the DHB at that time, I agree with Dr Devenish that by obtaining informal consultations from Dr F and Dr G and not formally referring Ms A to the gynaecology team, "the opportunity for fresh eyes to assess the overall picture, which was unusual, was lost".

173. Dr Devenish stated:

> "I believe that most Specialists would have sought the advice of a General Surgeon for this acute presentation or at least the Gynaecology Consultant On Call colleague at the time."

174. Dr Devenish considered that the failure to do so in the circumstances was a mild to moderate departure from accepted standards. I accept Dr Devenish's advice. I also agree with Dr Devenish's advice that the decision to discharge Ms A that night, or not to arrange early follow-up in person or by telephone the following morning, was a further lost opportunity to observe the symptoms to ensure that they settled after the removal of the IUCD. I also note Dr Devenish's further advice that Dr B should have considered seeking

another surgical opinion, "either at the time or before discharge home or, at the very least, to arrange review the next day, especially since no laparoscopy was performed".

Conclusion

175. I have concerns about the standard of care provided by Dr B, including:

- Failing to proceed with caution when she encountered difficulties in inserting the device, which affected the risks of the procedure, and not documenting these when complications eventuated.
- Failing to refer Ms A to the on-call gynaecology team during her presentation on 22 March.
- Failing to ensure adequate monitoring and follow-up after the 22 March procedure.

176. For the reasons set out above, I conclude that Dr B failed to provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

177. Overall, as discussed above, while I consider that Ms A was entitled to information that a reasonable consumer would expect in these circumstances, I accept that the risk of thermal injury is very rare, and is not information that a reasonable consumer would expect to receive. However, I consider that this case highlights the need for consistency in consenting procedures. I am reassured that Dr B has altered her practice in this respect, and that the manufacturer has also updated its information brochure.

Opinion: District health board — adverse comment

178. On 22 March 2017, Ms A was seen by Dr B at the public hospital. However, Ms A was not admitted through the emergency department and acute gynaecology team, which Dr Devenish advised would be normal practice.

179. The DHB said that at the time of these events there was an unwritten expectation that patients would be admitted under the acute team, but that at the time this was not explicit in its "Transferring and re-admitting Patients from Private Surgical Hospitals to [the public hospital]" guideline.

180. After her initial assessment, Dr B contacted Dr F to undertake an ultrasound scan. Dr F did not document her findings, and the scan results were not recorded. Similarly, when Dr G was called into theatre to assist with the removal of the IUCD, she did not record her findings or advice.

181. The DHB advised that it did not have any policies or guidelines in relation to the documentation of ultrasound scans performed outside the radiology department. In my view, that was unfortunate, and adequate records should have been made.

182. As noted by Dr Devenish, as a result of Ms A not being admitted through the acute gynaecology team, there was a missed opportunity for a "fresh eyes" review of her unusual presentation. This resulted in the differential diagnoses of perforation or peritonitis not being considered adequately.

183. I am critical that the informality of the arrangements at the public hospital contributed to Ms A's suboptimal care.

184. Had the DHB had clear guidelines in place for the management of patients from a private outpatient context being assessed at its facilities, many of these issues may have been avoided.

185. However, while aspects of the system in place at the DHB at the time were not ideal, I do not consider that the DHB can be held responsible for the care provided to Ms A in this case. Accordingly, although I am critical of some aspects of Ms A's treatment at the public hospital, I do not find the DHB in breach of the Code.

186. I note that as a result of this case, the DHB has taken steps to formalise its process for admitting private outpatients, and for recording informal ultrasound scans. I consider these changes to be appropriate.

Opinion: Private hospital — no breach

Consenting and information

187. The private hospital has generic consent forms in place, and it is the responsibility of the individual surgeon to obtain adequate consent for a procedure. I am satisfied that this is reasonable and consistent with many private hospitals in New Zealand. However, I note Dr Devenish's recommendation that the private hospital consider providing more space for information to be recorded, and including a check-box to indicate that the patient has received relevant written information about the procedure.

Procedure followed when Ms A contacted hospital on 22 March 2017

188. When Ms A contacted the private hospital on 22 March 2017 complaining of abdominal pain, initially the anaesthetist, Dr C, was contacted, and subsequently he contacted Dr B. The private hospital told HDC that it considers that this was reasonable since Ms A reported issues relating to pain. The decision to contact Dr C rather than Dr B also appears to have been influenced by Ms A knowing Dr C personally.

189. I note Dr Devenish's advice that in this situation, Dr B should have been contacted directly. Dr Devenish noted that according to RN E, Ms A did have Dr B's contact details available. While the delay in Dr B being contacted does not appear to have delayed Ms A's review by Dr B significantly, potentially Ms A's condition could have deteriorated before she was seen.

190. I note that the private hospital now ensures that the surgeon's telephone number is provided to all patients.

Recommendations

191. In accordance with the recommendation of the provisional opinion, Dr B provided a written apology to Ms A for the breach of the Code identified in the report.

192. The DHB has agreed to undertake an audit of its clinicians' private gynaecology patients who are referred or transferred to the public hospital for review, to ensure that they have been referred to and admitted by the acute team as outlined in its updated policy. The audit is to occur over a six-month period, and, where findings demonstrate a departure from policy, the DHB is to provide details of the steps it has taken to address this.

Follow-up actions

193. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand and RANZCOG, and they will be advised of Dr B's name.

194. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Health Quality & Safety Commission and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from Dr Celia Devenish:

"I have been asked to provide an opinion to the Commissioner for the above. I have read the Commissioner's guidelines and I agree to follow these guidelines.

I am a Specialist Obstetrician and Gynaecologist, working within a generalist scope of practice, and have been accredited with Fellowship of both RANZCOG and RCOG.

I have practised as a Consultant in both Obstetrics & Gynaecology for 35 years in both tertiary and secondary provincial centres, in public, academic, rural and private practice sessions.

I have worked in a joint clinical and academic position, as a Specialist at Dunedin Hospital for 17 years. I have also been Clinical Leader in Obstetrics.

As an Otago University Lecturer, I am involved in research and teaching in the Dunedin School of Medicine at undergraduate and postgraduate levels. I am an elected RANZCOG Board and Council member where I chair and sit on various committees including the FRANZCOG and DRANZCOG Examination Committees. I also sit on the New Zealand Committee and SIMG interview panels for New Zealand and Australia. I am involved in specialist training and organise various workshops in NZ.

1. **Was the consenting and information sharing process undertaken with [Ms A] prior to her endometrial ablation procedure adequate and consistent with expected standards? Would you expect the risk for thermal injury to be discussed?**

I believe the consent and information sharing process was inadequate in that the serious, but rare complications of uterine ablation were not documented as having been explained. I believe this for the following reasons:

Although [Dr B] confirms she had discussed risks and shared the [device's] patient information leaflet, the consent does not state damage to adjacent organs or serious complications. Uterine perforation, and the associated injuries from, e.g. perforation of the uterus at hysteroscopy D&C, is fundamentally different to procedures when thermal devices, such as [this], are used. In the case of [this device], there is a risk of burns and subsequent organ necrosis. If there is partial penetration of the uterine wall, then heat is easily transferred to adjacent structures, such as bowel, which are in close proximity. The complications that arise in this situation are delayed. Although very rare, they are life threatening. In comparison, Anaesthetists disclose the rare, but serious risks of epidural or general anaesthesia, which are of a similar magnitude. For this reason, I would expect the risks of thermal injury to be mentioned, as rare, but possible complications. This was not documented on the consent form.

I believe there was a moderate departure from the accepted standard of practice. Whilst the usual risks of uterine perforation were routinely discussed, [Ms A] states that she would not have proceeded with the [ablation] if she had known of any risk of serious damage to adjacent organs in pelvis and abdomen.

I believe my peers would discuss both the uterine perforation risk at hysteroscopy and curettage, with the attendant rare, but significant risk, of damage to adjacent organs in the abdomen and pelvis. Where there is an abnormality of uterine shape this is particularly relevant. Since there was no prior ultrasound scan of the pelvis, there was no knowledge in regard to anatomy prior to the procedure.

In future, it is recommended that thermal injury risk be mentioned to women in regard to all [device] and heat ablation procedures. I recommend that pelvic ultrasound be completed prior to such procedures to exclude endometrial shape and pathological anomalies, and also to confirm uterine wall and endometrial thickness.

I recommend the patient brochure should specifically mention thermal damage to adjacent tissues, as should the consent form.

2. Was [Ms A] a suitable candidate for the ablation procedure?

I believe at the time of initial consultation in February, [Ms A] appeared to be a suitable candidate for Endometrial Ablation. Pre operatively, a pipelle sampling of the endometrium had been taken, but no ultrasound of the pelvis, which is recognised as part of the general work up for menstrual problems. A new diagnosis of a uterine shape anomaly, a sub septate uterus, was made at the hysteroscopic procedure under GA. This was immediately prior to performing [the ablation procedure with this device], whilst the patient was asleep. This finding now made the candidate less suitable for the procedure. At this point in time there was an opportunity to halt the procedure following hysteroscopy and re-discuss the risks and benefits compared with other options with [Ms A]. This would have meant rebooking. Whilst the [device manufacturer] outlines uterine shape anomalies, as a relative contraindication, [Ms A] was not made aware of this new finding. The [device's] information manual describes a prospective study, in which uterine shape anomalies were an exclusion criteria to the study. Thus, when outlining complications and outcomes quoted in this study, which compared [device] outcomes with a first generation ablation method of wire loop excision, cases such as [Ms A's] uterine shape were not included. Therefore the complications rates quoted do not apply to cases such as [Ms A].

I believe there was a moderate departure from the accepted standard of practice.

I believe my peers would consider halting the procedure and reconsidering options, in such circumstances. This would also be the case, should the device not open to the correct width on initial insertion to the uterus, as [Dr B] describes or if it does not appear possible to fit the contour of the uterine cavity.

I recommend that if new findings change the risk profile, then the patient should be given the opportunity to reconsider the risks and review options before proceeding.

3. Does it appear [Ms A's] procedure was carried out in a manner consistent with manufacturer recommendations and expected standards of care?

[Dr B] states the procedure was performed, as recommended by the manufacturer. However there was a relative contraindication newly diagnosed at the time. [Dr B] describes applying pressure to the device, which she 'depressed centrally'. This was in an attempt to see if the device would fit the contour of the uterine cavity. Whilst it is possible that manipulating may have altered its function and ability to open, such an action is not recommended by the company. It is most likely that the device was inserted into one aspect of the uterine fundus, partially perforating the uterine wall and, therefore, allowing heat to transfer into the pelvic organs. The hysteroscopic photo images of the diagnostic hysteroscopy suggest that the uterine horns (areas leading to the right and left cornu and tubal junctions) were consistent with a subseptate uterus. [Dr B] describes each horn as being 1 cm longer than the central areas, so she set the device to be in the area beneath the horns. The post procedure photo #1 shows an area of darker blackening in the left aspect of the horn, which I believe would be consistent with a neo cavity tract, which was found on pathological examination of the uterus specimen. Certainly, the fundus in this area showed marked charring, consistent with placement of the [device] up against the fundus, yet the device was described by [Dr B] as set to ablate the area lower in the uterus because of the septum. It seems that the fundal myometrium was penetrated whilst opening the device the second time of insertion after manipulation. This is consistent with the pathological and operative findings.

I believe there was a moderate departure from the accepted standard of practice.

I believe my peers would agree with this.

I recommend that any newly diagnosed uterine shape anomalies be discussed with the woman before continuing the procedure.

I recommend that the device should not be manipulated, prior to uterine re-insertion, in an attempt to ensure it opens correctly, as this may affect its function and delivery of heat to tissues.

4. Are there any other matters in relation to [the private hospital] that you feel warrant comment?

I believe the consent form used by the hospital was limited, in that complications of a procedure, e.g. consequences of perforation, were not specifically mentioned.

Specifically relating to [the private hospital] follow up post procedure, the nurse phone call enabled [Ms A's] pain to be recognised, but it is not apparent if this information was passed on to [Dr B] directly.

It appears that [Dr B] was alerted by her Anaesthetist, as a consequence of a conversation with the nurse.

I believe there was a serious deviation from the normal standard of care, if [the private hospital] protocol did not ensure [Dr B], as the Surgeon, was advised of [Ms A's] post-operative pain symptoms.

I believe my peers would agree with this.

I believe that the protocols of post op follow up should ensure the Surgeon is advised at the earliest opportunity of any concerns raised by the patient.

I recommend that hospital protocols of post op phone follow up should ensure the surgeon is advised of any problems at the earliest opportunity.

5. Was [Ms A's] management by [Dr B] on the 22nd March 2017 consistent with expected standards of care? In particular, was there any reason to suspect uterine perforation or to investigate further for this possibility?

I believe [Ms A's] management fell short of the expected standard of care.

Whilst [Dr B's] intentions in seeing [Ms A] in the [gynaecology unit] treatment room on site were, no doubt, to provide continuity of care in a patient she knew and whose procedures she had performed, this was a departure from the expected care, which, in a public hospital, expects the On Call Team to see the acute case. It is likely that the visit was not expected to result in an admission or surgery. The reasons why I believe there was a departure from the expected standards of care are that:

1. [Ms A] did not get admitted by the emergency department, which is the normal avenue.
2. No routine observations, bloods or initial work-up after assessment were made.
3. The On Call Gynaecologist was not advised. This is the Consultant responsible for all acute gynaecological admissions.
4. The On Call Obstetrician, [Dr G], was asked to assist with ultrasound scanning in theatre to assist location of the IUD. [Dr G's] advice about possible uterine perforation resulting from her scan findings of fluid and fundal outline was disregarded.
5. The IUD was found misplaced on ultrasound imaging in the cavity of the uterus and the strings in the uterine cavity were seen in the cavity. There are no images of this hysteroscopic procedure. The day prior, the IUD strings would have been in the vagina at the conclusion of the surgery.
6. There was the opportunity to ask assistance from the On Call gynaecologist when faced with the unusually difficult removal of the IUD in theatre and in obtaining the hook device, which was eventually successful. Help from the On Call Gynaecologist was suggested by [Dr G], but not acted upon.
7. Consequently, the opportunity for fresh eyes to assess the overall picture, which was unusual, was lost.

8. Consent for laparoscopy had been taken prior to surgery. Had laparoscopy been performed at the time of hysteroscopy, then the nature of the abdominal and pelvic injuries would have been apparent twenty four hours earlier.
9. Discharge from the hospital at 11pm after a two hour procedure was unfortunate, as the opportunity to observe and ensure that all symptoms had settled after removal of the IUD was missed.

I believe there was a reason to suspect organ perforation because of the ultrasound findings and presentation with pain. The colleague was experienced in ultrasound. I believe perforation, as a possibility, should have been further considered at that point and another opinion sought from the person On Call for acute gynaecology admissions. I believe that further investigation was indicated. A diagnostic laparoscopy, already consented for, could have confirmed or ruled out the complication at the time.

I believe there was a serious deviation from the normal standard of care for the above reasons.

I believe my peers would agree with this.

I believe the admission protocols for the hospital should ensure adequate work up and review by the On Call Team prior to admission for surgery.

6. Was it reasonable for [Ms A] to be discharged from [the public hospital] around 11pm on the 22nd March 2017?

I do not believe it was reasonable to discharge [Ms A] from [the public hospital] at 11pm on the 22nd March 2017. The reason I believe this was that [Ms A] had undergone a two hour anaesthetic and removal of an IUD, which was not routine. Usually, the removal would have taken minutes, as an outpatient, but took considerably longer under general anaesthesia.

In view of the above and the significant pain, which had caused [Ms A] to be reviewed, I believe it was unreasonable that [Ms A] was not observed overnight. She returned from theatre 'after normal working hours'. Although she was observed for several hours, I do not feel this was sufficient in the context of her presentation and treatment. The recent operative course had not been straightforward. It is not recorded in the notes whether overnight stay was considered or if a hospital bed was available.

I believe there was a significant moderate deviation from the normal standard of care for the above reasons.

I believe my peers would agree with this.

I recommend that patients be kept overnight, if any unplanned and repeat surgery is performed, particularly when this is an unexpectedly prolonged procedure.

7. Was assessment and investigation of [Ms A's] abdominal pain, following her return to [the public hospital] at 3.18pm on the 23rd March 2017 undertaken in a timely and clinically appropriate fashion? Was surgery performed in a timely fashion?

I believe assessment and investigation was undertaken in a reasonably timely and clinically appropriate fashion.

I believe this because assessment of her post-operative pain score at presentation to ED was 3/10 and she was recorded as stable. Opiate analgesia had been given for transfer by ambulance.

Although it was regrettable that three hours lapsed before ED staff were able to review her, this is not uncommon in a busy major hospital with significant acuity. Once seen in ED by the emergency team, there was ready recognition of the acute abdomen and potential for complications. CXR was arranged and referral to Gynaecological and Surgical teams proceeded.

I believe appropriate imaging and investigations prior to surgery were arranged in a timely fashion. I believe these were essential for optimal surgical planning and best patient care.

Meanwhile, [Ms A] was stabilised, antibiotics given and [Ms A] assessed by the teams responsible for aspects of care.

I believe the Gynaecological and the General Surgical Teams attended promptly, after admission through ED, and arranged surgery together in a timely fashion with the necessary discussion and planning.

I believe there was no deviation from the expected standard of care.

I believe my peers would agree with this.

8. Please comment on the follow up actions undertaken by [Dr B] and [the DHB] in relation to [Ms A's] complaint and to the incident in question. Are there any remedial actions you feel might be considered appropriate?

I believe the follow up actions by [the DHB], particularly in providing a guideline for [use of the device] in [the public hospital], are excellent. I believe the temporary cessation of [use of the device] was appropriate until such time as adequate assessments were made.

I believe the serious incident investigating, not yet reported, was appropriate to instigate.

[Dr B] followed up the patient, visiting post laparotomy. She also attended the pathological examination of the laparotomy specimens, to better understand how the partial perforation, and the thermal injuries occurred.

Regarding remedial actions, I believe [the public hospital] staff should be made fully aware of the correct pathway for acute problems presenting after private surgery. Particularly, that admission should only be through ED and with the On Call Gynaecological Team advised. Thereby, the Gynaecology Team can take responsibility for the case in [the public hospital] and any surgery be arranged under their care. The private surgeon may remain in a supportive but not a clinical role. Should that person on call for the unit also be the private and acute on call surgeon, then it may be best to involve the second on call specialist.

9. Are there any other matters in relation to [the public hospital] that you consider warrant comment?

As stated above, I would advise review of teams' understanding of acute admissions, in the context of post private surgery. I am not certain if protocols exist for acute admission to hospital, but these should ensure full work up is performed, prior to any booking for acute surgery, by the On Call Team, irrespective of whether the patient was previously under the care of a private surgeon. [The public hospital] is a busy hospital. The non-availability of the IUD string hook in a main theatre would not be unusual, as they are very infrequently required in such an inpatient emergency surgery setting.

Regarding time delays in seeing ED admissions, I believe this is an ongoing problem when there is triaging needed to manage acuity.

I do not believe that [Ms A's] long term outcome was changed by this delay, but she did experience significant distress.

Celia Devenish
Consultant Obstetrician & Gynaecologist
MBBS FRCOG FRANZCOG"

Electronically reviewed & signed

The following further advice was provided by Dr Devenish:

"Thank you requesting further advice and comments, in respect to my previous report of 2017. I have reviewed the additional information provided by [HDC], which was received 2 Oct 2018.

1. Was the consenting and information sharing process undertaken with [Ms A] prior to her endometrial ablation procedure adequate and consistent with expected standards? Would you expect the risk for thermal injury to be discussed?

The consent completed by [Ms A] and [Dr B] covered the risks of bleeding, infection and uterine perforation. A RANZCOG information sheet is available for women undergoing hysteroscopic procedures. The relevant page of this patient information sheet 'Hysteroscopy' is attached. It outlines under bullet points in the section 'Possible Complications of Hysteroscopy and Hysteroscopic Surgery'

'
- *Cuts or puncture damage to nearby organs (such as bladder bowel or blood vessels) if perforation of the uterus has occurred. Laparoscopy or open surgery to repair damage may be necessary.*
- *Heat damage to nearby organs (such as the bladder, bowel or blood vessels) caused by electrical or laser instruments during cautery to stop bleeding, or during resection or ablation of tissue.'*

Whilst this RANZCOG information handout may not be provided to patients, it does outline standard of information expected when providing patient information and obtaining consent. If, in private practice outside a DHB, then it is the Fellow's responsibility to provide the appropriate patient information, and to ensure the patient is aware of the relevant risks and write these on a consent form.

From the information now available to me, [the DHB's] information sticker does not mention 'damage to adjacent organs', which is recommended by both RANZCOG and RCOG Consent Guidelines for such a procedure. Whilst thermal damage to adjacent organs is a rare occurrence, outlining potential damage to adjacent organs and the uterus is the expected standard of care, as per RANZCOG RCOG and many DHBs' expectation.

Please see the RCOG guideline re Consent for Dilations Curettage and Hysteroscopy under General Anaesthesia. This guideline also states that 'the risk of damage to adjacent structures' should be outlined, including thermal damage, and that 'damage may involve bowel, bladder and blood vessels'. Whilst this is 'rare' by definition, these complications occur at the rate of 1 in 1,000 to 1 in 10,000). (See attached RCOG guideline).

The [Device] Manual for Operators Instructions by the device manufacturer … does state a Thermal injury to adjacent tissue as a 1 in 10,000 risk. This is in the category of 'rare', but important to mention, as per RCOG guidelines when consenting.

2. Was [Ms A] a suitable candidate for the ablation procedure?

The interpretation of visual findings at hysteroscopy is more reliable than the images produced indirectly.

[Dr B], at the time of surgery, wrote sub-septate uterus. There will be varying opinions from a specialist of what is sub-septate and what arcuate and many practitioners will use the terms interchangeably or vary in their own definition of what each term means. It is not clear why the dictated operation note re operative findings was subsequently changed to 'arcuate'. There is no operative record of the two failed attempts to insert the device satisfactorily prior to the third attempt which proceeded when measurements suggested there was appropriate positioning.

Whichever term, either arcuate or sub septate was used, I believe there was a relative contraindication to continuing the procedure after initial failures to seat the device satisfactorily.

3. Does it appear [Ms A's] procedure was carried out in a manner consistent with manufacturer recommendations and expected standards of care?

It is noted that the [device's] instructions for Operators current at the time of the procedure in 2017 included 'sub-septate' uterus, as an exclusion criteria for the device and or any other congenital abnormalities ….

Although designed to detect a perforation of the uterine wall it is an indicator only and it might not detect all perforations in all circumstances. (Presumably both full thickness and partial wall perforations) *Clinical judgement must always be used.*

The current [device] advice includes amongst exclusions 'any other congenital uterine abnormality'. I believe that the expected standard of care would be that operators do not manually adjust the contour of the device after two failed attempts, in order to achieve a satisfactory [safety check pressure] reading. There is no advice that this should be performed in the instructors manual or apparent in the [device] literature. I believe that the standard of care would be to abandon the procedure. It was the lack of routine ease in achieving the expected satisfactory [safety check pressure] reading, which might have been a reason to stop the procedure after two attempts before manipulating the shape of the device. Abandonment of the procedure was suggested by the theatre nurse at the time in her statement. It may be that [Dr B] considered this. I believe most specialists would have considered abandoning at this point to review all possible options after discussion with the patient.

I do believe efforts to provide the planned patient care, as planned by [Dr B], were appropriate to a point, and that eventual completion of the procedure was a decision made in the context of this commitment.

Of note, the glandular hyperplasia diagnosed from the curetting obtained at the time of D&C hysteroscopy and [device] ablation on 21 March 2018 was of relevance in consideration that a hysterectomy may have been also an option, in this particular case.

I do believe there was a mild deviation from the expected standard of care in persevering with the procedure with the same device and manipulating the device. I believe my peers would agree with this.

I do believe that prior work up of the patient may have been beneficial to [Ms A]. Many DHBs do not accept referrals to the Gynaecology Outpatients without prior pelvic ultrasound scans. Similarly, prior sampling of the endometrium with pipelle is common practice to booking a [procedure using the device] or any ablative procedures, which subsequently destroys the endometrium. Whilst this may not be considered necessary in private practice, it is the private specialist who determines this.

4. Are there any other matters in relation to [the private hospital] that you feel warrant comment?

I understand from the information provided that [the private hospital] has generic consent forms and it is the responsibility of the individual surgeon to provide appropriate consent. I would suggest, however, that the space in which to write information, be larger and a check box that the patient had received written or other patient information regarding the procedure be available on this form.

In relation to the information re postoperative care, I note that [the private hospital] now provides the surgeon's contact number. I also note from the new information provided that the nurse who spoke with [Ms A] did state that [Ms A] had [Dr B's] contact number.

5. Was [Ms A's] management by [Dr B] on the 22nd March 2017 consistent with expected standards of care? In particular, was there any reason to suspect uterine perforation or to investigate further for this possibility?

I believe that the suspicion of uterine wall injury and heat injury to the bowel should have been greater at the time of [Ms A's] review on 22 March 2018 in [the public hospital]. It is unusual for a woman not to tolerate a speculum examination and to experience such pain as led to a request for nitrous oxide for analgesia. It appears because speculum examination was not tolerated, the admission for examination under a general anaesthetic occurred. It is also unusual to require a general anaesthetic for extraction of a recently placed IUD. If being expelled, it is unusual for a GA to be required for removal for an IUD, which is in the correct place. IUD expulsion was believed to be the cause of the pain, yet the degree of pain described by the Acute Gynaecology Unit Nurse, appears excessive. It is also unusual for the IUD threads to be missing immediately after insertion. These issues could have given rise to reflection on alternative causes of [Ms A's] pain. Consent for IUD removal, hysteroscopy and laparoscopy was subsequently obtained. Had the laparoscopy been performed, the uterine fundus thermal injury and large bowel injury would have been seen, and appropriate surgical measures taken at an earlier stage. This decision depended on an index of suspicion. It is difficult to diagnose a full thickness uterine wall injury at hysteroscopy when the cavity of the uterus has been recently ablated and charred. The IUD was also a distraction. The IUD was difficult to visualise with only the stem seen in the cavity on ultrasound. It is unusual for polyp forceps not to succeed in removing an IUD entirely within the uterine cavity. The operation note states only the threads were seen in the uterus at hysteroscopy. There is no record of the hysteroscopic findings following successful removal of the IUD device before completion of surgery on March 22 in [the public hospital], so it seems likely further inspection of the uterine cavity did not occur. Whether laparoscopy was performed at the time of hysteroscopy was a matter of clinical judgement of the risk of other complications. There was an opportunity to exclude other significant complications by a laparoscopy. At hysteroscopy following thermal damage with ablation, it would not be possible to assess the depth of thermal damage to the uterus, and difficult to exclude uterine perforation, partial or not. This would have been evident from a laparoscopy however.

There is no record that any differential diagnoses were considered as a cause for significant pain, on March 22 2017, the day after the [ablation] procedure. The 'displacement' of the IUD alone was considered as causal. My comments are not made with the 'benefits of hindsight', rather in the context that exclusion of other causes of pain is the expected standard of care. There is good knowledge of previous cases of injury to bowel after a range of thermal Hysteroscopic procedures. The expected standard is that specialists always consider the potential complications of perforation and or heat spread causing damage to adjacent structures whenever a procedure is performed on a hollow organ.

There are cases reported locally in NZ of heat damage from a range of intrauterine ablation techniques. These cases have not necessarily been referred to HDC. It is possible that another specialist opinion, (appropriately the On Call Gynaecologist), might have suggested a laparoscopy whilst the patient was still under anaesthesia, to ensure that there were no other problems associated with her presentation with pain. The diagnosis of uterine serosa or other organ damage is not possible at a post-ablation hysteroscopy. Even if this specialist On Call Gynaecologist was not on site, a call to discuss the case might have been an option. The On Call Gynaecologist is responsible for all gynaecology patients admitted to the Public Hospital, and may have added different insights.

I note that in the original statement from [Dr B] in her letter to [HDC] in 2017, page 3, a septum was mentioned, and that the [safety check pressure reading] was completed at the first attempt. The scrub nurse, [RN E], made a statement subsequently, which stated that [Dr B] performed three insertion attempts of the device, before obtaining the satisfactory [device] machine readings and that she herself had suggested abandoning the procedure.

I note also that in the recent response to HDC, [Dr B] states that the uterine cavity was arcuate, in contrast to her description to [HDC] of a septum. Whilst this inconsistency in descriptors may, or may not be material, it seems that the ablation procedure was not straightforward.

I believe the failure to consider other causes of pain and exclude these at the time of review and repeat surgery on March 23 2017 was a moderate deviation from the expected standard of care. I believe my peers would agree with this.

6. Was it reasonable for [Ms A] to be discharged from [the public hospital] around 11pm on the 22nd March 2017?

The procedure under GA lasted from 15.37 to 17.23 on 22.3.17, a total of around 100 minutes. Under general anaesthetic, pain relief medications of Tramadol, Pethidine and Buscopan, were given in the postoperative recovery area. I believe the opportunity to review [Ms A] overnight in hospital would have reduced the time interval to diagnosis of her complication. As an alternative to overnight observation, review early the next day in person or by a telephone call could have been arranged. I believe this would be the expected standard of care in the unusual circumstances of this case given [Ms A] was

post hysteroscopic ablation under GA with a repeat prolonged GA the next day for retrieval of missing IUD strings. It could be debated whether the responsibility to review [Ms A] lay with the private gynaecologist or [the public hospital], but ultimately, it was the responsibility of the surgeon in either capacity.

I believe this was a mild deviation from the expected standard of care, in that follow up in person or contact with [Ms A], was not made early the next day, in the absence of overnight observation. I believe this because there would have been reassurance, if [Ms A's] pain had settled postoperatively, following removal of the IUD in theatre, whereas, ongoing and worsening pain, as was the fact in [Ms A's] case, would have alerted the specialists to the suspicion of another complication, apart from cramps with the IUD. [Ms A] reported worsening pain, also worse on movement, during the morning following discharge 23 March. Review in the Emergency Department recorded 10/10 pain, prior to morphine injection, and she described severe lower abdominal cramps, shoulder tip pain and had a low blood pressure. Following a CT scan, which confirmed large uterine fundal and rectal perforations, definitive surgery was planned and completed overnight.

Peritonitis resulting from thermal damage to adjacent organs commonly presents on the third day post procedure. Fever and compromise usually only become evident after this time. Consequently, an appropriate index of suspicion for this complication is required when reviewing presentations with unusual pain post hysteroscopic procedures and this is relevant to best practice.

I believe there was a mild deviation from the expected standard of care because a planned routine follow up the next day after a late discharge was not made. I believe my peers would agree with this.

7. Was assessment and investigation of [Ms A's] abdominal pain, following her return to [the public hospital] at 3.18pm on the 23rd March 2017 undertaken in a timely and clinically appropriate fashion? Was surgery performed in a timely fashion?

I have no further comments to these already addressed. Given the acuity of the Emergency Department, I believe that [Ms A] was seen and treated within appropriate timeframes.

8. Please comment on the follow up actions undertaken by [Dr B] and [the DHB] in relation to [Ms A's] complaint and to the incident in question. Are there any remedial actions you feel might be considered appropriate?

I have no further comments to these already addressed, other than inclusion of 'damage to adjacent organs as a risk of a hysteroscopy procedure' to any consent stickers for this procedure. Whilst the consent 'stickers' provided by the local DHB may lack the risks of adjacent organ damage at the time of hysteroscopy, this does not obviate the individual practitioner's responsibility when working independently. I appreciate that the level of information shared may vary around different areas of

New Zealand. RANZCOG information material does attempt to standardise the information available to women. This information is available online for all Fellows.

I had not previously seen the report following the sentential event investigation, which was not available at the time I wrote my report. I was specifically asked by [HDC] to complete my report to HDC independently, prior to this becoming available. It meant I did not have the benefit of some information, however, I do not believe the subsequent reports and information significantly change my replies to the principal questions originally asked.

The [private hospital] notes are helpful in clarifying the consent, operative findings and postoperative checks and conversations held, but do not alter my concerns about the level of information documented that were given to the patient.

9. Adequacy of the policies in place at [the private hospital] and [the DHB]

I believe the policy on transferring patients from private practice to [the public hospital] and discharge criteria following day surgery are currently comprehensive.

I believe that the [private hospital] policies in relation to informed consent, discharge of patients and post discharge telephone contact with patients are adequate. I would suggest that the Consent Forms contain adequate space, in which to write the potential complications, and provide a check box to indicate that written information was provided to the woman.

I am aware that such tick boxes and a larger space to describe potential complications are provided in other hospitals' consent forms, both private and public. Provision of RANZCOG patient information RCOG or other guidelines re consent may also be useful for patients' best understanding of procedures and their risks.

In summary, I believe that any unexpected presentation following a surgical procedure should be assessed by the surgeon, as soon as possible and all potential differential diagnoses considered.

I believe there was a moderate deviation in the expected standard of care in respect to the assessment and management of [Ms A's] re-presentation day 1 post hysteroscopic ablation. I believe that the patient follow up plan at discharge should ensure contact with the woman, to confirm resolution of the presenting postoperative symptoms in such circumstances. The follow up plan is the responsibility of the specialist in charge of the patient's care. It is not evident from the notes what advice [Ms A] received following discharge at 11pm 22 March 2017.

Whilst serious damage to adjacent organs may be rare, it is the awareness that this risk can occur that is paramount. Such complications may occur after any hysteroscopic procedure and, therefore, necessitate an appropriate level of suspicion. Suspecting a potential complication allows timely diagnosis and interventions for rare but serious complications.

Systems regarding patient transfer to public hospitals from private care to Public hospitals have been adequately addressed.

Introduction of any new medical interventions and devices should be also accompanied by a comprehensive national audit in New Zealand. The results should be disseminated to all surgeons, who may then benefit of the learning points.

Celia Devenish
Consultant Obstetrician & Gynaecologist
MBBS FRCOG FRANZCOG"

Electronically reviewed & signed

The following further advice was provided by Dr Devenish:

"**Further advice**

1. Re documentation of initial procedure 21.3.17

My comments made in 2017 and 2018 were in the light of the hand-written operation note written at the time and without access to hysteroscopic images. This contemporaneous operation note described a sub-septate uterine cavity. Use of [this] device is not appropriate in such a uterus.

I accept the subsequent corrections made retrospectively to the operation procedure. After viewing the hysteroscopic photographs, I do not believe there was a sub-septate uterine anomaly, which would have precluded deployment of the device.

I note and agree with [Dr H's] comments in points 4 and 5 that he would not have used the device, given the 2.7 cm width.

I do note that throughout the procedure, reference was made to the 'septum'. The Anaesthetist present at the surgery, who responded to HDC with a statement, clearly confirming that [Dr B] spoke of a 'partial septum' during the procedure. I conclude that the uterine cavity was not entirely normal.

[Dr B] also states in her initial written response to HDC that the device was withdrawn to satisfactorily seat the device 'below the level of the septum', but in the event, the evidence suggests this did not occur.

There is another possible explanation for the initial appearance of the uterine cavity. The subsequent uterine pathology report describes a 2cm diameter intramural fibroid, adjacent to the area of the fundal myometrium, showing it is possible this posterior wall fibroid created a bulge, simulating a sub-septate or arcuate appearance. Since

there was no previous ultrasound scan, the fibroid had not been previously diagnosed. The quality photographic images do not completely clarify this question, but there is certainly no significant septum.

Of interest, this pathological examination, post hysterectomy, described a 2cm intramural fundal fibroid adjacent to a thermally created neo-cavity. Smaller fibroids or, indeed, an arcuate uterus, are not a contraindication to ablation.

I believe, as stated in both the Pathologist's report and that from [Dr H], that the device was applied close to or into the fundal myometrium to cause this neo-cavity, adjacent to the intramural fibroid and resulted in intra-abdominal damage.

As described by others, [the device] assumes a standard shape of a uterine cavity with some minor adjustments possible to width and depth of placement. Hence, the checks prior to deployment, if not in the correct position, the unequal spread of EM waves with distribution through to abdominal organs.

I note Dr H's comments in his statement, points 4 and 5, and that he would not have used the device, given the 2.7 cm width. I agree with these.

The device's safety mechanisms ideally prevent deployment when the device is malpositioned, but this is not fail-safe, especially if any force is used.

Irrespective of how many cases are performed by a Gynaecologist, there is an increased risk of an adverse event and of thermal injury beyond the endometrium, if the device is not correctly sited or seated with a width, where caution is advised.

[Dr B], in her initial reply to HDC, describes the technique she used was to withdraw [the device] 'to 5 cm, at or below the level of the septum'.

The maneuvers to ensure correct placement were not effective, on this occasion.

The ablation procedure carried out was with the incorrect siting of the device, but being a blind procedure, this was not recognised. This allowed EM wave transmission in internal organs, such as the adjacent sigmoid rectum, which caused necrosis and the rectal 0.5 cm perforation defect, in addition to the similar sized uterine fundal defect. These necrotic thermal injuries were complicated by abdominal peritonitis following the bowel perforation as found at laparotomy on the 23.3.17.

I believe this is the case because histological examination of the uterus, three days later (after hysterectomy), described a 'neo-cavity into the fundal myometrium, approaching the serosal surface (abdominal cavity aspect) continuous with the endometrial cavity'. Adjacent to this was the posterior fundal fibroid within the myometrium. The histology suggests the device was in direct contact and likely penetrating the muscle fundus, adjacent to the fibroid, and the thermal effect created a neo-cavity approaching the serosa with variable degrees of thermal damage around.

In summary, the pattern of charring from ablation described by the Pathologist does not concur with [Dr B's] description of 'having withdrawn the device below or at the level of the septum', as it appears one of the prongs was against or penetrating the fundal myometrium.

Documentation at the time of surgery describes the 'distance to the cornea was 9.5cm (lateral horns) 8.5cm to septum — sub-septate uterus able to get 55% coverage with ablation' post procedure 85% coverage was estimated. This was a normal sized uterine cavity.

I would expect that the expected standard of practice for a Surgeon, when they reflect on a statement written at the time of surgery, would be to correct this with an addendum to the hospital notes, especially in light of the serious complication that eventuated.

I believe this is a mild deviation from the expected standard of care. I believe my peers would agree with me.

If the uterus is arcuate in shape, there is no contraindication to ablation.

2. With regard to my own experience in operative generalist Gynaecology

I myself have performed diagnostic and operative hysteroscopy for over 25 years, this being from the time at which instrumentation became routinely available in New Zealand. This has included various techniques for endometrial ablation developed over time.

I have practiced generalist Gynaecology and Obstetrics for over 40 years and for ten years, I have practiced mainly operative generalist Gynaecology, which included many hysteroscopy and operative procedures in both public and private hospitals, as inpatient and outpatient procedures, and including [ablation using the device].

Endometrial ablation has been provided by our Gynaecology Department service at Dunedin Hospital for many years, including [the device].

I have attended courses re hysteroscopy and various modalities of ablation over this time. The most recent update being a three day course at RCOG. I continue to teach hysteroscopy operative procedures to trainee specialists in everyday theatre lists. I also convene and teach at the yearly RANZCOG Basic Surgical Skills courses for new ITP trainee registrars. Whilst I may not have ablation case numbers as large as some practitioners, I am well aware of the correct procedures and understand the difficulties and the importance of correct placement of the device, which is related to an appreciation of the uterine cavity itself and requires hysteroscopy skills and experience. I also convene and teach the annual RANZCOG trainees course in the anatomy of Surgical Complications, which includes those related to ablation and operative hysteroscopy, as well as how best to avoid these complications.

3. Regarding the surgery on 22.3.17 EUA Hysteroscopy and IUD removal

The difficulty in finding the misplaced IUCD is unusual, since the working diagnosis was this was being expelled and was partially sited in the cervical canal. It may be the acutely anteverted uterus was the factor as [Dr H] suggested. At hysteroscopy, the IUCD would appear as a white stem with threads visible. If in the uterus, this would be against a charred background of the treated cavity. Unfortunately, there is no image of this procedure to better understand the issue. Perhaps a photograph was not taken. It is possible that the IUCD was not entirely within the uterus. The threads of the device were eventually hooked by the 'pelican', after attempting to grasp with polyp forceps after some delay. The pelican is a device chiefly used in an awake, un-anaesthetised patient. It is a blind procedure. Commonly operating hysteroscopes are used to do this, as it allows removal of an IUCD under direct vision.

As no images were taken of the hysteroscopic views at this second procedure, it is not possible to know what the cavity looked like and if the fluid noted on abdominal ultrasound had leaked out from a defect in the uterine fundus.

I note consent for a laparoscopy was taken, but this was not performed. I believe, in the circumstances, most Specialists would have done this. I note [Dr H] also states this. The laparoscopy may have been planned, should there be the need to locate an IUCD, which may have been outside the uterus.

[The clinical director's] report states that the supporting Obstetric Consultant, who was doing the ultrasound scanning at the time, recommended review by another Gynaecology SMO, who was on acute call, or use of an operating hysteroscopy, to better locate and remove the copper IUCD and that she noted free fluid in the abdominal cavity.

There is no documentation that other causes of [Ms A's] pain were considered over this time, including risk of intra-abdominal injury. It would be unusual that a woman could not tolerate a speculum examination when awake, following a straightforward procedure.

I believe that most Specialists would have sought the advice of a General Surgeon for this acute presentation or at least the Gynaecology Consultant On Call colleague at the time.

I believe this is a mild to moderate deviation from the expected standard of care.

I believe that evidence of the consideration and documentation of all differential diagnoses is important, as part of the expected standard of practice. I believe my peers would agree with me.

4. Clarification re Patient information provision from RANZCOG (see attached)

Clarification re RANZCOG Hysteroscopy patient information: A guide for Diagnostic and Operative hysteroscopy edition 2.

I attach the patient information available to patients and practicing Fellows at the time of the procedure 21.3.17. It contains information re complications, including thermal injury.

This edition 2 is attached, as a scanned pdf.

The information relating solely to Basic diagnostic 'Hysteroscopy' risks and benefits was updated on a separate information sheet in July 2016.

I also attach below the online [device] advice to patients re risks of the procedure.

5. Re advice re risks given to patients at time of consent

It is the Clinician's responsibility to give information relevant to context of individual patients, i.e. the small risks of other organ damage and thermal injury has routinely been given to women in our unit undergoing endometrial ablation with [the device].

I am not aware of any objective New Zealand or international survey of what information is routinely shared with patients by gynecologists prior to [device] ablation technology, as part of informed consent. I and my colleagues believe that even if the risk is slight, any serious life-threatening complication should be mentioned to women, as it is relevant to informed patient consent. I accept there may be variation between specialists in New Zealand practice, in this regard. In other disciplines e.g. Anesthetics, it is the reason why very rare events consequent to a routine epidural or spinal and general anesthetic are described and consented about.

The [device] advice to patients available on line for patients contains mention of this risk also (as below).

In summary, I believe the key points to be considered are:

- Whether the uterine cavity was such that made the procedure more difficult than usual. Importantly, what led the device to be malpositioned and yet still deployed with subsequent injury.
- Whether wider advice, re [Ms A's] presentation with postoperative pain, assumed due to the IUCD expulsion, might have been sought on 22.3.17 when admitted to [the public hospital] for pain post ablation. This could have been from General Surgery or the On Call Gynaecology Consultants, as to whether a laparoscopy was indicated at this time. I believe this was a moderate deviation from the expected standard of care and to the hospital guidelines re acute admissions from private.

Re the 22.3.17 11pm discharge from hospital post-surgery.

- I believe that it would have been safer and very reasonable to keep [Ms A] in hospital overnight for observation or at least offer this option. Also, to seek another surgical opinion, either at the time or before discharge home or, at the very least, to arrange review the next day, especially since no laparoscopy was

performed. I believe my peers would agree with this. [Ms A] was in significant pain the next morning.

- Re Patient information re risks of surgery shared with the patient preoperatively. I understand that there may be some variation in information provided by Surgeons. All procedures have capacity for error, whether via the operator, device or systems. I believe patients should be aware of any risks significant to them, when giving consent, especially when there are rare, but serious complications. These are as suggested in patient information available from RANZCOG, as used in DHBs at the time and consistent with [device] on line information. I believe most of my peers would agree with this. I do not believe this was a significant deviation from the expected standard of care, as Clinicians vary in their views on this.

In light of the additional information provided, I would like to change my previous opinion re deviation from expected standards of care. This is because I accept [Dr B's] explanation that the uterus was not actually sub-septate, despite original documentation in theatre. I also appreciate that there may be some variation in the amount of pre-operative information provided to women before consent.

I believe there was a mild to moderate breach of standards, in relation to the original questions asked in 2017 and 2018.

Otherwise, I agree with the comments made by [Dr H].

I acknowledge [Dr B] has experience in using [the device]. However, there remains no explanation as to why the device, as a second generation [device] with safety mechanisms, could be deployed when incorrectly positioned with serious consequences to the patient."