Obstetrician and Gynaecologist, Dr B

Private Hospital

A Report by the

Health and Disability Commissioner

(Case 15HDC01925)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Ms A, aged 36 years at the time, privately consulted Dr B at a private hospital for assessment and management of heavy menstrual bleeding and post-coital bleeding.

2. On 15 December 2015, Ms A signed a consent form for a hysteroscopy, dilatation and curettage, endometrial biopsy and a Novasure endometrial ablation, to take place under general anaesthetic that day. Prior to the commencement of surgery, a "Time Out" check took place, which included reading out the procedure on the consent form.

3. Dr B experienced technical difficulties with the Novasure machine while attempting to perform the endometrial ablation, and therefore abandoned the procedure.

4. At this point, Dr B considered several alternative procedures, and had devices for these alternatives brought into the operating theatre. Dr B decided to insert a Mirena intrauterine device[1] into Ms A's uterus, despite Ms A having declined to have a Mirena inserted on a previous occasion, and not having given consent to have a Mirena inserted on this occasion. Dr B said that he considered the Mirena to be the safest and most easily reversible treatment option.

5. While in the recovery room, Ms A discovered what had occurred, and was distressed that a Mirena had been inserted without her consent. Dr B apologised to Ms A and removed the Mirena.

Findings

6. The principle of informed consent is at the heart of the Code of Health and Disability Services Consumers' Rights (the Code). Pursuant to Right 7(1) of the Code,[2] services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. It is the consumer's right to decide and, in the absence of an emergency or certain other legal requirements, clinical judgement regarding best interests does not apply. If the consumer will be under general anaesthetic, the Code provides an additional safeguard that consent must be in writing.[3]

7. It is plainly unacceptable that Dr B inserted the Mirena without having first obtained Ms A's consent. Ms A was particularly vulnerable as she was under a general anaesthetic. The right to decide was Ms A's, and she was deprived of it. By inserting the Mirena into Ms A's uterus when she had not given informed consent, Dr B breached Right 7(1) of the Code.

8. Adverse comment is made about registered nurse (RN) RN C, as she was aware of what was on the written consent form but did not query the absence of written consent with Dr B when he began considering alternative treatment options.

[1] The Mirena once inserted into the uterus releases synthetic progestogen. It is commonly used for contraception but may also be used to control heavy menstrual bleeding.
[2] Right 7(1) of the Code states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise."
[3] Right 7(6)(c) of the Code.

9. Adverse comment is made about the private hospital, as this case illustrates a missed opportunity to advocate for Ms A when she was under anaesthetic and vulnerable. Furthermore, the expectation set down by the private hospital in its informed consent policy, that "[n]o consent should be presumed", does not appear to have been adhered to.

Recommendations

10. The Commissioner referred Dr B to the Director of Proceedings for the purpose of deciding whether proceedings should be taken, and recommended that Dr B undertake further education and training on informed consent.

11. The Commissioner recommended that the private hospital:

a) use an anonymised version of this case for the wider education of its staff and the surgeons who use its facilities, with particular emphasis on informed consent and advocacy for the consumer; and

b) provide HDC with an update of the corrective actions it has taken since this incident, including copies of the updated consent form and informed consent policy.

12. The Commissioner recommended that the Medical Council of New Zealand consider whether a review of Dr B's competence is warranted.

Complaint and investigation

13. The Commissioner received a complaint from Ms A about the services provided by Dr B at the private hospital. An investigation was commenced on 9 June 2016 and the following issues were identified for investigation:

- *Whether, in 2015, Dr B provided Ms A with an appropriate standard of care.*
- *Whether, in 2015, the private hospital provided Ms A with an appropriate standard of care.*

14. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Dr B	Provider/obstetrician and gynaecologist
Private hospital	Provider
RN C	Provider/registered nurse — scrub nurse
EN D	Provider/enrolled nurse — circulating nurse
RN E	Provider/registered nurse — relief circulating nurse
Dr F	Provider/specialist anaesthetist

RN G	Provider/Surgical Services Manager for Ward and Day Stay Unit

Information gathered during investigation

Timeline of care

Background

15. On 23 January 2015 Ms A, aged 36 years, was referred privately by her general practitioner (GP) to Dr B for assessment and management of the post-coital bleeding Ms A had been experiencing for around 6–12 months.

16. Ms A first consulted Dr B on 17 March 2015. At this consultation, Dr B noted that Ms A experienced post-coital bleeding and that she had been "troubled with heavy periods leading to iron deficiency". Dr B examined Ms A and noted that there was no major ectopy[4] to explain the post-coital bleeding. Dr B's clinic letter to the GP recorded his recommendation that Ms A undergo a hysteroscopy,[5] possible polypectomy,[6] dilatation and curettage (D&C),[7] endometrial biopsy,[8] and insertion of a Mirena intrauterine device.

17. A Mirena is an intrauterine device (IUD) or intrauterine system (IUS) inserted into the uterus. The device releases the progestin hormone levonorgestrel. A Mirena is commonly used for long-term contraception, but may also be used to control menorrhagia (heavy menstrual bleeding). Dr B considered that a Mirena was a safe option for controlling Ms A's menstrual bleeding.

18. Ms A told HDC that she was very clear in telling Dr B that she did not want a Mirena fitted; however, Dr B continued to suggest this option and persuaded her to include the Mirena insertion on her medical insurance forms, in case she changed her mind on the day of the procedure. Mirena insertion was also recorded on the consent form. Dr B told HDC that Ms A did not decline the insertion of the Mirena at their first consultation. He stated: "Had [Ms A] declined the insertion of the Mirena prior to her scheduled surgery date I would have recorded it in the original letter to her GP and in my original clinical notes from our first consultation."

19. On 4 May 2015, Dr B performed a hysteroscopy, D&C, and biopsy on Ms A. Ms A said that, prior to the procedure, she confirmed with staff that she did not want a Mirena, and ensured that this was crossed off the consent form. Dr B told HDC that

[4] Cervical ectopy refers to a raw-looking appearance on the cervix. This occurs when the inner lining of the cervical canal comes out onto the part of the cervix that can be visualised with a speculum.
[5] A procedure used to diagnose the cause of abnormal bleeding, in which a thin, lighted tube is inserted into the vagina to examine the cervix and inside of the uterus.
[6] The removal of polyps.
[7] A brief surgical procedure in which the cervix is dilated and a special instrument is used to scrape the uterine lining. A D&C is used either to diagnose and treat certain uterine conditions such as heavy bleeding, or to clear the uterine lining after a miscarriage or abortion.
[8] A biopsy of the lining of the uterus (endometrium).

Ms A declined the Mirena insertion that day, and he wrote this in a clinic letter to the GP. Dr B also said that he advised Ms A that removal of the endometrial polyp and a D&C would not assist with her bleeding.

20. In response to the provisional opinion, Dr B stated that, at this time, Ms A was seeking reassurance that nothing sinister was causing her post-coital bleeding, and wanted to wait and see for the next few months. He told HDC that he discussed with Ms A at the time how the Mirena works and possible side effects associated with it.

21. On 14 July 2015, Ms A had a follow-up appointment with Dr B to discuss the biopsy findings and options for treating her heavy bleeding.

22. Ms A told HDC that, when she walked into the room, Dr B told her that he had fitted a Mirena during surgery, and she responded that she hoped he had not, because she did not want one. Ms A said that Dr B checked his notes, found that he had not fitted one, and said to her, "That's right, you changed your mind on the day." She said that she remembered this comment because she had not changed her mind; she had never wanted a Mirena. She stated that she pointed this out to Dr B. Dr B told HDC that, at the time of this consultation, he did not have Ms A's full patient folder with him and, when he reviewed his preoperative letter, it included the Mirena insertion. He said that when he reviewed his operative notes, he recalled that Ms A had declined insertion of the Mirena on the day of her surgery.

23. Ms A told HDC that Dr B continued to discuss with her the option of inserting a Mirena, and seemed annoyed when she kept refusing this option. She stated that Dr B told her, in a firm manner, that he was just trying to help her. Ms A said that she was clear that she did not want a Mirena and asked about alternative options.

24. In response to the provisional opinion, Dr B said that he did not pressure Ms A to have a Mirena inserted, and merely discussed the Mirena as a first choice minor procedure recommended by obstetricians and gynaecologists in New Zealand, Australia, the United Kingdom and elsewhere.

25. Dr B's letter to the GP, dictated on 14 July 2015, states:

> "… As you are aware [Ms A] declined the Mirena … Today again I have gone through the options of managing her menorrhagia with severe heavy bleeding with clots including oral progesterone,[9] oral non-hormonal treatment and endometrial ablation using thermachoice or novasure.[10] She will think about the novasure and thermachoice and she will come back to us if she wants to go ahead with endometrial ablation."

26. While considering her options, Ms A was referred for treatment of varicose veins. To avoid undergoing general anaesthetic twice, Ms A decided to have surgery for her

[9] Progesterone is a hormone released by the ovaries.

[10] An endometrial ablation is a procedure that surgically destroys (ablates) the uterine lining (endometrium). Endometrial ablation can be done in multiple ways, including with heat (Thermachoice device), radiofrequency (Novasure device), or electricity (a resectoscope with a loop or rolling ball electrode).

varicose veins at the same time as endometrial ablation. The procedures were scheduled for 15 December 2015 at the private hospital.

27. In response to the provisional opinion, Dr B told HDC that Ms A emailed Dr B's nurse and secretary requesting to have the ablation at the same time, and declined to come in for a further consultation to discuss and sign the consent form face-to-face because she lived some distance from the hospital.

Consent to 15 December 2015 surgery

28. On the day of surgery, Ms A signed a written consent form which recorded the procedure as "hysteroscopy, D&C, endometrial biopsy and Novasure endometrial ablation". The form used was the private hospital's standard surgical consent form. It contains the standardised statement: "I have received an adequate explanation of the benefits, risks and the expected outcomes of this surgery/procedure and the specialist has explained alternative options and the risks of **not** having the surgery/procedure" (emphasis in original). The "yes" box next to this statement is not ticked on Ms A's form.

29. The consent form has a specific section to include any special requests or instructions regarding the procedure, and this section was left blank on Ms A's form. Dr B told HDC that, prior to surgery, he did not discuss with Ms A possible alternative treatments if there was a problem with the Novasure machine as, having previously performed a hysteroscopy that showed that the uterine cavity was normal, he was not expecting any problems.

15 December 2015 surgery

30. Ms A was prepared for surgery. This process included a "Time Out" check, which included reading out the consent form. Registered nurse (RN) RN C was assisting in theatre, and said that she was present during the "Time Out" and was aware that Ms A had not given written consent to the insertion of a Mirena. Anaesthetist Dr F was also present for the "Time Out", but said that she cannot remember the exact details of this.

31. While attempting to perform the Novasure ablation, Dr B experienced technical difficulties with the Novasure machine, which failed to engage in Ms A's cervix owing to Ms A's anatomy. Dr B trialled the manufacturer's trouble-setting steps but these were unsuccessful and he abandoned the procedure.

32. Dr B told HDC: "[W]hen the Novasure machine failed, I asked for the Thermachoice machine to be brought in however it could not be used as [Ms A's] cervix was widely incompetent and there was a risk of bladder and vaginal burns if the hot water balloon slipped through the incompetent cervix." Dr B said that he then asked for a resectoscope[11] (a surgical instrument that would allow him to perform an endometrial resection or roller ball ablation). Dr B stated that he "considered immediately that

[11] A resectoscope is a surgical instrument used to remove tissue from the uterus, prostate, bladder or urethra. It is a type of endoscope, an instrument that combines a camera and instrumentation to allow a surgeon to view inside the body and perform surgery in a minimally invasive way.

[this] is a more prolonged procedure with more risks like fluid overload and hyponatremia".[12]

33. Dr B told HDC that he also considered the fact that he had not discussed the options (and associated risks) of a roller ball ablation or endometrial resection with Ms A prior to her surgery. Dr B had not obtained Ms A's consent to the Thermachoice ablation, or rollerball endometrial ablation or resection.

34. Dr B said he decided that the safest and most easily reversible treatment for Ms A's bleeding was to insert a Mirena. He considered that this could be an interim measure until further options could be discussed with her. He also noted that Ms A had advised of her anxiety about general anaesthetic, and wanted to avoid her having to be placed under an anaesthetic for a third time.

35. In correspondence with the private hospital on 16 December 2015, Dr B stated:

> "I said loudly in theatre that although she might not like the idea of a Mirena it is the only valid option now to treat her bleeding, and I will go and explain to her in the Recovery Room that this will be a temporary measure until we explore further options."

36. The private hospital's investigation report states that no theatre nurse recalled hearing this comment. In response to the provisional opinion, Dr B said:

> "[T]he theatre nurses may not have heard [my] comment because there was a lot of background noise at the time as the charge theatre Nurse was trying to fix the Storz endoscopy tower[13] and was speaking loudly on the phone with the medical representative."

37. RN C told HDC that consent for the Mirena was not discussed in theatre, but that "Dr B said that Ms A had menorrhagia and it would be the preferred treatment since the Novasure had failed and he would discuss this with her in the recovery room when she woke up".

38. RN C further said:

> "I do not know what was discussed between [Dr B] and the patient [prior to surgery]. [Insertion of a Mirena] was a closely related procedure which [Dr B] clearly believed was appropriate and acceptable at the time. It did not occur to me that consent would be an issue. He was not asking anyone for their opinion, but rather advising what his decision was. He is an expert in his field and I felt comfortable that he would be making the right decision."

39. RN E and enrolled nurse (EN) EN D were also in theatre during the operation. However, they were not present for the "Time Out" check, and neither were aware

[12] A condition that occurs when the level of sodium in the blood is abnormally low. Sodium is an electrolyte and helps to regulate the amount of water in the body's cells.
[13] The endoscopy tower is the unit that provides visualisation and documentation of an endoscopy procedure. Karl Storz is a manufacturer of endoscopes.

that Ms A had not provided consent for the insertion of a Mirena. RN E told HDC that there was no discussion regarding consent when the Novasure ablation was abandoned. She said that Dr B contemplated using the Thermachoice machine but felt that he had not done this treatment for some time, and then said he would insert a Mirena. RN E said she did not challenge his decision, as the insertion of a Mirena is a recognised treatment for menorrhagia, and she was not in a position to know what had been discussed between Ms A and Dr B prior to surgery. Similarly, EN D said: "[T]he issue of consent did not come up for me."

40. Dr F told HDC:

> "The hysteroscopy was performed and [Dr B] attempted a Novasure ablation, however this was unsuccessful. Other equipment was sourced and discussed but not used. … I was not aware of the Mirena insertion or any discussion pertaining to it. I do not recall the exact event because at this point I was most likely drawing up drugs and completing the drug chart for recovery and was concerned with the completion of the patient's anaesthetic care."

41. In response to the provisional opinion, Dr F added that she was aware that other equipment was being sourced but was not aware that it was a resectoscope or Thermachoice machine. Dr F said that she thought they were trying to source another Novasure machine or hand piece, and therefore did not query it with Dr B.

Postoperative events

42. Dr B said that he went to the recovery room to see Ms A before he started his next case, but she was not fully awake, so he intended to return.

43. On waking up from the anaesthetic, a nurse informed Ms A that a Mirena had been inserted. Ms A told staff that she had not consented to this. Ms A said that she spoke with Dr B, who apologised and told her that it had been inserted with good intentions and he had forgotten that she did not want one. Dr B recorded in the progress notes:

> "… Obviously [Ms A] was furious and angry as I did not [obtain] her consent and knowing that she declined that option previously (Although she had MIRENA earlier and it was OK). I apologized and admitted my wrong position but explained that I did insert MIRENA with good intentions and in … good faith acting for her best interests. I did not mean to violate her trust or consent to me."

44. With Ms A's consent, Dr B removed the Mirena in the recovery room.

45. Dr B referred Ms A to a fertility clinic for ongoing management. As an interim measure until Ms A could attend the clinic, Dr B prescribed her tranexamic acid[14] to be taken during her period to decrease the intensity of the bleeding.

Subsequent events

Ms A

46. Ms A told HDC:

[14] A medication used to prevent excess blood loss.

> "I feel very angry about this abuse of my wishes while I was under anaesthetic. In our consultations, I cannot recall any discussion about secondary plans for while in theatre, should the Novasure be unsuccessful — I would have expected nothing to be done. … I actively, firmly and clearly stated numerous times that I did not want a Mirena. At no point did my position alter. He wanted me to have it. I felt pressured but I am [a] strong person and felt able to say no. I do not feel that [Dr B] understands my choice not to have a Mirena and his preoccupation with giving me one contributed to me not being advised fully of all my options. … I … firmly believe he was aware I did not want a Mirena and that he used the circumstances to do what he felt I needed, not what I had wanted. He acted against my express wishes. He may well have had good intent however he knew I had not consented and that I did not want a Mirena."

Private hospital investigation

47. On 16 December 2015, Ms A met with RN G, Surgical Services Manager for the Ward and Day Stay Unit at the private hospital, to discuss her concerns. Following this meeting, RN G and the Operating Theatre Service Manager undertook an investigation[15] of Ms A's care, which found:

> "**Consent**
> On the consent form there was no mention of alternative treatments … However, [Dr B] advised that he did discuss other options with [Ms A] verbally in the clinic including the mirena and the therma choice endometrial ablation. He commented that she had declined the mirena on her previous hysteroscopy carried out in May 2015 and this was clearly recorded in her medical notes. She had not provided an explanation for declining the mirena in May 2015 and it was noted that she had previously used a mirena without any complications between her pregnancies.
>
> From [Dr B's] recollections the reluctance for the insertion of a mirena by the patient on this occasion (during the procedure carried out in December 2015) was not definite. He comments *'I discussed the endometrial ablation with the patient at clinic in July. Instead of coming to discuss the Consent form face to face in the clinic, [Ms A] contacted my nurse by email to say that she wanted to go ahead with the Novasure ablation while having her [varicose veins] stripped.*
>
> *I answered [Ms A's] queries by email thinking that [Ms A's] reason was the long distance she has to drive […]. She did not in the emails or when I saw her before surgery [mention] to me her wish not to have the Mirena.'*
>
> **Consent not challenged in OT:**
> Theatre staff acknowledge that the insertion of the mirena didn't appear on the consent explicitly and it wasn't raised directly with the surgeon when the device was requested by Dr B. Given that the Novasure ablation was unsuccessful and the decision to proceed with a therma choice hot water balloon ablation or roller ball endometrial ablation using the resectoscope was determined unsuitable, this was not challenged by the wider theatre team as it was considered a reasonable next

[15] In response to the provisional opinion, Dr B said that he initiated the meeting between Ms A and RN G, and asked RN G to start an internal inquiry about the incident.

step. Challenging this decision on the basis that it didn't appear on the consent form alone would not necessarily have been routine.

Consent Form:
The Admission/Consent form has a dedicated space for specific instructions relating to consent, though it is unclear that this may be utilised to outline alternative treatments as discussed between the surgeon and the patient in the event that planned surgery has to be abandoned. Unfortunately this was left blank.

…

Documentation:
Theatre staff have identified that documenting of dialogue amongst the team regarding events which took place versus planned surgery was inadequate."

48. The private hospital told HDC that it has apologised to Ms A in person and in writing, and has taken a number of corrective actions, including:

- reminding staff of the documentation standards and expectations in these types of circumstances. The private hospital said that it "expects staff to challenge procedures that are a variance to the consented operating procedure". Its informed consent policy is being strengthened to include this reminder and to remind staff of their role in patient advocacy;

- inviting theatre staff to reflect upon their communication and interactions with patients and to consider what steps they might take differently in future to avoid this type of situation occurring, and providing feedback on those reflections;

- reviewing its Admission/Consent Form. In particular, the section that asks patients to comment on what they do/do not consent to will be clearer and more space for patient comments provided; and

- joining with another DHB in the rollout of the Health Quality and Safety Commission — Improving Surgical Teamwork and Communication Initiative. The private hospital said that theatre teams are involved in a pre-surgery and post-surgery debriefing, and it feels that "this initiative will strengthen the communication and teamwork in the theatre environment by supporting a shared understanding of the procedure to be undertaken and promotion of an environment where individuals can share knowledge, advocate for patient safety and reflect on what went well and what might be done different next time".

Dr B

49. In Dr B's first response to HDC, he stated:

"[Ms A] expressly declined insertion of the mirena on 4 May 2015 however she had not expressly declined the option of the mirena insertion on this occasion and she had previously used a mirena between each of [her pregnancies] without any issues."

50. In response to the "information gathered" section of the provisional opinion, Ms A said that she never told Dr B that she had had a Mirena fitted previously. She said that she has had an IUD fitted between one of her pregnancies but not between each pregnancy. Ms A is unsure whether this was the Mirena brand, and noted that it was inserted and removed by her GP.

51. In his second response to HDC, Dr B acknowledged that he should have discussed the matter of the Mirena insertion with Ms A prior to surgery on 15 December 2015. He further said:

> "At the time of her surgery on 15 December 2015, what I considered medically best for her in the circumstances was at the forefront of my mind as opposed to her previous withdrawal (on 4 May 2015) of her consent for the Mirena insertion. My thought process at the time was that the insertion of the Mirena had not been expressly declined, it could easily be removed if she was not happy with it and it was the safest option for her.
>
> In hindsight I accept I did not make the correct decision to insert the Mirena. I understand the paramount importance of a patient's consent to medical treatment and their right to decline medical treatment. This was an error in judgement on my part and one that I do not intend to make again. I do not consider that my medical advice with regard to treatment, no matter how robust, should supersede a patient's right to consent to or decline that treatment.
>
> Again I sincerely apologise to [Ms A] for the distress caused to her as a result of the Mirena insertion. I have taken the concerns raised very seriously and have reviewed my practice with regard to confirming patient consent with regard to medical treatments."

52. Dr B said that he has taken Ms A's concerns very seriously and has made the following changes to his practice:

- He now documents all possible alternative treatments and possible complications on the consent form, and proposed to the private hospital that the form is changed to provide adequate space for this.

- He will ensure that all consumers give express consent for alternative treatments in the event of unforeseen circumstances, and if express consent is not recorded on the form, he will not carry out the procedure.

Informed consent policy — private hospital

53. The private hospital has an informed consent policy that includes the following information:

> "**ROLES & RESPONSIBILITY**
>
> …
>
> **The Consultant:**

- is ultimately responsible for ensuring the patient has received adequate explanation of the benefits, risks and expected outcomes of surgery/treatment and has explained alternative options and the risks of not having the surgery/treatment

…

GUIDELINES

…

Obtaining Informed Consent
Consent should never be presumed and must be obtained prior to the commencement of any treatment

… **Written Consent**
Written Informed Consent is mandatory for all surgical and medical admissions

Verbal Consent
No consent should be presumed. Verbal consent is acceptable for procedures/treatments where there is a known level of risk and where a person is conscious and able to refuse the procedure/treatment if they choose to …"

Responses to provisional opinion

Ms A

54. Ms A provided a response to the "information gathered" section of the provisional opinion. Where appropriate, her comments have been incorporated into the opinion.

55. In addition, Ms A said that she considers Dr B's consultation practices and note taking to be the crux of the issue. In Ms A's opinion, Dr B did not listen to what she said during the consultations, and his notes reflect this. Ms A would like to see changes to these aspects of Dr B's practice.

Dr B

56. Dr B provided a response to relevant sections of the provisional opinion. He stated that he accepts the findings and recommendations in the provisional opinion. Dr B acknowledges that he was responsible for obtaining Ms A's express consent to any procedure he carried out on 15 December 2015, and that, given that Ms A was under general anaesthetic, the consent needed to be in writing.

57. Dr B said that he "accepts that any earlier decisions made by [Ms A] in relation to Mirena devices were of no relevance to whether she consented to having one inserted on 15 December 2015".

58. Dr B made the following clarification about his decision to insert the Mirena in theatre, but advised that he was in no way resiling from his acceptance of responsibility:

"Although Mirena can be inserted in the outpatient department such insertion is associated with pains, cramps and sometimes fainting, vomiting and syncope. For some women with difficult anatomy or anxiety/[obsessive compulsive disorder]

> insertion under a general anaesthetic would be the preferred option. Removal however is a simple non painful procedure which can be done by the practice nurse."

59. Dr B said that Ms A's complaint was a catalyst for a review of perioperative policies and procedures, and he will not carry out elective procedures without the patient's express consent. Dr B stated that, prior to the "Time Out", he now performs a preoperative "sign-in" procedure with the patient awake. This takes place with the anaesthetist, anaesthetic technician and theatre nurse, and patients are given the chance to describe in their own words what the procedure is, what the alternative options are, and what the possible complications are. Patients are then asked if they have any questions or concerns before proceeding into theatre.

60. Dr B also advised that he has been reading literature on informed consent, and is organising the following training for himself and his colleagues:

- A study session on surgical consent, the Code and medical law in New Zealand, and has invited an experienced medico-legal lawyer to present.
- A teaching session for specialists and nursing staff at the private hospital about the Code and medical law in New Zealand.

The private hospital

61. The private hospital provided a response to relevant sections of the provisional opinion, and said that comments from RN C, RN E and EN D were incorporated into its response. In addition, Dr F (who is not employed by the private hospital) provided comments, which have been incorporated into the opinion.

62. The private hospital said that it accepts the provisional finding that staff assisting in the procedure did not query with Dr B the absence of written consent for the Mirena insertion.

63. However, the private hospital said that it does not believe that this event illustrates that it failed to foster an environment where its operating teams do not engage in intentional discussion regarding intraoperative events that fall outside of those planned, expected or consented. the private hospital said:

> "[I]t is apparent … that [Ms A] had been firm in her view that she did not want a Mirena placed … Had the staff been aware of [Ms A's] strongly held views, the private hospital is confident that staff would have challenged [Dr B] on the insertion of a Mirena.
>
> In the absence of that information, the Mirena was inserted following the unanticipated failure of a planned technique, and the surgeon's decision that alternative options were not clinically appropriate. The surgeon advised that this was an interim step being taken until he could have further discussion with the patient, who had experienced significant anxiety with undergoing an anaesthetic (and a repeat anaesthetic may not have been desirable). A Mirena insertion is also easily removed if that were required.

> There are occasions in a theatre environment where surgical plans have to be changed due to unforeseen events. When that change occurs, it is the surgeon who is aware of what has been discussed with the patient so as to best know what her views are. Not all those eventualities can be recorded on a consent form in advance as they simply cannot be foreseen, which is why something that would usually be viewed as a minor temporary step might not have been queried. It is obvious that [Ms A] does not view the issue as minor, but that information was not known by [the private hospital] at the time."

64. The private hospital accepted the proposed recommendations, and said that these are consistent with its desire for ongoing improvement.

Opinion: Dr B — Breach

Informed consent

65. The principle of informed consent is at the heart of the Code. Pursuant to Right 7(1) of the Code, services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. It is the consumer's right to decide and, in the absence of an emergency or certain other legal requirements, clinical judgement regarding best interests does not apply. If the consumer will be under general anaesthetic, the Code provides an additional safeguard that consent must be in writing.[16]

66. As the consultant surgeon, Dr B was responsible for ensuring that he had obtained Ms A's consent to any procedure he carried out on 15 December 2015. Further, as Ms A was under general anaesthetic, her consent needed to be in writing. This responsibility is also reflected in the private hospital's informed consent policy.

67. Dr B gained Ms A's consent for an endometrial ablation using the Novasure machine. Unfortunately, the Novasure machine failed, and Ms A had not provided consent for any alternative procedures. Despite this, Dr B inserted a Mirena intrauterine device while Ms A was under general anaesthetic. Dr B was fully aware that Ms A had not provided consent, and commented that although she might not like the idea, it was the only valid option.

68. The decisions that Dr B made in theatre on 15 December 2015 may well have been done with the best possible intentions. However, this was not an emergency operation. When the Novasure machine failed, and Ms A had not consented to any alternative procedures being performed, the only available option was to stop the procedure and discuss alternative options (including the insertion of a Mirena) with Ms A when she was awake.

69. Dr B said he decided that the safest and most easily reversible treatment of Ms A's bleeding was to insert a Mirena. He considered that this could be an interim measure

[16] Right 7(6)(c) of the Code.

until further options could be discussed with her. He also noted that Ms A had advised of her anxiety about having a general anaesthetic, and wanted to avoid her having to be placed under anaesthesia for a third time.

70. I stress that, in the absence of an emergency, Dr B's clinical preference once the Novasure machine had failed was not relevant. Furthermore, if Ms A had later consented to a Mirena, a further general anaesthetic would not necessarily have been required.

71. Dr B also told HDC that Ms A had not expressly declined the insertion of a Mirena on 15 December 2015. He acknowledged that Ms A had declined a Mirena on 4 May 2015, but said that she had had a Mirena inserted on several occasions in the past.[17] It was not Ms A's responsibility to expressly decline the insertion of a Mirena on 15 December 2015, and I am concerned by this rationale from Dr B. As with Dr B's clinical opinion, Ms A's earlier decisions about Mirena devices (if any) were of no relevance to whether she consented to having one inserted on this occasion. Nonetheless, in her most recent consultation with Dr B on 14 July 2015, Ms A had confirmed that she did not want a Mirena inserted, and Dr B had acknowledged this in the letter he wrote to Ms A's GP that day.

72. In addition to the insertion of the Mirena, Dr B considered multiple alternatives for which he had not obtained consent. Dr B told HDC that he did not consider these options for treatment to be suitable. He said that there were clinical risks involved with the Thermachoice hot water balloon ablation, and with the prolonged nature of the roller ball ablation or endometrial resection. In addition, Dr B said that he had not discussed the latter two procedures or the risks of those procedures with Ms A prior to surgery. I am concerned that, as with the insertion of the Mirena, Dr B did not consider the fundamental importance of consent, and the fact that he should not carry out those procedures without her consent.

73. It is plainly unacceptable that Dr B inserted the Mirena without having first obtained Ms A's consent. I am also concerned that Ms A was particularly vulnerable as she was under a general anaesthetic. The right to decide was Ms A's, and she was deprived of it. I am highly critical of Dr B's actions, and find that by inserting the Mirena into Ms A's uterus when she had not given informed consent, Dr B breached Right 7(1) of the Code.

Other comment

74. Ms A raised concerns with HDC about feeling pressured by Dr B to have a Mirena inserted. Ms A stated:

> "I felt pressured but I am [a] strong person and felt able to say no. I do not feel that [Dr B] understands my choice not to have a Mirena and his preoccupation with giving me one contributed to me not being advised fully of all my options."

[17] As stated above, Ms A told HDC that this is incorrect, and that she told Dr B she had had an IUD fitted (which may have been the Mirena brand) between one of her pregnancies but not between each pregnancy.

75. Ms A said that, on 17 March 2015, she told Dr B that she did not want a Mirena fitted but Dr B persuaded her to include the Mirena insertion on her medical insurance forms, in case she changed her mind on the day of the procedure. Mirena insertion was also recorded on the consent form for the 4 May 2015 surgery. Conversely, Dr B told HDC that Ms A did not decline the insertion of the Mirena at their first consultation, but declined it on the day of her first surgery on 4 May 2015. The clinical notes make no reference to Ms A's initial objection to the Mirena on 17 March 2015.

76. In response to the provisional opinion, Dr B also said that he did not pressure Ms A and merely advised that the Mirena is a commonly recommended first choice minor procedure option.

77. In these circumstances, I am unable to make a finding as to what was said.

Opinion: Private hospital — Adverse comment

Introduction

78. There is evidence to suggest that poor teamwork and communication in operating theatres has a negative impact on performance and patient safety.[18] A hospital provider should facilitate good communication within the surgical team. This applies equally in both public and private hospitals — in the latter, the surgical team will comprise employees of the provider hospital entity and independent contract providers who may or may not work together frequently. It is expected that hospitals, whether public or private, ensure that the appropriate protocols and procedures are in place, and that they are complied with by all members of the surgical team. Ms A's case illustrates a missed opportunity to advocate for Ms A when she was under anaesthetic and vulnerable.

Advocacy for the consumer

79. There were three nurses and an anaesthetist present in the operating theatre on 15 December 2015 when the Novasure machine failed. All of the nurses told HDC that there was no discussion regarding consent for alternative procedures when the Novasure endometrial ablation was abandoned. Prior to surgery, only one of the nurses, RN C, was present for the "Time Out", which involved reading out the consent form. The anaesthetist, Dr F, was also present for the "Time Out", but told HDC that she could not remember the exact details.

[18] Health Quality and Safety Commission, Improving teamwork and communication within surgical teams: A proof of concept project, available at http://www.hqsc.govt.nz/assets/Perioperative-Harm/PR-files--images/proof-of-concept-final-report-Apr-2015.pdf, page 7. Gawande, A.A., Zinner, M.J., Studdert, D.M., Brennan, T.A., "Analysis of errors reported by surgeons at three teaching hospitals", *Surgery* (2003) 133:614–21. Weller J., Cummin, D., Civil, I. et al., "Improved scores for observed teamwork in the clinical environment following a multidisciplinary operating room simulation intervention", *NZMJ* (2016) 129:1439. Failure in teamwork is also a feature of complaints to HDC. Examples include: 13HDC00594, 12HDC00779 and 12HDC01488, available at www.hdc.org.nz.

80. RN C told HDC that she was aware that Ms A had not given written consent to the insertion of a Mirena. However, RN C did not question Dr B about his plan to insert a Mirena once the Novasure machine had failed. RN C said:

> "… [I]t did not occur to me that consent would be an issue. He was not asking anyone for their opinion, but rather advising what his decision was. He is an expert in his field and I felt comfortable that he would be making the right decision."

81. Nurses have an obligation to intervene as necessary to safeguard health consumers,[19] including protecting a consumer's rights under the Code. RN C was aware that Ms A had not provided written consent for the insertion of a Mirena, and I am critical that it did not occur to her to query this with Dr B when he was considering alternative treatment options. As discussed above, whether the treatment was clinically appropriate was irrelevant to whether Ms A had provided consent.

82. I am not critical of RN E and EN D, as I consider it was reasonable for them not to question Dr B's actions, given that they had no previous knowledge of what procedures Ms A had provided consent for.

83. Dr F told HDC that she was not aware of the Mirena insertion or any discussion pertaining to it, as she believes that she was most likely drawing up drugs and completing the drug recovery chart at this time. In response to the provisional opinion, Dr F added that she was aware that other equipment was being sought but thought that this was another Novasure machine or hand piece, and therefore did not query it with Dr B. She said that she was not aware that a Thermachoice machine or resectoscope was being sought.

84. I am unable to make a finding about what Dr F knew about the equipment that was being sought.

85. In its incident review report, the private hospital commented that "challenging [the decision to insert a Mirena] on the basis that it didn't appear on the consent form alone would not necessarily have been routine". While subsequently it told HDC that it expects staff to challenge procedures that are a variance on the consented operating procedure, and is amending its informed consent policy accordingly, this statement concerns me. In my opinion, in the absence of an emergency, it should be routine to query a decision to perform a procedure on the basis that it does not appear on the consent form.

86. In response to the provisional opinion, the private hospital said that, had its staff been aware of Ms A's strongly held views against the insertion of a Mirena, it is confident that they would have challenged Dr B. It further stated that there are occasions in a theatre environment where surgical plans have to be changed because of unforeseen events, and not all those eventualities can be recorded on the consent form in advance, which is why something "usually viewed as a minor temporary step" may not have

[19] Right 6.9 of the Nursing Council of New Zealand Code of Conduct for Nurses 2012 provides: "Intervene to stop unsafe, incompetent, unethical or unlawful practice. Discuss the issues with those involved. Report to an appropriate person at the earliest opportunity and take other actions necessary to safeguard health consumers."

been queried. The insertion of a Mirena without consent should not be viewed as a minor temporary step. I expect providers always to think critically about informed consent, and to query with their colleagues if they are unsure whether consent has been obtained.

87. Furthermore, I am critical that the expectation set down by the private hospital in its informed consent policy, that "[n]o consent should be presumed", does not appear to have been adhered to.

Consent form

88. In my opinion, the private hospital's consent form could be improved by allowing more space for details about the surgical procedure (including alternative treatments if appropriate), and providing space to document the risks associated with surgery. I acknowledge that the private hospital is reviewing its consent form and has said that the section that asks patients to comment on what they do/do not consent to will be clearer, and there will be more space for patient comments.

Recommendations

89. I recommend that Dr B undertake further education and training on informed consent, and provide evidence of this training to HDC within three months of the date of this report.

90. I recommend that, within three months of the date of this report, the private hospital provide HDC with an update of the corrective actions it has taken since this incident, including copies of the updated consent form and informed consent policy.

91. I recommend that the private hospital use an anonymised version of this case for the wider education of its staff and the surgeons who use its facilities. Topics should include informed consent and advocacy for the consumer. Evidence should be provided to HDC within three months of the date of this report.

92. I recommend that the Medical Council of New Zealand consider whether a review of Dr B's competence is warranted.

Follow-up actions

93. Dr B will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.

94. A copy of this report, with details identifying the parties removed, will be sent to the Medical Council of New Zealand, the district health board, and the Royal Australian

and New Zealand College of Obstetricians and Gynaecologists, and they will be advised of Dr B's name.

95. A copy of this report, with details identifying the parties removed, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Addendum

96. The Director brought disciplinary proceedings against Dr B in the Health Practitioners Disciplinary Tribunal which resulted in a finding of professional misconduct and subsequent penalty orders. Dr B appealed part of his penalty (three months suspension) in the High Court. The High Court dismissed Dr B's appeal and upheld the Tribunal's decision. The Director did not take HRRT proceedings against Dr B.