Obstetrician and Gynaecologist, Dr C

Auckland District Health Board

A Report by the

Health and Disability Commissioner

(Case 13HDC00594)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. In mid 2010 Ms A underwent a termination of pregnancy (TOP) at Epsom Day Unit, Auckland District Health Board (ADHB).

2. When Ms A presented at Epsom Day Unit she was seen by at least eight staff members, including Dr C, many of whom recorded in Ms A's records that she planned to use condoms for on-going contraception. Ms A did not consent to having an intrauterine contraceptive device (IUCD)[1] inserted.

3. Dr C performed the TOP and then inserted an IUCD into Ms A's uterus. Dr C said that the nurse placed an IUCD on the instrument trolley and he inserted it assuming that Ms A had consented for this to take place. Dr C said that the error was caused by staff, and the systems within Epsom Day Unit.

4. In early 2013 Ms A visited her GP, having attempted to become pregnant for the past five to six months without success. Ms A underwent various tests, including a smear test. Her GP identified and removed the IUCD.

5. ADHB told Ms A that the insertion of the IUCD was a human error. An ADHB staff member said that she would write an apology letter to Ms A, but did not do so.

Findings

6. It was Dr C's responsibility to ensure that Ms A had consented to the insertion of the IUCD before he inserted it. The systems issues do not excuse this failing. By inserting an IUCD into Ms A's uterus without first obtaining her informed consent, Dr C breached Right 7(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[2]

7. The systems in existence at Epsom Day Unit at the time of these events also failed Ms A. The Commissioner stated that providing services with reasonable care includes the provision of the right service, at the right time, to the right patient. For a DHB, it means operating a system that ensures that patients do not receive treatment that they have elected not to receive. Ms A left the clinic with no knowledge of the IUCD having been inserted, which is clearly unsatisfactory. The systems operating at Epsom Day Unit for the checking of consent prior to the insertion of IUCDs were inadequate. ADHB therefore failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.[3]

8. ADHB also failed to take reasonable steps to prevent Dr C's error and, accordingly, ADHB is vicariously liable for Dr C's breach of Right 7(1) of the Code.

9. Adverse comment is made about the manner in which ADHB dealt with Ms A's complaint.

[1] A small device, often T-shaped, containing either copper or levonorgestrel, which is inserted into the uterus as a form of long-acting reversible contraception.

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

[3] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

Complaint and investigation

10. The Commissioner received a complaint from Ms A about the services provided to her by Dr C and Auckland District Health Board (ADHB). The following issues were identified for investigation:

- *Whether Dr C provided Ms A with an appropriate standard of care in 2010.*
- *Whether Auckland District Health Board provided Ms A with an appropriate standard of care in 2010.*
- *Whether Auckland District Health Board responded appropriately to Ms A regarding concerns she raised in [early 2013] that an intrauterine device (IUD) had been inserted without her consent during a termination of pregnancy (TOP) procedure in 2010.*

11. The parties directly involved in the investigation were:

Ms A	Consumer
Auckland District Health Board	Provider
Dr C	Provider

12. Information was also reviewed from:

Dr B	First certifying consultant
Ms D	Social worker
Dr E	General practitioner
Dr F	General practitioner
RN G	Charge Nurse Manager, ADHB
RN H	Theatre assistant nurse
RN I	Theatre IV nurse

Information gathered during investigation

Ms A

13. In 2010 Ms A consulted her general practitioner (GP), Dr F. Ms A suspected she was pregnant, and was uncertain whether she wished to continue the pregnancy.

14. Ms A underwent an obstetric ultrasound, which confirmed the pregnancy. Ms A saw Dr F and advised that she had decided to have a termination of pregnancy (TOP). Dr F referred Ms A to the Epsom Day Unit.

Appointment at Epsom Day Unit

15. Ms A attended the Epsom Day Unit, which is owned and operated by ADHB. She was seen by a social worker, Ms D, who noted that Ms A reported her feelings as "no-pro's only con's [sic] when I think about this decision", and that Ms A did not feel sure and was "stuck on 50/50".

16. Ms A was seen by the first certifying consultant,[4] Dr B, who discussed the TOP with her and noted that, at that stage, Ms A was 80% certain that she wanted a TOP. Ms A's plan for on-going contraception after the TOP was noted as being "condoms". Ms A was also seen by a registered nurse (RN), who noted that the planned contraception was condoms, and that Ms A "has own supply. Declining further contraceptive advice."

Termination of pregnancy

17. Ms A presented two weeks later at the Epsom Day Unit and was seen by Dr C. Ms D recorded that Ms A was "seen briefly prior to OT [operating theatre] — relaxed and cheerful". It was again noted that Ms A planned to use condoms for on-going contraception. There was no mention that Ms A had consented to having an intrauterine contraceptive device (IUCD) inserted.

18. Dr C performed the TOP and then inserted an IUCD into Ms A's uterus. Dr C said that he does not recall Ms A and so does not know how the error occurred, but he thinks that a nurse placed an IUCD on the instrument trolley and he inserted it thinking that Ms A had consented for this to take place. ADHB advised that the two nurses working in theatre at the time, whom the DHB identified as RN H and RN I, are no longer staff members.

19. When Ms A was taken to the recovery room after the TOP, there is no evidence that the handover information given to the recovery room nurses included Ms A having had an IUCD inserted. The only indication in Ms A's records that she had had an IUCD inserted is on page six (titled "EDU [Epsom Day Unit] care plan 3") where, under the "procedure" heading, there is a "CU 375[5]/Mirena[6]" row with a space for a "yes" or "no" entry. There is a dash ("—") partially in the "yes" column. The "operation record" section, on the same page, refers to "condoms". "EDU care plan 3" is signed by Dr C and RN I. The discharge summary prepared by the recovery room nurse does not refer to the IUCD, and again states the preferred contraception at discharge as "condoms". Ms A was not informed of the IUCD and, consequently, was given no follow-up instructions regarding the IUCD.

Discovery of IUCD

20. Ms A advised HDC that she visited her GP in early 2013, having attempted to become pregnant for the past five to six months without success. and underwent various tests, including a smear test. At that time the nurse mentioned that she could see a black thread, and asked Ms A whether she had "a coil".[7] Ms A said she did not, as it was not a method of contraception she would use because her family members had had difficulties with IUCDs. Ms A was then examined by her GP, who identified and removed the IUCD.

[4] Under section 33 of the Contraception, Sterilisation, and Abortion Act 1977, authorisation for a TOP must be certified by two consultants.
[5] A brand of IUCD.
[6] MIRENA is an intrauterine contraceptive system containing 52mg levonorgestrel, which is slowly released over five years at an initial rate of 20mcg/24 hours.
[7] A colloquial term for an IUCD.

Complaint

21. Ms A said that immediately after her GP removed the IUCD she contacted the Epsom Day Unit. Her call was returned the following morning by an ADHB Charge Nurse Manager, RN G, who advised that the insertion of the IUCD was a human error. RN G apologised verbally, and told Ms A that she would write her a formal apology letter. RN G stated that Ms A said that she would be laying a formal complaint, and so she (RN G) did not write an apology letter because she expected to receive a formal complaint from Ms A. RN G acknowledged that this was her misunderstanding, and stated that she regretted not writing a formal apology at that time.

22. Ms A then submitted an official complaint through the ADHB website. She said that she was contacted by a representative, who offered her a meeting with Dr C in order for him to apologise in person. A week later Ms A emailed the ADHB Consumer Liaison Team and advised that she did not wish to meet with Dr C.

23. Ten days later ADHB Consumer Liaison Team wrote to Ms A and apologised on behalf of ADHB, and included an apology and explanation from Dr C. The Consumer Liaison Team also apologised for RN G having failed to send an apology letter as agreed.

Effect on Ms A

24. Ms A stated that this incident caused her to suffer stress and disappointment each month when she did not become pregnant, and that she spent money on pregnancy vitamins, pregnancy tests, ovulation kits, doctor's visits and various other matters while trying to conceive.

Procedure at Epsom Day Unit

25. Epsom Day Unit is the largest provider of TOP services in New Zealand. ADHB advised that, out of the total number of TOP procedures conducted at Epsom Day Unit in 2010, 33.3% of the patients had an IUCD inserted. ADHB further advised that there was no policy — written or unwritten — that encouraged or required women to have an IUCD inserted following a TOP procedure.

26. ADHB, the nurses involved, and Dr C provided the following information about the usual procedure at Epsom Day Unit regarding TOPs. However, Dr C does not recall Ms A, so was unable to confirm whether or not this process was followed in her case. Similarly, neither RN H, who was the theatre assistant nurse (referred to as the "bottom-end nurse"), nor RN I, who was the theatre IV nurse (referred to as the "top-end nurse"), recall Ms A.

27. A summary of the process at Epsom Day Unit for conducting TOP procedures at the time of Ms A's procedure is as follows:

a) Assessment and certification by first certifying consultant.

b) Patient taken to waiting room on arrival at Epsom Day Unit.

c) Patient seen by second certifying consultant.

d) Informed consent taken for TOP (and IUCD if relevant) and certification completed.

e) Patient returned to waiting room.

f) Patient taken to recovery room, consent form checked, and preoperative medications administered.

g) Patient and patient's chart taken to operating theatre by top-end nurse.

h) Handover by top-end nurse to bottom-end nurse whether patient had consented to the insertion of an IUCD.

i) Placement of IUCD and scissors on trolley by bottom-end nurse.

j) Following TOP, insertion of IUCD by surgeon.

k) Patient taken to recovery room by top-end nurse and handed over to recovery nurse whether patient had had an IUCD inserted.

First certifying consultant

28. Patients requesting a TOP were referred to the service by a medical practitioner (usually their GP), and were initially seen by the first certifying consultant, a social worker, and one of the nursing staff. The first certifying consultant determined whether the patient met the legal requirements to have a TOP and discussed options and on-going plans for contraception with the patient. If the patient made a decision for on-going contraception following the TOP, that was documented in the medical records.

29. RN H stated that the decision about contraception should be written in the "contraception" section of the notes but, in 2010, the first certifying consultant did not necessarily write the decision in the notes. In response to my first provisional opinion, RN H explained that this was because the patient could be unsure, in which case a question mark was written in the space for choice of contraception.

30. The patient was given information about the TOP procedure, including the risks and complications, the processes on the day, and the drugs used during the procedure. The patient then went home and returned at a later date for the procedure to be performed.

31. RN H stated that throughout the TOP process, when staff were speaking to patients they were identified only by their Christian (first) names and their faces, for privacy reasons.

Second certifying consultant

32. When the patient returned to the Epsom Day Unit for the TOP, she would be given a surgical consent "agreement to treatment" to read in the waiting area. RN H stated that, in the time since their initial consultation, it was not uncommon for patients to have changed their mind about receiving an IUCD.

33. The "agreement to treatment" form included consent to take misoprostol[8] as a priming agent to assist in the surgical termination by softening the cervix.

34. Next, the second certifying consultant, who was usually the operating surgeon, would meet the patient for the first time and obtain her consent to the TOP and any contraceptive device such as an IUCD. The second certifying consultant also ensured that the legal requirements for the TOP had been met, prescribed the medication, and answered any questions from the patient.

35. The patient's choice of contraception would be confirmed with her, and this would be written on a care plan. The patient then returned to the waiting area.

Preoperative process

36. RN H stated that no verbal handover was given to the nurses after the second certifying consultant had obtained consent from the patient. In response to my first provisional opinion, RN I said that although that may have been the case on some occasions, she considers it was common practice for consultants to hand over any relevant changes made during the consultation.

37. RN H said that the patient was called into the recovery room from the waiting room by one of the four nurses (either one of the two recovery nurses, the top-end nurse or the bottom-end nurse). The nurse receiving the patient obtained the patient's information from the patient's records. The nurse confirmed with the patient the patient's name, date of birth, allergies, and contraception decision. If the patient was having an IUCD inserted, the nurse wrote "IUCD" in the care plan and placed a tick next to it to indicate that the patient still wanted it. The nurse then administered the preoperative medications. Dr C stated that the majority of patients were given midazolam[9] before they were taken to the theatre "so they are often quite sedated even before the procedure starts. Therefore there is not normally a lot of discussion about the operation with the patient once they enter the operating room".

38. RN H stated that at this stage it was common for women to change their mind about having an IUCD. She stated that she (and a number of her colleagues) believed that this was associated with the mistaken belief held by many women that the second certifying consultant would deny them the TOP if they told the consultant they did not want an IUCD. In response to my first provisional opinion, RN I said that she never saw or heard of women being pressured into accepting any form of contraception.

Storage and selection of IUCD

39. RN I advised that at some stage in 2010 there was a change in the next aspect of the process. She stated that she cannot recall when the change occurred, but ADHB stated that the change occurred "towards the end of 2010".

[8] Misoprostol softens and opens (dilates) the cervix, causes uterine contractions and starts (induces) labour.

[9] A medication commonly given to patients prior to a surgical procedure in order to cause drowsiness and relieve anxiety.

Former process

40. Previously, the IUCDs were kept in the operating theatre, and the bottom-end nurse would review the patient's chart and collect an IUCD from the cupboard if one was required. An IUCD would not be brought into the operating theatre with the patient. In response to my first provisional opinion, ADHB submitted that IUCDs were stocked in theatre because patients would commonly change their minds about insertion of an IUCD "up to and when they were actually in theatre". As stated, Dr C said that at that stage the majority of patients had been administered midazolam and were sedated.

Amended process

41. RN I stated that the new process was that the IUCDs were kept in a locked cupboard in the recovery room.

42. RN H stated that once the patient was prepared for the procedure, and if the patient had confirmed that she still wanted to have an IUCD inserted, the nurse attending to the patient took the chart to the nurses' station in the recovery room, took the IUCD packet from the cupboard, clipped the IUCD to the chart, and placed the chart in the chart slot. RN H stated that often the IUCD was not clipped to the chart as it should be, or the patient's choice of IUCD was not recorded on the chart. She said that during the transition to the operating theatre, the top-end nurse checked the chart to make sure there was an IUCD clipped on if it was needed. If there was a tick next to "IUCD", the top-end nurse took the IUCD with her to theatre and confirmed the IUCD with the patient (at that stage the patient was sedated).

43. In response to my first provisional opinion, RN H stated that this was the process she was taught. She noted that although the patients were able give correct answers prior to the procedure, after the procedure many could not do so and some did not realise they had been to theatre.

TOP procedure

44. After the second certifying consultant had obtained the patient's consent, the patient was not normally seen again by the operating surgeon until she entered the operating theatre and, once the operating list started, the operating surgeon usually remained in theatre for the duration of the operating list, as the turnover time between patients was only about 10 minutes.

45. The operating surgeon, two theatre nurses (the top-end and bottom-end nurses), the patient and, if the patient wished, a support person, were in the theatre during the procedure.

46. The patient and the patient's chart were collected from the recovery room by the top-end nurse, who checked the patient's name, date of birth, allergies, and contraception decision, and took the patient to theatre. Dr C stated that the top-end nurse then "administers further sedation in the form of Fentanyl 100mcg prior to the procedure starting and offers the patient Entonox gas which is patient controlled". By that stage, the majority of patients had been given midazolam and were sedated.

47. The top-end nurse brought the patient into the operating theatre, introduced and identified the patient to the bottom-end nurse (under the amended process the top-end nurse handed the IUCD to the bottom-end nurse and verbally confirmed that the IUCD was for that patient), positioned the patient on the operating table, administered further sedation, and monitored the patient's well-being during the TOP.

Whiteboard

48. The whiteboard in the theatre contained information relating to all of the patients on that particular operating list.

49. RN H stated that the whiteboard information was for the surgeon and the bottom-end nurse. She also stated that, first thing in the morning, the top-end nurse wrote up the whiteboard located in the operating theatre, based on the operating list. RN I advised that the whiteboard was designed to give the bottom-end nurse only an indication as to what supplies were required for the surgical list, and it was expected that the bottom-end nurse would check the patient's chart and not rely solely on the whiteboard.

50. The information on the whiteboard included whether the patient wished to have an IUCD inserted. RN H stated that if the bottom-end nurse identified the patient as having requested an IUCD, the nurse underlined all the patient's details on the whiteboard. In response to my first provisional opinion, RN H stated that the patient details on the whiteboard were always referred to by the surgeon.

51. However, all staff agreed that the information on the whiteboard was not always accurate or up to date because at times a patient changed her mind about contraceptive requirements between seeing the second certifying consultant and coming into theatre. RN H stated that if a patient had changed her mind about the insertion of an IUCD prior to entering theatre, it was the responsibility of the nurse who brought the patient into the theatre (the top-end nurse) to amend the whiteboard accordingly. In response to my first provisional opinion, RN H stated that amending the board was the responsibility of the nurse who brought the patient into the recovery room and checked her in, not specifically the top-end nurse.

Role of bottom-end nurse

52. The bottom-end nurse assisted the operating surgeon by bringing into theatre a new operating case cart with two sterile packs on it, one with the instruments for the procedure and the second for the surgical drapes. The bottom-end nurse then opened the packs and helped set up the theatre trolley, placing additional supplies for the surgery on the instrument trolley, including antiseptic wash and lubrication gel.

53. In both the former and amended processes, if the bottom-end nurse had identified the patient as having requested an IUCD, the nurse then opened a new sterile Multiload or Mirena IUCD and placed it and a pair of scissors on the operating trolley in order for the surgeon to insert the IUCD at the end of the procedure. In response to my first provisional opinion, RN H stated that the IUCD packet was opened by the bottom-end nurse before the procedure began, and RN I said that it was the responsibility of the bottom-end nurse "to check and establish written consent prior to opening an IUCD".

Consent check

54. Dr C stated that the medical and surgical staff did not perform a formal time out[10] or check the surgical consent before commencing each TOP because this was the only type of operation performed at Epsom Day Unit.

55. Dr C said that when patients came into theatre before the procedure started, it was not normal practice for the operating surgeon to check the surgical consent or any of the paperwork relating to the patient because the operating surgeon would normally have sterile surgical gloves on at that time in preparation for commencing the next case.

56. RN I advised that although the surgeon did not review every patient's clinical notes prior to surgery, the notes were available for the surgeon to review with the assistance of a nurse, without the surgeon needing to touch the notes, should he or she wish to do so.

Procedure after TOP

57. In response to my first provisional opinion, RN H stated that the surgeon wrote up the patient notes at the end of the procedure and included whether an IUCD had been inserted and whether PR (per rectum) Flagyl[11] had been used.

58. The bottom-end nurse took the used trolley out of the theatre at the end of the procedure.

59. RN H advised that after the TOP was completed, the top-end nurse took the patient out of the operating theatre to the recovery room and gave a verbal handover to one of the recovery nurses regarding medications and whether an IUCD had been inserted. The recovery nurse wrote on the care plan and entered on the computer that an IUCD had been inserted. She also wrote up the discharge summary that was sent to the patient's GP, and checked that the surgeon had ticked "IUCD" in the surgeon's operating theatre notes.[12]

60. The top-end nurse then brought the next patient into theatre for her TOP.

61. Patients were not normally seen again by the operating surgeon after they left the operating theatre unless one of the recovery nurses asked the surgeon to check the patient because of a clinical concern. Patients were discharged from the unit by the nursing staff and advised to see their GP within two weeks. Patients would be given a discharge summary letter to give to their GP. RN I confirmed that when the patient was discharged after having had an IUCD inserted, contraception was discussed again, and the patient was given a piece of paper with IUCD details and care instructions, and told to see her GP in approximately two weeks' time to "check strings etc".

[10] A period of time when everyone present in the operating room stops and conducts final safety checks immediately prior to surgery commencing.
[11] Antibiotic medication.
[12] As noted above, in Ms A's case, all the documentation refers to her wish to use condoms for contraception. The only indication in the notes that an IUCD was inserted is a mark made by Dr C on the operation record. Ms A was given no follow-up instructions regarding the IUCD.

62. Dr C advised that the information that an IUCD had been inserted is important as, should the patient's blood pressure fall with no outward sign of excessive bleeding, it could be related to "cervical shock", which can occur shortly after insertion of an IUCD, or possible internal bleeding such as from a uterine perforation.

Clinicians' comments

RN H

63. As stated, RN H does not recall Ms A.

64. RN H was the bottom-end nurse on the day of Ms A's procedure, which RN H confirmed by referring to her signature on the controlled drug register for the relevant day. She advised that she worked at Epsom Day Unit until March 2013. She began her employment in 2010, and would have been one to two weeks out of the orientation period at the time of this incident. She said that "this could have been [her] first duty in OT going solo", and that she would have been relying on the senior staff around her.

65. RN H stated that spare IUCDs were kept in the operating theatre in case the nurses did not bring them in, or if there was a breakage, or if an IUCD was dropped.

66. RN H recalls that staff were advised during training that a patient (not Ms A) had had an IUCD inserted without consent. In addition, she recalls another incident where, after the insertion of an IUCD, she noticed that the patient concerned was on the pill. After she expressed concern, the error was recognised and the patient was returned to the operating theatre and the IUCD was removed. RN H did not state which other staff were working with her on that occasion. In response to my first provisional opinion, ADHB submitted that this incident "is not substantiated by the more experienced [RN I] or the very experienced [Dr C]".[13]

67. RN H stated that the system was always being reviewed and changed by the nurse manager, but some nurses would get "sloppy". She said that the system was "like a conveyer belt" in terms of checking patients, as there was no patient assignment to specific nurses.

RN I

68. RN I's comments about the process have been incorporated above. She stated that she cannot recall any instance where an IUCD was inserted without consent, but said that sometimes an IUCD may not be inserted despite the patient's consent because the surgeon has encountered an anomaly or complication during the procedure.

Dr C

69. Dr C advised that he performed up to 10 procedures on each given day, two operating lists per week, and an additional operating list on alternate weeks. He worked in the Epsom Day Unit for almost 15 years and performed hundreds of surgical first trimester TOPs per year.

[13] RN I did not comment on this aspect of the facts gathered. Dr C accepted the opinion and did not contest the facts gathered.

70. As stated above, Dr C does not recall Ms A but, on reviewing her records, he was able to confirm that he inserted an IUCD into Ms A's uterus at the end of her TOP. He acknowledged that this had not been requested by Ms A and that she did not give informed consent for the insertion of the IUCD. He confirmed that the discharge papers given to Ms A when she left the Epsom Day Unit state that her on-going contraception plan was the use of condoms. Dr C apologised for the error.

71. Dr C advised that patients found the procedure easier to tolerate and less stressful if he told them what they would feel during the operation. He stated: "[A]s part of this commentary during the operation I would normally tell them once the operation is completed and also tell them when I am putting in an IUCD." However, he noted that the majority of patients had already been given midazolam before entering theatre for their operation, so were often quite sedated before the procedure started.

72. Dr C stated that the operating theatre was designed for optimal functionality for a right-handed surgeon. However, as he is left-handed, he operates on the opposite side of the patient, as would a right-handed surgeon. He noted that the whiteboard in theatre listing the patient information was positioned to be easily visible to a right-handed surgeon, but was behind his right shoulder and could not be seen by him during the operation unless he consciously turned 180° to look at it.

73. Dr C advised that he relied on the nursing staff to identify correctly which patients wanted, and consented to have, an IUCD inserted after their TOP. As noted above, Dr C stated that he has no recollection of Ms A's operation. However, he also stated:

> "[T]he bottom-end nurse … had opened a multiload IUCD and placed it on the instrument trolley and [he] therefore inserted it at the end of the operation believing that this was appropriate and that [Ms A] had given consent for this to occur."

74. Dr C stated that it was not uncommon for women who initially did not want an IUCD to change their mind by the time the operation took place, and decide to have an IUCD inserted. Dr C told HDC:

> "My mistake was to assume that this had taken place and that [Ms A] had changed her mind and wanted to have an IUCD as the assistant nurse had opened an IUCD and placed it on the instrument trolley for me to insert at the end of the procedure. In this case my assumption was incorrect as [Ms A] had not consented for this to take place."

75. Dr C noted that he had eight TOPs on his list that day. He said that Ms A was scheduled to be the third patient on the list, and that the first, second, fourth and sixth patients had all asked to have an IUCD inserted. Dr C does not recall whether the list ran as per the scheduled order.

76. Dr C stated that as the operating surgeon normally remained in the theatre between cases, he did not participate in the handover of the patient to the recovery staff. He stated that he would expect the handover performed by the nurse to have included

how well the procedure had been tolerated by the patient, whether there had been any concerns expressed during the procedure, and whether an IUCD had been inserted.[14]

77. Dr C stated that he believes that the error was caused by a combination of factors, and the failure of the whole team involved with Ms A's care that day, as well as the procedural systems that were in place at that time in the Epsom Day Unit. However, he acknowledged and accepted that he has to take responsibility for this clinical error, as he was the person who inserted the IUCD.

Changes since complaint

78. Dr C advised that if a patient requests an IUCD be inserted after completion of a TOP, he now documents that request on the patient's surgical consent form and obtains the patient's signature on the consent form.

79. ADHB advised HDC that the following changes have been implemented since 2010:

a) Surgeons now obtain written consent from patients for the use of Mirena, IUCDs and Jadelle.[15]

b) Written consent is now documented on the "agreement to treatment" form.

c) At the end of 2011, the Epsom Day Unit theatre layout was arranged to ensure that only equipment and instruments needed in theatre are stored in the theatre room. Regular weekly audits of the theatre and recovery room were put in place to ensure adherence to the standard operating procedure.

d) IUCDs and other long-acting contraceptives are now stored in a locked cupboard in the recovery room.

e) Before the nurse takes the patient to theatre, he or she now checks that written consent from the patient has been obtained to have an IUCD or Mirena, then collects the IUCD/Mirena, goes to the patient's bedside, and has the patient verbally confirm that she wants the IUCD/Mirena. The nurse then hands the IUCD to the assistant nurse and confirms that the patient has requested the insertion of an IUCD. Towards the end of the procedure, the assistant nurse opens the IUCD and places it on the sterile trolley for the surgeon to insert.

f) A new policy has been written to reflect the changes to the informed consent process and role of the nurses regarding the checking of IUCDs.

80. In response to my first provisional opinion, ADHB said that the current practice in the Epsom Day Unit is now as follows:

a) Written consent is obtained prior to insertion of an IUCD.

b) The top-end nurse introduces each patient to the surgeon and the bottom-end nurse on entry to the theatre.

[14] As noted above, there is no evidence that RN I's handover of Ms A to the recovery room staff included anything to indicate that Ms A had had an IUCD inserted.

[15] Norplant (Jadelle) is implanted under the skin in the upper arm of a woman, by creating a small incision and inserting capsules in a fanlike shape. Once inserted, the contraceptive works within 24 hours and lasts up to five years.

c) A formal time out occurs.

d) The top-end nurse verbally hands over whether the patient has consented to any contraceptive device or implant.

e) The top-end nurse shows the consent form to the surgeon and the bottom-end nurse.

f) All patients who have had an IUCD inserted are advised of that fact and provided with relevant information on discharge, in addition to the discharge summary.

Other incidents

81. HDC asked ADHB for details of every case in the past 10 years where an IUCD or similar device was inserted into a woman's uterus without her consent, and also details of any cases where an IUCD was not inserted, despite the patient having agreed and consented to the insertion of the device. ADHB responded: "[T]here is no searchable record kept (outside of RMPro[16] & FMPro) which allows us to a) ascertain when an IUCD (or similar device) was inserted **without consent** or b) when an IUCD (or similar device) was **not inserted** despite the patient having chosen and consented" (emphasis in original).

82. ADHB did, however, note that in a previous case referred to ADHB by this Office, ADHB had accepted that the patient had had an IUCD inserted without her consent. In that case, ADHB apologised to the woman and she subsequently withdrew her complaint.

Responses to provisional opinions

83. Responses were received from Ms A, ADHB, RN H, RN I and Dr C. Where appropriate, these have been incorporated into the facts gathered. In addition, the following responses were made.

Ms A

84. Ms A advised that she did not wish to comment further.

Dr C

85. Dr C stated that he accepted the conclusion that he breached Right 7(1) of the Code, and he provided a letter of apology for Ms A.

ADHB

86. ADHB's submissions included the following:

a) It accepts that it vicariously breached Right 7(1) of the Code.

b) Right 4(1) should not be interpreted as broadly as stated in my provisional opinions. The clinical outcome was achieved with reasonable care and skill. If this case is a breach of Right 4(1) because "the failure to obtain consent arose from flawed underlying systems, then logically all procedures undertaken when that

[16] RMPro is a web-based incident reporting and adverse event management system.

system applied must also have been provided without reasonable care and skill, whether or not consent was obtained".

c) There is insufficient evidence for finding that the consent system for insertion of an IUCD was inadequate while that for the TOP was adequate.

d) "There is no suggestion here that the clinical treatment provided was of concern; the issue is failure to obtain consent in one case amongst thousands of similar cases. In this case and the thousands of IUCD procedures [where] consent was obtained the clinical outcome was achieved with reasonable care and skill".

e) Formalising the consent to the insertion of an IUCD might result in women believing that giving consent to on-going contraception is a precondition to having a TOP.

f) This is the first breach report for a service that undertakes thousands of equivalent procedures per year without complaint.

g) The consumer suffered no physical injury or permanent harm, and the inconvenience to her was brief.

h) It has reacted promptly to create more formality regarding consents to IUCD insertion and, from 2013, all patients have given written consent.

i) It has several searchable systems for known errors, but it would not be possible to ascertain cases where the patient did not receive the treatment she consented to without a case-by-case review of tens of thousands of cases. As written consent was not required, a search would not reveal conclusively whether or not consent had been given.

j) It "remains of the view that a reasonable proposition given the nature of the issue is that the complaints received are indicative of the extent of the problem — not more than three in a decade".

k) Even if there have been three errors in three years, that level of error would indicate a system that is "reasonable" and "adequate" and that the opinion has replaced the legal concept of reasonableness with "a strict obligation to provide error free services".

Opinion: Introduction

87. In her complaint to my Office, Ms A expressed her distress at failing to become pregnant when she wished to conceive, and her anger when she discovered that she had been fitted with an IUCD without her knowledge or consent.

88. No health or disability service can be provided to a consumer without his or her informed consent. The right to make an informed choice and give informed consent is fundamental to individual autonomy, and is one of the central elements in the Code.

89. In its responses to my provisional opinions, ADHB has accepted that Ms A had an IUCD inserted without her consent, but denied that this denotes a lack of care and

skill on its part. ADHB stated that if this case is a breach of Right 4(1) because "the failure to obtain consent arose from flawed underlying systems, then logically all procedures undertaken when that system applied must also have been provided without reasonable care and skill, whether or not consent was obtained". My opinion is that ADHB had an inadequate system, which increased the likelihood of errors being made and remaining undetected. For the avoidance of doubt, I note that this opinion relates to the services provided to Ms A, and includes the system within which she received services.

90. I remain of the view that ADHB was operating a system that demonstrated a lack of reasonable care in that it failed to ensure that Ms A received only the procedure that she consented to, and did not receive the wrong treatment.

Opinion: Breach — Dr C

91. Dr C performed a TOP on Ms A, and then inserted an IUCD into her uterus. Dr C had seen Ms A before the procedure, at which time it was noted that she planned to use condoms for on-going contraception. She did not consent to the insertion of an IUCD, either then or later.

92. The primary responsibility for obtaining informed consent to treatment lies with the person who is to carry out the treatment or procedure, who, in this case, was Dr C. As the responsible operating surgeon, Dr C had a duty to take reasonable steps to ensure that Ms A had given informed consent to the insertion of an IUCD prior to inserting it. As discussed below, I do not consider that Dr C took such steps.

93. Dr C does not recall Ms A, but stated that, as per his usual procedure, he would have talked her through her TOP procedure while he was performing it, including telling her once the TOP had been completed that he was going to insert an IUCD. However, he acknowledged that, in view of Ms A's sedation, it was unlikely that she would have recognised the comment as being inappropriate and incorrect. I agree. In these circumstances, it would have been insufficient to have relied solely on any consent given by a sedated patient immediately prior to a procedure.

94. Dr C had seen Ms A earlier that day and noted her preference to use condoms for on-going contraception. Had Dr C checked Ms A's records at any time, he would have noted a clear absence of documented consent to the insertion of an IUCD. Her records note on multiple occasions that her preference for contraception was condoms.

95. Dr C stated that at that time no "time out" was conducted to check the procedure and surgical consent before starting each TOP, because there was only one type of operation performed at the Epsom Day Unit. Additionally, he stated that it was not normal for the operating surgeon to check the surgical consent, or any of the paperwork about the patient, before starting the procedure. He said that this was partly because the operating surgeon usually had on surgically sterile gloves because of the rapid turnover of patients. RN I advised that although the surgeons did not review

every patient's clinical notes prior to surgery, the notes were available for the surgeon to review with the assistance of a nurse — to avoid the surgeon touching the notes — should he or she wish to do so.

96. I find Dr C's explanations regarding sterile gloves and rapid patient turnover unconvincing. He was able to complete the operation record after each TOP, and I therefore do not accept that it would not be possible to peruse the notes of the next patient following completion of the previous patient's record, before donning fresh gloves, or to look at the notes with the assistance of a nurse.

97. It would not have been difficult for Dr C to have confirmed whether Ms A's consent had been obtained. As she was sedated at that stage, he would have had to rely on the records, the accuracy of which would depend on the nurses accurately recording any change of mind since he saw Ms A (before the operating list commenced). In Ms A's case, her records consistently stated that condoms were her choice for on-going contraception.

98. Even if Dr C did not read the patient records, there were other ways he could have checked that Ms A had consented to the IUCD. Dr C stated that he would have been reliant on the bottom-end nurse to identify whether Ms A had consented to an IUCD being inserted, and that the nurse would have opened the IUCD and placed it on the tray on the operating trolley. Dr C stated that if the nurse placed an IUCD on the operating trolley, he assumed that the device was for that patient. In my view, Dr C should not have made this assumption.

99. Dr C referred to the set-up of the operating theatre as having contributed to his error. He noted that although there was a whiteboard with information in the operating theatre, this was not necessarily kept up to date. Dr C said that the whiteboard is positioned in a way that is not optimal for a left-handed surgeon as, in order to look at the whiteboard, he would have had to turn around. While I acknowledge that this would have been inconvenient, it in no way excuses Dr C from his obligation to satisfy himself that he was aware of all relevant information about his patient before commencing the procedure. I do not consider that the whiteboard is relevant to Dr C's failings, given that both he and the nurses acknowledge that the information written on it was unreliable.

100. Dr C failed to ensure that Ms A had consented to an IUCD before inserting one and, as a consequence, he let Ms A down. It is not sufficient to state that Ms A was the third patient on Dr C's list, and that the first, second, fourth and sixth patients had requested the insertion of an IUCD, and that there was a rapid turnaround between patients. Furthermore, it is not sufficient to assume that consent had been obtained just because the nurse had placed an IUCD on the operating trolley. It was accepted that a patient might change her mind about contraception at any time. In my view, the system needed to ensure that accurate information was recorded, and Dr C had a duty to ensure that he was aware of that information.

101. In my view, if the system operating at the Epsom Day Unit impaired Dr C's ability to ensure that his patient had consented to the treatment he provided, it was his responsibility to take reasonable steps to ensure that the system changed.

102. To his credit, Dr C has acknowledged his error, offered to meet with Ms A, and apologised. However, I find that Dr C inserted an IUCD into Ms A's uterus without first obtaining her informed consent and, accordingly, Dr C breached Right 7(1) of the Code.

Opinion: Breach — Auckland District Health Board

Introduction

103. Under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), anything done or omitted by a person as the employee of an employing authority shall, for the purposes of the Act, be treated as having been done or omitted by that employing authority as well as by the employee. Under section 72(5) of the Act, an employing authority has a defence if it can prove that it took such steps as were reasonably practicable to prevent the employee's act or omission.

104. The systems in place at ADHB's Epsom Day Unit were less than satisfactory. While acknowledging his responsibility for the clinical error, Dr C pointed out his view that the error was caused by a combination of factors in the failure of the whole team involved with Ms A's care that day, as well as the procedural systems that were in place at that time at the Epsom Day Unit.

105. I share Dr C's concerns. Although it does not excuse his failings, the lack of clarity around the systems in place at the time appears to have impacted on Dr C's performance in this case.

106. As I have stated previously:[17]

> "In any healthcare system, there are a series of layers of protections and people, which together operate to deliver seamless service to a patient. When any one or more of these layers do not operate optimally, the potential for that level to provide protection, or deliver services, is compromised. When a series of such events occur, although each are often minor in themselves, the fabric that is wrapped around the patient in the delivery of a seamless service is torn. When a series of tears or holes line up, poor outcomes result. Patients are at risk of being harmed."

107. The nurses involved in the operating theatre when Ms A had the TOP have been unable to clarify whether the former or amended process applied at that time. ADHB and Dr C stated that the former process applied, as the amended process was introduced towards the end of 2010. As Ms A's TOP was in June 2010, I find it more likely than not that the former process applied at that time.

[17] Opinion 09HDC01883, 15 June 2012, at page 12.

Insertion of the IUCD

108. In response to my provisional opinions, ADHB expressed concern that I obtained no expert advice in this case. ADHB also submitted that there is insufficient evidence for a finding that the consent system for insertion of an IUCD was inadequate, while that for a TOP was adequate. I note that I have not commented on the consent system for the TOP. However, I remain of the view that there were features of the way the system operated that were inadequate in relation to checking consent prior to the insertion of IUCDs. I do not accept that expert advice is required to make that finding.

109. The systems issues in this case include the lack of clarity in communication between the nurses and the surgeon, and the fact that clinical and nursing staff did not perform a formal time out or check of the surgical consent before starting each TOP.

110. In my view, a time out prior to the TOP beginning would have limited the likelihood of error. ADHB submitted in response to my first provisional opinion that the opinion suggests "that before every procedure there must be a formal time out and check as to consent". That is not the case. This report relates specifically to the circumstances pertaining to Ms A's treatment at ADHB. However, I do consider that it is the responsibility of every DHB to develop sufficiently robust systems to ensure that it complies with the Code. I note that ADHB has now introduced a time out process.

111. In my first provisional opinion, I recommended that ADHB implement an appropriately designed system to ensure that the correct procedure is performed on the correct patient, and material information is confirmed prior to the procedure commencing. In response to that recommendation, ADHB submitted that the recommendation specifies my "expectation as to compliance for any and all surgery undertaken in New Zealand". I agree that this is my expectation, and it is the law in New Zealand. I remain of the view that ADHB has a responsibility to operate an appropriately designed system to ensure that the correct procedure (and no other procedure) is performed on the correct patient, and that material information is considered prior to that procedure commencing.

112. The system operating at Epsom Day Unit was intended to enable a high turnover rate, which meant that the operating surgeon remained in theatre for the duration of the operating list. Dr C said that it was not normal practice for the operating surgeon to check the surgical consent or any of the paperwork about the patient before starting the TOP procedure, partly because the operating surgeon would usually already have on sterile surgical gloves in preparation for commencing the procedure. In my view, if the system does not allow operating surgeons to carry out the necessary checks between cases, the system should be changed. As stated, however, RN I advised that although the surgeons did not review every patient's clinical notes prior to surgery, the notes were available for the surgeon to review with the assistance of a nurse, should he or she wish to do so.

113. ADHB stated that in mid-2010, a supply of IUCDs was kept in the operating theatre. In response to my first provisional opinion, ADHB advised that IUCDs were stocked in theatre because patients would commonly change their minds about insertion of an IUCD "up to and when they were actually in theatre". However, as stated above, Dr C

said that the majority of patients had already been given midazolam before entering theatre for their operation, so they were often quite sedated by that point.

114. Furthermore, once the patient had arrived in theatre, despite being responsible for ensuring informed consent, the operating surgeon was not involved in the process of confirming whether the patient had consented to the insertion of an IUCD. The practice was that if the nurses identified the patient as having consented to an IUCD, the bottom-end nurse would open a new IUCD and place it on the operating trolley to be inserted by the surgeon at the end of the procedure. The practice of not having the surgeon involved in this process, for example, by checking the patient's chart directly, led to heavy reliance on the presence or absence of an IUCD on the trolley as evidence of consent. This created the potential for error if, as may have happened in this case, the IUCD was on the trolley, despite the patient not having elected to have an IUCD inserted.

115. In this case, the system in existence at the time of her procedure failed Ms A. ADHB and Dr C conjectured that the error was contributed to by the bottom-end nurse wrongly placing an IUCD on the tray. However, there are a number of other possibilities, including staff relying on incorrect information on the whiteboard, the top-end nurse providing incorrect information to the bottom-end nurse, or the patients being brought into the operating theatre in the incorrect order. In the circumstances, I am unable to make a finding as to how the error occurred.

116. The top-end nurse was responsible for advising the recovery room staff that the patient had had an IUCD inserted. Dr C stated that the handover is important. However, despite an IUCD having been inserted, and Dr C stating that it was his practice to explain to the patient in theatre that he was inserting an IUCD, RN I did not hand over to the recovery nurses that Ms A had received an IUCD. This suggests that either:

a) Dr C's practice did not occur in Ms A's case; or

b) Dr C's practice did occur but RN I did not take note of the insertion of the IUCD; or

c) RN I took note of the IUCD but omitted to pass on that information; or

d) RN I took note of the IUCD and passed on that information, but the recovery nurse omitted to include this information on the care plan and discharge summary.

117. I am unable to determine which of the above occurred. In any case, Ms A left the clinic with no knowledge of the IUCD having been inserted, which is clearly unsatisfactory.

118. I note that the indication on the operation note that a CU375/Mirena had been inserted is just a dash, and the form also states that on-going contraception was to be "condoms".

Changes introduced

119. The evidence of RN H is that the process introduced toward the end of 2010 was unreliable, and that IUCDs were not infrequently either clipped to patients' charts when not required or not clipped when they were required. The new process still placed responsibility on the nurses to ensure the patient had consented to the insertion of an IUCD, and still did not require the operating surgeon to check the consent before performing the procedure. I consider that that was unsatisfactory. However, I note that ADHB has now further amended the process so that a formal time out occurs, the top-end nurse verbally hands over whether the patient has consented to any contraceptive device or implant, and the top-end nurse also shows the consent form to the surgeon and the assistant nurse.

120. Despite expressing concern in response to my first provisional opinion that formalising consent to the insertion of IUCDs might result in women believing that formal consent to on-going contraception is a precondition to a TOP, ADHB has introduced a practice of obtaining written consent prior to insertion of IUCDs. In my view, any concern relating to women possibly seeing on-going contraception as a precondition to a TOP should be able to be ameliorated by providing women with appropriate, accurate information.

Services not provided with reasonable care and skill

121. In my view, ADHB did not provide services to Ms A with reasonable care and skill because the systems operating at Epsom Day Unit for checking whether consent had been given prior to the insertion of IUCDs were inadequate. In response to my first provisional opinion, ADHB submitted that "[a] finding of 'inadequate' is not relevant to the consequential finding of a breach of Right 4(1). Right 4(1) is not about adequate services but about reasonable services". In my view, in this circumstance, these concepts are equivalent.

122. ADHB submitted that its service was reasonable because it had "completed tens of thousands of procedures with only one[18] documented and proven case of failure in respect to consent to insertion of an IUCD". ADHB further submitted that I have replaced the legal concept of reasonableness with a strict obligation to provide error-free services. I disagree. My view is that there were features of the way the system operated that were inadequate in relation to the checking of consent prior to the insertion of IUCDs.

123. As stated above, when my Office asked ADHB for details of every case in the past 10 years where an IUCD or similar device had been inserted into a woman's uterus without her consent, ADHB responded that it kept no searchable record to enable it to ascertain when an IUCD (or similar device) had been inserted without consent. In response to my second provisional opinion, ADHB stated that it has several searchable systems for known errors but it would not be possible to ascertain cases where the patient did not receive the treatment she consented to, without a case-by-case review of tens of thousands of cases. As written consent was not required, a search would not reveal conclusively whether or not consent had been given. ADHB

[18] As stated above, ADHB has acknowledged two–three cases.

stated that it "remains of the view that a reasonable proposition given the nature of the issue is that the complaints received are indicative of the extent of the problem — not more than three in a decade".

124. ADHB submitted that "providers do not guarantee outcomes" but the services must be provided with reasonable care and skill. I agree.

125. ADHB stated: "There is no suggestion here that the clinical treatment provided was of concern; the issue is failure to obtain consent in one case amongst thousands of similar cases. In this case and the thousands of IUCD procedures [where] consent was obtained the clinical outcome was achieved with reasonable care and skill". ADHB submitted that Ms A suffered no physical injury or permanent harm, and the inconvenience to her was brief. ADHB further submitted that it provided services to Ms A with reasonable care and skill because the clinical outcome was satisfactory, and therefore a breach of Right 4(1) is incorrect.

126. These submissions, in a context where a patient has left the service with an IUCD she does not know she has, and without any advice about the risks and management of the IUCD, are at once surprising and untenable. In my view, providing services with reasonable care includes the provision of the right service, at the right time, to the right patient. For a DHB, it means operating a system that adequately ensures that patients do not receive treatment that they have elected not to receive.

Conclusions

127. It is documented that Ms A reiterated numerous times that she wished to use condoms for on-going contraception, rather than have an IUCD inserted, yet an IUCD was inserted. As stated above, ADHB has a responsibility to operate an appropriately designed system to ensure that the correct procedure (and no other procedure) is performed on the correct patient, and that material information is considered prior to that procedure commencing.

128. In my view, the insertion of an IUCD without Ms A's consent was, at least in part, due to inadequacies in the system for checking consent prior to the insertion of IUCDs that was operated by ADHB at that time. As stated above, that system potentially involved a number of staff and processes. In my view, ADHB failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

129. As noted above, I consider that Dr C breached the Code for inserting an IUCD into Ms A's uterus without first obtaining her informed consent. In my view, ADHB failed to take reasonable steps to prevent that error, as evidenced by the failures in its systems identified above. Accordingly, I find ADHB vicariously liable for Dr C's breach of Right 7(1) of the Code.

Other comment

130. Ms A contacted the Epsom Day Unit in early 2013 immediately after the IUCD was removed from her uterus. RN G advised her that a formal apology letter would be written to her. However, due to a misunderstanding, no letter arrived. As a result, Ms A believed that her complaint had not been taken seriously.

131. Subsequently, Ms A emailed ADHB twice with regard to her complaint. The Consumer Liaison Team then wrote to Ms A and apologised for the failure to follow up the original complaint with an apology letter.

132. Although I do not consider that the handling of this complaint by ADHB amounts to a breach of Right 10 of the Code, the response to Ms A's complaint was unfortunate, and added to Ms A's distress. In my view, ADHB should reflect on the effect of giving an undertaking to a patient and then failing to follow it up.

Recommendations

133. In accordance with the recommendation made in my first provisional opinion, Dr C has provided an apology to Ms A for his breach of the Code, which has been forwarded to Ms A.

134. I recommend that ADHB apologise to Ms A for the insertion of the IUCD without consent, and for the manner in which her complaint was handled. The apology is to be sent to HDC within three weeks of the date of this opinion, for forwarding to Ms A.

135. In my first provisional opinion, I recommended that ADHB implement an appropriately designed system to ensure that the correct procedure is performed on the correct patient, and material information is confirmed prior to the procedure commencing. I note that there have been various changes to the processes over time.

136. I recommend that ADHB:

a. Arrange an audit, conducted by an independent third party, consisting of a records-based review to identify any inconsistencies apparent from the records of patients selected randomly from the first three months of 2010 and the first three months of 2012.

b. Arrange an audit, conducted by an independent third party, consisting of a records-based review to identify any inconsistencies apparent from the records of patients selected randomly from the first three months of 2014.

c. Arrange an audit, conducted by an independent third party, of the design and operation of the system implemented to assess whether the system is effective in ensuring that the correct procedure is performed on the correct patient, and material information is confirmed prior to the procedure commencing.

137. I recommend that ADHB report to me on the findings from the above audits within three months of the date of this opinion.

Follow-up actions

138.
- A copy of this report with details identifying the parties removed, except ADHB (Epsom Day Unit), will be sent to the Medical Council of New Zealand and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and each will be advised of Dr C's name.

- A copy of this report with details identifying the parties removed, except ADHB (Epsom Day Unit), will be sent to the Director General of Health, the Royal Australasian College of Surgeons, and the Health Quality and Safety Commission.

- A copy of this report with details identifying the parties removed, except ADHB (Epsom Day Unit), will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.