Southern District Health Board
(now Te Whatu Ora Southern)

Obstetrician and Gynaecologist, Dr C

A Report by the
Health and Disability Commissioner

(Case 20HDC01693)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a woman in her twenties by Southern District Health Board (SDHB) (now Te Whatu Ora Southern) [1] regarding the non-consented involvement of medical students in the insertion of a Mirena intrauterine device (IUD) under general anaesthetic.

2. In this case, the woman expected to have a Mirena inserted by a consultant obstetrician. However, the procedure was performed by a medical student and a registrar, and was observed by other medical students. Explicit consent to the involvement of medical students in this sensitive procedure was not obtained.

Findings

3. The Commissioner acknowledged the importance of medical education, but emphasised that there is a clear expectation that the presence or involvement of students in sensitive examinations or procedures can take place only with unequivocal informed consent, given the vulnerability of the person being examined. It is at the heart of patient-centred care.

4. The Commissioner considered that the woman was entitled to be notified about medical students' participation in her procedure, and concluded that the woman had earlier expressly refused it. While acknowledging that the woman's refusal appears not to have been known to the clinical team on the day of the procedure, consent was not otherwise obtained from her regarding the presence of medical students. The Commissioner found that by providing services involving teaching to the woman without first notifying her and obtaining her consent, SDHB breached Right 6(1)(d) and Right 7(1) of the Code. The Commissioner also considered that SDHB's systems for obtaining consent were demonstrably lacking, in that there were multiple forms at different stages of the process, and the "Time Out" processes were inadequate, and, accordingly, the Commissioner found that SDHB breached Right 4(1) of the Code.

5. The Commissioner was critical of the registrar, and considered that she should have reviewed the consent form for completeness, to ensure that consent to student involvement had been obtained.

6. The Commissioner was also critical of the anaesthetist, and considered that he should have acted on another anaesthetist's concern about the woman's capacity to consent to her anaesthesia, and documented his actions.

Recommendations

7. The Commissioner recommended that Te Whatu Ora Southern conduct an audit of cases within Obstetrics & Gynaecology in which students have observed or performed sensitive

[1] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all 20 District Health Boards. Their functions and liabilities were merged into Te Whatu Ora — Health New Zealand. All references in this report to Southern District Health Board (SDHB) now refer to Te Whatu Ora Southern.

procedures, to check whether consent was given and recorded; provide training to staff within Obstetrics & Gynaecology on informed consent, capacity, communication between clinicians, and the requirement to review clinical records; and apologise to the woman in writing.

8. The Commissioner recommended that the registrar undertake training on informed consent. In accordance with the recommendation in the provisional opinion, the registrar provided a written apology, and this has been forwarded to the woman.

9. The Commissioner also recommended that the anaesthetist provide a written apology to the woman for the criticisms in this report.

Complaint and investigation

10. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided to her by Southern District Health Board (SDHB).[2] The following issues were identified for investigation:

- *Whether Southern District Health Board provided Ms A with an appropriate standard of care in 2018.*
- *Whether Dr C provided Ms A with an appropriate standard of care in 2018.*

11. The parties directly involved in the investigation were:

Ms A	Complainant/consumer
Ms B	Complainant's mother
Mr B	Complainant's stepfather
Dr C	Provider/obstetrician & gynaecologist
SDHB	Provider

12. Further information was received from:

Mr D	Medical student at the time of these events
Dr E	Registrar
Dr F	Specialist anaesthetist

13. Also mentioned in this report:

Dr G	General practitioner (GP)
Dr H	Specialist anaesthetist

[2] Ms A was supported in making her complaint by her mother, Ms B.

Information gathered during investigation

Introduction

14. This report relates to the involvement of medical students, without consent, in a sensitive procedure performed on Ms A at Dunedin Hospital in 2018.

15. At the time of these events, Ms A was aged in her twenties. She has a mild intellectual disability. She told HDC: "I have difficulty saying what I mean at times, but I can and do make my mind up." Ms B (Ms A's mother) stated:

> "[Ms A] is a [woman in her twenties] who has mild intellectual disability but is able in my experience to agree or disagree with questions about her health. [Ms A] is not sexually active and is very private and modest."

16. Dr G referred Ms A to Dunedin Hospital because of Ms A's issues with abdominal pain during menstruation, and her potential future contraceptive needs.

Initial outpatient appointment with Dr C — 29 January 2018

17. On 29 January 2018, Ms A, accompanied by Ms B, attended an appointment at the Gynaecology Outpatient Clinic with obstetrician & gynaecologist Dr C.

18. Dr C told HDC that she was aware that Ms A has an intellectual disability, so she took time to ensure that matters were addressed with Ms A and Ms B comprehensively.

19. Dr C stated that Ms A's previous experience with another contraceptive[3] was discussed, and a range of available options considered, including a Mirena IUD.[4] Dr C discussed the process of inserting a Mirena and, because of the possible discomfort, Ms A's preference was for insertion to take place under a general anaesthetic.

20. Dr C stated that as Ms A's history included a background of abdominal pain, it was explained to her that a Mirena would not necessarily resolve or improve the pain. Ms A declined a physical examination at that time.

21. Ms B told HDC that the discussion about contraception options for Ms A and the decision to proceed with a Mirena IUD was concluded over a short period of time.

22. On 30 January 2018, Dr C wrote a reporting letter to Dr G stating that Ms A would be reviewed in a month's time, at which time she would be put on the waiting list for day surgery. Ms A's next appointment was scheduled for 21 February 2018.

[3] Depo-Provera, which is a contraceptive injection containing progestogen. The injection is given every 12 weeks. It can cause irregular or prolonged bleeding.
[4] Mirena is a small, T-shaped intrauterine device (IUD).

Second outpatient appointment with Dr C — 21 February 2018

23. Ms A saw Dr C in the Gynaecology Outpatient Clinic on 21 February 2018. The outpatient record sheet notes that Ms A wished to proceed with the Mirena insertion. Dr C said that as Ms A was going to be eligible for a cervical smear screening test within the next month, it was agreed that the smear would be performed while she was under general anaesthetic.

24. Dr C told Ms A that prior to hospital admission she would have a Pre-Admission Clinic (PAC) visit, during which she would be taken through the consenting process, and have general admission health checks performed by another doctor. Ms A was told that there would also be a nurse assessment, where administrative information regarding admission would be provided. In addition, an anaesthetist would review Ms A prior to admission.

25. Dr C stated that they completed the national preoperative scoring system form (CPAC)[5] and the hospital surgical booking form during this appointment. Dr C also stated that Ms A was given and later completed Anaesthetic Pre-admission Clinic (APAC) information forms. Dr C said that Ms A was given a Preoperative Health Questionnaire for her to complete for the anaesthetist to review at the APAC.

Anaesthetic Pre-admission Clinic — 1 June 2018

26. On 1 June 2018, Ms A and Ms B attended the APAC. An Anaesthesia Consent form was completed by Ms A and specialist anaesthetist Dr H. The anaesthesia assessment notes:

> "GA,[6] needs 2nd doctor to sign consent form, nobody has legal guardianship, not convinced [patient] understands any of the discussion as per tick box. I have signed one signature."

27. The Anaesthesia Consent form was signed by Ms A and Dr H that day, but it states: "[R]equires 2nd doctor signature please"; however, there is no second doctor's signature on the form. It also states that the consent form was to be completed on the day of surgery.

28. HDC asked SDHB what action the anaesthetist present at the time of the procedure, Dr F, took with regard to this notation. Dr F responded (via SDHB):

> "… Informed consent for general anaesthesia was obtained by the anaesthetist in the pre-op clinic, according to his note. We as anaesthetists do not consent the patients for the actual surgical operation; that is done by the gynaecology consultants and registrars, and it is documented on separate forms, with their names and signatures, so I am unaware of any details concerning that."

29. Dr F did not respond at that time to HDC's query about why he did not provide a second signature.

[5] The Clinical Priority Assessment Criteria (CPAC) form in use at the time.
[6] General anaesthetic.

30. In response to the first provisional opinion,[7] SDHB provided further comment from Dr F. He said that he has no recollection of this actual procedure, but faced with a scenario as occurred with Ms A, his normal process would be to converse with the patient directly. He would turn his mind to whether the patient was consenting to anaesthesia, and would enquire specifically (as is his normal procedure) whether the patient had any further questions about what was to occur. Provided he was satisfied that the patient was still consenting to the procedure, he would then go through with the anaesthesia. Ms A's clinical records do not contain any reference to this, nor do they contain a signature by a second doctor as requested by Dr H. SDHB said that Dr F "does not have any understanding that [a] second doctor's signature on the consent form carries any legal significance".

31. HDC also obtained a response to the second provisional opinion directly from Dr F. He stated that Ms A was competent in her own right to make informed decisions about her health care, with or without a support person present. He said that Dr H and Ms A signed off the completed Anaesthetic Consent form during the APAC with the support of Ms B, and added: "These factors taken cumulatively, indicated to me that [Ms A] was aware of and consented to anaesthetic being administered on the day of her procedure."

32. Dr F repeated his standard practice and added that it is standard practice for elective procedures that, in addition to the APAC, a consenting discussion will also take place on the day of any procedure. He stated:

> "This provides a 'safety net' in that it:
>
> - ensures relevant details are reiterated to the patient more than once;
> - allows patients to go away and consider whether they have any questions on the information provided, or to do their own research before proceeding with a procedure;
> - reminds patients of the material aspects of a procedure, appreciating that time may have passed since the initial consenting conversation."

33. The Anaesthesia Consent form includes a statement headed "Medical teaching", which contains the following wording:

> "Dunedin Hospital is closely associated with [a] School of Medicine and is thus actively involved in teaching of health care professionals, especially medical students. Such students work under the direct supervision of your anaesthetist.

[7] In accordance with HDC's usual processes, and to meet natural justice requirements, the relevant parties were offered the opportunity to comment on a provisional opinion before it was finalised. In this case, owing to the complexities of information received following the first provisional opinion, a second provisional opinion incorporating changes was issued. This provided the parties a further opportunity to comment before its finalisation.

> We request your co-operation and permission for this teaching. If you decide not to allow the students to take part in your care, this will in no way affect the treatment you receive.
>
> I agree/do not agree to medical student involvement during my anaesthetic (delete as appropriate)
>
> Signed"

34. On the copy of the form that is in Ms A's clinical records, this section is blank and has not been signed. In response to the second provisional opinion, SDHB said that as there were no students involved in the anaesthetic, this section was not relevant under the circumstances, and so was not completed.

PAC 16 July 2018

35. The PAC took place on 16 July 2018. Ms A stated that she and her mother arrived at the PAC at 9am and reported to the receptionist.

36. Dr C told HDC that the PAC process involves patients seeing a series of doctors and nurses in rotation through different rooms, with the aim being to allow the patients to arrive at the hospital on the day of surgery ready for theatre. She stated:

> "Patients are consented by the SMO [senior medical officer][8] and/or trainee at the PAC and the consent form is reviewed on the day of surgery before the procedure commences, by the person performing the procedure and also during time-out.[9]"

37. Dr C said that generally patients are seen first by the SMO and/or the person who is to undertake the procedure or attend to the surgical list, to obtain the patient's consent. A house officer or intern will then see the patient and undertake a check of general health and fitness, query symptoms, confirm medications, and answer any questions or concerns the patient may have. The PAC nurse will then see the patient and provide information on admission time, directions around eating and drinking, and where to present on the day of surgery. The nurse tests and records vital observations and body mass index (BMI) and arranges blood tests.

Forms in PAC

38. According to Ms A and Ms B, while at the PAC they discovered that they had left forms that Ms A had already completed at home, so they asked for more forms and filled out those in the waiting room. Ms A said that she was given two forms — one related to health questions, and the other concerned students being present.

[8] Senior medical officers (SMOs) are doctors employed or contracted as consultants/specialists.

[9] "Time Out" is a final safety check to ensure that everyone in the operating theatre is "on the same page" before the surgery commences. Usually, Time Out is led by the surgeon or anaesthetist, with a theatre nurse checking details against the consent form. It identifies the patient, the procedure, and aspects of the consent form, and then identifies every person in the room to one another.

39. Ms B stated that Ms A read out the form that said: "Do you want students involved in your care?" and Ms A said twice that she did not wish to have students involved. There is no evidence that any staff at the PAC heard these comments. Ms A and Ms B do not recall the title of the form that referred to the presence of students. In response to the first provisional opinion, Ms A noted that to her recollection, the only time she was asked whether students could be present was when she was filling in the forms with her mother.

40. Ms A said that she filled in forms in the waiting room that clearly stated "no students". In response to the second provisional opinion, SDHB stated that it does not have forms where a patient would indicate "no students" on the form. It said that the only written information about students at the clinic is on the posters and the information sheet, neither of which are completed by the patient, so this recollection cannot be correct. SDHB said that while Ms A may have orally expressed to her mother that she did not wish student involvement, this was not conveyed to anyone else at the clinic. SDHB said that if its staff had been aware of this view, there is no way that a student would have been involved in Ms A's care.

41. Ms B stated that once they had completed the forms, they handed them back to the receptionist, and a nurse went through more forms and questions with Ms A. While she was doing that, Dr C arrived and took Ms A and Ms B into her office.

42. Ms A's records contain a dated two-page form completed that day that sets out a number of health questions, and a completed undated unsigned form, "Adult Pre-operative Health Questionnaire (Otago)". Neither form refers to the presence of students.

43. Dr C said that at outpatient visits, the receptionist routinely provides written information to all women about medical students being present in the Women's Health Department. She noted that if Ms A requested no student involvement, this was not communicated to her.

44. SDHB provided HDC with a Women's Health Clinic poster that states:

> "Dunedin Hospital is a training base for Medical Students and is dependent on goodwill from patients. Fifth year students attend clinics to give them an opportunity to learn about Women's Health. If you consent, ONE student will be involved with your care that will involve taking a medical history. Sometimes the consultant will recommend an examination, and if you consent, the student may also observe or undertake the examination with supervision from the consultant. The clinic nurse will ask you if you are willing to have a student — if not this will not affect your treatment. Thank you."

45. In response to the first provisional opinion, SDHB stated that the information sheet used in the admission clinics is not a form to be completed, and it could not have been completed in the way described by Ms A and Ms B. SDHB said that as there was no form relating to students, there is no way that this would have ever been in the PAC folder.[10] In response to the second provisional opinion, SDHB said that the only forms in existence at SDHB that

[10] This submission does not allow for the possibility that Ms A was given replacement APAC forms that do include written consent for the presence of medical students.

included written consent for student involvement were the anaesthetic and surgical consent forms.

46. Dr C stated that before she met with Ms A, she referred to her PAC folder, which contained the Surgical Consent form, Surgical Booking form, completed CPAC form and APAC form (as completed by Ms A and Dr H during the APAC), the Anaesthesia consent form, and medication and observation charts.

Discussion about procedure

47. Dr C stated that during the PAC she again discussed with Ms A the Mirena insertion procedure and the risks and potential side effects. Dr C said that she explained the mode of action of the IUD, along with potential effects on menstruation, and Ms A appeared to understand the information provided. Dr C stated:

> "I was particularly careful to clarify who should give consent, and whether confirmation of consent might be required by a parent. When I asked [Ms A] and her mother whether it was appropriate for [Ms A] to sign her consent, both replied in the affirmative."

48. The risks set out on the Informed Consent form are "(small) perforation, infection, bleeding". The form has a section headed, "Involvement of students or other personnel". That section of the form is not completed, but Dr C hand wrote on the form an asterisk, with the words "To check on admission", and next to the box for verbal consent, "TBC [to be confirmed]" and a question mark.

49. Dr C told HDC that it was her usual practice to discuss with patients that medical students are part of the surgical team, but acknowledged that she did not raise the subject of medical students being present during the procedure. Dr C stated:

> "I unfortunately and in error did not raise with [Ms A] the question about whether she would be comfortable for medical students to be present during the procedure. This was contrary to my usual practice."

50. Dr C said that at no point during the consultation did Ms A or Ms B raise the topic of students attending the procedure, or mention any forms that had been completed addressing this. Dr C stated: "Had they indicated they did not wish students to be present, I would have issued a clear directive to this effect in the medical record."

51. Dr C also told HDC: "At the PAC, the members of the team are outlined, including the SMO and the registrar likely to be present at surgery, however patients are advised that these details can change." There is no written record that Ms A was given this information.

52. Ms A then consented to the Mirena insertion procedure as well as the cervical smear and a blood test for ferritin.

53. Ms A stated that Dr C went through the form in a very casual way and then asked her to sign it, saying, "Are you happy with everything I have told you?" Ms B stated:

> "The whole meeting was sloppy and casual. At no stage did [Dr C] say that anyone else, other than her, would be doing the procedure. We were never asked by [Dr C] if students could be present. At the end of [Dr C's] meeting she smiled and said she would see [Ms A] in the operating theatre."

54. In response to the first provisional opinion, Dr C submitted that she made extra efforts to assist Ms A during the consultations with her. Dr C does not believe the description of her approach as "sloppy and casual" is a fair one. She said that her focus extended beyond arranging the IUD insertion, and she also arranged a green prescription to enable Ms A's weight loss, and spent time explaining the potential benefits of weight loss.

Outstanding questions

55. Ms A stated that following the meeting with Dr C, they returned to the waiting room and waited for the nurse. Shortly thereafter, the nurse came to get them and resumed the questions she had begun asking previously. Ms A said that at no stage did the nurse ask about students being present during the procedure.

56. Dr C told HDC:

> "On review of the PAC folder after the PAC and prior to the procedure, I discovered that the check box on page three of the consent form — addressing whether the patient was comfortable with students being present in the operation — had not been completed. I realised that I had omitted to raise this with [Ms A] and her mother at the PAC. To ensure this was remedied in advance of the procedure I noted on the consent form that the presence of students needed 'to be checked on admission' and that consent was 'TBC'."

57. Dr C stated that as she expected to undertake the procedure, she anticipated that she would ensure that the outstanding element on the form was completed as required on the day of the procedure.

Procedure 30 July 2018

58. Ms B stated that on 30 July 2018, she and Ms A arrived at 12pm for Ms A's procedure. Dr C told HDC that she was operating at the time Ms A presented at Dunedin Hospital, and the ward staff did not advise her of any concerns raised on admission. Prior to the procedure, Ms A was taken from the ward to the anaesthetic room.

Handover from Dr C to registrar

59. Dr C stated that contrary to her expectation, she was not able to perform Ms A's procedure herself, as she was called to assist with an unexpected emergency that required her immediate attention. Dr C said that before being called away, and in anticipation that she would be undertaking the operation, she had confirmed that Ms A had been sent for. Dr C stated:

> "Towards the end of the preceding case I popped my head into the adjoining anaesthetic room and said hello to [Ms A] as she arrived from the admission ward …

> [T]he previous case was still on the operating room table at this time. The final post procedure 'time out' was yet to be completed, and I completed documentation while waiting on the reversal of anaesthesia. It was at this point I received the message of the emergency situation that required my attendance."

60. Dr C stated that she delegated Ms A's case to her "very competent" senior registrar, Dr E, who was credentialled to perform such a case. Dr C said that she confirmed with Dr E that she would undertake the case, and immediately left the operating room.

61. In response to the second provisional opinion, and although she does not now recall these events, Dr E said that she and Dr C would have been scrubbed in with the first patient. Before that procedure was finished, Dr C would have left to speak with Ms A in the anaesthetic room while she (Dr E) most likely remained with the first patient.

62. Dr C recalls seeing Dr E go into the anaesthetic room. Dr C stated that it was her expectation that Dr E would have introduced herself to Ms A in the anaesthetic room; however, Dr C did not specifically witness this. She said: "I believe that the senior registrar would have explained to [Ms A] that the procedure would be performed by her as the primary surgeon." However, Dr C said that she had not been able to check with Dr E whether she did do so.

63. Dr E's evidence is that she does not recall in detail her interactions with Ms A or the specifics of the procedure undertaken. Dr E stated that the normal practice was that prior to a surgical case, the lead surgeon and/or assistant surgeon and members of the surgical team would meet the patient in the anaesthetic room and introduce themselves, confirm the details of the procedure, and reconfirm the consenting details.

64. Dr E does not remember when Ms A was handed over to her, when she was able to leave the first patient and attend Ms A, or how much time she had with Ms A in the anaesthetic room before Ms A was moved to theatre. Dr E said that it is possible that Dr C started to meet with Ms A in the anaesthetic room and then handed over to her at a point when she (Dr E) understood that the paperwork had been checked already. In response to the second provisional opinion, Dr E said that from her perspective, Dr C would have left the theatre to attend to Ms A in the anaesthetic room, and Dr E considers that it would have been Dr C's responsibility to be clear when handing over Ms A to her (Dr E) what steps she (Dr C) had completed. Dr E said that during handover, Dr C must not have told her that part of the form was incomplete. Dr E stated that several clinicians in the anaesthetic room would have been present for both Dr C's and her time with Ms A, but there is no evidence that any of the team intervened (as would be expected) to alert her that Dr C had not yet gone through the consenting documents.

65. Dr E told HDC that it is her usual practice to introduce herself to patients prior to any operation. In response to the first provisional opinion, Dr E said that Ms A may not have understood or remembered everything that happened that day. Dr E stated that if Ms A was handed over to her while conscious, she is "absolutely certain" that she would have introduced herself and explained that she would be responsible for performing the procedure.

66. In response to the first provisional opinion, Ms A said that she has a clear recollection of being in the anaesthetic room, but does not remember being introduced to anyone in the room. She stated that there were many people in the room, which intimidated her. Ms B recalled that Ms A was alert and aware as she walked with her when the orderlies took her to theatre.

Process for checking consent

67. Dr C stated that the expectation is that the surgeon who is to perform a case will review the consent form for completeness in all aspects. This occurs either when seeing the patient on the admitting ward prior to the list, or, if this is not possible owing to admission time, the consent form is checked at a "Time Out" by the person who is to perform the procedure.

68. Dr C outlined in detail the process when a patient arrives for surgery. She said that the first identification of the patient is on arrival on the preoperative ward, when all notes, consents, and patient details are checked. The first "Time Out" occurs when the patient is uplifted at the ward by an orderly to go to the Main Theatre. She said that the second "Time Out" is when the patient is in the anaesthetic room, where the nurse, anaesthetist, and anaesthetic technician check the patient details. The third "Time Out" is in the operating theatre after the general anaesthetic, and is led by the person who is to perform the surgery, and a charge theatre nurse.

69. Dr C said that had she maintained responsibility for undertaking the operation, she would have completed the omitted aspect of the form at the "Time Out". She had expected that Dr E would identify the note "to check on admission", and ask Ms A for her view on student involvement in response to the note. Dr C stated that it is the practice of the theatre nurses to check the completeness of the consent form on the patient's arrival at the theatre, and the "Time Out" then takes place. She said that she had felt comfortable that the systems and checks in place would enable the outstanding information to be gathered.

70. Dr E noted that Dr C's comment on the consent form about students must have been missed by the team handling the paperwork in theatre at the "Time Out" following general anaesthesia.

Persons present at commencement of procedure

71. Ms A was taken from the anaesthetic room to the theatre, and the procedure took place around 3pm. She stated that she saw Dr C, two male doctors, three students, and the anaesthetist in theatre. Ms A said that she did not know they were students at the time, and she was feeling very vulnerable, as it was her first time under anaesthetic.

72. In response to the first provisional opinion, SDHB said that there were not two male doctors in theatre at that time. The only male doctor was the anaesthetist, and Dr C was not present. Dr E noted that she is a female doctor, and Ms A did not mention her presence. Dr E stated:

> "This makes me wonder whether [Ms A] did not take on board what I would have discussed with her pre-operatively when I introduced myself and my role and went through the paperwork."

73. However, Dr E also said that she herself cannot recall who was present in the operating theatre on the day of the procedure. She noted that the records refer to Dr F being the anaesthetist and a fifth-year medical student being present (Mr D[11]). Dr E stated that it would be usual to also have a scrub nurse, a circulating nurse, and an anaesthetic technician present in theatre as well, but their names are not noted in the records. She said that it was customary for the nurse who escorted the patient to theatre to make introductions to the operating theatre staff while the operating surgeon was reviewing prior patients who could be ready for discharge, or commencing their surgical scrub.

Student involvement

74. The operation note completed on 30 July 2018 states that the Mirena was inserted by a fifth-year student, Mr D. The operation note is signed by Dr E. Both Dr C and Ms A remember seeing other students present, observing (albeit at different times).

75. Although she cannot recall these events, Dr E stated that if students were present at the procedure, they would have been introduced to Ms A and identified as students who would be part of the theatre team.

76. Dr E stated that she was very aware of the importance of obtaining a patient's full consent to the presence and involvement of medical students, and she is unable to explain why consent was not obtained in this case. She stated: "I am quite confident I would never allow students to be present if I had any appreciation that that was against the wishes of the patient."

77. Dr E also noted Ms A's statement that she had filled in forms at the PAC that indicated that she did not want students involved. Dr E said:

> "Having these forms with the paperwork would have been hugely helpful, as it would have been another document checked in the anaesthetic room/another layer of safety — particularly given the potential for a perceptual error/misreading of the box regarding student involvement which could easily have been mis-read as having been ticked and initialled …"

78. Dr E said that it is the responsibility of the most senior doctor to ensure that the paperwork has been completed correctly.

79. Dr C told HDC:

> "I popped my head into theatre shortly after the procedure had commenced to advise [Dr E] that I was leaving … [Dr E] was seated performing the procedure, and I was reassured all was well. I noted students were present and assumed that consent had been provided by [Ms A] to the same."

[11] Mr D qualified as a doctor after these events.

80. Mr D told HDC that he recalls assisting the registrar during Ms A's procedure, but cannot recall a specific discussion around patient consent. He said that his practice was to confirm with the doctor or theatre charge nurse that patient consent had been given for student involvement, prior to entering the theatre. He stated: "It was my experience that consent for students assisting in procedures was not uncommonly refused and therefore confirmation of patient consent was routine."

81. In response to the first provisional opinion, Mr D clarified that as he was a male student, female patients frequently refused their consent. That fact of common refusal, and knowing the sensitivities around having students involved in the care of female patients for procedures involving their genitalia, meant that he was always "finely tuned to the issue of patient consent". He said that he is certain that he would not have been present or involved in theatre if he had been advised that the patient's consent for student involvement had not been granted.

Further abdominal pain

82. Ms B stated that when Ms A woke up from the anaesthetic, she complained that her abdomen was painful. She was discharged from hospital at 7pm and went home with her mother.

83. Ms A continued to have abdominal pain, so she booked an appointment with Dr G on 17 August 2018. During the appointment, Dr G reviewed the notes from Dunedin Hospital. Ms B stated:

> "We were horrified to see that a fifth year medical student had done the operation. [Ms A] said '… I said No Students' and broke down in tears. [Dr G] was also very shocked and said this is serious and should go straight to Medical Council."

Referral 17 August 2018

84. On 17 August 2018, Dr G referred Ms A to Dunedin Hospital. The referral states that Ms A had experienced five days of worsening pelvic pain and cramping. It also states that Dr G had reviewed the operation note, which refers to the involvement of a student, Mr D, with Ms A and her mother, and that "they both became extremely upset as neither of them gave permission for students to be in attendance let alone perform the procedure".

85. Ms A presented at the Emergency Department (ED). Dr C stated that she went to the ED because there was a concern that the Mirena might have been displaced or misplaced. Dr C said that she examined Ms A's abdomen and confirmed that all her vital observations were normal. Dr C arranged an urgent ultrasound scan, and transabdominal and transvaginal scans confirmed that the Mirena was placed in the uterus correctly, and there were no other abnormalities found in the pelvis.

86. Dr C told HDC that following the ultrasound scan, she met with Ms A's parents to advise them of the findings, during which she explained that she was unable to find any particular

underlying cause for Ms A's pain. Dr C said that she explained that it was possible to remove the Mirena, but there was no guarantee that this would improve the pain symptoms.

87. Dr C stated:

> "I also very genuinely apologised for the upset they and [Ms A] experienced in relation to learning that students had been present and involved in her procedure. I was very sorry to learn that this had happened."

88. Dr C said that she also apologised for not being able to be in theatre for the procedure.

89. Ms A was discharged home.

Further events

90. At a follow-up consultation with Dr C on 21 August 2018, Ms A stated that she continued to have abdominal pain and she wanted to have the Mirena removed. Dr C removed the Mirena without difficulty.

91. Subsequently, Dr C asked a consultant gynaecologist to review Ms A because she (Dr C) was going on leave. On 3 October 2018, the gynaecologist reported to Dr G that she had seen Ms A and her family, and it had been decided to start Ms A on the oral contraceptive pill Ava 20. Ms A was discharged back to the care of Dr G.

Further information — Dr C

92. Dr C said that there was always a prospect that she would be called away and not be able to perform the procedure, but in that event she would expect her registrar to understand the notation she had made on the consent form and ensure that the information was clarified with Ms A before proceeding.

93. Dr C emphasised to HDC that neither Ms A nor her mother indicated Ms A's views on the presence or involvement of medical students during the pre-procedure appointments, nor during her interactions with them after the procedure. However, at the consultation on 17 August 2018, Ms A and her parents communicated their upset at the presence of medical students.

94. Dr C stated that she was not aware that a student was going to insert the Mirena, and this had not been discussed with her. She said that it would be usual for the registrar to confirm the patient's expectations about the procedure, including confirming consent for the presence of students, when greeting the patient in the anaesthetic room.

95. Dr C noted that in retrospect she considers that she could have actively reminded Dr E that the section relating to the presence of medical students had not been completed.

Further information — Ms A

96. Ms A told HDC that she considers that Dr C did not treat her with respect. Ms A said that she did not at any time agree for a medical student to be in the room or to perform any

procedure, let alone a sensitive procedure. She stated that she wants the hospital to make sure that people with special needs are treated properly and with dignity.

SDHB

97. SDHB told HDC that in 2018, fifth- and sixth-year medical students were considered part of the team and did not require additional consent. In response to the first provisional opinion, SDHB clarified that sixth-year medical students, being trainee interns, were generally regarded as part of the team as they are involved in patient care doing certain tasks under the oversight of the remainder of the team, which is not the position for fifth-year medical students. In response to the second provisional opinion, SDHB stated that "part of the team" would not encompass performing a procedure such as Ms A underwent, or even being in theatre while it was being performed. SDHB said that its earlier response related to medical students observing treatment, and was not directed at procedures in theatre.

98. The policy in force at the relevant time, "Informed Consent for Health Care Procedures Policy (District)" states:

> "…
>
> | | |
> |---|---|
> | **Presence of Students and Others** | Additional informed consent must be gained for the presence or involvement of students or other personnel who do not have a direct role in the consumer's treatment team during the health care procedure.

The reasons for the presence or involvement of any such personnel must be fully explained to the consumer.

The clinician is expected to exclude any students during the discussion to allow the consumer to make a decision without undue (real or perceived) pressure. |
> | **Competency to Give Consent** | |
> | **Assessing Competence** | Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing otherwise.

It is the clinician's responsibility to ascertain whether the consumer is competent to give informed consent.

Medication, intellectual disability, mental illness, inebriation, or physical injury may affect the informed consent process." |

99. SDHB stated that the policy was revised in 2019. SDHB said that it has undertaken considerable and ongoing work to support effective informed consent processes, and more

recently this has included an extensive review of its informed consent for healthcare procedures policy and its consent forms. SDHB said that the Deputy Chief Medical Officer led this review in 2018–2020 with legal input and extensive end-user consultation (mostly medical staff). The new consent forms were launched formally in June 2020.

100. SDHB said that it has also worked with the Medical School to ensure that policy regarding consent for sensitive examinations under anaesthesia by medical students was included in the Student and Trainee Intern Handbooks.

Responses to first provisional opinion

101. Responses to the first provisional opinion were received from Ms A, SDHB, Dr C, Dr E, and Mr D. Where appropriate, the responses have been incorporated into the "information gathered" section above. In addition, the following responses were received.

Ms A

102. Ms A is concerned that a lack of consent for the involvement of medical students is taken as consent for them to be present. She noted that to her recollection, the only time she was asked whether students could be present was when she was filling in the forms with her mother.

103. Ms A does not recall being informed at any time that another doctor could be performing the procedure, let alone a student. She noted that the procedure was not urgent and could have been delayed when Dr C was called away.

104. Ms A noted that Dr C has made changes to her practice. However, Ms A said that she would be more reassured if there was an outline of how these changes are being audited.

Dr C

105. Dr C acknowledged that she made an error in completing the PAC form, but submitted that as she provided a clear directive that it be remedied, and as SDHB's processes should have detected and remedied the incomplete consent, there was no justification for an adverse comment about the care she provided.

106. Dr C stated that the expectations and practices within the SDHB and within her team were clear around consent, and she considers that the fact that these expectations and practices were not complied with when she was not present to ensure that this occurred has no bearing on her capabilities or conduct.

Dr E

107. Dr E said that she understands how upsetting what happened has been for Ms A, for which she is truly sorry. Dr E stated that she will provide a written apology to Ms A, and hopes that this will be of help to her.

108. Dr E said:

> "I have always placed, and continue to place, the utmost importance on gaining informed consent and ensuring explicit consent is obtained for any involvement of medical students. I plan to attend an MPS[12] workshop on the consenting process to update my practice and consider continuing medical education to be an essential part of medical practice."

SDHB

109. SDHB stated that it considers that the consent form in relation to student involvement was misread at the time the check occurred in the anaesthetic room. The DHB said:

> "Consent to students would have then been confirmed with [Ms A], and she has not recalled this response correctly later on. It is not unheard of for patients not to recall the specific interaction immediately prior to theatre."

110. SDHB submitted that its staff must have formed an impression — based on the consent form and what had been discussed with Ms A during the anaesthetic room interaction — that Ms A had consented to students being involved in her care. The DHB stated:

> "It is therefore not correct to take the position that 'no person acted on [Dr C's] alert'. Rather, it would appear most likely that there has been a misreading of that alert indicating that consent has been provided, and then that has been verbally confirmed with [Ms A] at the time."

111. SDHB submitted that this was not a problem at a systemic level.

112. SDHB submitted that the chances of student involvement occurring without Ms A's consent is so remote that SDHB "considers it highly unlikely that it actually occurred". It stated that a more likely occurrence is that "[Ms A] has provided authorisation for student involvement in the anaesthetic room. In doing so she either did not realise she was providing this authorisation, or she has failed to recall that she provided this."

113. The DHB said that Ms A did not express a refusal of consent to the involvement of students in her care to any SDHB staff member.

114. SDHB disputed the finding in the first provisional opinion that it breached the Code of Health and Disability Services Consumers' Rights (the Code).

Responses to second provisional opinion

115. Responses to the second provisional opinion were received from Ms A, SDHB, Dr C, Dr F, and Dr E. Where appropriate, the responses have been incorporated into the "information gathered" section above. In addition, the following responses were received.

[12] Medical Protection Society.

Ms A

116. Ms A said that she had discussed with her mother several times before the procedure that she did not want students involved. Ms A stated that there were many people in the anaesthetic room and they talked a lot but did not ask her any questions. She submitted that it appears that SDHB is assuming that silence is consent, and added: "[W]e believe silence is not consent."

Dr C

117. Dr C said that she had no further comments to make on the decision, but wished to draw to HDC's attention that recently she completed two MPS courses on mastering shared decision-making and risk assessment.

Dr E

118. Dr E submitted that she was not told about the complaint until about 32 months after the procedure, and that given the time that had passed there are no grounds to criticise her for not recalling one brief procedure. Dr E said that she accepts responsibility for the failure of the team/system to identify a lack of consent during the surgical/operating theatre "Time Out", but does not accept that any failings in the anaesthetic room were her fault, and she thinks it is likely that she was called in from attending to the first patient "at literally the last minute", and she was provided with an inadequate handover from which she reasonably believed that the usual anaesthetic room processes had already been completed.

Dr F

119. Dr F said that he is sorry for the distress Ms A has faced in relation to her care at SDHB. Dr F stated: "I have learned from what occurred and were I to face the same situation again, where a colleague had requested I confirm in writing my separate review, I would be careful to ensure I did so."

SDHB

120. SDHB said that students would not have been present in the theatre unless the staff present had understood that Ms A had consented to them being present, and they would have been permitted entry only once this understanding had been established, which it says casts further doubt on the accuracy of Ms A's recollection.

121. SDHB stated that it does not take a lack of consent for student involvement to mean consent. In this case, staff would have had the impression that Ms A did consent, owing to a misreading of the form and a discussion preoperatively that no one can specifically recall due to the passage of time.

122. SDHB noted that Ms A said that she was not told that any doctor other than Dr C might perform the procedure. In response, SDHB commented that this statement contrasts with Dr C's account that Dr E saw Ms A in the anaesthetic room.

123. SDHB stated:

> "It is regrettable that no one at SDHB knew about [Ms A's] expressed wishes not to have students involved in her care. But without knowing that view, a misunderstanding of her view has led to the view not being respected."

124. SDHB submitted that it is also unfortunate that in this case Dr C's desire to have the issue of student consent specifically addressed has led to a notation on a form that would have misled staff. The events in this case have led to a perception of a cumbersome and disjointed system, but in usual circumstances the system is neither cumbersome nor disjointed, and usually would ensure that consent was obtained before student involvement. The system involved:

- Patients being informed at clinic of students being present and that a patient could refuse consent for their involvement in care (without affecting their treatment).
- Clinic staff seeking consent for student involvement if students were present in clinic.
- A surgical consent form that specifically addressed the issue of students being involved at a procedure that would be completed with the patient.
- An anaesthetic consent form that specifically addressed the issue of medical students being involved in the anaesthetic that would be completed with the patient.
- A process that involved three separate checks that consent had been obtained before medical students had involvement in a procedure within theatre.

Opinion: Southern District Health Board — breach

125. The Cartwright Cervical Cancer Inquiry (1988) was critical of practices at that time where students, under supervision, undertook internal vaginal examinations on anaesthetised women without their consent. Among other things, this informed the rights contained in the Code.

126. Right 9 of the Code extends the rights in the Code to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching.[13] Right 6(1) of the Code states:

> "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including — … notification of any proposed participation in teaching … and any other information required by legal, professional, ethical, and other relevant standards …"

[13] Clause 4 of the Code defines "teaching" as including training of providers.

127. I, of course, acknowledge the importance of medical education, and that students training to become doctors need to learn how to perform sensitive examinations and procedures. However, the Medical Council of New Zealand considers "conducting an intimate examination of a patient in the presence of students or other parties without the patient consenting to the presence of the students or other parties" as an example of "sexual impropriety in the doctor–patient relationship".[14]

128. There is a clear expectation that such examinations can be conducted only with unequivocal informed consent, given the vulnerability of the person being examined. It is at the heart of patient-centred care. In 2015, the *New Zealand Medical Journal* published a Consensus Statement on medical students and informed consent, prepared by medical schools (including the medical school referred to in this report), district health boards, the New Zealand Medical Students' Association, and the Medical Council of New Zealand.[15] The Consensus Statement outlined a unified approach to seeking consent for medical student involvement in patient care. It highlighted how in certain circumstances, such as the performing of sensitive examinations, particularly those under anaesthesia, meticulous care is required in seeking and documenting consent for the involvement of medical students.

129. In this case, Ms A expected to have a Mirena inserted by consultant obstetrician Dr C, and (according to Ms A's and her mother's evidence) had not given consent to the involvement of students in her care. However, that sensitive procedure was performed by a medical student and registrar Dr E, and was observed by other medical students. In my view, the system failed Ms A, for the reasons discussed below.

Preliminary comment — Ms B's support

130. Before considering the specific issues of the consenting process it is necessary to address submissions made on behalf of SDHB calling into question the reliability and credibility of Ms A's and Ms B's account of what occurred.

131. SDHB, through counsel, submitted that there has been no actual account of what occurred directly from Ms A — but rather her mother (Ms B) has largely authored the complaint and provided additional detail. SDHB identified discrepancies in the information provided by Ms B, which it submits casts doubt on Ms A's recollection, and suggests the possibility that Ms A may have provided consent in the anaesthetic room (or that people may have perceived her to have provided consent).

132. Ms A has a mild intellectual disability. Her HDC complaint (submitted on 15 June 2020) identifies that she has some learning disabilities, needs more time and less pressure to make decisions than most people, and that she had had assistance filling out the complaint form.

[14] Medical Council of New Zealand, "Sexual boundaries in the doctor–patient relationship", 2009 (page 3).
[15] Warwick Bagg, John Adams, Lynley Anderson, Phillipa Maplas, Grant Pidgeon, Michael Thorn, David Tulloch, Cathy Zhong and Alan Merry, "Medical Students and informed consent: A consensus statement prepared by the Faculties of Medical and Health Science of the Universities of Auckland and Otago, Chief Medical Officers of District Health Boards, New Zealand Medical Students' Association and the Medical Council of New Zealand", NZMJ 15 May 2015, Vol 128 No 1414.

It is imperative that complaints mechanisms are accessible for all people, including those with intellectual disability. That a person may need assistance to complain should not lead to a conclusion that such a complaint is lacking in credibility or reliability. I also do not accept that Ms B writing her daughter's complaint means Ms B cannot corroborate her daughter's account, as has been asserted by SDHB.

Involvement of medical students

133. Ms A's complaint to HDC was not her first complaint about this episode of care. At a GP consultation 17 days after the Mirena insertion, Ms A learned that a medical student had inserted the Mirena. Her shock and upset at that revelation is corroborated by her mother and her GP, who noted it in a referral letter to the hospital that same day. Dr C also accepts that on 17 August Ms A and her family were upset about this fact. On 17 January 2019, the family made a formal written complaint to SDHB.

134. In relation to the essential facts, Ms A, supported by her mother, is clear that:

a) She completed a form at the PAC expressly refusing the presence of medical students; and

b) She did not consent to the presence of medical students.

135. These assertions were made in proximate time to the events in question, including in the January 2019 complaint. I discuss my findings in respect of each point below.

Failure to action refusal of consent

136. Ms A and her mother said that she filled in a form at the PAC, in which she clearly indicated that she did not want students involved in her care. There was no such form on her file. In response to my first provisional opinion, SDHB stated that the information sheet about student involvement provided at the PAC is not a form to be completed, and it could not have been completed in the way described by Ms A and Ms B.

137. Having reviewed all the evidence, I have identified the following forms as having been completed either with or by Ms A, or given to her, between her second outpatient appointment with Dr C on 21 February 2018 and the PAC on 16 July 2018.

- On 21 February at the second outpatient appointment, Dr C completed the CPAC and surgical booking forms. She also gave Ms A APAC information forms, which Ms A "later completed". According to Dr C, this included or consisted of a Preoperative Health Questionnaire, which was given to Ms A to complete for the anaesthetist to review at the APAC. There is a copy of a completed Preoperative Health Questionnaire on Ms A's file, but it is undated.
- On 2 June at the APAC, Dr H completed an anaesthesia consent form, but did not complete the section relating to student involvement in the anaesthetic.

- On 16 July at the PAC, Ms A completed two health questionnaires, and Dr C completed the surgical consent form, which sought consent to student involvement, but Dr C had marked this section to be checked on admission.
- Also at the PAC, Ms A said that she had forgotten to bring the forms she had already completed at home, so asked for and was given replacement copies of the forms. She said that one form had health questions and the other had a question "do you want students involved in your care?". She stated that she filled out the form refusing consent to students, and handed it to the receptionist.
- There is also a women's health clinic information sheet routinely provided to outpatients, which refers to student involvement but does not seek patients' consent. SDHB said that if students had been present at the clinic, Ms A would have been asked for her consent to their involvement, but there is no form to be completed recording such consent (other than the anaesthetic form and surgical consent form).

138. I acknowledge SDHB's submission that the women's health clinic information sheet is not a form to be filled in. However, both Ms A and Dr C acknowledge that Ms A was given forms at the outpatient clinic appointment on 21 February 2018 that were to be reviewed at the APAC appointment on 2 June 2018. The anaesthesia consent form, completed by Dr H at the APAC, included a section for consenting to student involvement in the anaesthetic. Ms A's mother has corroborated Ms A's evidence that at the PAC Ms A requested replacements for forms she had been given at a previous appointment, and subsequently completed a form at the PAC refusing consent to the presence of medical students, and that they had a conversation about it.

139. Ms A's and Ms B's evidence has been consistent in this respect. Indeed the first complaint to SDHB (January 2019) led with their question as to what happened to the forms Ms A had filled out expressly stating "no students".

140. In response to the second provisional opinion, SDHB said that no form has existed at any time at SDHB that could be completed to refuse the presence of medical students (other than what could be noted on the surgical and anaesthetic consent forms), so it is impossible that such a form was completed. I disagree with this submission.

141. It appears possible that the forms Ms A asked for and completed at the PAC may have been the Preoperative Health Questionnaire and a further anaesthetic or surgical consent form. However, I am unable to conclude that with certainty. Nevertheless, it is accepted that Ms A was given forms to complete and return to the APAC. I also accept both Ms A's and Ms B's consistent and clear evidence that a form refusing consent to student involvement was completed at the PAC. Ultimately, I am unable to determine what that form was or why it was not placed on Ms A's file after she gave it to the receptionist.

142. The anaesthesia consent form specifically sought consent to students being involved in the anaesthesia, as opposed to the procedure itself. SDHB said that this section is blank on the copy on Ms A's file because it was known that no students would be involved in the anaesthetic despite the form being completed on 2 June and the procedure not taking place

until 30 July. SDHB's process allowed for a separate checking of consent to student involvement for the procedure itself. I consider that this distinction (between consent for surgery versus anaesthesia) would not necessarily be clear to a consumer in Ms A's circumstances. Having indicated her refusal of consent to students on a form, possibly the anaesthetic consent form, it was reasonable for Ms A to believe that she had informed Dunedin Hospital of her wishes in this respect.

143. In saying that, I accept that the relevant clinical staff involved in her care up to and including the day of the procedure were not aware of Ms A's explicit written refusal. This was because the form she completed did not make its way to her file. However, this does not alleviate the duty of those staff to have obtained her explicit consent to the presence and involvement of medical students — as discussed below.

Failure to obtain consent to medical students

144. Following the system's failure to action Ms A's refusal of consent to student involvement, the system also failed to actively seek and obtain/confirm Ms A's consent before students were permitted to be involved in the procedure on 30 July 2018. There were several opportunities where consent should have been obtained or clarified.

PAC

145. The PAC was, in my view, the primary opportunity to ascertain Ms A's consent to participate in teaching. The surgical consent form prompted clinicians to obtain explicit consent to student involvement, and the PAC offered adequate access to senior clinicians to provide information about student involvement, and adequate time for consumers to digest information and reach a decision before the procedure was undertaken. However, when Ms A saw Dr C in the PAC, the subject of student involvement was not raised, and the consent to students section of the surgical consent form was not completed.

146. I agree with Dr C that the responsibility lay with her to obtain Ms A's informed consent to the presence and involvement of medical students at that time. I have addressed that below in respect of Dr C individually.

On the ward

147. Sometime after the PAC, but before the procedure, Dr C recognised that she had omitted to complete the checkbox on the consent form addressing whether the patient consented to students being present during the procedure. Dr C therefore noted on the consent form that the presence of students needed "to be checked on admission", and that consent was to be confirmed.

148. Dr C stated that when a patient arrives on the preoperative ward, all notes, consents, and patient details are checked. Similarly, the first "Time Out" process for checking consent occurs when the patient is uplifted at the ward by an orderly to go to the Main Theatre (via the anaesthetic room). However, there is no evidence that anyone, including Dr C, acted on Dr C's alert when Ms A was admitted or uplifted for the procedure, or sought Ms A's consent to student involvement. In response to the second provisional opinion, SDHB said that on

the day of Ms A's procedure, Dr C's only involvement with Ms A prior to the procedure was a brief episode in the anaesthetic room before being called away for other tasks. SDHB stated: "It would be impractical for a doctor such as [Dr C] to leave the operating theatre to check a patient's documentation." As discussed below, Dr C handed over care to Dr E and would have expected the system to detect any lack of consent.

Anaesthetic room

149. The second "Time Out" process for checking consent is when the patient is in the anaesthetic room, where the nurse, anaesthetist, and anaesthetic technician check the patient details. According to Dr C, the person undertaking the procedure, Dr E in this case, would also check the consent in the anaesthetic room before entering theatre. There is, again, no evidence that anyone acted on Dr C's alert in the anaesthetic room or sought Ms A's verbal consent to student involvement.

150. In response to the provisional opinions, SDHB submitted that it would appear most likely that staff misread Dr C's alert on the surgical consent form and thought it indicated that consent had been provided, and/or that it must have been verbally confirmed with Ms A in the anaesthetic room before the procedure was undertaken.

151. SDHB submitted that although no one can recall exactly what occurred at the time of the procedure, the chances of student involvement occurring without Ms A's consent is so remote that SDHB "considers it highly unlikely that it actually occurred". SDHB said that Ms A did not express a refusal of consent to the involvement of students in her care to any SDHB staff member. It stated that a more likely occurrence is that "[Ms A] has provided authorisation for student involvement in the anaesthetic room. In doing so she either did not realise she was providing this authorisation, or she has failed to recall that she provided this." SDHB said that it relies on Mr D's evidence that he would not have been present if he had been advised that the patient's consent had not been granted.

152. However, Ms A is adamant that she never consented to the involvement of students in this sensitive procedure. While I have little difficulty in accepting Mr D's belief that consent had been given, that cannot lead to the conclusion that it was, in fact, given. Mr D was not present for any consent discussion and has no recollection of any specific consent discussion. He has not said that he was in the anaesthetic room with Ms A, and so he would not have been aware of what took place there.

153. SDHB has called into question Ms A's credibility, noting that at times Ms A has difficulty saying what she means. SDHB stated: "That scenario supports the possibility that, while she may not have consented in her own mind, people she spoke with could reasonably have perceived an opposite view."

154. I accept that there is confusion in parts of Ms A's evidence — for example, her description of who was present in theatre. However, the context is relevant, including that Ms A, a mildly intellectually impaired young woman, was anxious about the upcoming procedure and first experience of anaesthesia. Ms A, who would have been under general anaesthesia during most of her time in theatre, would have been unlikely to be able to identify the roles

of the people present or who the people were, particularly as they would have been wearing masks and caps. In my view, the lack of certainty in Ms A's evidence about who was present in theatre does not call into question the credibility of her consistent evidence that she never at any time gave consent to students being involved, including in the anaesthetic room.

155. SDHB has submitted that Ms A must have consented to students, or given the impression of having consented, otherwise students would not have been involved. I do not accept SDHB's implication that the fact that medical students were involved is probative of Ms A having given consent to their involvement in her procedure. I also do not accept that an impression of having consented would be sufficient. With reference to the Consensus Statement, any such consent needed to be explicit. It was not Ms A's responsibility to inform staff of her refusal — it was SDHB's responsibility to explicitly obtain her consent for the involvement of students.

156. Ultimately, I do not accept SDHB's submission. There is no evidence that Ms A consented, no evidence that any SDHB staff member recalls Ms A agreeing to the involvement of students, and there is no documentation to support the speculation that Ms A verbally consented to the presence of students in the anaesthetic room. SDHB's submission is purely speculative with no evidential foundation.

157. Furthermore, I do not accept that student involvement without consent is highly unlikely — there is certainly precedent for such events having occurred at other hospitals.[16]

158. Referencing "usual practice" as to what occurred in the anaesthetic room relating to the consenting process must also be considered with reference to all the evidence, including what was, and what was not, documented. Taking all the evidence into account, I prefer and accept Ms A's account that she did not verbally consent to the presence or involvement of medical students in the anaesthetic room (or, for the avoidance of doubt, at any other time). In doing so, I again note:

- The lack of documentation of verbal consent to the presence or participation of medical students;[17]
- Speculation that the surgical consent form was misread (to indicate a tick and initials) is not accepted and somewhat implausible noting that several staff members would have

[16] Phillipa J Malpas, Warwick Bagg, Jill Yielder, and Alan F Merry, "Medical students, sensitive examinations and patient consent: a qualitative review", NZMJ 21 September 2018, Vol 131 No 1482. In fact, while this report was in its final stages, a further study was published demonstrating that student involvement without consent is still a reasonably frequent occurrence — Harsh Bhoopatkar, Carlos F C Campos, Phillipa J Malpas, Andy M Wearn, "Adherence to a national consensus statement on informed consent: medical students' experience of obtaining informed consent from patients for sensitive examinations", NZMJ 20 May 2022, Vol 135 No 1555.

[17] There is a peri-operative pathway document that has a tick in the box marked "consent form". It was submitted by Counsel that in order for the tick to be placed, the nurse was satisfied that consent had been obtained. The form is not sufficient evidence that consent was obtained properly.

had to misread the form in the same way (failing to account for the clear "?" after the letters "TBC" and the specific written instruction on the form "to be checked on admission"); and

- Ms A's mindset prior to the procedure (that she refused consent) and her shocked reaction after the procedure to learning of the involvement of medical students, is inconsistent with the suggestion that she may have consented in the anaesthetic room.

159. The importance of allowing patients adequate time to reflect on information provided to them prior to surgery has been highlighted in previous HDC cases.[18] Even allowing for the possibility that student involvement was mentioned to Ms A in the anaesthetic room, while this was an appropriate point to have rechecked whether the consent forms had been completed, having regard to Ms A's particular needs it would not have been an appropriate time to have initiated a discussion seeking consent either to the anaesthetic or to the involvement of students.

160. In light of Ms A's intellectual disability (and that there was a question regarding her understanding of the information provided as identified in the anaesthesia consent), the sensitive nature of the procedure, Ms A's anxiety, her youth, and that her support person was not present, it would have been inappropriate to have sought her consent while in this vulnerable position. In my view, these issues should have been covered off either at the PAC or at the time of admission, when Ms B was present to support Ms A.[19]

Theatre

161. The third "Time Out" is in the operating theatre after the general anaesthetic, and is led by the person who is to perform the surgery, and a charge theatre nurse. Usually nurses check the completeness of the consent form when the patient arrives in the operating theatre, followed by a final "Time Out", during which the consent form would be reviewed further. Again, nobody present identified that the section relating to consent to the presence of students had not been completed on the surgical consent form, and there is no evidence that Ms A gave verbal consent to students on her arrival to theatre.

Conclusion — involvement of medical students

162. Ms A was, understandably, distressed by the services provided by Dunedin Hospital. She expected the procedure to be performed by Dr C, and had not consented to involvement of medical students; indeed, she had explicitly refused consent on the form she completed on 16 July 2018. Despite this, a student was permitted to insert a Mirena while other students observed. Ms A's distress is entirely reasonable in these circumstances.

163. The Medical Council statement in place at the time, "Information, choice of treatment and informed consent",[20] stated: "Obtain consent before involving medical students in the care

[18] See Opinion 09HDC01691, Opinion 08HDC20258, and Opinion 05HDC07699.
[19] I note that the Consensus Statement (referred to at paragraph 128 of this report) also says that informed consent to student involvement should be sought with respect and compassion for patients, taking into account their circumstances and vulnerabilities at the time.
[20] March 2011.

of patients. Inform the patient about the extent of the involvement of the student and the student's experience."

164. It was the responsibility of the DHB and the relevant clinicians to obtain consent, not Ms A's responsibility to repeatedly alert staff to her refusal to have students present. There were several lost opportunities by multiple staff to obtain her unequivocal informed consent to medical student involvement in the actual procedure, as well as observing.

Failure to check consent to anaesthesia

165. Separate to the issue of consent to student involvement is the concern that alerts raised following the APAC on 1 June 2018 were possibly not acted on. Specialist anaesthetist Dr H was concerned that Ms A may not have understood the discussion, and so he noted his view that the Anaesthesia Consent form required a second doctor's signature and that consent was to be confirmed. Despite this, no second signature was obtained, and there is no direct evidence that the concern about Ms A's capacity to consent to her anaesthesia was addressed. In particular, there is no supporting documentation addressing the question of Ms A's competence and understanding.

166. Dr F said that he was satisfied that informed consent for general anaesthesia had been obtained by the anaesthetist in the APAC. He further stated that he does not recall Ms A, but his usual practice would be to converse with the patient directly. He would specifically turn his mind to whether the patient was consenting to anaesthesia, and would enquire whether they had any further questions about what was to occur. Provided he was satisfied that they were still consenting to the procedure, he would then go through with the anaesthesia. There is no record of Dr F undertaking those steps in this case, and no witnesses that he did so. He has not signed the form as the "second doctor", which had been requested. I have discussed this further in relation to Dr F individually below.

167. Right 7(3) of the Code provides that if a consumer has diminished competence, he or she retains the right to make informed choices and give informed consent to the extent appropriate to his or her level of competence. I accept that on the basis of Ms A's and her mother's evidence, with suitable support, Ms A was capable of giving informed consent to having a general anaesthetic on her own behalf. However, I am critical that there is no evidence that the alerts on the forms were acted upon by the operating team. This was a "red flag", and suggested that prior to the procedure, care should be taken to reiterate to Ms A the risks of the anaesthetic and confirm her consent. Given the concerns about her capacity, it would have been appropriate to do so with her support person present, and allow her the necessary time to reflect on the information provided.

Systems

168. SDHB has submitted that the issues regarding consent do not indicate a systemic failing.

169. I disagree. It is relevant that the consenting process was deficient in two respects — relating to the presence and involvement of students, and not having evidence of second-doctor sign-off (in relation to concerns about competence) on the consent for anaesthesia. I

consider it reasonable to infer an overall lax attitude to the processes for obtaining and checking consent.

170. This was compounded by inadequate policy on the subject of student involvement. The Consensus Statement sets clear expectations for consent to medical student involvement, including that for sensitive examinations it must be explicit and documented. However, SDHB told HDC that in 2018 no consent was required for the involvement of fifth- and sixth-year medical students, as they were part of the team. Subsequently, it stated that this related only to sixth-year medical students. In response to the second provisional opinion, SDHB stated that "part of the team" would not encompass performing a procedure such as Ms A underwent or even being in theatre while it was being performed. SDHB said that its earlier response related to medical students observing treatment, and was not directed at procedures in theatre.

171. However, the policy at that time provided that additional informed consent was required for the involvement of students or other personnel who did not have a "direct role in the consumer's treatment team" during the healthcare procedure. In my view, this policy was ambiguous, as the meaning of "direct role" is unclear. In any case, the policy did not reflect the Code accurately, as the Code gives consumers the right to know of *any* proposed participation in teaching, not simply those situations in which there is a "direct role". Therefore, it follows that informed consent was required for students both performing and observing Ms A's procedure.

172. I am satisfied that the lax attitude at SDHB demonstrated by the multiple failures outlined above point to a problem at a systemic level. I acknowledge that subsequently SDHB amended its policy.

Conclusion

173. On 30 July 2018, a student performed an intimate procedure on Ms A, observed by other students, when Ms A was unaware of, and had not consented to, their involvement. Indeed, she had expressly refused it.

174. Ms A was entitled to be notified about medical students' participation in her procedure. In providing services involving teaching to Ms A without first notifying her and obtaining her consent, SDHB breached Right 6(1)(d)[21] and Right 7(1)[22] of the Code.

175. SDHB's system for obtaining consent was demonstrably lacking. A form on which Ms A had refused consent to students did not make its way onto her file. Dr C assumed that Dr E or one of the other clinicians would confirm Ms A's consent for the presence of students, but nobody did. Dr H expected action to be taken with regard to the anaesthesia consent,

[21] Right 6(1)(d) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including … notification of any proposed participation in teaching …"

[22] 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 …"

whereas Dr F either assumed that this was a matter to be attended to at the Anaesthetic Pre-admission Clinic or by the gynaecology consultants and registrars, or he followed his usual process to confirm consent, but did not document that he had acted on Dr H's red flag. "Time Out" processes were wholly inadequate, as the lack of consent for the involvement of medical students was not picked up. Given that this was a failure across a number of individual providers, I consider that it reflects a systems failure to provide services to Ms A with reasonable care and skill, and, accordingly, I find that SDHB breached Right 4(1) of the Code.[23]

Opinion: Dr C — no breach

Obtaining consent to student involvement

176. As she has acknowledged, it was Dr C's responsibility to complete the surgical consent for Ms A during the PAC. However, Dr C overlooked the subject of medical students being present during Ms A's procedure, and so did not obtain her consent for that. This was a missed opportunity to ascertain Ms A's views about the involvement of students.

177. On subsequent realisation that the part of the form relating to student consent had not been completed, Dr C documented that the presence of students needed to be "checked on admission", and that consent was to be confirmed.

178. I accept that Dr C expected that she would undertake the procedure and would be in a position to cover off the issue of consent to the involvement of students on the day of the procedure. However, she did not talk to Ms A at the time of admission when Ms B was present to support her daughter and, when she spoke to Ms A in the anaesthetic room, she did not raise the issue with her. Further, when she was unexpectedly called away to an emergency, again Dr C did not raise the issue with Ms A, or alert Dr E to the need to take such steps. This was a third missed opportunity to clarify Ms A's views.

179. Despite those missed opportunities, I acknowledge that Dr C was not the clinician responsible for the decision to permit students to be involved in Ms A's procedure. She made a clear notation on the records that the involvement of medical students should be discussed with Ms A on admission and her consent or refusal obtained. In the context of an emergency situation, she delegated the case to an experienced registrar, and it was not unreasonable to expect the registrar to peruse the consent form, see the notation, and obtain the consent. Furthermore, there were a number of process checks in place that should have picked up the lack of consent earlier. In light of those factors, and the presence of issues at a systems level, I do not consider that Dr C breached the Code.

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

Communication — other comment

180. Ms B accompanied Ms A to most of her appointments with Dr C, and was very involved in her daughter's care. I note Ms B's concerns that the discussion with Dr C about contraception options for Ms A was conducted over a short period of time. Ms B also told HDC that the PAC consultation with Dr C was "sloppy and casual".

181. In contrast, Dr C stated that she was aware that Ms A had an intellectual disability and so she took time to ensure that matters were addressed with Ms A and Ms B comprehensively. Dr C submitted that she made extra efforts to assist Ms A during the consultations with her. Dr C does not believe the description of her approach as "sloppy and casual" is fair. Dr C said that her focus extended beyond arranging the IUD insertion, and she also arranged a green prescription to enable Ms A's weight loss, and spent time explaining the potential benefits of weight loss.

182. SDHB has provided positive references regarding Dr C's demeanour and approach to consultations.

183. Given the differing perspectives on what occurred, I am unable to reach a conclusion as to the nature of the consultation and, therefore, no finding in relation to the Code is made.

Opinion: Dr E — adverse comment

184. When Dr C was called away to an emergency, she delegated responsibility for Ms A's procedure to Dr E. Dr E was experienced and credentialed to undertake Ms A's procedure.

Information about person performing procedure

185. Given the intimate nature of Ms A's procedure, I consider that a reasonable consumer in Ms A's circumstances would expect to be told who would be performing it. At the end of the PAC meeting, Dr C said that she would see Ms A in the operating theatre. Consequently, Ms A quite reasonably believed that Dr C would be the operating surgeon.

186. Dr C said that the usual practice at the PAC was to inform the patient about the members of the team, including the SMO and the registrar likely to be present at surgery, and to tell the patient that these details could change. However, Ms B said that Dr C did not at any stage say that anyone else, other than her, could be doing the procedure. There is no record that Ms A was told that the person intending to perform the procedure might change.

187. I accept that Dr C intended to undertake the procedure, but was unexpectedly called to assist with an emergency. At that stage, she reasonably delegated Ms A's case to her experienced registrar, Dr E. There is no record that Ms A was informed that Dr E would now be performing the procedure. However, Dr E stated that it was her usual practice to introduce herself to patients, and she is certain that she would have done so in Ms A's case.

188. Based on Dr C's evidence that she saw Dr E enter the anaesthetic room, and Dr E's usual practice, I accept the likelihood that Dr E introduced herself to Ms A as the operating surgeon. The question then becomes whether Ms A gave consent to the presence or the role of students in the procedure.

Permitting student involvement

189. Dr E told HDC that she was very aware of the importance of obtaining a patient's consent to the presence and involvement of students. She was unable to explain why consent was not obtained in this case, and given the lapse of time she does not recall the specifics of Ms A's procedure. However, Dr E submitted that she would never assume consent had been given, and that the way the process worked at the time was for consent to be obtained as part of the PAC. This included seeking consent for students to be present, where it was explained to patients that students may be invited to assist with aspects of the procedure under close supervision, where safe to do so. Dr E suggested that Dr C must have handed over to her at a point where she (Dr E) understood that the paperwork had already been checked.

190. I remain of the view that, as the operating surgeon, it was Dr E's responsibility to confirm that Ms A had given consent to student involvement, especially as Dr C had left to attend to an emergency. Even if a check of the paperwork caused a slight delay, Dr E should not have concluded that Dr C had already performed the checks. This is again consistent with the Consensus Statement.

191. I accept that Dr E was unaware that Ms A had not consented to the involvement of students, and that she was not aware of Ms A's earlier refusal of consent. However, as I have outlined above, there was opportunity for Dr E to have identified that consent had not been given — in the anaesthetic room prior to the procedure, during the theatre "Time Out", or when she permitted the student to insert the Mirena. In response to the second provisional opinion, Dr E said that she was not aware that it was accepted practice to stop for a mid-procedure second surgical/operating theatre "Time Out". That may be so, but I remain of the view that it was incumbent on Dr E to ensure that Ms A had given consent before she permitted a student to perform a sensitive procedure.

192. It is clear that Dr E did not read the consent form sufficiently carefully, which, had she done so, would have alerted her that consent was outstanding. While it is arguably possible that at a glance Dr E may have misinterpreted the "T" in "TBC" as a tick (although this is speculative), closer reading would have identified Dr C's comment about the need for consent confirmation and the question mark after "TBC". This should have put Dr E on alert to clarify the consent.

193. In my view, as the primary operator and the person who permitted a medical student to insert the Mirena, responsibility rested with Dr E to review the consent form for its completeness, and ensure that consent to student involvement had been obtained. In many circumstances, I would consider the omission to obtain consent could amount to a breach of the Code. However, I accept the possibility that Dr E believed consent had been obtained prior to her involvement, that her involvement was sudden and unexpected, and there were

issues at a systems level that should have alerted Dr E and the rest of the clinical team to the inadequacy of the consent. I am satisfied that those factors mitigate against a finding that she breached the Code.

Opinion: Dr F — adverse comment

194. At the APAC on 1 June 2018, specialist anaesthetist Dr H was concerned that Ms A may not have understood the discussion. He noted his view that the Anaesthesia Consent form required a second doctor's signature and that consent was to be confirmed.

195. Dr F was the anaesthetist during the procedure. There is no evidence that Dr H's concern about Ms A's capacity to consent to her anaesthesia was acted upon, and in particular, no supporting documentation.

196. In response to the second provisional opinion, SDHB said that Dr F had understood that a second doctor's signature on the consent form did not carry any legal significance, which was why the clinical records do not contain this. He understood that there was a consent form signed by Ms A for the anaesthetic.

197. Dr F said that he was satisfied that informed consent for general anaesthesia had been obtained by the anaesthetist in the APAC. He further stated that he does not recall Ms A, but his usual practice would be to converse with the patient directly. He would specifically turn his mind to whether the patient was consenting to anaesthesia, and would enquire whether they had any further questions about what was to occur. Provided he was satisfied that they were still consenting to the procedure, he would then go through with the anaesthesia. There is no record of Dr F undertaking those steps in this case, and no witnesses that he did so. SDHB stated: "The fact he then performed the anaesthetic is consistent with him being satisfied that she did consent". I do not accept this submission — in my view, the fact of something having occurred (the anaesthetic) is simply not evidence of it having been consented to, and it cannot be reasonably inferred.

198. In response to the second provisional opinion, Dr F stated that Ms A was competent in her own right to make informed decisions about her health care, with or without a support person present. He said that Dr H and Ms A signed off the completed Anaesthetic Consent form during the APAC with the support of Ms B, and added: "These factors taken cumulatively, indicated to me that [Ms A] was aware of and consented to anaesthetic being administered on the day of her procedure." I disagree — Dr H's notation on the form makes it clear that he was not satisfied that Ms A was competent to give informed consent at the APAC.

199. Right 7(3) of the Code provides that if a consumer has diminished competence, he or she retains the right to make informed choices and give informed consent to the extent appropriate to his or her level of competence.

200. I accept that, with suitable support, Ms A was capable of giving informed consent to having a general anaesthetic on her own behalf. However, I am critical that there is no evidence that the alerts on the forms were acted upon. This was a "red flag", which suggested that prior to the procedure, care should be taken to reiterate to Ms A the risks of the anaesthetic and obtain her consent.

201. Given that red flag, it would not have been appropriate to proceed without clarifying Ms A's competence, and this should have been documented. Based on the contemporaneous documentation, there is a clear question as to whether consent for the anaesthesia was obtained properly. Even allowing for the possibility that Dr F had a discussion with Ms A in accordance with his usual practice, and was satisfied that she had sufficient capacity to consent to anaesthesia, he should have documented the steps he took to reassure himself of Ms A's capacity. Moreover, given the importance of this issue, it would have been appropriate to involve her support person in that process. I remind Dr F of his obligations in this respect.

Changes to practice

202. Dr C stated that since Ms A's surgery there has been a significant change in the form of consent and policy around student involvement. In the latter part of 2018, the Medical School directed that students must be specifically consented for any involvement at the time of a patient's surgery, as part of informed consent. In 2020, a new consent form was introduced that clearly indicates consent for student involvement in any procedures, including intimate examinations.

203. Dr C said that she has made the following changes to her practice:

a) She now takes additional care to ensure that all parts of the consent form are completed before the woman leaves her consultation room for another part of the PAC clinic process.

b) She is particularly vigilant that she documents the discussion regarding students being in theatre before the next person sees the woman as part of the PAC process.

c) She noted that the new consent form highlights the importance of this by ensuring that this section is prominent on the front page.

d) She asks women directly if they have read the information about medical students being rostered to clinics in theatres before commencing the PAC visit consent process, or at any consultation, or on any occasion when taking consent.

e) She explains that registrars who are training to be specialists are part of the surgical team and will be present at the operating list. She names them if the roster allows that, and advises patients that registrars may not only assist, but also may undertake procedures themselves.

f) She ensures that women have the opportunity to discuss their preferences again, before the day of the elective surgery, because some women change their mind between the clinic and the day of the procedure.

g) She now requests that registrars meet all patients on admission before the actual surgery, and go through the consent form again with the patient in person. If that is not possible, she requires that they become acquainted with the patient's needs from the information in the hospital notes.

h) She no longer allows medical students to remain in the theatre following a previous case. They are invited in, and meet the patient prior to entering the theatre procedural area, to ensure that they are not in the theatre by default.

204. Dr C stated that she plans to attend an MPS course on the consenting process to improve her understanding further.

205. Dr E has also indicated her intention to attend an MPS course on the consenting process to update her practice.

Recommendations

206. I recommend that Te Whatu Ora Southern (formerly SDHB):

a) Conduct an audit over a three-month period of cases within Obstetrics & Gynaecology in which students have observed or performed sensitive procedures, to check from the patient's clinical records whether consent was given and recorded, and report the findings and any steps being taken to remedy any deficiencies, within six months of the date of this report.

b) Provide further training to staff within Obstetrics & Gynaecology, with regard to informed consent, capacity, communication between clinicians, and the requirement to review clinical records. Te Whatu Ora Southern is to report back to HDC within 12 months of the date of this report, with details of the content of the training and evidence of it having been conducted.

c) Provide a written apology to Ms A for the breaches of the Code identified in this report. The apology is to be sent to HDC, for forwarding to Ms A, within three weeks of the date of this report.

207. I encourage Dr C to undertake the MPS informed consent training she has indicated her intention to complete.

208. I recommend that Dr E undertake the MPS or similar training on informed consent that she has indicated her intention to complete, and report to HDC with evidence of having done so within three months of the date of this report.

209. In accordance with the recommendation in the provisional opinion, Dr E provided a written apology to Ms A, and this has been forwarded to Ms A.

210. I recommend that Dr F provide a written apology to Ms A for the criticisms in this report. The apology is to be sent to HDC, for forwarding to Ms A, within three weeks of the date of this report.

Follow-up actions

211. I have given careful consideration as to whether Te Whatu Ora Southern should be referred to the Director of Proceedings, and in particular have considered the public interest in ensuring that appropriate proceedings are taken where that public interest requires.

212. I consider the matter finely balanced. While I have serious concerns about the identified failures in this case, I consider that owing to the time elapsed since these events and that the public interest can be met by my breach opinion, a referral will not be made. I note that following these events SDHB reviewed its policies, process, and forms concerning student involvement. I am also mindful that the public interest will be served by a national approach to the issues raised. With that in mind, I have taken the steps outlined below at paragraph 216 to address these matters at a systemic level. I would hope, however, that the issues raised by Ms A's experience, and the seriousness with which they are viewed by me and my office (as indicated in this opinion), will be reflected on and acted upon by providers involved in sensitive examinations and procedures in the future.

213. I note that SDHB offered to engage directly with Ms A and her family either by way of mediation or other appropriate process regarding the concerns raised in this matter, should Ms A and her family agree. I will leave this with the parties.

214. A copy of this report with details identifying the parties removed, except Dunedin Hospital and SDHB/Te Whatu Ora Southern, will be sent to the Medical Council of New Zealand, and it will be advised of Dr C's name.

215. A copy of this report with details identifying the parties removed, except Dunedin Hospital and SDHB/Te Whatu Ora Southern, will be sent to the Royal Australian and New Zealand College of Obstetricians & Gynaecologists, the Deans of the Medical Schools in New Zealand, and the Health Quality & Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Final general comment

216. As noted above in footnote 17, while finalising this report a study was published in the *New Zealand Medical Journal* that showed serious lapses in obtaining informed consent for the involvement of medical students in sensitive examinations. It is particularly disappointing that this issue is continuing, noting that a study published in 2018 (also referred to in the same footnote) made similar findings. In my view, this is a systemic issue. Clear ethical leadership is required to embed a culture of vigilance around informed consent. This requires positive and ethical role modelling. Following the publication of the study in May 2022, I wrote to all DHBs, medical schools, and Te Whatu Ora — Health New Zealand to reinforce the message that informed consent must be sought for student involvement in sensitive examinations, and to follow up on the actions they are taking in respect of the findings of this study. I will continue to monitor this issue closely and will follow up with Te Whatu Ora — Health New Zealand.