Health New Zealand|Te Whatu Ora Waitematā
(formerly Waitematā District Health Board)

A Report by the
Health and Disability Commissioner

(Case 19HDC01260)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. A nurse complained about the adequacy of senior medical staff's supervision of junior medical staff at North Shore Hospital, and patient consent for the involvement of students and other trainees in clinical care.

2. The Commissioner criticised Health New Zealand|Te Whatu Ora (Health NZ) Waitematā but found that it had not breached the Code. The Commissioner considered that from 2018 there were weaknesses in the systems in place at Health NZ (Waitematā District Health Board at the time of events), including that the 2018 policy did not require consent if teaching was part of sound care provision, when the Code makes no such distinction (when teaching occurs within the clinical team even as part of the optimal provision of care for that patient, appropriate informed consent is necessary); its process for obtaining consent to teaching, including its consent forms, underplayed the involvement of students and clinicians in training, and did not prompt introductions, or an explanation about the role of the person being taught or the degree of supervision in place; and if verbal discussions about teaching supplemented the matters listed on the consent form, this was not documented adequately.

3. The Commissioner concluded that consumers cannot be involved in teaching without giving informed consent, and providers of health and disability services must ensure that they have a robust system and culture for obtaining that consent. It is imperative that they do not rely on broad notifications that teaching may occur as absolving them from providing consumers with information relevant to their particular circumstances. Senior clinicians and teachers must lead from the top, and ensure that they model good, transparent consent processes to their junior colleagues. Basic courtesy and respect for patients apply, and wherever practicable, consumers should know who is to be providing their care and what they will be doing. This is information that a reasonable consumer involved in teaching can expect to receive.

Recommendations

4. The Commissioner recommended that Health NZ Waitematā develop patient information material around clinical teaching, ensuring that this is written simply and emphasises patient choice; provide a report on the outcome of an audit of patient feedback on informed choice to teaching that takes place; and provide evidence of training to staff to ensure that SMOs are aware of, and comply with, the processes for informed consent. The Commissioner also recommended that Health NZ report back to HDC on the progress of the development of a national policy on informed consent and associated documentation, using the findings of this report to inform the development of these policies and processes.

Key principles

5. Several key principles relating to the involvement of medical students and junior medical staff in consumers' care can be distilled from this decision:

- Consumers cannot be involved in teaching without giving informed consent, and providers of health and disability services must ensure that they have a robust system and culture for obtaining that consent.
- All medical student involvement in patient care represents teaching, and Right 9 and Right 6(1)(d) of the Code will therefore apply to these scenarios. The Consensus Statement[1] provides guidance for providers in this respect.
- House officers and registrars are qualified doctors and therefore, their involvement in the care of a patient does not *prima facie* mean that teaching, necessitating consent, is taking place. Whether or not teaching is occurring will be fact dependent.
- Where doctors who are not certified in the procedure are performing that procedure under the direction and supervision of the doctors who are certified in the procedure, and who are available as a safety net and to impart their knowledge, experience, and instruction along the way, this represents teaching, and consequently Rights 6(1)(d) and Right 9 apply.
- Consent forms are an important prompt or starting point for discussions between clinicians and consumers about several matters, including the involvement of students in the consumer's care. As such, consent forms need to be written carefully to ensure that they set out information relevant to a consumer's particular circumstances (and are followed by an opportunity to make a meaningful choice). However, a form cannot and should not represent the entirety of discussions between the provider and consumer, and providers must tailor such discussions to an individual consumer's circumstances.
- A reasonable consumer undergoing surgery would expect to be told who will be performing their surgery and who will be present, including those who are part of the treatment team and those who are not. The line between assisting and performing parts of a procedure will, at times, be blurred, and it may be difficult to know in advance the exact role that a trainee will have. However, if it is anticipated that the trainee will move from doing something within their scope of practice to being taught during a procedure, the consumer should be made aware of that, with the teaching not taking place unless consent has been given. If it cannot be communicated with certainty

[1] At the time of the events of this complaint, the following Consensus Statement was in place: Bagg W, Adams J, Anderson L, Maplas P, Pidgeon G, Thorn M, Tulloch D, Zhong C and Merry A, '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' (15 May 2015). NZMJ Vol 128 No 1414, 27–35. In 2023, this was updated: Walker S, Reid P, Anderson L, Bull S, Jonas M, Manning J, Merry A, Pitama S, Rennie S, Snelling J, Wilkinson T, Bagg W. Informed consent for medical student involvement in patient care: an updated consensus statement. 2023 Jul 21; 136(1579). ISSN 1175–8716 https://journal.nzma.org.nz/.

what role a trainee will have, providers could advise consumers of the kinds of roles that trainees would usually have in procedures similar to theirs.

- Consumers undergoing sensitive/intimate examinations should know beforehand who will be involved and what their role will be, including any observers. Explicit consent is required.
- Broad, generic statements that teaching may occur in the environment (for example, 'This is a teaching hospital') does not absolve providers from giving consumers, in their particular circumstances, the information they need to make an informed choice, including to participate in teaching.
- In general, consumers must be notified who will be undertaking their procedure, and the roles and responsibilities of those involved, including observers.

Complaint and investigation

6. The Health and Disability Commissioner (HDC) received a complaint from registered nurse (RN) A and her support person regarding their concerns about adherence to informed consent processes at Health New Zealand|Te Whatu Ora[2] (Health NZ) Waitematā (formerly Waitematā District Health Board).

7. Following a preliminary assessment of this complaint, the Commissioner decided to commence an investigation on her own initiative pursuant to section 40(3) of the Health and Disability Commissioner Act 1994 because the concerns raised potentially affect multiple consumers and relate to wider systems issues at Health NZ. The following issue was identified for investigation:

- *The standard of informed consent at Waitematā District Health Board with regard to the involvement of trainees in providing and observing obstetrics and gynaecology services at North Shore Hospital since 1 January 2018.*

8. The parties directly involved in the investigation were:

RN A	Complainant/registered nurse
Complainant/support person	
Health NZ Waitematā	Provider

[2] Formerly Te Whatu Ora|Health New Zealand.

Information gathered during investigation

Background

Complaint

9. The concerns in the complaint relate to the adequacy of senior medical staff's supervision of junior medical staff at North Shore Hospital, and patient consent for the involvement of students and trainees in clinical care. RN A's position is that a reasonable consumer would expect to be informed about the involvement of a trainee doctor and, more specifically, about the proposed extent and nature of their involvement.

Giving informed consent to teaching

10. The *Report of the Cervical Cancer Inquiry* (1988)[3] was critical of practices at that time where teaching took place in Obstetrics and Gynaecology services (O&G services), sometimes on anaesthetised women, without their consent. Among other things, this informed the rights contained in the Code of Health and Disability Services Consumers' Rights (the Code).

11. The Health and Disability Commissioner Act 1994 (the Act) requires the Code to contain provisions that 'no health care procedure shall be carried out without informed consent' (s 20(1)(a)), and to specify the rights of consumers (and the duties of providers) in relation to 'health teaching' (s 20(1)(c)). The Act defines 'informed consent' for a procedure as consent that is 'freely given' by the consumer or by any person who is entitled to consent on that consumer's behalf and 'obtained in accordance with [the] requirements [of] the Code' (s 2).

12. Right 9 of the Code extends all the Code's rights to 'those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching and research'. 'Teaching' is defined in clause 4 of the Code as including the 'training of providers'.

13. In addition, Right 6(1)(d) of the Code gives consumers the right to information that a reasonable consumer in their circumstances can expect to receive, including notification of any proposed participation in teaching. By virtue of Right 7, consumers then have the right to make an informed choice and/or give informed consent about whether to participate and also the right to refuse services and withdraw consent to services.

Medical training and relevant terminology

14. Medical students in New Zealand undertake six years of undergraduate study. Following the third year of study, students gain clinical experience through exposure to patients, including through inpatient and outpatient services at hospitals. The sixth year of medical school is designed to introduce clinical responsibility for patients, and sixth-year medical students are referred to as 'trainee interns'.

[3] Committee of Inquiry, *The Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters* (Government Printing Office, Auckland, 1988).

15. In response to the provisional opinion, Health NZ said that University of Auckland medical students begin limited supervised clinical work on hospital wards in the middle of their third year of undergraduate study. Health NZ noted that the sixth year of training was historically termed a 'trainee Intern' year, and that term is still in common use by hospital clinicians and others. However, that description is no longer used by the universities, and 'sixth year students' is the correct description.

16. All practising doctors must be registered in an authorised 'scope of practice'.[4] A scope describes the type of registration the doctor will hold and the work a doctor is allowed to do (subject to any limitations imposed by the Medical Council of New Zealand (MCNZ)). There are five broad scopes of practice:

- Provisional general scope
- General scope (which can be conditional — see paragraph 17)
- Provisional vocational scope
- Vocational scope
- Special purpose scope

17. Following graduation, first-year postgraduate doctors (known as house officers, house surgeons and/or interns) practise in supervised clinical settings under provisional registration in a general scope. Prevocational Training under the oversight of MCNZ is a minimum of 24 months, and usually it is completed continuously in the first two postgraduate years. During the first 12 months, the clinician is provisionally registered and under close clinical and educational supervision. If the clinician meets standards and is signed off by the Director of Clinical Training, the district Chief Medical Officer, and a consumer representative, the clinician is granted General Registration. However, that General Registration status has conditions on it, specifically that the doctor must continue to work in a supervised hospital or community setting under the educational structure accredited by MCNZ. After a further 12 months, if MCNZ standards are achieved, the doctor will be granted full General Registration.

18. The MCNZ continuing education requirements of General Registration (administered through a bpac^{nz} programme) commence at this point, and no earlier than the third postgraduate year. Many trainees enter vocational training programmes at this stage, which obviates the requirement to complete bpac^{nz}.

19. A doctor who has completed the requirements of a provisional general scope will be registered within a general scope of practice. Doctors practising within a general scope are required to participate in an approved recertification programme to assist them in maintaining their competence. Usually they will be house officers (past their first year of practice) and registrars. Registrars are generally doctors with over two years' postgraduate

[4] See 'WHAT YOU NEED TO KNOW ABOUT MEDICAL REGISTRATION IN NEW ZEALAND', Medical Council of New Zealand March 2019.

experience. Registrars can be both non-training registrars or training registrars, depending on whether they have been accepted onto a vocational (specialist) training programme.

20. A doctor can apply for registration within a vocational scope once their programme of specialist training has been completed. Most specialist training programmes take at least five years to complete. Doctors practising within a vocational scope of practice are referred to as consultants, specialists, or senior medical officers (SMOs).

21. Postgraduate clinical medical training is based on an apprenticeship model. This means that most clinical training occurs in public hospitals, and Health NZ is the employer of both the trainees and the specialist staff who provide the training.

22. Health NZ told HDC that the term 'resident medical officer' (RMO) does not cover sixth-year students, except in the preliminary statement in the collective agreement of the union — the Resident Doctors' Association. Health NZ suggested that the term 'RMO' should be applied only to postgraduate doctors employed in the public sector who have not gained vocational registration, which is the use of the term by Health NZ, MCNZ, and the wider sector.

23. Various job titles, including intern, junior doctor, house officer, house surgeon, senior house officer/surgeon, registrar, and advanced trainee, are used for RMOs at different stages of their training.

24. Health NZ told HDC that the term 'trainee' includes postgraduate RMOs, but particularly refers to those RMOs undertaking advanced vocational training as registrars, in this case in O&G. These RMOs/trainees will be doctors in at least their third postgraduate year who maintain general registration under the MCNZ, and some advanced trainees will have been practising doctors for more than 10 years.

25. The scope of this investigation regards the involvement of trainees. It is intended to cover both undergraduate medical students and postgraduate doctors in training. However, for ease of reference, I will use the term 'trainee' to describe a qualified doctor who is not vocationally registered, in particular house officers and registrars. I will use the term 'medical student' to refer to an undergraduate medical student, including a sixth-year student.

Health NZ

26. Health NZ Waitematā told HDC that it provides secondary hospital services and some tertiary services for more than 630,000 people. It has two major acute hospitals, North Shore Hospital and Waitakere Hospital, which together have 132,000 admissions per annum. Health NZ Waitematā undertakes approximately 36,000 procedures in theatre per annum, as well as many diagnostic and other interventions. Health NZ Waitematā said that it hosts around 250 medical students on clinical attachments from the University of Auckland each year.

27. Health NZ Waitematā said that it is accredited by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) as a training site. In the regular

accreditation process, Health NZ is assessed against standards specified by RANZCOG, and also those standards set by the MCNZ and the Australian Medical Council (AMC).

28. Health NZ Waitematā told HDC that RMOs are a critical element of the health workforce in public hospitals in New Zealand and are employed to provide round-the-clock patient care within team structures that support supervision and an apprenticeship model of learning. Health NZ said that broadly, 70% of the 'training' is actually experiential learning gained while undertaking the specific clinical work for which they are employed. Formal bedside structured teaching makes up approximately 20%, and the remaining 10% is didactic lectures or book learning.

29. Health NZ said that the progression through advanced training requires the achievement of defined competencies and skills, and RANZCOG has detailed requirements for procedural skills that reflect both a volume of cases and the case mix and complexity. An O&G trainee must be certified in a particular skill to be able to undertake it without direct supervision from a vocationally registered consultant. Certification requires both documentation of supervised participation in a pre-specified number of cases, and a formal observed summative assessment of that particular skill. For example, to fulfil the criteria for competency for LLETZ procedures,[5] a minimum of 10 LLETZ procedures must be completed (under supervision) before a summative assessment is undertaken.

30. Health NZ stated that RMOs employed as registrars or house officers in O&G are required to attend the operating theatres and assist the consultants in a range of operations. This requirement to provide clinical service allows RMOs to gradually acquire the skills needed to progress in their training, under direct supervision. Such work is therefore part of the 70% of experiential learning described above. Health NZ said: 'For the RMO, the clinical job is indistinguishable and inseparable from the training.'

RN A's raising of concerns with Health NZ Waitematā

31. RN A provided HDC with examples of the cases she raised with Health NZ, as well as other examples once her complaint to the HDC had been made. As an overview, the examples describe situations where medical students, house officers, and registrars were involved in patient care. RN A has questioned the information provided to consumers about trainee and medical student involvement, and whether appropriate consent was obtained.

32. RN A first raised concerns with Health NZ in 2012/2013. Health NZ said that the concerns raised by RN A were taken very seriously, and, as a consequence, its existing policies and consent form were reviewed, and a project was undertaken to review and rewrite the policy for informed consent and the consent form. A lengthy period of consultation occurred, and Health NZ's 'Informed Consent' policy was formally issued in May 2014. Clinical staff were widely communicated with at the time of the policy being issued, and Health NZ worked with the Waitematā Campus of the University of Auckland Faculty of

[5] A LLETZ procedure uses an electrical wire loop (or diathermy loop), inserted vaginally, to remove any abnormal cells in the cervix.

Medicine and Health Sciences to ensure that the students then attending the relevant hospitals were made aware of the policy. Teaching sessions on the policy were held.

33. RN A said that initially there was some improvement following the review of the informed consent policy and the consent form, and education sessions for the theatre team were provided at that time.

34. Health NZ's informed consent policy was updated in 2018 (see relevant extract in Appendix A).

35. RN A returned to work at North Shore Hospital in 2018. She told HDC that she found at that time that the situation at North Shore Hospital had 'significantly deteriorated'. She stated that the informed consent policy was not being adhered to, the revised consent form had been withdrawn and replaced with a version that was much less auditable (because of the lack of tick boxes or other means to indicate what the patient consented to), and breaches of informed consent continued.

36. Health NZ stated that again the concerns RN A raised were treated seriously. The concerns were reviewed and investigated, and there was agreement that consent was not always being obtained correctly for the presence and involvement of medical students in the operating theatres. It was also agreed that RN A had appropriately raised concerns about the level of supervision being provided by SMOs in several specific cases. Health NZ said that a theatre action plan was agreed, and it was outlined in writing to RN A on 19 December 2018. This included creation of education modules and consideration of developing a method to audit the process of consent.

37. RN A said that despite the changes that were supposed to have been made, little changed in the culture or practice.

38. At the beginning of 2019, all registrars and house officers who were on the O&G service were required to read the Health NZ policy on informed consent, and attest in writing that they understood it and would comply. A register of this process was kept. The SMOs in the service were reminded of the policy requirements during service meetings and in writing.

39. Throughout 2019, RN A continued to raise concerns about medical student and first-year registrar involvement in theatre. However, Health NZ considered that staff had complied with the policies appropriately.

40. In April 2019, Health NZ agreed to review the Informed Consent policy and consent form and conduct an education programme to support staff.

41. Health NZ and Auckland University subsequently jointly clarified the guidance to SMOs and RMOs regarding medical students and consent, with an organisation-wide memorandum on 31 July 2019 (See Appendix B: Information to staff July 2019). The memorandum required the SMO or RMO to record in writing that patients' consent had been obtained for activities such as suturing.

Health NZ Informed Consent policy and consent forms

42. There have been several versions of the Health NZ Waitematā consent form since 2014. The 2014 'Consent to Treatment' form mentioned the presence of students/trainees (not just students) and a tick box, 'Yes' or 'No', for the patient or guardian to sign. Regarding students/trainees, the form states: 'It has been explained to me that as a teaching hospital that there may be students/trainees present and I agree to their involvement in my care or procedure under direct trained supervision.'

43. Health NZ Waitematā's Informed Consent policy 2018[6] specifically addressed consent in the context of training. Key components are:

> 'All healthcare settings should be learning environments where clinical teaching and learning occur as part of day to day practice. Additionally, as a teaching institution, formal teaching occurs. This includes further education for registered and employed clinical staff and training for unqualified students. **Patients, however, have a right to consent to or decline involvement in teaching including the presence of observers during treatment or examination.** The primary obligation is to provide the patient with sufficient information for them to give or withhold their informed consent. This includes being informed of the identity and qualifications of the provider.
>
> Patients also have the right to be treated with respect and to receive effective communication.
>
> Teaching of qualified staff occurs in a range of situations from undertaking of procedures under supervision to directly observing procedures to discussion of case studies. Teaching therefore covers both the provision of healthcare services and the use and disclosure of health information.
>
> …
>
> Some teaching occurs within the clinical team as part of the optimal provision of care for that patient e.g. care discussion or assistance with a procedure. Teaching is simply a secondary element of sound care provision. The basic provisions of common courtesy and respect apply, however specific patient consent is not required. Where teaching [including assessment, or discussion or observation] occurs that is additional to normal clinical requirements or involves someone not qualified to undertake the procedure on their own, [i]n this case, an explanation is to be given to the patient and their explicit permission sought.'

44. The Agreement to Treatment/Consent form (2018) had a longer statement than that in the 2014 form but no tick boxes. It asked the patient to give consent after the following provisions were listed:

[6] The current Health NZ Waitematā informed consent policy (undated) states: 'Teaching and observers: Our healthcare settings are learning environments where clinical teaching and learning occur as part of day-to-day practice as well as formal teaching. As a patient you have a right to consent to or decline involvement in teaching, including the presence of observers during treatment or examination.'

I agree that:

- I have had adequate opportunity **to** ask questions and I have received all the information that I require.
- I understand that during this procedure images or pictures relevant to my / the patient's care may be captured and incorporated into my / the patient's clinical record.
- I understand that in the event of an emergency, and as determined by my / the patient's medical team at the time, there may be other procedures undertaken to save my / the patient's life or prevent harm.
- I understand that my / the patient's care is occurring in a teaching hospital and there may be healthcare students (medical, nursing) present. I understand they will be appropriately supervised but at any time I can ask for them not to be present.
- I understand that no assurance can be given that a particular clinician will be performing my / the patient's procedure but that the clinician will be suitably qualified and, if in training, will be appropriately supervised by a senior clinician.

45. The Health NZ Consumer Council commented on the 2018 form via feedback from a workshop on 14 August 2019. The Council said that more information on the role of students/learners on the procedure would be useful and that the way the statements are presented is 'confronting' and it 'doesn't feel like there is an option to opt out'. The word 'present' was said to be misleading since it implied observation only. Also, it was not clear whether the reference to 'training' referred to a different staff group to the students and, if tick boxes were not to be reinserted in the form, it must be made clear to patients/guardians that they could cross out any statement they did not agree with. The Consumer Council also said that it 'would rather see an option to opt in to having a student'.

46. The current consent form, introduced in July 2020, states:

I agree that: *[Cross out anything you don't agree with]*

- I have had an opportunity to ask questions and I have received all the information I need.
- In an emergency, my medical team will decide if other procedures are needed to save my life or prevent harm.
- If I am receiving care in a teaching organisation, healthcare students may be present to watch and learn. I understand they will be appropriately supervised and I can ask them to leave at any time during the procedure.
- My care will be delivered by a team which may include doctors, nurses, midwives, allied health, scientific, and technical clinicians, or clinicians in training.
- If possible, I will be introduced to the clinical staff carrying out my procedure.
- If any clinicians carrying out my procedure are in training, they will be appropriately supervised by a senior clinician.

47. Health NZ said that improvements were made in the clarity of language to enhance patient understanding. The 2020 consent form has been implemented across Health NZ Waitematā. Health NZ told HDC that the Chair of the MCNZ confirmed that Health NZ Waitematā's current Agreement to Treat/Consent form aligns well with the Council's proposed revised statement on informed consent.

48. Health NZ said that on 17 December 2019 all SMOs and RMOs at Health NZ Waitematā were advised:

> 'For surgical/procedural situations, we expect that an RMO should introduce themselves and explain their role. For example: "I'm Dr Jones, I'm the doctor who will be undertaking your surgery today. I'm an advanced trainee in surgery and will be undertaking this procedure with the supervision of Dr Smith who is the consultant operating with me." If an RMO is asked directly about their training level/competence by a patient or their whānau, they should respond honestly and appropriately.'

49. Health NZ told HDC that this guidance has been implemented since January 2020 for any involvement of trainees in O&G services at North Shore Hospital. However, Health NZ does not require specific disclosure of the stage of training of any trainees observing or assisting in the provision of O&G services and does not seek specific consent to their participation (unless any proposed participation is additional to normal clinical requirements or involves someone not qualified to undertake the entire procedure on their own).

RN A's concerns about consent form

50. RN A considers that the 2020 consent form is deficient because the way in which it is drafted gives the clear impression that the patient has no choice. She said that the sentence 'I can ask for them to leave at any time during the procedure' does not ameliorate the situation sufficiently; it puts the onus on the patient to reject the involvement of a trainee rather than requiring the hospital to ask for permission at the outset.

51. RN A told HDC:

> 'The consenting process in practice glosses over patient rights. From recent personal experience, patients are told that it is a teaching hospital and that there will be a student present, rather than being given a more fulsome explanation or being offered an opt-in to accepting a student, rather than an opt-off. Vulnerable patients may be unaware or feel unable to challenge the process when it is presented as a fait accompli.'

Further information from Health NZ

Effect of trainee involvement in care

52. Health NZ Waitematā said that it has received no complaints from the patients or whānau in relation to the incidents alleged by RN A. In 13 of the cases investigated by Health NZ, the patient had regional anaesthesia and was awake and alert, and a support person was present. Health NZ said that this reflects that most of the concerns were raised around Caesarean sections, where patient and whānau attendance and participation is prioritised.

53. Health NZ stated that there were no severity assessment code (SAC) 1 (severe) or SAC 2 (major) events confirmed following review. All patients made uncomplicated recoveries. In the few cases where there were intraoperative issues, these were well understood complications of the surgery being undertaken and were considered to be unrelated to the clinicians undertaking the surgery.

54. In response to the provisional opinion, RN A stated that many if not all the patients in the cases to which she referred will be unaware that any issues occurred during their procedure or birth and therefore it is no answer for Health NZ to assert that no complaints were received in relation to any of the incidents she identified. She said: 'Compliance with the Code is not premised on whether an individual consumer raises a concern after the event.'

Supervision

55. Health NZ noted that the adequacy of supervision by the responsible SMO was raised in several cases, and stated:

> 'This is distinct from the process of informed consent. The MCNZ has recently released new guidance on delegation of care which inform clinical practice in settings where SMOs are overseeing RMOs.'

56. Health NZ stated that in the three cases where the surgery was completed without an SMO present, the supervising RMOs were formally certified to undertake the surgery without the direct oversight of the SMO. In all other cases the SMO was in the operating theatre and 'scrubbed in'.

Members of clinical team

57. Health NZ said that in all the incidents raised regarding RMOs, the doctors were members of the clinical team or service that was providing ongoing care for the patient. They were undertaking the clinical work required of their role, which included assisting in the operating theatre. The RMOs had personally met the patients, and in the majority of cases had completed the entire consent process and documentation of consent for the surgery.

Consent form

58. Health NZ stated that in all cases the completed consent form contains statements notifying the patient of the potential for student observers and doctors in training to be present or participating in their care. The correct designation of the RMO (registrar, house officer) was recorded on the form in all cases where the RMO completed the consent form personally.

Explicit consent

59. Health NZ stated that in its view, to require explicit written consent from patients for teaching or training would seriously impair the delivery of clinical care in the public hospital system and prevent the training of the future workforce.

60. Health NZ said that there is scant data on what would happen if specific consent for training were required, but it referred to a 2012 Porta et al study from the United States,[7] where 316 patients scheduled for elective surgery were presented with the option to

Porta CR (MD), Sebesta JA (MD), Brown TA (MD), Steele SR (MD), and Martin MJ (MD), 'Training Surgeons and the Informed Consent Process: Routine Disclosure of Trainee Participation and Its Effect on Patient Willingness and Consent Rates'. Arch Surg. 2012;147(1):57–62. Published online September 19, 2011. doi:10.1001/archsurg.2011.235.

consent to various scenarios of trainee participation. Only 57.6% of patients were willing to consent to the trainee assisting a consultant surgeon, and only 32% would consent if the trainee was doing the operation with the direct assistance of the surgeon. The authors conclude that 'calls for routine mandated disclosure should be carefully analysed prior to implementation to avoid adverse effects on surgical training'.

61. Health NZ said:

> 'This data highlights the potential magnitude of the impact of requiring an RMO and other trainee health practitioners to obtain explicit written consent to assist in surgery and for teaching to occur during that assistance on every occasion where they are required to assist. If more than 40% of patients declined to consent to the involvement of an RMO as an assistant to a consultant surgeon, as Porta et al suggest, New Zealand's ability to train its future health workforce would be severely impaired.'

62. Health NZ believes the approach it has taken strikes an appropriate balance between the desire for disclosure of training to the individual patient and the wider public good regarding service provision and workforce development. It noted that patients are told the nature of a hospital as a teaching institution, and that clinicians in training are part of the team delivering their care. Health NZ stated that patients are given the opportunity to object, by crossing out the relevant lines in the consent form — 'but in [Health NZ's] experience to date, no patient has objected'.

63. In response, RN A said that the Porta et al study noted that 'patients overwhelmingly opined that they should be informed of the level of resident participation and that this information could change their decision of whether to consent'. She said that similarly, in a study conducted by Kempenich et al in 2016,[8] '80% [of patients surveyed] agreed or strongly agreed that they expect to be asked permission for residents to be involved in their care'. In response to the provisional opinion, RN A added that the statistics in the Porta study are not borne out by experience in New Zealand and there is no evidence of patients withholding consent or preventing training.

National practice

64. In 2018, 2022, and 2023, studies concluded that medical students had been involved in sensitive examinations on patients in O&G and other specialties without the patients' knowledge or consent.[9] The studies highlighted the need for better education and

[8] Kempenich JW (MD), Willis RE (PhD), Blue RJ (DO), Al Fayyadh MJ (MD), Cromer RM (MD), Schenarts PJ (MD), Van Sickle KR (MD), and Dent DL (MD), 'The Effect of Patient Education on the Perceptions of Resident Participation in Surgical Care'. *Journal of Surgical Education* Volume 73, Issue 6, November–December 2016, Pages e111–e117.

[9] Malpas PJ, Bagg W, Yielder J and Merry AF, 'Medical students, sensitive examinations and patient consent: a qualitative review' (21 September 2018). NZMJ 131(1482), 29–37; Bhoopatkar H, Campos CFC, Malpas PJ, and Wearn AM, 'Adherence to a national consensus statement on informed consent: medical students' experience of obtaining informed consent from patients for sensitive examinations' (20 May 2022). NZMJ 135(1555), 10–18; Ekta B and Leung E, 'A further look into obtaining informed consent for medical students'

processes for doctors and medical students regarding their responsibilities for gaining and ensuring appropriate consent for medical student involvement in patient care. The studies also noted the need for better information to be provided to patients about potential student involvement.

65. The initial studies prompted HDC to ask Health NZ regions for copies of their informed consent policies. HDC also asked for copies of other current Health NZ O&G surgical consent forms to ascertain the consent given by patients to the involvement of trainees.

66. A review of 14 of these policies showed an almost unanimous reference to Right 6 of the Code,[10] including Right 6(1)(d) (the right to be notified of any proposed participation in teaching) in the context of outlining the information that needed to be provided to a patient. Similarly, the principles of Right 6(3) of the Code[11] were also widely emphasised, with some policies going further to require proactive provision of information about the identity and experience of persons performing a procedure, including in some cases information about the trainees and the extent of their involvement.

67. Outside the reiteration of the wording in Right 6, most of the policies had an explicit requirement to obtain informed consent to participation in teaching. However, this varied in its format and direction in the following ways:

- Who was responsible for obtaining consent to teaching (that is, the teacher or the person being taught).
- Whether their teaching expectations applied to qualified staff in training as well as undergraduate students.
- What kinds of teaching attracted the need to obtain consent. For example, some referred to any participation, whereas others required consent if the person being taught was undertaking the procedure.
- Whether verbal or written consent to teaching was necessary, and when written consent was required.
- When explicit or specific permission to teaching needed to be sought versus when a generic 'tick-box' consent to involvement in teaching could apply.

68. Consent forms from other regions were also reviewed. One consent form did not refer at all to students/trainees. Two others had a section for obtaining consent for the involvement of undergraduate students but made no reference to trainees.

(14 April 2023). NZMJ 136(1573), 106–113. Malpas et al (2018) describe sensitive examinations as examinations of female breasts and pelvis, female and male rectums and male genitalia.

[10] The right to be fully informed.

[11] Right 6(3) of the Code gives the right to honest and accurate answers to questions relating to services, including questions about the identity and qualifications of the provider.

Consensus Statement

69. In 2015, a Consensus Statement on medical students and informed consent was published in the *New Zealand Medical Journal*, prepared by medical schools at Otago and Auckland, district health boards, the New Zealand Medical Students' Association, and the MCNZ (the Consensus Statement). It comprehensively set out expectations for medical students involved in patient care. The Consensus Statement notes that it is not intended to set standards, but to 'outline New Zealand's existing legal and regulatory requirements in [a] practical way'. I refer to the Consensus Statement and its requirements in my opinion section below. The Consensus Statement has since been reviewed and revised, and in July 2023 it was published in the *New Zealand Medical Journal*.

70. In response to the provisional opinion, RN A noted that the 2015 Consensus Statement specifically states that 'the patient's right to refuse consent or withdraw consent takes precedence over the provision of training for students'.

71. In response to the provisional opinion, Health NZ noted that there is no expectation that the Consensus Statement would be used to guide consent requirements for doctors in training who are members of the clinical team. Health NZ said that the statement highlights the difference between students and employed clinicians, and it noted: 'This is particularly significant in the case of student involvement because students are not registered health professionals.' It added that it does not support the standards in the Consensus Statement being expanded or applied to registered doctors responsible for patient care as members of the clinical team.

MCNZ standards

Sexual boundaries in the doctor–patient relationship (November 2018)

72. MCNZ introduced a statement on 'Sexual boundaries in the doctor–patient relationship' in November 2018. The statement states that 'examining the patient intimately without his or her consent' and/or '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' is considered sexual impropriety. Sexual impropriety means any behaviour, including gestures or expressions, that are sexually demeaning to a patient, or that demonstrate a lack of respect for the patient.

73. Regarding students or trainees, the statement provides:

> 'As part of their education, health professional students and trainees need to have the opportunity to access and learn from senior doctors with on-the-job training. This means attending actual patient consultations. Participation in teaching is covered by the Code of Health and Disability Services Consumers' Rights. If a doctor would like to have one or more students or trainees attend a consultation the patient should be provided with an explanation prior to the consultation about the role that the student or trainee may take in the consultation and asked whether they consent to the student or trainee being present. If a student or trainee is present during a consultation, they should be formally introduced to the patient.'

Informed consent standards

74. The 2011 MCNZ standard 'Information, choice of treatment and informed consent' (March 2011) (the 2011 Standard) required doctors to 'obtain consent before involving medical students in the care of patients,' and to 'inform the patient about the extent of the involvement of the student and the student's experience'.

75. The 2011 Standard was replaced in 2019 by the MCNZ standard 'Informed Consent: Helping patients make informed decisions about their care' (September 2019) (the 2019 Standard).[12] This version required a clinician to obtain consent in advance before students or observers attended a consultation or participated in a patient's care. It states:

> 'This is especially important if sensitive issues are discussed and/or intimate examinations are conducted. Inform the patient about the observer's role and what is expected of the observer.'

76. The 2019 Standard required doctors to explain to the patient:

- The status and clinical experience of those attending;
- The role and involvement of those attending (such as whether they would be observing, or participating in the care by taking a clinical history or examining the patient);
- What was to be expected of those attending; and
- That the patient had the right to refuse their involvement at any point in time.

Other relevant standards

77. MCNZ also has a statement on 'When another person is present during a consultation' (June 2004).[13] It provides for situations where a student or trainee is present as a third person in a consultation, and states:

> 'If a doctor would like to have one or more students or trainees attend a consultation the patient should be provided with an explanation prior to the consultation about the role that the student or trainee may take in the consultation and asked whether he or she consents to the student or trainee being present.
>
> If a student or trainee is present during a consultation he or she should be formally introduced to the patient …
>
> Not every patient will want to have a third person in attendance, especially if there is an intimate aspect to the consultation that includes a physical examination for which the patient may have to undress …
>
> A patient has the right to decline a third person being present.'

[12] The 2019 Statement was superseded in June 2021 but the wording regarding care provided in teaching environments is unchanged from the 2019 Statement.
[13] This version of the Standard was replaced in June 2022.

78. In response to the provisional opinion, Health NZ stated that the 2019 MCNZ Guidance used the term 'students and observers', which in its view clearly indicates those who are supernumerary to the responsible clinical team and the provision of care. Health NZ said that the 2004 statement on 'When another person is present during the consultation' also focuses on observers who are not a necessary part of the team employed to provide patient care. Health NZ stated: 'Neither of these MCNZ statements was intended to guide expectations around team RMOs who are tasked with delivering healthcare in the public hospital system.'

79. *Cole's Medical Practice in New Zealand* (2017)[14] states:

> 'Where medical trainees are involved in the treatment or care of a patient, the patient should be informed about the extent of the involvement of the trainee and the trainee's experience. Consent should be obtained from the patient if the care or treatment is part of the trainee's education. This is a requirement even if the trainee is simply observing. The patient has a right to refuse to participate in teaching or have an observer present.'

80. The New Zealand Medical Association Code of Ethics (2008) states:[15]

> '53. Clinical teaching is the basis on which sound clinical practice is based. It is the duty of doctors to share information and promote education within the profession. Education of colleagues and medical students should be regarded as an ethical responsibility for all doctors.
>
> 54. Teaching involving direct patient contact should be undertaken with sensitivity, compassion, respect for privacy, and, whenever possible, with the consent of the patient, guardian or appropriate agent. Particular sensitivity is required when patients are disabled or disempowered, e.g. children. If teaching involves a patient in a permanent vegetative state, the teacher should, if at all possible, consult with a nursing or medical colleague and a relative before commencing the session.
>
> 55. Wherever possible, patients should be given sufficient information on the form and content of the teaching, and adequate time for consideration, before consenting or declining to participate in clinical teaching. Refusal by a patient to participate in a study or teaching session must not interfere with other aspects of the doctor–patient relationship or access to appropriate treatment.'

[14] This version of *Cole's Medical Practice in New Zealand* was replaced in 2021, and the additional sentence added: 'Patients should be informed of any increased risks arising where the treatment is provided by a trainee.'

[15] The 2008 Code of Ethics was updated in 2020. Both statements are similar.

Responses to opinion

RN A

81. RN A was given the opportunity to comment on the 'Information gathered' section of the provisional opinion and on the draft final opinion. Her comments have been incorporated into the opinion as relevant. In addition, she made the submissions below.

82. RN A had many years of nursing experience. She said that following, and largely due to, the events relating to the issues raised by this investigation, she retired from nursing.

83. RN A stated that she remains concerned that the revised consent form does not attempt to modify the behaviour or impose an expectation that patients give individual consent to have students and trainees present and/or involved in their treatment.

84. RN A noted that Health NZ's Informed Consent policy includes under '2.1 Core Principles' that 'basic provisions of common courtesy and respect apply, however specific patient consent in this instance is not required'. She commented that common courtesy does not equate with informed consent, and she remains concerned at this language.

85. RN A endorsed HDC's recommendations requiring Health NZ to demonstrate, with evidence, that it has developed appropriate patient information material around clinical teaching; and that Health NZ be required to demonstrate, with evidence, an improvement in its consenting processes and consent forms.

86. Health NZ was provided with the full provisional opinion. Its comments have been incorporated into the opinion as appropriate. In addition, it made the submissions below.

87. Health NZ accepted the adverse comment on aspects of its consent processes in the Obstetrics and Gynaecology service during the period 1 January 2018 to June 2019. It said that it took the complaints seriously and, following investigation and careful review, it made substantial improvements to its informed consent policy, supporting documents, and clinical practice.

88. Health NZ 'broadly accept[ed]' the recommendations proposed in the provisional opinion (see paragraph 181 below) and noted that it has progressed several pieces of work aligned with the recommendations, particularly in the development of material for patients and auditing patient feedback regarding consent processes in Obstetrics.

89. Health NZ said that undergraduate medical students and postgraduate doctors in varying stages of training are fundamentally different, and it considers that national guidance for consent for undergraduate students to observe and participate in clinical care for learning purposes should not be extended to postgraduate clinicians.

90. Health NZ said that in 2020, to further clarify the expectations regarding RMOs undertaking the clinical work they are employed to do, as distinct from students and observers, MCNZ added to its 2019 guidance:

> 'If a doctor who is training to undertake an interventional procedure will be performing any part of that interventional procedure, then this should be discussed with the patient as part of the informed consent process.'

91. Health NZ stated that it concurs with the MCNZ guidance that when people are present who are supernumerary to the care being provided, specific individual consent is required, no matter what level of training or clinical practice the observer holds. However, Health NZ considers that this should be clearly separated from the situation where an RMO is employed to undertake the clinical work as a member of the responsible team.

92. Health NZ said that it agrees with the MCNZ 2020 additional guidance regarding the involvement of RMOs in interventional procedures, and has adopted this approach of discussion and notification, consistent with Right 6(1)(d) of the Code. However, it emphasised that it considers that this guidance and standard do not apply to the situation where the RMO present is employed to undertake that clinical work as a member of the responsible team.

93. Health NZ submitted that many surgical procedures require a team of doctors. A sole consultant surgeon cannot undertake the procedure alone and an assistant is needed, and, in the public hospital system, the role of assistant is commonly filled by an RMO. While working as an assistant, the RMO is gaining elements of experience (experiential learning) and adding to the 'logbooks' of work completed under the requirements and oversight of an external training body (typically a College). Although experiential learning is occurring, specific teaching may not be happening much of the time and the role of surgical assistant is primarily a service role. Health NZ also submitted that it is impossible to define a boundary at which point experiential 'learning through service' ends and formal 'teaching' starts when an RMO is a member of the team undertaking a procedure.

94. Health NZ said that if individual consent were to be required for the RMO's involvement in this context, and if that consent was withheld by the patient, then it is likely that the procedure could not go ahead, or a far less qualified person (such as a scrub nurse) would have to take the RMO's place. That substitution would presumably then require a separate discussion and consent, whether or not teaching was occurring.

95. Health NZ suggested that in interpreting and applying Right 6(1)(d), more emphasis should be placed on the context of healthcare delivery in public hospitals, which fundamentally are teaching institutions. It stated that consumers will encounter and be cared for by learners at all levels and in all professional groups in the hospital setting, and in many cases those learners are also the clinicians employed to provide care. At the same time as providing that care, those postgraduate and registered clinicians will be gaining experience and being taught. As such, being part of a teaching environment is unavoidable for consumers in our public health system. Health NZ also submitted that greater emphasis needs to be placed on the teaching environment in public hospitals, and the practical limitations of consumer preference in this context, while still respecting patient choice when practicable.

Opinion: Health NZ Waitematā — adverse comment

Introduction

96. At the outset I acknowledge and commend the efforts made by RN A over an extended period to raise concerns about informed consent processes at North Shore Hospital. I note that she has experienced difficulties as a result and has since retired from nursing. Her complaint has provided a relevant and important opportunity to address an area of practice in which there is significant inconsistency between providers and a lack of clarity regarding the application of Code rights. It has also enabled me to consider broader principles that may guide future practice across Aotearoa New Zealand. In addition, RN A's advocacy for patient rights has demonstrated the importance of a speak-up culture in hospitals and other health and disability service settings.

97. As then Judge Cartwright acknowledged in her *Report of the Cervical Cancer Inquiry*, the acquisition of sound clinical skills through well-run teaching programmes is important for the future care of all health and disability services consumers. I too accept the importance of medical education and that students and doctors in training must learn the skills of their profession in practical settings. Clinicians continue to learn new skills throughout their careers, and so may be 'trainees' at any stage. However, the Code stipulates that teaching involving consumers must be undertaken only with their knowledge and consent.

98. The basis for this investigation is the examples raised by RN A. I note that RN A's concerns are at times directed at the adequacy of supervision in place, the suitability of patients as candidates for teaching, and the eventual harm apparently caused by the student or trainee's involvement. Those issues are important, and relevant to whether teaching was carried out with reasonable care and skill. However, this inquiry is focused on the standard of informed consent obtained, and consequently those issues are beyond its scope. For the avoidance of doubt, I have made no findings about the individual cases (due in large part to evidential concerns) but have instead focused on the broader, systemic issues.

99. Health NZ has stated that no serious harm to consumers is recorded as having eventuated from the circumstances complained about. I note that RN A disagrees with the assertion that no harm occurred, and there is at least one incident that necessitated an ACC claim to be lodged. I have insufficient evidence to conclude that any harm that did eventuate was caused by poor supervision, as opposed to other factors (such as the procedure carrying innate risk). I take this opportunity to remind Health NZ of the value of adequate supervision, and that if it is in place, it needs to be focused on maximising patient safety. In a similar vein, careful consideration should be given to whether a consumer's individual circumstances make them an appropriate candidate for teaching, but ultimately the consumer has the right to decide to participate in teaching, if they have received appropriate information, as discussed further below.

100. There is scant evidence in the examples to support findings about the nature of the teaching taking place at North Shore Hospital, and discussions with and consent obtained from the consumers in each case. As Health NZ has commented, in many situations verbal consent to teaching is obtained, rather than written consent, and, given the passage of

time, it would be difficult to obtain sufficient, reliable evidence around verbal consent in the case examples.

101. I note also that it is clear from the analysis of other hospital policies that national practices for the obtaining of informed consent to teaching are inconsistent.

102. Taking these matters into consideration, as well as noting the responses of Health NZ to RN A's concerns when they were raised initially, together with the changes made by Health NZ, and that the issue of unconsented student involvement in care has been highlighted as a national concern in recently published articles,[16] I have decided not to make a finding that there has been a breach of the Code. Rather, while I am critical of several aspects of Health NZ's policy and practice, I have elected to take an educational approach to address the issues raised and provide some guidance for potentially nationally consistent practice. Following is a discussion of my key concerns.

103. In response to this approach, RN A said that it is very frustrating to her that a reason for not making a breach finding is Health NZ's responses to her concerns when they were raised initially. She stated that it does not reflect the history of Health NZ having been on notice since 2012 when she first began raising concerns, and the fact that thereafter adequate changes were not made to protect women's rights in a consistent and meaningful way. RN A noted that the most recent changes to the informed consent form were made only once she had made her complaint to HDC. I acknowledge these concerns but remain of the view that making adverse comment about Health NZ's practices and taking an educational approach is appropriate in the circumstances.

Consent policy and forms

104. At the outset, I wish to comment on Health NZ's policy for obtaining informed consent to teaching, including its consent form. The 2018 Informed Consent policy directed staff to offer patients an explanation and obtain their explicit permission, if teaching (including assessment, discussion, or observation) was in addition to normal clinical requirements or involved someone not qualified to undertake the procedure on their own. It stated that where teaching 'is simply a secondary element of sound care provision', specific consent was not necessary.

105. The Code makes no mention of, or distinction between, the need for explicit consent, or the circumstances when a generic consent to teaching (such as that in the consent form) can suffice. Instead, the Code requires that a consumer is provided with the information they can reasonably expect to receive and has given their consent to participate in teaching.

[16] Malpas PJ, Bagg W, Yielder J, and Merry AF, 'Medical students, sensitive examinations and patient consent: a qualitative review' (21 September 2018) NZMJ Vol 131 No 1482, 29–37; Bhoopatkar H, Campos CFC, Malpas PJ, and Wearn AM, 'Adherence to a national consensus statement on informed consent: medical students' experience of obtaining informed consent from patients for sensitive examinations' (20 May 2022). NZMJ 135(1555), 10–18.

106. I accept that in some situations, a consumer may be happy to consent to any and all teaching by agreeing to a generic notification that teaching will be part of their care. I also agree with Health NZ that consumers can reasonably expect to be specifically told of teaching when it falls outside of normal clinical requirements, or the procedure is conducted by an unqualified or inexperienced doctor. However, in my view, the meaning of 'sound care provision' as identified in the policy is ambiguous, and it is foreseeable that such care could involve teaching that may also require a more fulsome notification and information provision than that on the consent forms. I discuss this further below in respect of the specific cases identified by RN A.

107. Health NZ's policy sat alongside the treatment consent form, which had two iterations relevant to this inquiry. The 2018 consent form informed consumers that students could be part of their treatment. It also stated that there was no assurance that a particular clinician would provide treatment, but if they were in training they would be supervised appropriately. The 2020 consent form was similar, but it added that care would be provided by a team that could include clinicians in training, and also invited consumers to delete any statement in the consent form with which they disagreed.

108. Right 6(1)(d) requires providers to notify consumers of proposed participation in teaching, and I accept that both the 2018 and 2020 consent forms notified consumers that clinicians in training and students could be part of their care. However, Right 7(1) of the Code gives consumers the right to make a choice about whether to participate, and that choice needs to be given freely, on the basis of information they could reasonably expect to receive beforehand. Consent means offering consumers real choice and control, and it builds trust and engagement.

109. I acknowledge that the forms may not represent the entirety of informed discussions, and nor should they. I would expect providers to ensure that consent discussions are tailored to an individual consumer's circumstances. However, the consent forms are an important prompt or starting point for those discussions, and I do not consider that either the policy or the consent forms fully equipped Health NZ's staff to discharge their duties under the Code. The statements in the consent form are expressed in a way that suggests that they are Health NZ's expectation of what could happen or are explanatory statements, rather than information relevant to a consumer's particular circumstances followed by an opportunity to make a meaningful choice. I elaborate further below, dealing first with the issue of medical students and then with qualified trainee doctors.

Medical students in theatre

110. The examples of Patients G, H, P, R, X and CC are about the presence of medical students in theatre. Medical students, including sixth-year students, lack the necessary qualifications and registration to practise medicine. Students' clinical placements are the setting for their final years of medical training.

111. The Consensus Statement outlines three ways in which medical students may become involved in patients' care: (1) by observing or examining patients, or carrying out or assisting with procedures for their educational benefit; (2) in a bedside tutorial with a

patient; and (3) students may contribute to the care of patients, under supervision, such as by taking blood or holding a retractor in surgery.

112. In my view, it is reasonable to infer from each of the three above scenarios that teaching is taking place. Consequently, I consider that Right 9 and Right 6(1)(d) of the Code will apply to all medical student involvement in patient care.

113. The next question becomes whether the examples indicate that Health NZ discharged those duties under the Code adequately. In each example provided by RN A, the 2018 consent form was completed, which generically mentioned that students might be present:

> 'I understand that my/the patient's care is occurring in a teaching hospital and there may be healthcare students (medical, nursing) present. I understand they will be appropriately supervised but at any time I can ask for them not to be present.'

114. The actual presence of the medical students in theatre was not documented formally, and there is no evidence that the patient was introduced to the students or told what they would be doing. For Patients G, H and CC it appears that the students were observing. However, in the cases of Patients P and R, a medical student was invited to participate actively, in the former by suturing a wound, and in the latter by assisting with the procedure. In the example of Patient X, it is alleged that the consent form was updated after a patient had been anaesthetised to record that the medical student had permission to do a vaginal examination. Unfortunately, I am not able to make a finding as to whether the consent form was amended and, if it was, whether it was updated to reflect an earlier conversation with the patient, or whether it was recording consent that had not been given, the latter of which would clearly be inappropriate.

115. Health NZ considered, with reference to the Consensus Statement, that explicit consent was not necessary for medical students assisting in theatre, and that their involvement was covered by the generic provision in the 2018 consent form.

116. The Consensus Statement says that consent forms should contain generic consent for the involvement of medical students in observing or contributing to surgery, anaesthesia, and other basic procedures in theatre under direct supervision. It considers that such generic consent will cover 'basic procedures', such as observation, bag mask ventilation, holding a retractor or examining normal anatomy. In contrast, more 'substantive' procedures or procedures involving any material risk will require explicit consent, such as any sensitive examination, intubation, insertion of IV or arterial lines, or closing wounds.

117. As stated above, I accept that in some situations a consumer may be content to be notified generally that medical students may be present, and to be given the opportunity to agree or disagree to that. However, I consider that Health NZ's 2018 consent form did not explain adequately that student involvement could extend beyond the mere 'presence' of students. While Health NZ has allowed that verbal consent to active participation may have been obtained, I am concerned that it was unable to provide evidence of this in the

patients' clinical records. Both the 2011 and 2019 Medical Council Standards require doctors to keep clear and accurate patient records of the information discussed and the decisions made. I would expect verbal consent to teaching (and, in particular, more substantive involvement) of medical students to be documented, with reference to those standards.

118. Furthermore, the generic provision in the consent form stated that students *may* be present — that is, it is expressed as a possibility but not a certainty. The Consensus Statement states that '[a]s far as reasonably possible, patients should be informed about the proposed extent and nature of student involvement'. Similarly, the Medical Council's 2011 and 2019 Informed Consent Standards required consent before involving medical students in the care of patients, and information to be given to the patient about the extent of the involvement of the student and the student's experience. I do not consider that notifying a consumer of the possibility of students' presence adequately meets those expectations, particularly if the student's role is likely to go beyond observation.

119. Right 1 of the Code gives consumers the right to be treated with respect. I consider it to be a minimum standard of courtesy and respect that healthcare providers involved in a procedure, including medical students, introduce themselves, or be introduced, to the consumer, and their role in the clinical team identified. I also consider this to be information that a reasonable consumer undergoing a procedure in theatre would expect to receive. There is no evidence of such introduction in the examples provided by RN A.

120. Health NZ's policy required an explanation to be given and explicit consent obtained if teaching, including observation, was to occur and involve someone not qualified to undertake the procedure on their own. Given that requirement, and as students are unquestionably in training and the Medical Council sets clear standards for their involvement, I do not consider a generic notification that students may be present will be evidence of appropriate information provision for all participation of students in patient care. In some circumstances it is foreseeable that consumers may require additional information, such as the extent to which their body will be exposed and the number of observers. As this Office has stated previously:

> 'If the teaching is to involve "hands on" examination or treatment by the trainee, a reasonable consumer is likely to request a fuller explanation and reassurance that an experienced clinician will oversee the procedure.'[17]

121. Clinicians must be mindful that informed consent is more than just a tick-box exercise, and they must be alive to individual patient circumstances. The wording of Health NZ's 2018 consent form and apparent reliance on it to justify all medical student involvement beyond observation was a significant weakness in Health NZ's consent practices.

[17] Opinion 00HDC06794 (19 June 2001).

122. I suggest that Health NZ consider adding to its national consent form (which is under development, discussed below) a prompt to direct clinicians to identify and describe the medical student and their role to the consumer, and record any consent given or refused.

Trainees who are part of the team

Did teaching of trainees occur?

123. Most of RN A's examples are about the involvement of trainees, specifically house officers and registrars, in patient care. I acknowledge that RN A believes that consumers are entitled to be told any time a trainee is involved in their care, and explicitly agree to their involvement.

124. However, Right 6 says that the information to be provided to consumers about teaching must be information that a reasonable consumer, in that consumer's circumstances, would expect to receive, and would need to make an informed choice and give informed consent. It is a mixed subjective and objective test, and there will be significant variation across the circumstances of patient care, and the level of a trainee's experience.

125. House officers and registrars are qualified doctors and are permitted to practise medicine within a provisional or general scope of practice. In my view, house officer and registrar involvement in the care of a patient does not *prima facie* mean that teaching is taking place, and it will be necessary to consider each circumstance on its facts.

126. The examples outlined in respect of Patients C, I, J, U, V, W and BB (first category) simply raise concern that a registrar was involved in consumers' care, but there are no concerns raised about the nature of the registrar's role or experience, or the teaching (if any) that was taking place. For this reason, I do not consider that the first category of examples provides any indication that teaching was taking place without consent, or that informed consent processes were otherwise deficient.

127. The examples of Patients D, E, F, K, L and AA (second category) describe situations where house officers assisted SMOs in surgery and actively participated in the surgical procedure.

128. The cases of Patients A, B, M, N, Q, S, T, Y and Z (third category) are about junior registrars and house officers performing procedures in which they lacked experience, mostly under the supervision of senior registrars. Although in each case the supervising doctor was certified to conduct the procedure without supervision, the junior doctor was not.

129. Health NZ said that registrars and house officers are required to attend theatres and assist SMOs as part of their role, and their clinical role is indistinguishable and inseparable from their training.

130. I have no difficulty accepting that house officers and registrars are integral members of the clinical team. I also accept that junior doctors assisting senior doctors is a necessary part of their role and within their scope of practice. However, this does not in and of itself mean that teaching is not taking place. I acknowledge Health NZ's statement that training is

inseparable from their job, but the Code's jurisdiction is not confined to training that falls outside a clinician's job description or 'sound care provision'.

131. Similarly, the Code's jurisdiction is not confined to teaching situations where there is inadequate supervision. Health NZ has answered RN A's concerns by noting that the doctors supervising their junior colleagues were certified to perform the procedure independently. In my view, this is beside the point. The Code makes no reference to the existence of another doctor supervising as absolving providers of the obligation to obtain patients' consent to teaching. I note that Health NZ's 2018 policy recognised that if a clinician required supervision due to a lack of qualifications, explicit consent to teaching should be obtained.

132. The O&G profession has considerable structure around its training programme, whereby trainees become certified to undertake a particular procedure without supervision after completing a certain number of the procedures to the requisite level of skill and undergoing a formal assessment. In the second category of examples, an SMO certified in a procedure was assisted by a house officer who was not certified in that procedure and who participated actively. Similarly, in the third category of examples, a senior registrar certified in a procedure supervised a junior doctor who was not certified, as the junior doctor performed the procedure.

133. It is reasonable to infer from the second and third category of examples that the doctors who were not certified in the procedure were training under the direction and supervision of the doctors who were certified in the procedure, who were available as a safety net and to impart their knowledge, experience, and instruction along the way. For that reason, I am satisfied on the facts that both the second and third categories of examples represent teaching, and consequently that Rights 6(1)(d) and Right 9 applied. The next question becomes whether appropriately informed consent was obtained.

Was appropriate informed consent obtained?

134. In each example, the patients had signed a consent form that mentioned that training could occur. Health NZ stated that the involvement of clinicians in training is an integral part of its consent form. The generic provision in its 2018 consent form, which it relied on as evidence of informed consent to teaching, stated:

> 'I understand that no assurance can be given that a particular clinician will be performing my/the patient's procedure but that the clinician will be suitably qualified and, if in training, will be appropriately supervised by a senior clinician.'

135. In addition, Health NZ stated that in most cases, the consent form was personally completed by the junior doctor, the patients had met the junior doctor before the procedure and were aware that the junior doctor was a member of the clinical team undertaking the procedure, and the patients had given consent accordingly.

136. Whether this amounts to adequate informed consent in the circumstances is finely balanced. On the one hand, as Health NZ's consent policy acknowledges, minimum

standards of courtesy and respect apply and, in my view, this means that healthcare providers involved in a procedure will introduce themselves, or be introduced, to the consumer. Although at least one patient (Patient A) did not know who was treating her, it is reassuring that most of the clinicians in training had met the patient beforehand.

137. It is also apparent that in most examples, the junior doctor notified the patient that clinicians in training could be involved, identified themselves as part of the clinical team, and obtained the patient's signed consent to the procedure on that basis. I accept that some consumers would be satisfied on that basis that they had received sufficient information to give their consent to teaching of trainees being part of their procedure.

138. On the other hand, it is unlikely that the consent process described would meet the Code's requirements in every circumstance, for the reasons discussed below.

139. First, the 2018 consent form emphasises that there is no guarantee that the expected clinician will perform the procedure. The mention that clinicians in training may be involved seems secondary, with less emphasis in the context of the clause. Consequently, the possibility of teaching of trainees is underplayed and, if not accompanied by a verbal discussion, could be missed by the patient.

140. Secondly, as discussed above, the 2018 consent form simply states that trainees could be involved by way of a disclaimer, and it does not give the patient a meaningful choice to agree to teaching in their particular circumstance.

141. Thirdly, the responsibility for obtaining consent to teaching was evidently delegated to the person being taught. As noted in the Consensus Statement (albeit regarding students rather than trainees), patients differ in their assertiveness and in how empowered and robust they feel at any particular time, and patients may find it difficult to decline consent to teaching in the presence of a student. The Consensus Statement suggests that it may be better for the clinician to ask the patient privately if they consent to students being present. In my view, this principle can extend beyond medical students to teaching generally, and I consider that it could be difficult for a patient to refuse consent to teaching of a trainee, if the trainee is seeking consent personally. It is my expectation that where practicable, consent to teaching should be obtained by the teacher. For the avoidance of doubt, I am not suggesting that the Consensus Statement applies to postgraduate trainees. It applies to undergraduate medical students. Nevertheless, the principles recognising the inherent power imbalances between patients and clinicians are sound and have broader application as I have described.

142. Fourthly, there is no evidence that the consent discussions or consent form clearly identified the trainee's role and extent of involvement in the procedure. Training is expressed in the consent form only as a possibility, and the patient does not know for certain that it will occur or what it may involve for them. Although in some of RN A's examples the doctor's designation (house officer or registrar) has been marked on the consent form, it is not known if or how this was communicated to the consumer. I note that expressions such as trainee intern, intern, junior doctor, house officer, house surgeon,

senior house officer/surgeon, registrar, and trainee/advanced trainee may have little meaning for patients and give no indication of the nature of teaching that is likely to occur.

143. Previously this Office has found that information regarding who will be performing a consumer's surgery is information that a reasonable consumer would expect to receive, particularly if that person is in training.[18] In the context of teaching situations, this Office has also found that a doctor's role and status, and reason for their presence, should be made clear to consumers.[19] As Commissioner Paterson stated (in relation to an overseas doctor observing a surgical procedure in order to learn it): '[The doctor's] role and status, and the reason for her presence, were not made clear to [the consumer]' and there needed to be 'a frank explanation of the qualifications, responsibilities and the status of the surgeons who were to be involved'.[20] In response to my provisional opinion, Health NZ submitted that this previous HDC decision was specifically in reference to a third-party observer who was not part of the team providing clinical care, and that observer was neither a student nor an RMO. Health NZ considers that this case does not have bearing on RMOs who are members of the clinical team.

144. I acknowledge Health NZ's comments but am still of the view that a reasonable consumer undergoing surgery would expect to be told who will be performing their surgery and who will be present, including those who are part of the treatment team and those who are not.

145. In a similar vein, the MCNZ requires that patients are told about the extent of a trainee's involvement and experience, and the patient's consent is to be obtained if the care or treatment is part of the trainee's education.[21] If trainees are present as third parties, those trainees must be formally introduced to the patient, and the patient must be given an explanation about their role, and consent obtained.[22]

146. I am not saying that a junior doctor or trainee must identify themselves as being 'in training' in every interaction with a patient. The Code explicitly requires information about 'the identity and qualifications of the provider' to be given only if a patient asks specifically.[23] Simply identifying themselves as a 'doctor' will likely be sufficient information in those patient interactions that form part of the trainee's scope of practice and competency.

147. However, I have found above that the second and third categories of examples involved teaching. It is difficult to see how a patient can give informed consent to proposed teaching unless the person being taught is identified to them and they are given some indication of the nature of the teaching that will occur, by clear identification of the roles

[18] Opinions 09HDC01565, 13HDC01345, and 16HDC01498.
[19] Opinion 03HDC05435.
[20] Opinion 03HDC05435.
[21] *Cole's Medical Practice in New Zealand* (2017).
[22] 'When another person is present during a consultation' (June 2004).
[23] Right 6(3) of the Code.

of the teacher and person being taught, as well as their responsibilities. The consent form provides no such information.

148. I also consider that a generic notification that clinicians in training *may* be involved is too simplistic. As stated above, it is my expectation that, assuming there is no emergency, consumers are informed of who will be providing care to them, including if the surgery will be performed by a junior doctor under supervision, or by a senior doctor with assistance from a junior doctor. Health NZ appropriately captured this in its directions to SMOs and RMOs on 17 December 2019, when it outlined its expectations for RMOs to introduce themselves and explain their role, such as saying, 'I'm Dr Jones, I'm the doctor who will be undertaking your surgery today. I'm an advanced trainee in surgery and will be undertaking this procedure with the supervision of Dr Smith who is the consultant operating with me,' and then answering honestly any resulting questions. However, as previously stated in this report, I remain of the view that consent to teaching should be, wherever practicable, obtained by the teacher rather than the trainee. As such, ideally such introductions should take place after consent to the involvement of a trainee has already been given by the consumer.

149. The way the 2018 consent form is worded (giving no assurance that a particular clinician would perform a procedure) can justify last-minute changes to service providers. Clearly flexibility is desirable and necessary in a large hospital, and I agree that it is helpful to put patients on notice that the person who is to perform their procedure may change. However, this does not absolve its staff from clearly introducing and identifying themselves to the patients to whom they will be providing care, including what their role will be, and, whenever possible, that process should done again if clinicians change.

150. In response to the provisional opinion, Health NZ submitted that at a practical level, it is impossible to define a boundary at which point experiential 'learning through service' ends and formal 'teaching' starts when an RMO is a member of the team providing care or undertaking a procedure.

151. I appreciate that the line between assisting and performing parts of a procedure will, at times, be blurred, and that it may be difficult to know in advance the exact role that a trainee will have. However, in my view, if it is anticipated that the trainee will move from doing something within their scope of practice to being taught during a procedure, the consumer should be made aware of that, with the teaching not taking place unless consent has been given. If it cannot be communicated with certainty what role a trainee will have, providers could advise consumers of the kinds of roles that trainees would usually have in procedures similar to theirs.

152. In general, consumers must be notified of who will be undertaking a procedure and what their roles and responsibilities are. Each case will turn on its own facts, and situations may arise when this is not possible.

153. In response to the provisional opinion, Health NZ submitted that greater emphasis should be placed on the teaching environment in public hospitals, and the practical limitations of consumer preference in this context. It also said:

> 'The reality of our public health system is that the choice to decline the involvement of an RMO in care does not meaningfully exist in most situations. Right 7(8) provides for an expression of preference in the provision of services, but it is rarely practicable for a consumer to decline the involvement of RMOs in most aspects of their care in our hospitals.'

154. I disagree. Consumers may choose not to go ahead with the procedure or make other arrangements. The right to informed consent in the Code is not confined to circumstances where application of the rights is convenient or practicable. That said, there is value in clinical settings promoting that they are teaching institutions in the interests of enhancing patients' understanding (provided, of course, that such promotion does not displace the need to obtain specific consent in the individual circumstances of the patient).

155. In response to the provisional opinion, Health NZ agreed that high quality supervision of learners is a key accountability of providers. I agree. If teaching is taking place, I consider that the extent to which a trainee will be supervised by a senior colleague is information that a reasonable consumer would expect to receive before making an informed choice about whether to participate. Both the 2018 and 2020 consent forms state that if any clinicians carrying out a procedure are in training, they will be supervised appropriately by a senior clinician. That assurance could be part of the reason why the patient agrees to participate in teaching and, as such, it is integral to the informed consent process.

156. I would be concerned if Health NZ relied only on the generic wording in its consent forms to inform consumers about teaching. It is foreseeable that some proposed teaching will warrant a more fulsome explanation specific to an individual patient's circumstances, or the nature of the teaching, or a trainee's role or experience. Although the 2018 consent form was updated in 2020 to include further provisions notifying patients that clinicians in training may be involved in their care, and the opportunity to cross out statements with which patients disagree, it still gives no prompts to discuss what that possible involvement may be. In response to the provisional opinion, Health NZ agreed that there is scope for its consent form to prompt clinicians to advise patients of who will be working in the team and discuss the involvement of an RMO, consistent with the MCNZ standards.

157. I am unable to determine on the facts provided exactly what information was verbally conveyed to patients by the junior doctors who obtained their consent. This again reinforces why appropriate documentation of verbal discussions is necessary. Consequently, I cannot know whether the patients were aware that the procedure would involve teaching of the junior doctor, and what the extent of their role in the clinical team or procedure would be. In the absence of that evidence, and as the junior doctor had met the patient, identified themselves as part of the clinical team, and obtained a completed consent form, I have declined to make a finding that Health NZ's practices breached the Code.

Sensitive examinations and procedures under general anaesthesia

158. The case of Patient O describes a registrar proposing to involve a house officer in a vaginal examination of a woman under general anaesthesia. RN A told HDC that she intervened, saying that no consent had been gained for the vaginal examination by the house officer, and the examination did not go ahead. I commend RN A for her actions in this respect.

159. This example is similar to the facts in a previous decision[24] in which I found a district health board in breach of the Code for allowing a medical student to perform a sensitive examination[25] and insertion of an intrauterine contraceptive device on an anaesthetised woman, without her knowledge or consent. The key difference above is that it was a qualified doctor, rather than a student who was involved.

160. I accept that in general, a house officer may be qualified to perform a sensitive examination, and it is not clear on the facts what teaching may have been occurring. It seems possible that there could have been an element of teaching, given that the house officer was more junior than the registrar.

161. Clearly, it would be highly concerning if a vaginal examination was proposed to be undertaken without the patient's knowledge or consent. In such circumstances, explicit consent is clearly required.

162. If the patient had consented to a vaginal examination, I would be very concerned if Patient O was not aware that the house officer would be involved in her examination. In my view, consumers undergoing sensitive examinations should know beforehand who will be involved and what their role will be, including any observers. This is information that a reasonable consumer in that person's circumstances would expect to receive.

163. The importance of allowing patients adequate time to reflect on information provided to them prior to surgery has been highlighted in previous HDC cases.[26] This is particularly important if the procedure will involve sedation or anaesthesia, wherein the patient's capacity to consent to teaching either immediately before or during the procedure will be affected by the medication. I consider that any unnecessary last-minute invitations to trainees or students to participate or observe a sensitive examination or procedure is entirely inappropriate — in the case of a general anaesthesia because the patient is unconscious and unable to be made aware of the change, or because an awake patient will likely be prepped, in a state of undress and possibly sedated, and vulnerable. I would be very concerned if the generic provision in the 2018 consent form was used to justify a last-minute decision to involve teaching in the consumer's care (such as by inviting a student or other doctor into theatre once the procedure was underway), without allowing the consumer time to make a freely given informed choice.

[24] Opinion 20HDC01693 (25 July 2022).

[25] The Consensus Statement defines 'sensitive examination' as including breast, rectal, and vaginal examinations, and those of the external genitalia.

[26] See Opinion 09HDC01691, Opinion 08HDC20258, and Opinion 05HDC07699.

164. The MCNZ 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'.[27] I note that this statement was issued after the events involving Patient O.

165. The Consensus Statement sets out clear expectations for obtaining consent to medical student participation in sensitive examinations. It requires that when performing sensitive examinations, particularly those under anaesthesia, meticulous care is required in seeking and documenting consent for the involvement of medical students. In particular, it states that any generic consent to teaching of students should not be taken as consent to conduct sensitive examinations, and that such examinations require explicit consent, in writing if the patient is under anaesthesia. It notes that in sensitive examinations there should be no possibility for the consent to have any element of coercion by, for example, asking a patient to consent after they have undressed or in front of the student.

166. While the Consensus Statement applies to undergraduate medical students, in my view those principles apply equally to teaching of postgraduate clinical staff. I also consider that potentially the principles could extend beyond sensitive examinations to any physical examination or procedure that may have an intimate aspect, where the patient may have to undress, or where cultural considerations require a more sensitive approach. Given the vulnerability of the person in those circumstances, there is a clear expectation that patients give unequivocal, explicit informed consent. It is at the heart of patient-centred care.

Patient awake during procedure and support persons

167. Health NZ explained its practices by noting that in many cases, being Caesarean sections, the patients were awake and alert. In response to the provisional opinion, Health NZ said that it raised this to note that Caesarean sections bring a unique set of circumstances to the operating theatre, in that people outside the designated surgical team are present routinely, including other clinicians with obstetric expertise. Health NZ also re-emphasised that it did not receive complaints from any parties other than RN A, and in particular no complaints from the supporting clinicians (such as the Lead Maternity Carers) involved in any of the cases in this inquiry.

168. Health NZ said that it did not intend to imply that an awake patient would be assumed to be able to give consent, or for such consent to be considered valid.

169. In response to the provisional opinion, RN A said that the fact that a person was conscious and/or had a support person present does not equate to informed consent, nor recognise the inherently vulnerable position of the patient, particularly those undergoing intimate procedures, including births.

170. I remain of the view that evidence that a patient is awake during a procedure does not equate to evidence that they gave informed consent to teaching. In the context of a

[27] Medical Council of New Zealand, 'Sexual boundaries in the doctor–patient relationship', 2009 (page 3).

Caesarean section, the patient would be draped, and the clinicians would be wearing gowns, masks, and caps. The draping would prevent the patient from seeing the surgeon(s) and the operative site. It is difficult to see how, in the absence of introductions, the patient would have any idea of the roles of those present.

171. I acknowledge that verbal consent to teaching could have been obtained while the procedure was underway but, as noted above, an awake patient undergoing a procedure is in a vulnerable position, and I would have serious concerns about the validity of any consent obtained in those circumstances.

172. Similarly, Health NZ noted that in many of the cases the patient had a support person and/or their LMC present in theatre. Although appropriate support is vital for a patient in this situation, it is not evidence that a patient has consented to participate in teaching. Furthermore, a support person is not usually legally entitled to give consent on behalf of the patient. However, I note that Health NZ responded that it did not intend to infer that supporters could give the consent.

Consumers' refusal of consent to teaching as a reason not to tell them

173. Health NZ has made much of the potential for a requirement to obtain specific informed consent to have a chilling effect on the training of doctors. I note that the Consensus Statement states that the majority of patients do say yes when asked about medical student involvement in their care. In any case, I do not consider a concern that patients may refuse consent is a valid reason for failing to provide information that they can reasonably expect to receive and allowing them the opportunity to make an informed choice.

174. A consumer cannot insist that a particular provider, such as an SMO, will perform their procedure. Under Right 7(8) of the Code, a consumer has the right only 'to express a preference as to who will provide services and have that preference met where practicable'. I accept that in many cases it will not be practicable to have the SMO perform a procedure, both from a resourcing perspective but also having regard to the need to upskill existing clinical staff. If a consumer is concerned about who will provide the services, under Right 7(7) they have the right to refuse consent or withdraw consent to the services.

Conclusion

175. The Code is clear that consumers cannot be involved in teaching without giving informed consent. Providers of health and disability services must ensure that they have a robust system and culture for obtaining that consent. It is imperative that they do not rely on broad notifications that teaching may occur as absolving them from providing consumers with information relevant to their particular circumstances. Senior clinicians and teachers must lead from the top, and ensure that they model good, transparent consent processes to their junior colleagues. Basic courtesy and respect for patients apply, and wherever practicable consumers should know who is to be providing their care and what they will be doing. This is information that a reasonable consumer involved in teaching can expect to receive.

176. While, on the facts and bearing in mind the relevant context and circumstances of these events (as discussed in further detail in paragraphs 96 to 103 above), I have declined to make a finding that Health NZ breached the Code, in my view, there were weaknesses in Health NZ's systems in place from 2018, as follows:

- The 2018 policy did not require consent if teaching was part of sound care provision, when the Code makes no such distinction. When teaching occurs within the clinical team as part of the optimal provision of care for that patient, appropriate informed consent will be necessary.
- Its process for obtaining consent to teaching, including its consent forms, underplayed the involvement of students and clinicians in training, and did not prompt introductions, or an explanation about the role of the person being taught or the degree of supervision in place.
- If verbal discussions about teaching supplemented the matters listed on the consent form, this was not documented adequately.

177. I acknowledge that Health NZ has taken RN A's complaints seriously and undertaken a careful, ongoing review and improvement of its informed consent policy and practice. I commend its efforts in this regard. Acknowledging that there is uncertainty and inconsistency in the application of Rights 9 and 6(1)(d) of the Code, my Office is undertaking further work on this area.

Changes made as a result of issues raised by RN A

178. Health NZ said that there have been significant changes to consent documentation, policies, and processes, and staff education at Health NZ in recent years, both in response to issues raised by RN A and as part of its ongoing quality improvement initiatives. However, Health NZ does not accept that overall, its previous informed consent policy and practice were deficient.

179. Health NZ stated that in response to the concerns raised by RN A, a formal improvement project was undertaken covering all areas of the informed consent process, and led to the following key changes and improvements:

- The 2020 Agreement to Treatment/Consent form was developed and endorsed by its Clinical Governance Board (CGB). The new wording on this form has been refined in consultation with the Consumer Council, clinicians, the General Counsel, and language experts.
- Policy documents have been reviewed and revised where appropriate.
- An ongoing programme of education has been developed and implemented.

- Health NZ has implemented an electronic 'dashboard' in the Obstetrics service, which provides clarity about the achievement of surgical competencies for the Advanced Training registrars. This ensures that the service is aware of the varying supervision needs of the individual registrars. This in turn informs the overall process of informed consent, highlighting where a doctor in training will require direct supervision in the operating theatre for a specific procedure.
- Enhanced patient information materials were to be developed as part of the larger informed consent project at Health NZ. However, this work was deferred during the COVID-19 pandemic, and it has now commenced as a separate project led by i3 (the institute for innovation and improvement).
- There is ongoing audit and development of structured patient feedback on informed consent. This work builds on the audit completed in 2020, and will be overseen by the CMO, Quality Executive Committee, and i3. The focus of the audit underway is on the patient's view of consent and their experience with the surgical team in elective Caesarean deliveries.
- Throughout this period of investigation and continuous improvement, there has been close oversight and governance from the Health NZ Board and Board Chair. The Board and its Hospital Advisory Committee (HAC) have received regular reports from the General Counsel and the CMO.

Nationally consistent approach to informed consent

180. In April 2024, Health NZ advised HDC that work is underway on a national policy on informed consent, with the goal of being able to achieve a nationally consistent approach. Four Health NZ districts have undertaken significant work on their informed consent policies in the last two years, and this work is informing the document. The policy will be accompanied by a longer procedure document that expands on the principles and process of informed consent, including a section on research, teaching, and observers, as well as nationally consistent consent forms.

Recommendations

181. I recommend that within six months of the date of this report, Health NZ Waitematā take the following steps and report to HDC on the outcome:

a) Develop O&G patient information materials around clinical teaching, ensuring that these are simply written and emphasise patient choice. It may be helpful to consider how to define trainees and medical students within the patient information.

b) Provide a report on the outcome of the audit of patient feedback on informed choice to teaching that takes place within the O&G service.

c) Provide evidence of training to staff to ensure that SMOs within the O&G service are aware of, and comply with, the processes for informed consent.

182. In the provisional decision, I recommended that Health NZ Waitematā review its policy and consent processes in light of this report. Acknowledging the work that is being undertaken towards a nationally consistent approach to informed consent, I recommend that at six-monthly intervals until the project is complete, Health NZ report back to HDC on the progress of the development of a national policy on informed consent and associated documentation. In addition, the findings of this report should inform the development of these policies and processes.

Follow-up actions

183. A copy of an abridged report with details identifying the parties removed, except Health NZ Waitematā and North Shore Hospital, will be sent to Health New Zealand|Te Whatu Ora head office, Deans of the Medical Schools, MCNZ, the Nursing Council of New Zealand, and the Midwifery Council of New Zealand, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Extract from 2018 Informed Consent policy

'**2. Teaching and Observers**

All healthcare settings should be learning environments where clinical teaching and learning occur as part of day to day practice. Additionally, as a teaching institution, formal teaching occurs. This includes further education for registered and employed clinical staff and training for unqualified students.

Patients, however, have a right to consent to or decline involvement in teaching including the presence of observers during treatment or examination. The primary obligation is to provide the patient with sufficient information for them to give or withhold their informed consent. This includes being informed of the identity and qualifications of the provider.

Patients also have the right to be treated with respect and to receive effective communication.

Teaching of qualified staff occurs in a range of situations from undertaking of procedures under supervision to directly observing procedures to discussion of case studies. Teaching therefore covers both the provision of healthcare services and the use and disclosure of health information.

2.1 Core principles

Consent for involvement in teaching applies not only to interventional procedures but also to observation of them.

Some teaching occurs within the clinical team as part of the optimal provision of care for that patient e.g. case discussion or assistance with a procedure. Teaching is simply a secondary element of sound care provision. The basic provisions of common courtesy and respect apply, however specific patient consent is not required.

Where teaching [including assessment, or discussion or observation] occurs that is additional to normal clinical requirements or involves someone not qualified to undertake the procedure on their own. In this case, an explanation is to be given to the patient and their explicit permission sought.

This section applies to:

- Students in training
- Staff in recognised training programmes
- Registered and employed clinical staff undertaking on the job training and further education
- All teaching staff

2.2 Principles for Clinical Teaching

Where teaching [including assessment or discussion or observations] occurs that is **additional to normal clinical requirements for that patient in that patient's circumstance,** or involves someone not qualified to undertake the **procedures on their own,** an explanation is to be given to the patient and their explicit permission sought.

Common courtesy indicates that there should be an appropriate introduction of the student and identification of their role. An explanation of what is occurring and why, should be given as part of the **usual interaction with the patient**.

Patients who are not able to give informed consent on their own behalf should not generally be involved in procedural teaching without the consent of their representative.

Where practicable, the request to the patient should be made without the student present so the patient is able to freely decide whether or not to be involved in the teaching situation. However, where the trainee/student attends on their own they must obtain the patient's agreement.

Every patient has the right to withdraw from the teaching session at any stage and must receive a clear prior assurance that refusal to participate in teaching or withdrawing from teaching will not jeopardise his or her care in any way.

Patients have the right to have a support person present at any time including during intimate examinations such as rectal or vaginal examinations.

Verbal discussions about involvement in teaching should be recorded in the clinical record for reference. There are further obligations in regard to involvement of students in training.

2.3 Intimate Examinations

Such examinations are of critical importance and need to be properly learned by health professionals. The commonest cancers (prostate and breast) for both men and women are disclosed by such examinations.

Responsibility for eliciting the essential consent to teach these procedures rests with the supervising clinical teacher.

Multiple intimate examinations on one patient by a group of students is prohibited.

Intimate examinations by students under general anaesthetic require the same consent process i.e. the patient MUST consent for teaching BEFORE anaesthesia or pre-medication is given.

- Multiple examinations are, as in the general setting, prohibited.
- Should use chaperones appropriately when teaching intimate examinations.

Patients have the right to have a support person present particularly during intimate examinations such as rectal or vaginal examinations.

2.4 Clinical Teaching of Students in Training

In the partnership between patients, teaching staff and student, the paramount consideration must always be the welfare and interests of the patient.

Patients are not to be involved in clinical teaching of students without their being fully informed and their freely given consent. Verbal discussion about involvement in teaching must be recorded in the clinical record for reference.

Informed Consent

Teachers and students must ensure that other requirements of this policy are met in clinical teaching situations. This includes the requirements for Effective Communication — Specific Requirements.

Physical examination or specific procedures undertaken by a student must not be repeated unreasonably on any patient, or to the patient's detriment and must not produce or prolong unreasonably any distress, embarrassment or pain.

Students should comply with any other policy requirements including the presence of a chaperone where indicated.

Students are entitled to question or challenge their supervisor/other staff if they believe these provisions are not being met appropriately. If on challenging their supervisor, the students receive a response that they consider unhelpful or inadequate, advice should then be sought from their teaching institution.

2.5 Supervision of Student Experience

An effective healthcare setting needs a continuing supply of qualified staff. An essential requirement for training health professionals is access to well-planned and properly supervised practical experience.

Good quality experience for students is based on a three-way partnership between:

- the patient who agrees to be part of teaching/learning processes
- teaching staff
- and the student

This involves cooperation between the teacher and other qualified staff.

The quality of patient care is the responsibility of the clinical team and not the student.

Students providing aspects of clinical care and treatment must be supervised by their clinical team and supported by the teaching staff.

2.6 Consent for Involvement of Students

Every patient has the right to decide whether he or she agrees to an interview, examination or other specific procedure carried out by a student or in the presence of a student.

Every patient has the right to withdraw from the teaching session at any stage and must receive a clear prior assurance that refusal to participate or withdrawing from teaching will not jeopardise his or her care in any way.'

Appendix B: Information to staff July 2019

'TO: ALL SMOS, RMOS

RE: INFORMED CONSENT FOR MEDICAL STUDENTS — REMINDER

1. Waitematā DHB strongly supports the supervised apprenticeship learning of medical students in our healthcare facilities.

2. Patient consent is essential for the involvement of students in their care. Such consent should be informed and sensitively obtained, and proportional to the situation. The national consensus statement (NZMJ — attached) states that "Verbal consent, obtained simply, politely and in the context of the general interactions between practitioners and patients is both adequate and appropriate for most situations".

3. The responsible clinician (eg: SMO or RMO) is accountable for ensuring consent is obtained for the involvement of students. Students are responsible for ensuring that such consent has been gained by the responsible clinician.

4. Specific issues relating to the operating theatres and procedural areas:

   a. The generic statement on Waitematā's "Consent Form" regarding the involvement of students should be understood to be limited to observation and very basic procedures only.

   b. For a student to observe in theatre, or assist in a minor way (such as holding a retractor), Waitematā DHB's consent policy requires that the responsible clinician obtain verbal consent for that student's involvement.

   c. For a student to actively undertake aspects of a procedure (eg: suturing at closure in surgery) the responsible clinician should document the patient's consent prior to the procedure.

   d. Written consent is mandatory for students to undertake intimate examinations (such as vaginal or rectal exams), and such examinations must be directly supervised and limited to one student with a patient.

…

Sent to all SMOs, RMOs and Students 31 July 2019.'