

1.2. Medical Students and informed consent

A national consensus statement was developed to promote a pragmatic, appropriate and unified approach to seeking consent for medical student involvement in patient care. Please review article below:

Medical Students and informed consent:

A consensus statement prepared by the Faculty of Medical and Health Sciences of the University of Auckland and the University of Otago Medical School, Chief Medical Officers of District Health Boards, New Zealand Medical Students' Association and the Medical Council of New Zealand

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ABSTRACT

To develop a national consensus statement to promote a pragmatic, appropriate and unified approach to seeking consent for medical student involvement in patient care. A modified Delphi technique was used to develop the consensus statement involving stakeholders. Feedback from consultation and each stakeholder helped to shape the final consensus statement. The consensus statement is a nationally-agreed statement concerning medical student involvement in patient care, which will be useful for medical students, health care professionals and patients.

The Code of Rights establishes the rights of consumers, and the obligations and duties of providers to comply with the Code. It is a regulation under the Health and Disability Commissioner Act. Nevertheless, there is evidence that the practice of seeking consent for the involvement of medical students in patient care is presently very variable. This consensus statement is an attempt to promote a pragmatic, appropriate, and unified approach to seeking such consent.

The document aims to deal with the potential (and at times actual) tension between the fundamental requirement to respect patients and their rights, and the obligation on the health system and health professional educators to provide learning opportunities for students. While these two requirements are by no means mutually exclusive, thoughtful care is required on both sides. Medical students learn in clinical environments and are legitimate and integral members of healthcare teams. The student learning covers a

continuum of experiences and responsibilities, ranging from directly providing care to an individual patient to being part of a team providing care. As medical students transition from novices to junior doctors, patient interaction becomes an increasingly important part of their learning. Senior students (Trainee Interns) are integral members of the healthcare team providing care in hospital and general practices, and consent requirements need to reflect this.

However, before becoming involved in any patient's care, the consent of the patient must be obtained. Such consent should be informed: ie the patient (or another person as legally appropriate) should understand what he or she is granting permission for. This implies a conversation and communication, which includes listening to patients as well as giving them information. It is important to be sensitive to perceived or real imbalances in power between patients and healthcare providers. The process can usually be simple, verbal and

informal, particularly when the student's involvement is limited. When the risks are higher or the student's involvement greater, more information will be required and in some instances it would be prudent for explicit consent to be documented, or even obtained in writing, with a signature from the patient.

It is the spirit of informed consent that matters most: the important thing is to demonstrate respect and compassion for patients (and their families), in the context of their values, interests and vulnerabilities. Gaining and maintaining the consent of a patient is not a one-off event or simply an exercise in 'ticking boxes'. Rather, it is an ongoing process of communication and building trust, and patients must feel free to withdraw their consent at any time. Therefore, those involved (practitioners and students) should at all times remain sensitive to any change in each patient's sense of comfort over who is present or what is being done.

The aim of this consensus statement is to assist medical students, doctors and other registered health professionals responsible for supervising them to understand what is expected and required in relation to consent for students to be involved in patients' care.

Background

Medical students learn in an apprenticeship model under the supervision of registered healthcare professionals. Contact with patients occurs early in the journey towards becoming a doctor. Initially, this may be as an observer in a general practice, or in a class when a patient consents to being interviewed during a lecture. As learning progresses, students will be observers in surgical theatres, participate in the administration of anaesthetics, learn to undertake sensitive examinations, assist in the delivery of babies, and participate in many aspects of patient care in primary, secondary and tertiary care settings. The boundaries between observation and participation are sometimes blurred. Underpinning all these interactions is the trust of patients in those involved in their medical treatment and care. This trust is precious and must be respected.

Medical students become involved with patients in different ways, contexts and settings (see Table 1), and at different stages of their training. There are settings and contexts in which gaining consent is straightforward, and others where it is not. The relevant principles are not dependent on the setting or the context, but the way in which they are applied. These may vary and will require judgement.

Table 1: Some of the diverse settings in which students may become involved with the care of patients

Hospital care
• Clinics
• Emergency departments
• Intensive care units
• Neonatal units
• Operating rooms – In a surgical or anaesthesia context
• Psychiatry units
• Wards, adult or paediatric
Primary care or community care
• After-hours community clinics
• Air ambulances
• Ambulances
• Audiology clinics
• Community nursing clinics
• General practices
• Health care trusts
• Hospice
• Patients' homes
• Pharmacies
• Podiatrist clinics
• Private specialist clinics
• Rest homes
• Retinal screening clinics

On the whole, most patients welcome medical student involvement and understand the importance of training doctors (and other health professionals) for the future. The majority of patients say "yes" when they are asked about such involvement, and complaints about students are very rare.¹⁻³ Thus, the process by which consent is obtained can and should be proportional to the involvement of the medical student and the nature of the interaction and consequent risk or inconvenience to the patient. It is not appropriate

to overstate the implications of the simple involvement of students, particularly as observers, and to do so may even have the perverse consequence of adding unnecessarily to the stress felt by some patients. 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.

The interactions between patients and medical students often occur in very busy settings in which clinical staff are under pressure, turnover of patients is rapid, and the opportunities to ask for consent are limited. Pragmatic solutions will be helpful in ensuring that the consent process is not unsettling or arduous for patients nor unworkably onerous for staff, but in the end the need to gain consent cannot be set aside on the grounds of inadequate time or resource. Irrespective of the context of the interaction, or the workload, patients should never feel coerced or pressured into providing consent.

There are some common principles about how consent should be obtained and by whom. These are outlined in the next section, and illustrated by examples and lists in boxes and tables.

Principles pertaining to informed consent for the presence of a medical student during the care of patients

1. Consent for the involvement of students in patient care is required by the Health and Disability Commissioners' (HDC) *Code of Health and Disability Services Consumers' Rights* ('the Code'—see Rights 5,6,7 and 9). It is also an important aspect of building rapport with patients, and of maintaining the trust and goodwill that exists between patients and the health professionals who care for them—including medical students.
2. Organisations that care for patients have a responsibility to ensure that appropriate consent is obtained for all aspects of patient management, including the involvement of medical students in the care of patients. Therefore, the workplace environment should facilitate the gaining of such consent. To this end, general measures should be implemented to promote awareness that the organisation is involved with teaching and that medical students might be involved in patient care (see Table 2).
3. The primary responsibility for ensuring that consent is obtained for the involvement of a medical student in a patient's care lies with the registered health professionals responsible for that patient at the time (see Box 1).
4. The HDC considers medical students who are providing care to be healthcare providers, and they are therefore also accountable for ensuring that consent has been given before they become involved in patients' care.

Table 2. Some general measures to promote awareness that students might be involved in patients care. Some or all of these may apply in various settings, including (for example), hospital wards, general practices, and outpatient clinics.

- Policies
- Signage
- Pamphlets for patients (available or given on admission)
- An appropriate section on forms for consent to anaesthesia and surgery
- Informed in letters sent to patients about other matters, such as confirmation of outpatient visits
- The practice, by doctors and nurses, of routinely mentioning to patients the possibility that students may be involved in their care (at least as observers) and of the possibility that patients can refuse student involvement

Box 1. Patients on wards and the responsibility for seeking consent

On ward rounds, students should be introduced to patients as part of the team (explicitly as *student* members of the team) by the doctor conducting the round. Students may also initiate introducing themselves to patients where appropriate.

Before students on wards seek out patients with educationally valuable presentations and take a history or perform an examination on them, they must seek permission from an appropriate member of that patient's healthcare team (doctor, charge nurse or nurse caring for the patient) to approach the patient. Once permission has been obtained to approach the patient, the student should gain verbal consent from that patient for history taking and examination. It may be prudent for the student to record this in the patient notes with an entry such as: "Bill Smith, Year 4 medical student, examined Mrs Jones – verbal consent obtained". An additional benefit of this approach is that the record would clearly indicate how many students had interacted with that patient, and be helpful in ensuring that a patient is not approached too often.

It should often be possible for a senior doctor, interested in teaching and keen to encourage students to see patients, to obtain permission from patients at a convenient time (eg, on a ward round) for students to seek consent to obtain histories or conduct examinations. Thus the burden of establishing which patients are open to such approaches need not be excessive.

5. Medical students should actively assess how comfortable patients and their family/whānau are with their involvement in care. If they perceive patients or their family/whānau to be uncomfortable, they should have a low threshold for disengaging. This is a matter of basic courtesy and ongoing sensitivity to the rights and comfort of patients.
6. Informed consent should be sought with respect and compassion for patients, taking into account their circumstances and vulnerabilities at the time (see Box 2).

Box 2. An example of a potentially difficult situation in seeking consent for a medical student's involvement in the care of a patient

A patient is unclothed and surrounded by the healthcare team, and asked to consent to a student examining her abdomen, with the student in the room.

Patients differ in their assertiveness and in how empowered and robust they feel at any particular time. It might be quite difficult for a patient in this situation to decline in the presence of a student. It may be better for the consultant to ask the patient privately, if they consent to students being present and, if the patient consents, to then ask if one (or perhaps two) of them could examine her abdomen during the round.

7. Patients need to know that they do have a choice about the involvement of medical students, and that they are entitled to change their mind at any time about such involvement, without any negative consequences for their care. The patient's right to refuse consent or withdraw consent takes precedence over the provision of training for students. For many purposes, notably many instances of observation, it is appropriate to obtain (or confirm) consent verbally and informally; for other purposes it is prudent for the consent to be documented, or even obtained in writing, with a signature from the patient (see Point 16). Note that there is a legal requirement for signed consent for procedures under anaesthesia.
8. Language is key to communication: If a patient is not competent in English (eg, because this is not his or her first language) then a competent interpreter must be used to obtain consent for the involvement of medical students; this can often be done during the more general processes of patient care, which will also require an interpreter.
9. Patients need to understand clearly what a medical student is (see Box 3).

Box 3. The need to explain what a medical student is

It may seem surprising, but many patients don't seem to understand the term 'medical student' unless it is explained. The term 'student doctor' is probably even less well understood, so 'medical student' is probably preferable. A brief clarification should be included in general informational material provided to patients, and this should be reinforced during conversations about medical students' involvement in patients' care. Name badges clearly indicating that the wearer is a medical student are also important.

10. As far as reasonably possible, patients should be informed about the proposed extent and nature of student involvement. There are three ways in which students may become involved in patients' care, although in reality the distinction is blurred, as any interaction with a student contributes to a patient's care (Box 4):
- Students may observe patients, or examine them, or carry out or assist with procedures on them for their educational benefit as students, or
 - Bedside tutorials, when a senior doctor conducts a tutorial with a group of medical students, usually focused around examination of a patient the doctor may or may not be clinically involved with, or
 - Students may contribute to the care of patients, under supervision (eg by taking blood, holding a

retractor during a surgical procedure, or performing bag-mask ventilation under anaesthesia).

11. Patients who are temporarily or permanently incompetent to make an informed decision are particularly vulnerable (see Table 3 and Boxes 5 and 6). In such circumstances, consent should be obtained from the patient's legal representative if one exists and it is practical and possible. If no legal representative exists, then any views ascertained from the patient should be taken into account. If this is not possible, the views of other suitable, available persons who are interested in the patient's welfare should be taken into account. When there is no practical opportunity to obtain permission, student involvement under supervision may entail observation, history taking and general examination, unless the treating doctor decides that greater student involvement remains in the best interests of the patient. Judgement and experience is needed in respect of children under 16 years old. The consent process with children is complex. In some situations, the child may be able to consent for themselves. In other cases, the child's parent or guardian may need to make a decision for the child. Where this occurs, the assent of the child should also be obtained, as appropriate and possible. The principles remain the same, but in many cases eg, neonatal intensive care,

Box 4. Ways in which students may become involved with patients' care, and how they might explain this

An interaction with a patient on a ward might begin by a consultant saying something like "I have spoken with Mrs Jones in bed seven and she is willing to have one student listen to her heart and another student take some blood."

In case a) a student might say something like, "Hello Mrs, Jones. My name is Helen. I am a medical student. That means I am training to be a doctor. I am in my fourth year of medical training. I understand from Dr Smith that you have a medically important heart condition. Would you mind if I listened to your heart with a stethoscope and examined your heart and a few other things that might be affected by your condition, so that I can learn about it? Please feel free to say no if you prefer."

In case b) a student might say something like, "Hello Mrs, Jones. My name is Bill. I understand from Dr Smith that you need a blood test taken. I am a medical student. That means I am training to be a doctor. I am in my fifth year of medical training and have been taught how to take blood for blood tests. Do you mind if I take your blood sample, instead of the phlebotomist?"

In either case the student should make a brief entry in the patient's notes documenting his or her involvement.

there may be a parental perception that their child is too vulnerable to be examined by anyone other than an expert. This requires particular sensitivity and reassurance. Often the consent will be for the teacher to examine the child in front of students, rather than hands on, and it is obviously important to invite the parents to be present if possible.

Table 3. Some examples in which a patient might not be competent to make a decision or give consent.

- Under anaesthesia
- On a ventilator under sedation in an Intensive Care Unit
- During sedation (including so called "conscious sedation")
- Very young patients
- Mentally or cognitively impaired patients or patients who are semi-conscious
- Patients impaired with alcohol and drugs
- Patients in shock, extreme pain or extreme distress
- Patients who are dying

Box 5. Patients in intensive care under sedation and/or on ventilators

It is important for intensive care units to have information available in the form of signage and pamphlets explaining that students may be present and may be involved in the care of patients. Given that most patients in intensive care units are very vulnerable, this is a situation where principle 11 applies. Except where it is possible and appropriate to obtain explicit consent for greater involvement, the role of medical students in intensive care units should usually be restricted to observation.

12. Some circumstances require a particularly high level of sensitivity to the potential vulnerability of patients and their families (See Table 4); in such circumstances meticulous care is required in seeking and documenting consent for the involvement of medical students.

Table 4. Examples of circumstances in which the potential vulnerability of patients or their families is increased, and in which extra sensitivity is appropriate regarding the need for informed consent for student participation

- Sensitive examinations (particularly under anaesthesia)
- Discussion of withdrawal of life support
- Discussion of organ donation
- The breaking of very bad news (which will be contextual for the patient)
- Catheterisation
- Patients with rare or particularly interesting conditions
- Patients who feel under obligation to their treating clinician
- Retrieval of patients from a referring hospital

13. Sensitive examinations (includes breast, rectal, vaginal examinations and those of the external genitalia) in competent awake patients require explicit consent. This can be verbal but should be documented in the patient's notes. It is essential that there should be no possibility for the consent to have any element of coercion (eg, it may make it harder for a patient to refuse if the patient is asked after undressing or in front of student. See Box 2).
14. Sensitive examinations under anaesthesia require formal written consent obtained in advance and signed by the patient. It is essential that there should be no possibility for the consent to have any element of coercion (eg, asking in front of a student may make it harder for a patient to refuse). Without such consent a student cannot undertake such activity.
15. A section should be included on the forms used to document generic consent for the involvement of medical students in observing or contributing to surgery, anaesthesia and other basic procedures undertaken in operating theatres, under direct supervision of an appropriate

Box 6. Some practical points about anaesthesia attachments

Students allocated to an anaesthetic run may anticipate attending a particular list with a particular anaesthetist, and that anaesthetist may obtain consent from the relevant patients. However, on the day there may be scheduling changes such that there is little educational value in this list, while a much more educationally rewarding list is occurring in one of the other theatres. In fact, the best utilisation of time may come from moving between lists during the day as opportunities present. Generic consent obtained from all patients at the time of their consent to surgery will facilitate this. Therefore it is ideal for such generic consent to be obtained at the same time as consent for anaesthesia and surgery, as a matter of routine.

It is important to recognise that some patients may decline permission for students to be present, and a system will be needed to ensure that these patients are clearly identified, and that students do not inadvertently transgress their wishes.

Table 5. Examples of things typically included (under direct supervision) and excluded from general consent for students to be involved in surgery and anaesthesia; the latter require explicit consent.

Included, basic procedures, such as:

- Observation
- Bag mask ventilation
- Holding a retractor
- Examining surgical pathology or normal anatomy

Excluded, more substantive procedures, such as:

- Any sensitive examination
- Endotracheal intubation (because there is a risk of damage to teeth or even of causing a sore throat)
- Insertion of an IV line or arterial line
- Closing wounds, including surgical incisions

Box 7. An unexpected surgical finding

Where a student on a surgical run is observing a surgical procedure, there may be an unexpected finding that he or she would benefit from scrubbing in and examining. It would be reasonable for generic consent to cover such a situation in most instances. However, it wouldn't be appropriate for multiple students to examine the finding in a single anaesthetised patient, and any examinations of a sensitive nature must be the subject of explicit consent, which must be in writing.

Box 8. Primary or community care

Health care providers in primary or community care settings agree to undertake student supervision through Clinical Access Agreements. In each case there will be a primary supervisor who has completed the Clinical Access Agreement and is responsible for ensuring appropriate consent is obtained for students to be involved in the care of patients.

As always, signage and pamphlets are important for informing patients about the likelihood that they will meet medical students in a particular practice or setting. For example, in general practice, a notice should be placed facing the patient waiting room, stating words to the effect that this is a teaching practice and students may be involved in the delivery of health care. A member of staff (such as the receptionist) should be expressly asked to draw the sign to the attention of patients when they arrive, and to check with them on each visit that they are comfortable with the presence of students.

Before the start of the consultation, the GP should ask the patient if he or she is comfortable for the medical student to be involved in the interview, observation or procedure. Opportunity for the patient to decline this request must be given, so this request should take place without the student present. The principles of consent related to patients undergoing sedation or sensitive examinations are the same as for any other setting.

registered health professional (note Right 7.6 of the Code). The important element of seeking such consent is, as always, the conversation between the doctor gaining consent and the patient.

16. Generic consent obtained under 15 should be understood as limited to observation and basic procedures and should not be taken as consent to conduct sensitive examinations while under anaesthesia or procedures with any material risk (see Table 5). Such examinations or procedures require explicit, and in some cases, including sensitive examinations, written consent.
17. In primary care settings (see Table 1 and Box 8), where students might accompany registered health professionals on visits to patients' homes or their rooms in a rest home, verbal consent for the student to enter the room or house should be sought from the patient and/or family/whānau who might be present. Where possible this should be done before the visit.
18. Patients' medical records are confidential and medical students should only access such records in line with a purpose that has been notified to the patient at the point of collection. There must be a genuine educational reason to do so, and with the permission of the health professionals responsible for the patient's care. It is reasonable to construe consent for a student to be involved in a patient's care as including consent for that student to read relevant patient records, but it would

usually be courteous to mention this point to patients.

19. Students must respect the confidentiality of all information acquired by them in connection with patients. Under no circumstances should students disclose any information whatsoever on any form of social media about the patients they have been involved with, even in the absence of specific identifying information.

The above text is a consensus statement that was agreed by multiple stakeholders, after careful and considered consultation to provide a guideline. The paper is not intended to set standards but rather to outline New Zealand's existing legal and regulatory requirements in a practical way.

The paper is intended to provide guidance to medical students and supervising doctors in clinical settings. We have limited its scope to medical students for pragmatic reasons. Similarly, we have not attempted to cover every possible clinical situation where consent is required in relation to the training of medical students, but instead have chosen examples to illustrate the principles in some settings that we think may be particularly challenging. Notwithstanding these limitations, we hope this consensus statement will prove useful in clarifying expectations for informed consent in this context in New Zealand today.

We hope that this consensus statement will engender discussion within our hospitals and universities, and in the correspondence section of the *Journal*. This will inform a planned revision of the statement after it has been in use for a year. It may also be appropriate to expand its scope at that time.

Competing interests: Nil

Note:

The NZMA Ethics Committee, MCNZ Consumer Advisory Group and HDC have been consulted.

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Excerpts from the Code of Ethics of the New Zealand Medical Association (NZMA)

Code of ethics

All medical practitioners, including those who may not be engaged directly in clinical practise, will acknowledge and accept the following Principles of Ethical Behaviour:

1. Consider the health and well-being of the patient to be your first priority.
2. Respect the rights, autonomy and freedom of choice of the patient.
3. Avoid exploiting the patient in any manner.
4. Practise the science and art of medicine to the best of your ability with moral integrity, compassion and respect for human dignity.
5. Protect the patient's private information throughout his/her lifetime and following death, unless there are overriding considerations in terms of public interest or patient safety.
6. Strive to improve your knowledge and skills so that the best possible advice and treatment can be offered to the patient.
7. Adhere to the scientific basis for medical practise while acknowledging the limits of current knowledge.
8. Honour the profession, including its traditions, values, and its principles, in the ways that best serve the interests of the patient.
9. Recognise your own limitations and the special skills of others in the diagnosis, prevention and treatment of disease.
10. Accept a responsibility to assist in the protection and improvement of the health of the community.
11. Accept a responsibility to advocate for adequate resourcing of medical services and assist in maximising equitable access to them across the community.
12. Accept a responsibility for maintaining the standards of the profession.

Guide to the ethical behaviour of physicians

The profession of medicine has a duty to safeguard the health of the people and minimise the ravages of disease. Its knowledge and conscience must be directed to these ends. Ethical codes have developed to guide the members of the profession in achieving them. The Hippocratic Oath was an initial expression of such a code. More recent codes have developed from this and from a consideration of modern ethical dilemmas and these are embodied in a number of important declarations, international codes and statements from the World Medical Association. These include:

1. The Declaration of Geneva (1948, amended in 1968, 1983, 1994, 2005, 2009)
2. The World Medical Association International Code of Medical Ethics (1949, 1968 and 1983, 2004)
3. The following statements by the World Medical Association which deal with particular issues:
 - The Declaration of Helsinki dealing with biomedical research (1964, 1975 and 1983, 1989, 1996, 2000, 2002, 2004, 2008).

- The Declaration of Oslo on therapeutic abortion (1970, 1983, 2006).
- The Declaration of Tokyo on a doctor's responsibility towards prisoners (1975, 2005, 2006).
- The Declaration of Lisbon on patient's rights (1981, 1995, 2005).
- The Declaration of Venice which deals with terminal illness (1983, 2006).
- The Declaration of Ottawa on child health (1998, 2009).
- The Declaration of Washington on patient safety (2002).
- The Declaration of Madrid on euthanasia (1987, 2005).
- The Declaration of Delhi on health and climate change (2009)

For latest updates and new Declarations, regularly check the website of the World Medical Association, www.wma.net

These have been endorsed by each member organisation, including the New Zealand Medical Association, as general guides having worldwide application.

The New Zealand Medical Association accepts the responsibility of delineating the standard of ethical behaviour expected of New Zealand Medical Practitioners.

An interpretation of these principles is developed in the following pages, as a guide for individual doctors.

Responsibilities to the patient

1. Standard of care

Practise the science and art of medicine to the best of one's ability in full technical and moral independence and with compassion and respect for human dignity.

2. Continue self-education to improve one's personal standards of medical care.
3. Ensure that every patient receives a complete and thorough examination into their complaint or condition
4. Ensure that accurate records of fact are kept

5. Respect for patient

Ensure that all conduct in the practise of the profession is above reproach, and that neither physical, emotional nor financial advantage is taken of any patient.

6. Patient's right

Recognise a responsibility to render medical service to any person regardless of colour, religion, political belief, and regardless of the nature of the illness so long as it lies within the limits of expertise as a practitioner.

7. Accepts the right of all patients to know the nature of any illness from which they are known to suffer, its probable cause, and the available treatments together with their likely benefits and risks.
8. Allow all patients the right to choose their doctors freely.
9. Recognise one's professional limitations and, when indicated, recommend to the patient that additional opinions and services be obtained.
10. Keep in confidence information derived from a patient, or from a colleague regarding a patient, and divulge it only with the permission of the patient except when the law

requires otherwise.

11. Recommend only those diagnostic procedures which seem necessary to assist in the care of the patient and only that therapy which seems necessary for the well-being of the patient. Exchange such information with patients as is necessary for them to make informed choices where alternatives exist.
12. When requested, assist any patient by supplying the information required to enable the patient to receive any benefits to which he or she may be entitled.
13. Render all assistance possible to any patient where an urgent need for medical care exists.

Continuity of care

Ensure that medical care is available to one's patients when one is personally absent. When professional responsibility for an acutely ill patient has been accepted, continue to provide services until they are no longer required, or until the services of another suitable physician have been obtained.

Personal morality

When a personal moral judgement or religious conscience alone prevents the recommendation of some form of therapy, the patient must be so acquainted and an opportunity afforded the patient to seek alternative care.