



Consent and provision of information to patients in Australia regarding proposed treatment

This statement has been developed and reviewed by the Women's Health Committee and approved by the RANZCOG Board and Council.

A list of Women's Health Committee Members can be found in Appendix A.

Disclaimer This information is intended to provide general advice to practitioners. This information should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The document has been prepared having regard to general circumstances.

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Objective: The purpose of this statement is to assist doctors with some of the legal principles and guidelines that apply in Australia to the issues of patient consent and the duty to inform.

Target audience: Clinicians providing obstetric and gynaecological care, and patients.

Background: This statement was first developed in 1993 and most recently reviewed in March 2020.

Funding: The development and review of this statement was funded by RANZCOG.

1. Plain language summary

The person undergoing medical care has the right to make an informed choice about their care and, in most instances, must give permission to proceed with treatment. This permission is called informed consent and it is an interactive process between the doctor, the patient and sometime those close to the patient, such as their family.

It is the doctor's responsibility to ensure informed consent is obtained, and to communicate and work with their patient to help them make the best decision for themselves. The doctor undertaking the treatment is responsible for the overall informed consent process. The patient has the right to withdraw consent and refuse treatment.

2. Introduction

The purpose of this statement is to assist doctors with some of the legal principles and guidelines that apply to the issues of patient consent and the duty to inform in Australia.

Informed consent is a person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved. Good medical practice involves:

- Providing information to patients in a way that they can understand before asking their consent.
- Obtaining informed consent or other valid authority before you undertake any examination, investigation or provide treatment (except in an emergency).
- Ensure that your patients are informed about your fees and charges.
- When referring a patient for investigation or treatment, advising the patient that there may be additional costs, which patients may wish to clarify before proceeding.
(reference MBA Good practice guidelines)

Obtaining consent is an interactive process, not a one-off event. It is a process of shared decision-making where the doctor helps the patient understand their medical condition and the options for treating (or not treating) that condition. It is more than signing forms and completing paperwork. Take the time to ask questions so that you understand what matters to your patient, and what their concerns, wishes, goals and values are.

In obtaining consent, the relevant jurisdictional law must be observed, so Fellows are advised to seek information about the laws which apply in their country, State or jurisdiction in addition to the information provided in this statement.

3. Duty to inform of risks

It is the responsibility of the treating doctor to provide the patient with as much information about the proposed intervention as is practically possible, before obtaining the patient's consent.

The patient should be provided with all relevant information that is necessary to allow her to make an informed decision about treatment.

The law requires that a doctor has a duty to warn a patient of a material risk inherent in any proposed procedure or treatment.

A risk will be considered material if, in the circumstances of the particular case, a reasonable person in the position of the patient, if warned of the risk, would be likely to attach significance to it, OR if the medical doctor is aware, or should reasonably be aware, that the particular patient, if warned of the risk, would be likely to attach significance to it.

Thus, when considering the need to inform a patient of a particular risk, there will be two separate matters that require consideration:

1. Would a reasonable person, in the position of the patient, be likely to attach significance to the risk?
2. Is the doctor aware, or should the doctor be reasonably aware, that this particular patient would be likely to attach significance to that risk?

Having regard to these questions, ask whether, if informed of the risk, the patient might change their mind about having the treatment or procedure.

Treating doctors should also keep in mind that their legal obligation to inform a patient of a proposed treatment and/or examination is non-delegable. Therefore, while time constraints, for instance, may cause a treating doctor to have a junior doctor explain to the patient the nature of the proposed operation, if a junior doctor fails to properly discharge the treating doctor's responsibility, the fault lies with the treating doctor.

The National Health and Medical Research Council's *General Guidelines for Medical Practitioners on Providing Information to Patients* lists several matters it believes treating doctors must discuss with their patients before conducting an examination and/or treatment:

1. The possible or likely nature of the disease or illness the doctor proposes to treat;
2. The proposed approach to investigation, diagnosis and treatment:
 - What the proposed approach entails;
 - The expected benefits;
 - Common side effects and material risks (Test: Would a reasonable person in the patient's position attach significance to the risk if it were explained to them fully?);
 - Whether intervention is experimental or conventional; and
 - Who will conduct the intervention?
3. The degree of uncertainty of any diagnosis arrived at;
4. The degree of uncertainty as to any therapeutic outcome;
5. The likely consequences of not choosing the proposed diagnostic procedure or treatment, or of not having any procedure or treatment at all;
6. Any significant long term physical, emotional, mental, social, sexual or other outcome associated;
7. The time involved;

8. The costs involved, including out of pocket costs (i.e. not just those covered by health insurance, if any).

The NHMRC also recommends that treating doctors encourage patients to ask questions about what is being proposed and the financial implications of undergoing the treatment. This not only includes the patient in the decision-making process, but also enables the treating doctor to gauge the patient's concerns and ascertain what the patient deems to be important. In obtaining consent for treatment, doctors have a duty to answer all patients' requests for information. Clear and precise written or audio-visual information can be used, but only to complement any information a doctor provides to a patient verbally.

It is also useful to note that while standard consent forms can be of some use, they are **not** a sufficient substitute for actual medical advice provided in a consultation between patient and treating doctor.

In some instances a patient may indicate that he or she does not wish to be fully informed about a proposed treatment. While the doctor is not required to burden a patient with unwanted information, the doctor is still obligated to explain the procedure to the patient (at least in broad terms), the alternatives to the treatment, the likelihood of a satisfactory outcome, and the more serious and common possible side effects or complications. Information should not be withheld from a patient unless the doctor believes that the patient's physical or mental health could be seriously harmed by provision of the information.

Doctors should also keep clear, contemporaneous notes of the advice and information with which they have provided a patient, including the specific risks that have been discussed and the provision of information or literature (if any). It may be that a reference to the advice given is needed in a letter to a referring doctor. Where appropriate, a note should be made of the fact that the patient has received written or other information in a set form.

4. Capacity to consent

The consent of a patient who is not legally competent is not valid. The more obvious categories of legally incompetent patients are those who are intellectually disabled or unconscious. Doctors must assess the competence of each patient. If a patient is not competent to consent to treatment, the consent of a guardian, a person charged with the patient's medical treatment by power of attorney, or sometimes even a court must be obtained before the examination or treatment of the patient can proceed. If the doctor is unsure whether or not a patient is competent to consent to treatment, the doctor should seek a second opinion from a medical professional qualified to make a capacity assessment (for example, a neuropsychologist or psychiatrist) or seek legal advice (e.g. from his or her medical defence organisation).

In the case of an unconscious patient or an emergency situation where urgent treatment is needed to save life or avoid serious harm, the law recognises that full information cannot always be provided to the patient, and that it is not always possible to obtain consent. While it is also wise to consult family relatives (if possible) in such situations, doctors must always act in the best interests of the patient.

5. Consent from children

Where the patient is a child, and consent has not been obtained from both the child and the parent(s), complex issues as to consent arise. The obvious question is whether the child's consent is enough on its own. One school of thought is that a child may consent to medical treatment if the treating doctor is convinced:

1. That the child is sufficiently intelligent; and
2. That the child sufficiently comprehends:
 - What the doctor is proposing;
 - The nature of the treatment; and
 - The consequences and risks of the treatment.

In providing care to children, there are specific statutory requirements in some jurisdictions relating to consent to treatment and refusal of treatment. Doctors must be aware of the relevant requirements in their jurisdiction. The safest option is, whenever possible, to seek the consent of a parent or guardian, especially if a major intervention is proposed. Where this is not possible, doctors should seek a second opinion from a colleague and/or their medical defence organisation.

6. Obtaining consent from patients whose first language is not English

When a patient's first language is not English, the medical practitioner must assess whether the patient has a sufficient understanding of the information provided to consent to the treatment (taking into consideration both the complexity of the issues and the patient's proficiency in English). If an interpreter is required, it is highly desirable that an independent, professionally qualified health interpreter assist, either in person or by telephone.

The Australian Government, through the *Translating and Interpreting Service National*, offers a free telephone interpreting service (131 450) to assist doctors in private practice providing Medicare-rebatable services to non-English speaking Australian citizens or permanent residents. It undertakes to provide interpreters in major community languages within three minutes.

If a professionally qualified interpreter is not available (or is not acceptable to the patient), assistance may be sought from family members or bilingual staff.

7. Consent while teaching and supervising

Teaching, supervising and assessing other doctors, clinical staff and students is important for their development and for the care of patients. Creating opportunities for learning improves their clinical practice and nurtures the future workforce. Patients' permission should be obtained in advance if students or observers attend the consultation or participate in the patient's care. Particular attention

should be given to situations where sensitive issues are discussed and explicit consent must be obtained for any intimate examination.

Good medical practice includes:

- Making the scope of the student's role in patient care clear to the student, to patients and to other members of the healthcare team.
- Informing your patients about the involvement of students and obtaining their consent for student participation while respecting their right not to consent. This should specifically include explaining:
 - The status and clinical experience of those attending
 - The role and involvement of those attending (such as whether they will be observing or participating in the care by taking a history or examining the patient)
 - What is expected of those attending
 - That at any point in time they have the right to refuse the involvement of those attending.

8. Demonstration procedures

Where a Fellow is a visiting surgeon conducting a demonstration/ teaching session for peers on a patient of another practitioner, the visiting surgeon must still undertake a consultation covering the nature and teaching format for the surgery, and obtain written consent from the patient for the procedure. This is necessary even if the patient's treating specialist has already undertaken a consultation and obtained consent (as the treating specialist may not have been in a position to give full details of the demonstration surgery and possible complications).

Fellows are also referred to the College Statement (C-Gen 6) Guidelines for Visiting Surgeons Conducting Demonstration Sessions for additional information; see link below.

9. Links to other College statements

Consent and provision of information to patients in New Zealand regarding proposed treatment (C-Gen 2b)

[https://ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Consent-and-provision-of-information-NZ-\(C-Gen-2b\).pdf?ext=.pdf](https://ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Consent-and-provision-of-information-NZ-(C-Gen-2b).pdf?ext=.pdf)

Guidelines for visiting surgeons conducting demonstration sessions (C-Gen 06)

[https://ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Guidelines-for-visiting-surgeons-conducting-demonstration-sessions-\(C-Gen-6\)-Mar-18.pdf?ext=.pdf](https://ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Guidelines-for-visiting-surgeons-conducting-demonstration-sessions-(C-Gen-6)-Mar-18.pdf?ext=.pdf)

Evidence-based Medicine, Obstetrics and Gynaecology (C-Gen 15)

https://www.ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-

Consent and provision of information to patients in Australia regarding proposed treatment
C-Gen 2(a)

[MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Evidence-based-medicine,-Obstetrics-and-Gynaecology-\(C-Gen-15\)-Review-March-2016.pdf?ext=.pdf](http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/e57.pdf)

11. Other suggested reading

National Health and Medical Research Council. General Guidelines for Medical Practitioners on Providing Information to Patients. 2004. Available at:

<http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/e57.pdf>

National Health and Medical Research Council. Communicating with Patients: Advice for Medical Practitioners. 2004. Available at:

<http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/e58.pdf>

12. Links to services

Doctors' Priority Line, Translating and Interpreting Service National – Telephone 131 450 or see:

http://www.immi.gov.au/living-in-australia/help-with-english/help_with_translating/free-services.htm

Appendices

Appendix A Women's Health Committee Membership

Name	Position on Committee
Professor Yee Leung	Chair and Board Member
Dr Gillian Gibson	Deputy Chair, Gynaecology
Dr Scott White	Deputy Chair, Obstetrics and Subspecialties Representative
Associate Professor Ian Pettigrew	Member and EAC Representative
Dr Kristy Milward	Member and Councillor
Dr Will Milford	Member and Councillor
Dr Frank O'Keefe	Member and Councillor
Professor Steve Robson	Member
Professor Sue Walker	Member
Dr Roy Watson	Member and Councillor
Dr Susan Fleming	Member and Councillor
Dr Sue Belgrave	Member and Councillor
Dr Marilyn Clarke	ATSI Representative
Associate Professor Kirsten Black	Member
Dr Thangeswaran Rudra	Member
Dr Nisha Khot	Member and SIMG Representative
Dr Judith Gardiner	Diplomate Representative
Dr Angela Brown	Midwifery Representative, Australia
Ms Adrienne Priday	Midwifery Representative, New Zealand
Ms Ann Jorgensen	Community Representative
Dr Rebecca Mackenzie-Proctor	Trainee Representative
Dr Leigh Duncan	Maori Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Christine Sammartino	Observer

Appendix B Overview of the development and review process for this statement

i. Steps in developing and updating this statement

This statement was originally developed in September 1993 and was most recently reviewed in March 2020. The Women's Health Committee carried out the following steps in reviewing this statement:

- Structured clinical questions were developed and agreed upon.

- An updated literature search to answer the clinical questions was undertaken.
- At the March 2020 committee meeting, the existing consensus-based recommendations were reviewed and updated (where appropriate) based on the available body of evidence and clinical expertise. Recommendations were graded as set out below in Appendix A part ii).

ii. *Grading of recommendations*

Each recommendation in this College statement is given an overall grade as per the table below, based on the National Health and Medical Research Council (NHMRC) Levels of Evidence and Grades of Recommendations for Developers of Guidelines. Where no robust evidence was available but there was sufficient consensus within the Women’s Health Committee, consensus-based recommendations were developed or existing ones updated and are identifiable as such. Consensus-based recommendations were agreed to by the entire committee. Good Practice Notes are highlighted throughout and provide practical guidance to facilitate implementation. These were also developed through consensus of the entire committee.

Recommendation category		Description
Evidence-based	A	Body of evidence can be trusted to guide practice
	B	Body of evidence can be trusted to guide practice in most situations
	C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
	D	The body of evidence is weak and the recommendation must be applied with caution
Consensus-based		Recommendation based on clinical opinion and expertise as insufficient evidence available
Good Practice Note		Practical advice and information based on clinical opinion and expertise

Appendix C Full Disclaimer

This information is intended to provide general advice to practitioners, and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient.

This information has been prepared having regard to general circumstances. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual patient and the particular circumstances of each case.

This information has been prepared having regard to the information available at the time of its preparation, and each practitioner should have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available.