INFORMED CONSENT

BACKGROUND

Patients are entitled to make their own decisions about treatment. To do so they need access to appropriate and readily understandable information about treatment options, associated risks and the expected outcomes. Surgeons should give advice, with no coercion. Disclosure of information and discussion is best performed by the surgeon who will be conducting the treatment. The patient should be free to accept or reject the advice offered. The process of Informed Consent has legal ramifications. If in doubt, the Royal Australasian College of Surgeons (RACS) recommends that a surgeon seek appropriate legal advice.

PRINCIPLES

The following principles apply to the process of obtaining informed consent:

1. **Open dialogue**: An open dialogue between surgeons and patients is crucial for informed consent discussions. High importance should be given to patients and their families on receiving such information about their health and their concerns in a frank and honest way.

2. **Information for Patients**: Information concerning the medical condition, investigation options, treatment options, benefits, possible adverse effects of investigations or treatment, and the likely result if treatment is not undertaken, should be provided. Complete information on predicted outcomes and risks cannot be determined with absolute certainty.

3. **Respect and Clarity**: Sensitivity should be given when patients may be sick, injured or traumatised, or along with their relatives, feel anxious about a procedure. Clarity and simplicity in language is recommended. Respect must be given to a competent patient making their own decisions about their medical treatment and their right to grant, withhold or withdraw consent before or during examination, investigation, or treatment.

4. **Legality**: Whilst RACS produces policies and guidelines that may be consulted in disciplinary or civil proceedings to help decide whether the surgeon has behaved reasonably in giving information, it is ultimately the role of the courts, tribunals or commissions to decide the reasonableness of the surgeon's behaviour in any given case. The legal duty to warn patients of risks is covered under common law.[1]

GUIDELINES FOR OBTAINING INFORMED CONSENT

The relationship between a surgeon and their patient can be unbalanced based upon the difference between the surgeon's and patient's clinical knowledge and medical expertise. RACS understands that obtaining informed consent can be a difficult task and recommends the following:

1. **Content**: Discussion should be inclusive of:

   a) The possible or likely nature of the illness or disease
   b) The proposed approach to investigation, diagnosis and treatment
   c) The expected benefits
   d) Common adverse effects and material risks of any intervention
   e) Whether the intervention is conventional or experimental
   f) Who will undertake the intervention
   g) Other options for investigation, diagnosis and treatment
   h) The degree of certainty of any diagnosis

[1] *Rogers v Whitaker* (1993) 67 ALJR 47 which helped to define that a medical practitioner had a duty to warn about the risks associated with a medical procedure.

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i) The degree of certainty about the therapeutic outcome
j) The likely consequences and risks of not choosing a diagnostic procedure or treatment, or of not having any treatment
k) Any significant long-term physical, emotional or other outcome which may be associated with the proposed intervention
l) The time involved for recovery
m) The expected costs involved, including out-of-pocket costs (see position papers on Surgeons Fees and Informed Financial Consent)

2. **Risk:** Information concerning the risks of any intervention that may influence the patient's decision to proceed must be given alongside any known risks and adverse outcomes, no matter how slight or rare in severity. There is a legal duty to warn patients of any risks. One approach would be for the surgeon to first ask themselves the following questions:

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

3. **Conveying the Information**: A surgeon's judgment is crucial when determining what information concerning risk needs to be conveyed to their patient – medico legal cases involving informed consent can revolve around whether a doctor failed to meet the required standard of care. The liability rests with the treating surgeon to provide their patient with specific individualised information. In conveying information, the following should be considered:

   a) The seriousness of the patient's condition
   b) The nature of the intervention
   c) Whether the procedure is complex or straightforward, or whether it is necessary or purely discretionary? Complex interventions require more information, as do interventions where the patient has no symptoms
   d) The higher the risk of the intervention or procedure having an adverse outcome, the more necessary it is to inform of risks and consequences
   e) The desire for information by the patient
   f) The temperament and health of the patient
   g) The existence of emergency situations, or lack of opportunity for proper counselling or discussion, which may affect the obligations to disclose
   h) Where special issues arise in relation to obtaining consent and giving adequate information regarding children, teenagers, the intellectually disabled and those where English is not the first language

4. **Presenting the Information:** Information should be presented in a manner appropriate to the patient's situation. Information should help a patient understand the illness, manage options and show reasons for any intervention. If necessary, this could be spread over more than one session either in written form or orally. Patient questions should be encouraged. After a session has been completed, reasonable time should be given to the patient to reflect or consult their family and others. The use of a competent interpreter where the patient is not fluent in English is recommended (It is preferred that such an interpreter be a trained medical interpreter and not a family member; although this may not always be possible).

5. **Withholding Information**: A surgeon's discretion is required when in extraordinary circumstances, information may need to be withheld from the patient on reasonable grounds that the patient's physical or mental health may be seriously harmed . If the patient does not want the offered information, the doctor still has a legal duty to advise the patient of material risks as well as basic information concerning their illness and proposed intervention. If in doubt, the surgeon must seek to obtain appropriate legal advice.

6. **Jurisdiction**: Different jurisdictions may be bound by different laws. These are covered by legislation concerning power of attorney, guardianship, blood transfusions for children without parental consent, legal representation, law relating to end-of-life choices, and similar legislation. Other laws may influence how records are kept concerning any discussion about material risk and consent.
7. **Vulnerable Patients**: Specific care should be taken in circumstances involving children, the mentally impaired, unconscious patients, and in emergency situations.
8. **Cultural and Religious Beliefs**: Different belief systems and practices may affect the patient's or decision maker's ultimate decision to accept, reject or qualify consent for investigations and subsequent treatments.
9. **Written Consent:** RACS recommends when practicable to obtain written confirmation of consent from the patient.
10. **Documentation**: RACS recommends that surgeons keep their own documentation which details a patient's consent of the understanding of a procedure, and that the information provided was deemed adequate and informative.
11. **Standard Consent Forms and Information Sheets:** Outside of being a simple aid or educational tool for the patient to take away and discuss with their surgeon later, these documents may not be enough in themselves to provide informed consent. RACS recommends that surgeons provide the patient with specific and individualised information.
12. **Signature**: A patient's signature alone on a consent form is not conclusive proof that valid consent has been obtained. A signed informed consent document with information specific to the patient, providing details of what was discussed, is recommended.
13. **Emergencies**: In an emergency when immediate intervention is necessary to preserve life or prevent harm it may not be possible to provide complete information or obtain written consent. In these circumstances and where practicable, consent should be sought from next of kin, family or those with power of attorney. Efforts to obtain consent should be documented.

ASSOCIATED DOCUMENTS

RACS Surgeons Fees Position Paper
RACS Informed Financial Consent Position Paper
RACS Code of Conduct
Information, Choice of Treatment and Informed Consent (Medical Council of New Zealand)
Good Medical Practice: A Code of Conduct for Doctors in Australia (Australian Medical Council)
Informed Financial Consent – A Collaboration between Doctors and Patients (Australian Medical Association)

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