



## Short title: Informed consent BP

### 1. Introduction

The accompanying document was last reviewed in 2005. Since that time there have been changes in technology with the advent of digital records, as well as other changes including the promotion of Advanced Care Directives.

The intention of the accompanying statement is to describe where the college stands on the issue of informed consent with a view to promoting best practice and to support practitioners in complying with jurisdictional and regulatory requirements.

### 2. Background

Informed consent is vital both ethically and legally and represents the principle of patient autonomy as applied to their right to decide on their treatment. On the basis of landmark legal rulings,<sup>1,2</sup> the matter of consent has received particular attention and has directed medical practice. It has highlighted the fact that obtaining consent is a process, as described in the accompanying statement, and that the presence of a signature alone, in the absence of the process, does not constitute acceptable consent.

In the past, anaesthesia consent was sought as part of surgical consent and the presence of a signature on a single form sufficed. The current expectation is that anaesthesia consent is a separate process from surgical or procedural consent and warrants its own separate consultation. While a single form may be used, separate signatures or acknowledgement are required for each consent.

### 3. Discussion

#### 3.1 Change of title from Guideline to Statement

During this review it was acknowledged that there was significant variation in the types of healthcare facilities in which anaesthesia services were provided and that the physical facilities in some were less than ideal for undertaking the necessary consultation and consent. Privacy was one such concern where pre-anaesthesia consultations were undertaken in holding bays with only a curtain separating patients and other staff.

Within the hierarchy of ANZCA professional documents (Position) "Statements" sit above "Guidelines" as they describe the college's position on relevant issues. The professional documents serve to support the college's role in advocacy with the aim of driving improvements in standards resulting in some recommendations being aspirational. As a statement it was agreed that this may better assist fellows in negotiating with facility administrators for more suitable conditions for this crucial aspect of consent, as opposed to a guideline.

Despite the jurisdictional authorities regarding ANZCA professional documents as standards, irrespective of whether they are statements or guidelines, facility administrations tend to view them in a hierarchical fashion. As such, it is hoped that a statement describing the college's position may be a more useful tool for fellows.

### **3.2 Clinical setting of consent**

There was considerable discussion around the principles and process of consent in the context of the varied setting of pre-anaesthesia consultations ranging from pre-anaesthesia assessment clinics through to day of surgery admissions. Both the facilities and the timing of such consultations pose challenges to the anaesthesia consent process. Nonetheless, where urgency permits there needs to be sufficient time to consider, review, and seek advice relating to all matters of consent to ensure that consent is adequately informed and understood.

### **3.3 Capacity to provide consent**

All persons are presumed to be competent to give consent unless there are reasonable grounds to believe otherwise. Such may be the case in patients considered too young to understand or patients with diminished mental capacity.

The age at which children are deemed capable of consenting varies across countries as well as jurisdictions, and each practitioner needs to ensure that they are familiar with the specific regulations in the jurisdiction in which they are practising.

There may also be circumstances where patients are under the influence of medications that may impair judgement or cognitive function, which would render them incapable of providing informed consent. Such situations may arise when there is a decision to amend the proposed surgical procedure and the patient is requested to sign the consent form after having been administered premedication sedation or when emergency patients are affected by alcohol or illicit drug use.

The issue of timeliness of the consent, including financial consent, and the inappropriateness of obtaining patient signatures in the induction room or theatre/procedure room was also considered. These issues have been addressed within items 5.2 and 5.3 of the accompanying Statement.

### **3.4 Medico-legal considerations**

Informed consent is mandated under law in both New Zealand and Australia despite some variation between the two countries. Similarly, in cases of medico-legal litigation the issue of consent is pivotal in the outcome.

Consent must be informed and consequently requires that the process of open and honest communication has occurred, and the patient has had an opportunity to consider the information and ask questions.

Permission to perform a treatment is consequent upon ascertaining competence to understand and decide on the treatment; permission being voluntary and inclusive of the right to refuse a plan; disclosure of material information; and explanation of alternatives.<sup>3</sup>

The challenge for anaesthesia consent is that the regulatory demands appear onerous and the circumstances for fulfilling them may be suboptimal.<sup>4</sup> Preadmission clinics are a means of addressing some of these concerns, however, such clinics are usually not operational in the private practice setting.

The volume of information expected to be imparted to patients is considerable, and the question arises as to whether it is helpful to patients. There is a view that attempts to provide all-encompassing information may result in overload, contributing to confusion or failure to absorb and understand the content and its implications. The intention of informing patients is to allow them to make informed decisions. However, much of the decision to be made revolves around

risk.<sup>4</sup> The difficulty with this is that risk can be quantified only on a statistical basis and not for any particular patient. While their individual risk can be provided in qualitative terms, that is either more than or less than the population statistical risk, it cannot be quantified in individual terms.

Some patients will undergo a procedure irrespective of the risks because their present condition is unacceptable to them and they are prepared to take any risk to remedy their problem. However, most patients will place significance to risks despite them being expressed in statistical terms for the population.

A knowledge of the risks of medication interactions and pharmacodynamic effects may influence anaesthesia management and advice provided to patients. For example, patients on oral contraceptives should be advised whenever medications known to render oral contraceptives less effective are used.

Admissions on day of procedure limit the ability to undertake the ideal consultation, and late additions to operating/procedural lists compound the problem. Within the Document Development Group (DDG) there was discussion regarding the appropriateness and need for providing exhaustive information that possibly served to confuse patients rather than assist them, as well as impacting on throughput.<sup>5</sup> Indeed, it was suggested that there may be an untenable disparity between the principles of informed consent and the real world of anaesthesia practice. In this context the DDG discussed whether the college should consider advocating for rational application of the consenting process, given that conflicts can be found when using principles-based ethics.<sup>6</sup> For these reasons item 5.3.1 was included in the accompanying Statement.

### **3.5 Advanced Care Directives (Australia)/Advanced Directives (NZ)<sup>i</sup>**

There has been increasing publicity to encourage the community to consider their health, while they are of sound mind, and determine their preferences for future treatments and care. Strict requirements must be met in developing such directives as they have legal standing and significant impact on any individual's outcomes.

Anaesthetists and sedationists must confirm whether any ACD/AD exists and its specific demands. Some hospital admission forms collect information about the existence of any ACD, although some forms combine both ACD and Power of Attorney. In these cases, it is important to identify which is in effect.

### **3.6 Documentation of consent**

It was agreed that a signature alone on a form consenting to a procedure does not constitute consent or proof of consent. There was some debate around the issue that patients present for their procedure and that anaesthesia is the vehicle that allows the procedure to be performed. Consequently, anaesthesia consent should focus on whether or not the patient agrees to anaesthesia rather than considering the multitude of factors that may be pertinent.

The consensus, however, was that there are risks associated with anaesthesia that may influence any patient's decision whether to proceed with the proposed procedure, and therefore, the broader approach was taken. To that end, practitioners are strongly encouraged to at least briefly document, in some format, the relevant issues discussed and have patients countersign the notes.

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<sup>i</sup> In New Zealand the term Advanced Directives is used and defined in Right 7(5) of the Code.

Over time memory tends to falter and the only means of establishing facts is the provision of contemporaneous documentation.

The need for patients to sign consent forms was discussed in the context that the presence of a signature does not confirm that the consent process necessarily occurred. In New Zealand, patient signatures are mandatory, However, in Australia it was agreed that patient signatures in conjunction with appropriate documentation is likely to be confirmatory and therefore, should be encouraged. The introduction of electronic medical records requires the incorporation of means to document acceptance and understanding of information and consent. With patient notification and approval digital recording of the consent discussion is one such option.

Another option is voice recording of consent by telephone or videocall as is already done by some institutions.

Regarding the volume of documentation, a view was presented that any requirement for excessive documentation should be actively discouraged as irrelevancies are not helpful and may be counterproductive. While it was acknowledged that excessive documentation may be less than ideal it is difficult to define what constitutes excessive. The consensus was that the volume of documentation should be commensurate with any patient's co-morbidities, proposed procedure(s) and anaesthesia risks, and this is reflected in item 5.3 of the accompanying Statement.

#### **4. Summary**

Informed consent is mandated under law but there are also powerful ethical reasons for mandating consent. Australian and New Zealand laws differ, and it is imperative that doctors are familiar with their applicable jurisdictional requirements. Practitioners treating patients in New Zealand must refer to the Code and abide by it.

The demands of informed consent may be onerous; however, The College supports the principle of informed consent and the accompanying statement has been developed with the intention of assisting practitioners and healthcare facilities to comply.

#### **Document development group**

The oversight committee for the review of PS26(A) was the Safety and Quality Committee and the DDG members were:

- Dr Andrew Ross, Vic
- Dr Antonio Grossi, Vic
- Dr Hamish Gray, NZ
- Dr Helen Maxwell-Wright, Vic (Consumer representative)
- Dr Leona Wilson, NZ
- Dr Mike Keane, Vic
- Dr Neroli Chadderton, NZ
- Dr Peter Roessler, Vic (Director of Professional Affairs – Professional Documents, lead)

#### **Related ANZCA documents**

PG06(A) Guideline on the anaesthesia record

PG07(A) Guideline on pre-anaesthesia consultation and patient preparation

## Further reading

Medical Board of Australia. Good medical practice: a code of conduct for doctors in Australia. Canberra: Medical Board of Australia; 2020 Oct. Available from: <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx> Accessed 6 March 2024.

Medical Council of New Zealand. Information, choice of treatment and informed consent. Medical Council of New Zealand; 2011 Mar. \*This reference has been superseded by: Informed Consent: Helping patients make informed decisions about their care, 2021. Available from: <https://www.mcnz.org.nz/assets/standards/55f15c65af/Statement-on-informed-consent.pdf> Accessed 6 Mar 2024. Note: this updated reference has not yet been reviewed by ANZCA.

Medical Council of New Zealand. Cole's medical practice in New Zealand. Medical Council of New Zealand; 2017 Nov, updated 2021. Available from: <https://www.mcnz.org.nz/assets/standards/da3a9995b9/Coles-Medical-Practice-in-New-Zealand.pdf> Accessed 12 April 2024. Note: this updated reference has not yet been reviewed by ANZCA.

Medical Council of New Zealand. Statement on best practices when providing care to Māori patients and their whanau. 2006 Aug. \*This reference has been superseded by: He Ara Hauora Māori - a Pathway to Māori Health Equity, 2019 Oct. Available from: <https://www.mcnz.org.nz/assets/standards/6c2ece58e8/He-Ara-Hauora-Maori-A-Pathway-to-Maori-Health-Equity.pdf> Accessed 6 Mar 2024. Note: this updated reference has not yet been reviewed by ANZCA.

Health and Disability Commissioner. The code of health and disability services consumers' rights. Regulations 1996. Health and Disability Commissioner; 2014. Available from: <https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/> Accessed 6 Mar 2024.

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Savulescu J, Kerridge IH. Competence and consent. *Med J Aust*. 2001 Sep 17;175(6):313-5.

## References

1. *Rogers v Whitaker* (1992) 175 CLR 479.
2. *Beausoleil v Sisters of Charity* (1964) 53 DLR (2d) 65:55.
3. Braun AR, Skene L, Merry AF. Informed consent for anaesthesia in Australia and New Zealand. *Anaesth Intensive Care*. 2010 Sep;38(5):809-22.
4. Chrimes N, Marshall SD. The illusion of informed consent. *Anaesthesia*. 2018 Jan;73(1):9-14.
5. Anderson OA, Wearne IM. Informed consent for elective surgery - what is best practice? *J R Soc Med*. 2007 Feb;100(2):97-100.
6. Slater R. Rethinking anaesthetic consent. *Australasian Anaesthesia*; 2007, p. 111-16.

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