

Point of view

Informed consent and the incompetent adult patient in intensive care – a New Zealand perspective

It is generally accepted and expected that a competent adult patient can only be provided with health care interventions following the provision of informed consent. The legal intricacies of informed consent vary from one country to another. In New Zealand, this particular right is protected by the Health and Disability Commissioner Act 1994 (the Act)¹ and its associated Code of Health and Disability Services Consumers' Rights 1996 (the Code).²

Obtaining informed consent engages the two ethical principles of autonomy (i.e. self-determination) and veracity (i.e. truth telling). It can be argued that if the principles of beneficence and non-maleficence are always guaranteed to patients, then the need for informed consent would largely become redundant. When a loss of mental faculty creates uncertainty regarding a patient's capacity to be both informed and autonomous, ethical practice obliges medical practitioners to provide as much information and self-determination as is possible to the patient. The right to be involved in the decision making process, even with a diminished competence, is protected by the Code (Right 7 (3)). At the same time the other three principles of beneficence, non-maleficence and social justice must be protected.

Many intensive care patients are unable to provide informed consent. The law and practice relating to treating incompetent patients is an exacting area where many acute care staff are not necessarily familiar. When an individual is clearly unable to refuse or consent to treatment, clarification of the process required under the Act can be provided by the example of a severely head-injured patient who requires a tracheotomy to facilitate ventilatory support. Tracheotomy has both immediate and delayed risks that must be balanced against potential benefits.^{3,4} Addressing both the benefits and risks must form an integral part of any informed consent process.

Currently, in New Zealand intensive care practice it is not uncommon for proxy consent to be sought on behalf of the incompetent patient from those who are identified as next-of-kin. A recent informal evaluation

of consent practices within ICU's throughout New Zealand revealed a variety of approaches. Most acknowledged the legal worthlessness of proxy consents, which are nonetheless still obtained in many units. Whilst this practice is often viewed as documentation of the consultation process, the attainment of proxy consent has no legal standing and should be discouraged. The specific obligations required for such a medical treatment to proceed can be considered as part of a stepwise authorisation process.

An authorisation process

Obtaining consent

Obtaining consent and the requirements for treating patients unable to consent is detailed in Right 7 of the Code. Actions must be those which are in the patient's best interests. As informed consent can only be obtained from a competent patient, an early assessment of the patient's competence is necessary.

Determination of competence

Competence is presumed unless there are grounds for believing otherwise.² In New Zealand practice, determination of diminished competence of intensive care patients rarely presents a difficulty, and has never been challenged legally. However, the assessment will need to be justifiable if queried later. A second opinion is required when a patient's competence is unclear. In extreme circumstances, a psychiatric opinion or legal determination may be necessary. Each step taken must be recorded in the case notes, detailing why the patient is not competent.

At the time an informed choice is necessary, the patient's competence may be temporarily impaired by factors such as shock or pain. In all circumstances a patient should be consulted, as far as that is possible, about his or her treatment preference, even when not fully competent. Clearly coma prevents this.

Proxy consent

Consent provided by another person on behalf of an incompetent patient is only valid in limited circumstances.² For example, when the patient who requires treatment is:

- (a) a minor, the parent or legal guardian provides the proxy consent,
- (b) one who is deemed to require a guardian pursuant to the Protection of Personal and Property Rights Act 1988⁵ (the person who has been appointed as a welfare guardian provides the proxy consent), or
- (c) one who has given an enduring power of attorney to another (that person who holds the enduring power of attorney provides the proxy consent).

Contrary to public perception, a patient's spouse, next-of-kin, family, or whanau has no automatic authority to provide consent on behalf of an incompetent patient. Many New Zealand intensive care units make use of standard patient consent forms to formalise and document family consultation and agreement in authorising procedures for incompetent patients. Consent provided by a person not in the three categories above is invalid, has no legal basis, and does not protect the medical practitioner in any way. Furthermore, some view this as placing an unreasonable additional burden upon the already stressed relatives whose decision-making capacity is likely to be impaired.⁶

Obligation to consult

The clinician must take reasonable steps to ascertain any indication of what choice the patient would have made if he or she were competent.² Where circumstances allow, this must include discussing the proposed treatment with those people who are closest to the patient.

If the patient's views are not apparent, then the clinician must take into account the views of other suitable persons who are interested in the welfare of the patient and who are available to advise the clinician. The views of these people need only to be taken into account, and their views can only be persuasive rather than determinative. In different situations, the views will be accorded differing weights. In the event of vehement opposition from any or all of the persons so consulted, it is prudent practice to ensure that the determination of 'best interests' is robust, readily justifiable and clearly documented. Extremely persuasive or strongly stated views from interested 'others' may alter the balance of such 'best interests'. The consultation process imparts knowledge to the family and the provision of information is a fundamental component of good clinical practice.

For a variety of reasons Maori and Polynesian people are disproportionately large *per capita* consumers of intensive care services in New Zealand⁷⁻¹⁰. Whilst the Code does not treat Maori or Polynesian patients differently to other patients, it affords to any health consumer an express right to the respect of cultural needs, values and beliefs.² Accordingly, in the case of Maori and Polynesian patients, this may necessitate consulting with a group which is wider than the 'European' nuclear family.

In all situations, the obligation to consult must be balanced against the need for timely treatment. In an emergency where time precludes consultation, the clinicians should proceed to treat the patient based on their own considered assessment of the relative benefits.

Best interests - the overriding concept

When valid consent cannot be obtained, an incompetent patient can be treated where the treatment is in the patient's best interests. The obligation to consult forms an integral component of determining what is in the particular patient's best interests.

Emergency and elective procedures

The important concept is 'necessity' not 'emergency'. The treatment must be necessary to preserve the life, health and well-being of the patient. Elective procedures meeting this standard may be undertaken if they are in the best interests of the patient.

The obligatory reasonable steps taken to ascertain the patient's views will clearly be different between emergency and elective procedures. In the former, it may not be practicable to discuss the proposed treatment with anyone else. This is not uncommonly the case in intensive care. In the latter, there is an obligation to consult more widely. If it is possible to do so without undue risk, an elective procedure should be delayed until such time as the patient regains decision-making competency.

Process implementation

For the case under consideration, the process is now clarified. The patient is obviously unable to provide consent on his or her own behalf. No one holds welfare guardianship or power of attorney in this case. The patient has not previously expressed any thoughts about various procedures (e.g. tracheostomies). Discussion, explanation and consultation must follow with his or her next-of-kin and immediate family, but they cannot offer or refuse consent on the patient's behalf.

Two particular difficulties can ensue. Firstly, ensuring the consultative process has appropriate breadth. There is no generic answer to this problem and each individual situation requires judgement. The second difficulty arises when there is opposition from, or disagreement within the group consulted. Whilst assent is not required, the practicalities and social expectations invite a consensus decision. Having completed these processes, the responsible clinician may authorise the procedure without requiring further consent.

Specific considerations

Organ donation and research are two areas of intensive care practice that require special consideration. Cadaveric organ donation is covered by the Human Tissue Act 1964,¹¹ and the Code of Practice for Transplantation of Cadaveric Organs 1987.¹² The requirement is for the absence of objection from both

the deceased person and the family.¹³ The ANZICS guidelines¹³ are used as a standard, and no organs are retrieved without the authority form having been signed by the next of kin.

The Declaration of Helsinki¹⁴ and its revisions, to which New Zealand is a signatory, sets out provisions for medical research in patients unable to consent, where research is of potential diagnostic or therapeutic value for the individual participant. It also contains additional recommendations for when the patient is unable to consent, as well as provision for situations where research may require no patient consent.

Recommendations include an independent committee to consider whether to approve the research. The regional ethics committees, acting as the independent review boards, have generally adopted a conservative but facilitative approach, consistent with the Declaration of Helsinki and the revisions.

A mandatory requirement for written informed consent from a patient for research has been suggested by various draft documents.^{15,16} If implemented, this requirement would produce a formidable barrier to research involving patients unable to consent. The Code, in Rights 7 and 9, covers participation in research, although research on unconscious patients is not explicitly mentioned. The international conventions, current legislation and various guidelines are not easily reconciled.¹⁷ The ethical and legal issues surrounding research in intensive care have been examined in detail by Moore *et al.*¹⁸

The Code is subservient to other statutes. It does not license a breach of any duty or obligation imposed by authorised enactment and it does not preclude actions required by other Acts. Circumstances will arise where primacy will be given to the Crimes Act 1961,¹⁹ with governing principles of the obligation to provide the necessities of life and the standard of care expected of a reasonable person. Such circumstances require to be considered separately from those that relate to orthodox treatments in routine management of the incompetent adult patient in intensive care.

Conclusion

In the New Zealand health sector, the practice of seeking consent from the next-of-kin of an incompetent adult patient is invalid. The Code of Health and Disability Services Consumers' Rights² provides clear processes whereby the responsible clinician can authorise a procedure for an incompetent patient, after having considered all factors affecting the determination of that which is in the patient's best interest. Social expectations clearly invite a documented consensus decision, but this is not a legal requirement.

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