Questions

2. Capacity to consent to medical and dental treatment

Question 2.1: "Incapable of giving consent"

(1) Is the definition of a person "incapable of giving consent to the carrying out of medical or dental treatment" in s 33(2) of the *Guardianship Act 1987* (NSW) appropriate? If not, what should the definition be?

We would argue that legislation should contain a definition of capacity rather than a definition of incapacity. The presence of capacity is a pre-condition for informed consent to medical treatment or intervention. For some individuals, capacity can change over time and attempts should be made to engage the person in consent to treatment or intervention while capacity is present.

Capacity to consent definition should have the following components:

1. The person understands information given in relation to a health care decision.
2. The person is able to make a decision based on the reasonably foreseeable consequences of making or not making a decision.
3. The person can communicate his or her decision (this may or may not involve verbal communication).

We do not support a definition of incapacity for two reasons:

1. It is capacity rather than incapacity that should be determined prior to a consent process.
2. The definition provided is not relevant to health care decision making in that having an understanding of the "general nature and effect" of the intervention is inadequate in terms of capacity to consent.

(2) Should the definition used to determine if someone is capable of consenting to medical or dental treatment align with the definitions of capacity and incapacity found elsewhere in the *Guardianship Act 1987* (NSW)? If so, how could we achieve this?

No. The definition of capacity should stand alone.

3. Types of medical and dental treatment

Question 3.1: Withholding or stopping life-sustaining treatment

(1) Should Part 5 of the *Guardianship Act 1987* (NSW) state who, if anyone, can consent to withholding or stopping life-sustaining treatment for someone without decision-making capacity?

Yes.

(2) If so, who should be able to consent and in what circumstances?

The individual through an Advance Care Directive, the Tribunal, the guardian or the person responsible. We also believe that a medical practitioner in agreement with a second medical practitioner may made a decision to withhold or stop life sustaining treatment only in circumstances where the hierarchical list of health care decision-makers has been

exhausted through reasonable efforts to make contact with them. In practice, where this option is available, it is rarely resorted to.

For the purpose of clarity, there should be a hierarchical approach to decision-making with the person's Advance Care Directive at the top. A person appointed by the patient (before losing capacity) should be next on the list. After that, the person's responsible should be listed. We support the extension of the list of person's responsible to include more categories of family members whilst maintaining a hierarchy. The reason for placing the Advance Directive at the top of the list is, that from an ethical perspective, we want first to uphold the wishes of the person expressed while he or she had capacity and, only where they are unknown, to act from a best interest position. Where a person has never had capacity to make a health care decision we act from a best interests position. This may, in some circumstances involve taking into consideration the wishes of the person, considering the extent to which they understand the risks and consequences of the decision.

Additional to questions: We submit that the term 'futility' should not be used in legislation in reference to determining if a treatment or intervention may be withheld or withdrawn. There is no academic agreement on the meaning of 'futility'. Some ethicists and medical academics suggest it refers to the whether or not the treatment has a good chance of achieving its own aim (whether or not, for example, performing cardiopulmonary resuscitation will restart the heart or whether a ventilator will help the patient breathe). Others refer to 'futile treatment' as those undertaken during the dying process that will not provide an appreciable benefit to the patient. The focus should always remain on whether the patient would have wanted such interventions, and secondly, on what is in the patient's best interests.

The current Tasmanian policy is based on a Western Australian case (Brightwater Care Group v Rossiter) and this may be a starting point for helping NSW define "life-sustaining treatment" rather than "withholding palliative care".

Question 3.2: Removing and using human tissue

(1) Should Part 5 of the *Guardianship Act 1987* (NSW) state who, if anyone, can consent to the removal and use of human tissue for a person who lacks decision-making capacity?

Yes.

(2) If so, who should be able to consent and in what circumstances?

For persons without capacity regarding tissue for transplantation, this should be a tribunal only. The risk to the donor must be the pre-eminent consideration. Current and future health risks to the potential donor should be given a higher value than the possible psychological and emotional risks associated with not donating.

To the extent to which the individual without capacity understands the consequences of their decision, their views should form a part of the consideration. Where the individual has a strong objection to donating, the donation should not take place.

Question 3.3: Treatment by a registered health practitioner

Should the definition of medical and dental treatment in Part 5 of the *Guardianship Act 1987* (NSW) include treatment by a registered health practitioner?

It should include treatment by a health care practitioner (registered or otherwise). I consider here, for example, university-trained naturopaths who should, by nature of their training and to protect the public, be registered.

Question 3.4: Types of treatment covered by Part 5

(1) Are there any other types of treatment excluded from Part 5 of the *Guardianship Act 1987* (NSW) (or whose inclusion is uncertain) that should be included?

See above as an example.

(2) Should any types of treatment included in Part 5 of the *Guardianship Act 1987* (NSW) be excluded?

No, the list should not limit the range of health care providers to those who currently have registration: a person who has lost capacity may have demonstrated specific preferences for their health care while they had capacity. Currently, paramedics are not registered health care practitioners however the definition of medical and dental treatment should include prehospital care given by paramedical practitioners.

4. Consent to medical and dental treatment

Question 4.1: Special treatment

(1) Is the definition of special treatment appropriate? Should anything be added? Should anything be taken out?

Bariatric surgery.

(2) Who should be able to consent to special treatment and in what circumstances?

Only the tribunal

(3) How should a patient's objection be taken into account?

The objection should be considered by the tribunal considering the degree to which the person understands the consequences of the decision.

(4) In what circumstances could special treatment be carried out without consent?

Emergency circumstances *only* with the aim of saving life or preventing serious harm.

Question 4.2: Major treatment

(1) Is the definition of major treatment appropriate? Should anything be added? Should anything be taken out?

Surgical treatments requiring general anaesthesia or sedation should be added.

We would support the addition in 4.21 of the word s 'immediately necessary' to save the patient's life or prevent serious damage to the patient's health. In all other circumstances consent can be sought.

(2) Who should be able to consent to major treatment and in what circumstances?

Tribunal.

How should a patient's objection be taken into account?

To the extent that the person without capacity understands the consequences of the decision.

(3) In what circumstances could major treatment be carried out without consent?

In emergency circumstances *only* with the aim of saving life or preventing serious harm.

Question 4.3: Minor treatment

(1) Is the definition of minor treatment appropriate? Should anything be added? Should anything be taken out?

We believe the definition is adequate.

(2) Who should be able to consent to minor treatment and in what circumstances?

Tribunal, guardian, person responsible.

(3) How should a patient's objection be taken into account?

To the extent to which the patient understands the consequences of the intervention.

(4) In what circumstances could minor treatment be carried out without consent?

Emergency only with the aim of saving life or preventing serious harm. For all other circumstances consent should be sought.

Question 4.4: Treatment that is not medical or dental treatment

Does the *Guardianship Act NSW* (1987) deal with treatments that fall outside of the Part 5 regime adequately and clearly?

Question 4.5: Categories of treatment as a whole

(1) Does the legislation make clear what consent requirements apply in any particular circumstance? If not, how could it be clearer?

(2) Do you have any other comments about the treatment categories and associated consent regimes in Part 5?

Question 4.6: Person responsible

(1) Is the "person responsible" hierarchy appropriate and clear? If not, what changes should be made?

We submit that the categories should be extended and how other decision-makers operate in relation to the person responsible list.

Our suggestion is:

1. Advance Care Directive
2. Tribunal
3. Guardian as appointed by a legal body.
4. Person appointed by the person to make decisions for them in the event of loss of capacity.

Persons responsible:

5. Spouse or person lived with as a spouse in a relationship of some permanency.
6. Adult son or daughter
7. Parent
8. Grandparent
9. Aunt or uncle
10. Nephew or niece

For the categories occupied by more than one relative, the eldest should be preferred as decision-maker.

If desired, for minor medical treatment only, a doctor, supported by another doctor, may make a decision ONLY where the hierarchical list is exhausted. In practice, this would be a rare event. Our understanding is that is NSW doctors are given greater latitude to make health care decisions than in other jurisdictions.

(2) Does the hierarchy operate effectively? If not, how could its operation be improved?

It is doubtful that the current hierarchy is sufficiently clear.

Question 4.7: Factors that should be considered before consent

Are the factors a decision-maker must consider before consenting to treatment appropriate?

Include:

- The proposed intervention, risks and potential benefits, including material risks.
- Why the intervention is being proposed including the patient's condition.
- Nature and effect of all treatment alternatives.

It will not always be necessary to consider why the person is incapable of giving consent. This may be valuable in a tribunal setting but for an elder with advanced dementia who has a 'person responsible' the situation regarding incapacity may be obvious to all.

Question 4.8: Requirement that consent be given in writing

Is the requirement that consent requests and consents must be in writing appropriate? If not, what arrangements should be in place?

It is not clear to us how a written consent form standing alone would ever constitute a legally adequate consent. A decision-maker must be informed of the nature of the intervention, its potential benefits, risks and the alternatives and a form could therefore aid the disclosure aspect of the consent process. What is missing from the process where only a form is used is a demonstration of understanding of the information, an opportunity to ask questions of the provider and receive answers that satisfy them. Thus, forms should always be considered as a tool in the consent process and not the process itself.

Documentation of oral consent processes is always advisable for legal reasons. The provider would document the treatments discussed, risks and benefits discussed, material risks discussed and the decision.

Question 4.9: Supported decision-making for medical and dental treatment decisions

(1) Should NSW have a formal supported decision-making scheme for medical and dental treatment decisions?

Yes.

(2) If so, what should the features of such a scheme be?

For special and major decisions, a tribunal might be made to consider the person's wishes to the extent to which they understand the consequences.

For minor decisions, this is not so necessary but we do believe the person's wishes should be taken into consideration to the extent they understand the consequences.

The manner in which a minor health care decision for a person without capacity is to be approached could be legislated. i.e. act first according to known wishes for people who have lost capacity, move to a best interests position if wishes are unknown. For those who have never had capacity to make a health care decision, consider the wishes of the person to the extent to which they understand the consequences of the decision.

Question 4.10: Consent for sterilisation

(1) Who, if anyone, should have the power to consent to a sterilisation procedure?

Tribunal

(2) In what ways, if any, could the *Guardianship Act 1987* (NSW) better uphold the right of people without decision-making capacity to participate in a decision about sterilisation?

The degree to which the person understands the consequences of the decision should be taken into consideration.

Question 4.11: Preconditions for consent to sterilisation

What matters should the NSW Civil and Administrative Tribunal be satisfied of before making a decision about sterilisation?

- Sterilisation that is medically necessary, may need to be qualified with examples. For example, removal of reproductive organs with the purposes of treating cancer.
- The potential nature and risks of sterilisation.
- The patient is unlikely to regain capacity
- Sterilisation is in the patient's best interests
- The patient has been consulted and there is an understanding of whether or not the patient understands the consequences of the decision. A formal assessment may help achieve this.

Question 4.12: Matters that should not be taken into account in sterilisation decisions

(1) Is there anything the NSW Civil and Administrative Tribunal should *not* take into account when deciding about sterilisation?

We are in agreement with the considerations of pregnancy, pregnancy as a result of sexual abuse and attempts to prevent passing on an inheritable disorder (eugenics), should not be considered.

(2) Should these be stated expressly in the *Guardianship Act 1987* (NSW)?

Yes.

Question 4.13: Legislative recognition of advance care directives

(1) Should legislation explicitly recognise advance care directives?

Yes.

(2) If so, is the *Guardianship Act 1987* (NSW) the appropriate place to recognise advance care directives?

The Guardianship Act 1987 (NSW) could briefly consider the role of advance directives. However, we submit that separate legislation outlining the role of advance directives, whom may consent and the parameters of consent may be useful in clarifying this area for health care workers. In such an Act, the hierarchical health care decision-making list may find a more appropriate

home. Such an Act might include information on making an advance directive, appointing a health care decision-maker for time of incapacity, revoking the directive, penalties for ignoring an Advance Directive etc. The Act would also need to contain the hierarchy of decision-makers and a definition of capacity as well as how decisions should be approached by those making health care decisions for individuals without capacity (known wishes first, best interests where wishes unknown for those who have lost capacity and best interests with consideration of the person's wishes to the extent that they understand the consequences of the decision for those who have not had capacity.

Question 4.14: Who can make an advance care directive

Who should be able to make an advance care directive?

Any person with capacity including any young person who demonstrates Gillick competence.

No other person should be able to make an advance directive for another person noting that making a decision in advance is not the same process as making an advance directive. For example, a person responsible, where appropriate, may make a decision not to resuscitate where it is believed to the person would have wanted it, or in the absence of that knowledge, it is believed the person's best interests are served by not resuscitating.

Question 4.15: Form of an advance care directive

What form should an advance care directive take?

Any form can be used. The Act should simply state the legal requirements i.e. written, signed, dated and witnessed where the document has not been written in the patient's own hand. It is very important to consider that an advance directive expresses an individual's autonomous wishes and should be considered in the light of the current medical context. Medical contexts should not dictate the nature of an advance directive form.

Question 4.16: Matters an advance care directive can cover

What matters should an advance care directive be able to cover?

Any health care matter.

(We would also submit that a person should be able to express their wishes for organ and tissue donation on an advance directive and would argue that their wish should be honoured upon their death whether or not the family agrees with the decision).

Question 4.17: When an advance care directive should be invalid

In what circumstances should an advance care directive be invalid?

In very few circumstances if signed and dated by the maker:

- If the maker of the directive did not have capacity at the time it was written.
- Where the person has revoked their advance directive or made a new (later-dated) advance directive.
- If the advance care directive was not witnessed by an independent person

Question 4.18: Part 5 offences

(1) Are the various offences of treating without authorisation and the maximum penalties that apply appropriate and effective?

(2) Is there a need for any other offences relating to medical and dental treatment?

5. Clinical trials

Question 5.1: Definition of "clinical trial"

How should the *Guardianship Act 1987* (NSW) define "clinical trial"?

We submit that the term 'clinical trial' as used should be replaced with the broader term 'research'. Research should be defined as per the National Statement on Ethical Conduct in Human Research "investigation undertaken to gain knowledge and understanding or to train researchers" and then suggest examples such as clinical trials "a form of research designed to find out the effects of an intervention, including a treatment or diagnostic procedure". It should be noted somewhere that clinical trials are not aimed at benefiting the participant but the broader group of patients with a condition or gaining knowledge about an intervention.

Question 5.2: Categories of medical research

(1) Should there be more than one category of medical research?

Yes

(2) If so, what should those categories be and what consent regimes should apply to each?

We submit that the National Statement on Ethical Conduct in Human Research should inform this section including Chapter 2.3 p. 23 and 4.4 p. 61.

Question 5.3: Who can consent to clinical trial participation

(1) Who should be able to approve a clinical trial?

All research should be approved by an HREC and then must go through a site specific approval process for the institution where the research will be carried out.

(2) Who should be able to consent to a patient's participation in a clinical trial if the patient lacks decision-making capacity?

This depends on the risk associated with the research.

Those interventions that would be considered special or major would need to go to the Tribunal. Minor interventions could be consented to by guardians or persons responsible.

(3) How can the law promote the patient's autonomy in the decision-making process?

The law could require assent to participate from the potential participant where this is possible. Consent from the appropriate decision-maker and assent from the participant would be required. The research would need to be explained to the person in a manner in which they can understand.

Question 5.4: Considering the views and objections of patients

(1) If the patient cannot consent, should the decision-maker be required to consider the views of the patient?

Yes, where practicable. This would depend upon considering the degree to which the person understands the consequences of the decision.

(2) What should happen if a patient objects to participating in a clinical trial? Should substitute consent be able to override a patient's objection? If so, in what circumstances?

No, substitute consent should not override a patient's wishes in the case of research. Research is not undertaken for the purpose of benefiting patients. It would therefore be difficult to argue that the research is in the patient's best interests.

Question 5.5: Preconditions for consent

What preconditions should be met before a decision-maker can consent to participation?

- Research involves minor interventions and is not considered to be high risk.
- Full disclosure of information about interventions and burden of participation.
- Assent of the participant where possible (for some this will not be possible so a judgment will need to be made).

Question 5.6: Requirements after consent

What should researchers be required to do after consent is obtained?

- Ensure assent is obtained.
- Respect the participant's wish not to continue participating.

Question 5.7: Waiver of clinical trial consent requirements

Are there any circumstances in which the individual consent requirements for clinical trials should be waived?

In accordance with the National Statement on Ethical Conduct in Human Research p. 24 and as decided by an HREC.

Question 5.8: Other issues

Do you have any other comments about the consent requirements for clinical trials?

6. The relationship between the *Guardianship Act* and mental health legislation

Question 6.1: Relationship between the *Guardianship Act* and the *Mental Health Act*

(1) Is there a clear relationship between the *Guardianship Act 1987* (NSW) and the *Mental Health Act 2007* (NSW)?

(2) What areas, if any, are unclear or inconsistent?

(3) How could any lack of clarity or inconsistency be resolved?

Question 6.2: Relationship between the *Guardianship Act* and the *Forensic Provisions Act*

(1) Is there a clear relationship between the *Guardianship Act* and the *Forensic Provisions Act*?

(2) What areas, if any, are unclear or inconsistent?

(3) How could any lack of clarity or inconsistency be resolved?

Question 6.3: Whether mental health laws should always prevail

(1) Is it appropriate that mental health laws prevail over guardianship laws in every situation?

(2) If not, in which areas should this priority be changed?

7. Restrictive practices

Question 7.1: Problems with the regulation of restrictive practices

What are the problems with the regulation of restrictive practices in NSW and what problems are likely to arise in future regulation?

Yes, we are in agreement there is insufficient clarity in this area. A guardian or person responsible may advocate for restriction to prevent a fall but in doing so limit a person's autonomy and ability to enjoy life by moving freely and unrestricted. Long-term care is an area where such dilemmas play out regularly often fuelled by paradigmatic issues, such as those arising from safety and quality and falls-prevent discourse. Further, there is not a lot of clarity around what constitutes restraint and there is a lack of focus on least restraint practices.

Question 7.2: Restrictive practices regulation in NSW

(1) Should NSW pass legislation that explicitly deals with the use of restrictive practices?

No

(2) If so, should that legislation sit within the *Guardianship Act* or somewhere else?

The Guardianship Act should mention that least restraint is to be used.

What other forms of regulation or control could be used to deal with the use of restrictive practices?

State wide policy is probably more effective. Legislation cannot be as detailed as this area needs to be.

Question 7.3: Who should be regulated?

Who should any NSW regulation of the use of restrictive practices apply to?

All citizens.

Question 7.4: Defining restrictive practices

How should restrictive practices be defined?

NDIS is a good starting point.

Question 7.5: When restrictive practices should be permitted

In what circumstances, if any, should restrictive practices be permitted?

- Temporarily, in emergency or other circumstances (such as after surgery) to prevent harm to the patient.
- Under a regime of monitoring (locally and by a government authority).

Question 7.6: Consent and authorisation mechanisms

(1) Who should be able to consent to the use of restrictive practices?

Tribunal, guardian and personal responsibilities

(2) What factors should a decision-maker have to consider before authorising a restrictive practice?

Why the intervention is being considered.

The patient's quality of life and freedom (for example, quality of life should not be compromised

What is in the patient's best interest.

This is a complex decision involving different paradigms of thought and pressures can be brought to bear on decision-makers by health care staff. Thus, health care staff need to have a strongly worded guiding policy about the use of least restraint.

(3) What should be the mechanism for authorising restrictive practices in urgent situations?

An independent government authority. It could, perhaps, sit under or with the tribunal.

(4) What changes, if any, should be made to NSW's consent and authorisation mechanisms for the use of restrictive practices?

Independent decision-making (tribunal) and independent monitoring.

Question 7.7: Safeguards for the use of restrictive practices

What safeguards should be in place to ensure the appropriate use of restrictive practices in NSW?

An independent monitoring authority.

Question 7.8: Requirements about the use of behaviour support plans

(1) Should the law include specific requirements about the use of behaviour support plans?

Yes, support plans can be useful in managing 'difficult to manage' behaviours.

(2) If so, what should those requirements be?

Practically speaking, support plans are going to be best prepared by involving those caring for the patient and family members. However, I would suggest that a behavioural psychologist or similar person could contribute much to the plan and advise on how to manage a patient in the least restrictive way.

Perhaps the need for a behavioural psychologist to assist with these plans could be legislated.