Te Kaunihera Rata o Aotearoa
Medical Council of New Zealand

11 April 2019

Medical Council of New Zealand's draft revised statement on *Information, choice of treatment and informed consent*

The Medical Council of New Zealand (Council) is reviewing its existing statement on ***Information, choice of treatment and informed consent***, and is seeking your input.

The statement was last reviewed in March 2011. The draft revised statement (the draft) will retain most of what is in the existing statement with some paragraphs tweaked so that they read better and are more patient-centred. There is more emphasis on involving the patient's family/*w*hānau/caregivers in discussions about the patient's care and treatment. As well, several new paragraphs have been added to provide guidance on:

- Instances where the doctor delegates the provision of treatment or advice to another doctor.
- The time pressures and resource constraints that doctors face, and the impact this has when giving patients information and supporting them to make a decision.
- Factors to consider when the clinical presentation of an anaesthetised patient is such that it warrants further investigation or intervention which the patient has not consented for.
- Obtaining the patient's consent if an observer attends the consultation.

Appendix 1 is a draft version of the revised statement on *Information, choice of treatment and informed consent* that Council is proposing. The existing statement in March 2011 is also enclosed for reference (Appendix 2). The key changes to the draft are outlined below with a number of questions for your input. Please provide any comments that you consider relevant.

(A) Summary box at the outset

The outset of the statement includes a box that summarises the following key messages in the draft:

- Informed consent is an interactive process between a doctor and a patient to help the patient gain understanding about their condition and to make an informed decision about their care. It is more than completing paper work about a patient.
- Under the Code of Health and Disability Services Consumers Rights, every patient has the right to make an informed choice and to give informed consent except if the patient is not competent to do so.
- You must convey information to a patient in a form, language and manner that helps the patient understand the advice or treatment proposed, and to do so openly and honestly.

1. Are there any other key points that should be included or omitted from the summary box?

We understand and recognise the challenges of providing a summary of an entire piece of guidance. We would suggest the following.

The first bullet point states that the process of informed consent is 'to help the patient *gain an understanding* about their condition and to make an informed decision about their care' This could be interpreted as meaning that only an understanding about their condition is necessary for a patient's consent to be informed when, we'd argue, the information patients need in order to make a decision also includes:

- The options for treating or managing the condition, including the option not to treat

- The risks of harm and potential benefits of each of the options

Also, the Code of Health and Disability Service Consumers' Rights which is discussed below includes a title on 'the right to *be fully informed*,' which suggests a greater level of understanding than '…to gain an understanding' for consent to be an informed process.

Reference is also made to the exception to informed consent where the patient is 'not competent to do so.' It may be helpful to make clear in this summary box that medics must start from the presumption that the patient has capacity. And you may also wish to make reference to the possibility that a patient's capacity/competence may fluctuate and that it is decision-specific (if indeed that is the case in legislation in New Zealand).

(B) Expanded 'Background'

This section in the existing statement notes the importance of open and honest communication, and that trust is vital in the doctor-patient relationship. It also sets out doctors' statutory obligation under the Code of Health and Disability Services Consumers' Rights (the Code) in helping patients to make an informed choice and to give informed consent.

The draft proposes to expand paragraph 2 by encouraging doctors to work in partnership with their patients regarding decisions about their care and treatment, and to involve the patient's family/whānau/caregivers where possible. This recognises that patients have a network of familial and other relationships that matter to them, and that decisions about the patient's care and treatment often impact those close to the patient.

2. In your view, are there any other points that should be covered in 'Background'?

As well as informing the patient of the potential risks and benefits of the options available we would recommend adding wording which makes clear that there is an option to do nothing –i.e. not have any treatment. At paragraph 9 in our guidance on Consent we say that doctors must give patients information they want or need about options for treating or managing the condition, including the option not to treat.

In paragraph 2 rather than describing informed consent as a process where the patient gains an understanding of their condition *'and how that should be managed'*, we'd suggest replacing this with, for example 'and the options for managing it'. That way it's reinforcing the idea that it's the patient's choice, and the doctor mustn't put pressure on them to accept the treatment they recommend.

Finally, in the same paragraph, you say that the doctor should work in partnership with the patient

(and involve their family/whanau/caregivers where possible)…

We'd suggest that third parties are only involved if the patient has requested or agreed that this should be the case.

(C) Proposed changes to the section 'The right to be fully informed'

This section references several rights from the Code. While this section will remain largely unchanged from the existing statement, paragraphs 9-12 have been expanded in relation to the communication between patient and a doctor. Specifically:

- Paragraph 9 adds a third sentence that it is important for a doctor to explain to a patient that the doctor may not have all the information readily available and that another practitioner might need to share the responsibility for care and treatment of the patient.
- Paragraph 10 inserts the phrase 'any specific concerns or requests expressed during the discussion' as another area to document in the patient's records.
- Paragraph 11 includes guidance on instances where the patient is making a decision that the doctor considers is unwise.
- Paragraph 12 inserts a second sentence reminding doctors that patients may have a different understanding about the risks of harm and potential benefits, and replaces 'risky or innovative procedures' with 'more complex treatment'.

3. Do you agree with the proposed changes to the section 'The right to be fully informed' as outlined above and set out in the draft?

We don't have any comments about paragraphs 9-11. For the changes to paragraph 12, we're not sure that the phrase 'a different understanding' is quite right: rather than it being about the patient's understanding it's about the patient's values, concerns, and preferences, and the importance that the patient attaches to each of the harms and benefits.

Also 'more complex treatment' doesn't really capture the uncertainty of the outcome inherent in the phrase 'risky or innovative procedures'.

4. What other changes, if any, should Council include in the section on 'The right to be fully informed'?

At paragraph 7(b) the guidance quotes the Code of Health and Disability Services Consumers' Rights as entitling patients to 'an explanation of the options available,' later at paragraph 8 the statement states that doctors should be aware of all the reasonable alternatives.' It would be helpful to clarify whether reference to a patient's entitlement to 'an explanation of the options available' includes all available options or only those *reasonable alternatives*?

Also we would hope that the wording of paragraph 8(*'**before** providing information about treatment options, you should make sure that you are aware of all the reasonable alternatives')*, wouldn't result in delays to communicating with patients. It would be reasonable for the doctor to share information about the treatment options they are currently aware of, before checking to make sure they've considered *'all the reasonable alternatives'*, as long as they are honest with the patient about what they know and don't know.

(D) Proposed changes to the section 'Informed choice and consent'

Including a reference to telehealth

Paragraph 14 of the draft states that a doctor who is providing treatment or advice is responsible for ensuring that the patient makes an informed choice and consents before initiating treatment. While it retains the same wording as paragraph 14 of the March 2011 statement, a second sentence has been added to clarify that 'treatment and advice' includes any care provided by telehealth as it is increasingly common for aspects of a patient's care to be provided by another health professional who may not be in the same room as the patient. The expanded paragraph 14 (bold) is intended to read as:

> (14) If you are the doctor who is providing treatment or advice, then you are responsible for ensuring the patient makes an informed choice and consents before initiating treatment. **This includes any care provided by telehealth.[Footnote 7]**

Footnote 7
Refer to Council's statement on *Telehealth*.

New paragraphs on delegation
The medical workforce in public hospitals often includes doctors in training such as interns and registrars. Depending on their skill, knowledge and experience, senior doctors may at times delegate certain tasks to a less experienced colleague or a colleague in another specialty. Paragraphs 15 and 16 provide guidance on those instances. The following wording is proposed:

> (15) If you delegate the provision of treatment or advice to another doctor, you must make sure the person you delegate to:
> (a) is sufficiently skilled and qualified in the relevant area of medicine;
> (b) has sufficient knowledge of the proposed intervention, and understands the risks involved and the potential benefits;
> (c) is sufficiently informed of the patient's needs (including their clinical history, test results and diagnosis);
> (d) understands and agrees that they will contact you for further advice or information if necessary; and
> (e) is clear about which doctor is responsible for obtaining informed consent from the patient and that the patient has made an informed decision.
>
> (16) When deciding whether it is appropriate to delegate, you should consider:
> (a) the nature of the intervention, including its risks and complexity;
> (b) the level of uncertainty surrounding the outcome of the intervention;
> (c) your existing relationship with the patient and any relationship your patient has with the person to whom you are considering delegating;
> (d) any concerns you anticipate the patient may have; and
> (e) whether the patient or anyone else who is involved in the decision has enough time and information to make a decision, and/or to express their views.

Revised paragraph on doctors only managing aspects of the informed consent process for which they are competent
Paragraph 15 of the March 2011 statement discusses house surgeons (interns) and informed consent, in particular that they should never be placed in a position of having to manage the entire consent process on their own. As this principle is applicable not just to interns, paragraph 17 of the draft has been re-worded so that it reads as:

> (17) A doctor should only manage aspects of the informed consent process for which they are competent.[Footnote 8]
>
> Footnote 8
> In the case of interns, their role in the informed consent process is addressed in Council's resource on 'Prevocational training' (https://www.mcnz.org.nz/maintain-registration/prevocational-training-pgy1-pgy2-and-nzrex-requirements/).

Involving the patient's family/whānau/caregivers
Similar to paragraph 2, a second sentence has been inserted in paragraph 18 to encourage doctors to involve the patient's family/whānau/caregivers in discussions about the patient's care and treatment where appropriate.

5. Do you agree with the proposed changes to the section on 'Informed choice and consent' as outlined above and set out in the draft?

Yes

6. What other changes, if any, should Council include in the section on 'Informed choice and consent'?

Paragraph 20 deals with consent where a proposed treatment is expensive or innovative. Paragraph 16b of *Good medical practice* states that doctors must *provide effective treatments based on the best available evidence.* If treatment is not evidence-based this must be made clear to the patient – we'd suggest strengthening the requirement *'you should attempt to present to the patient a clear and balanced summary of the scientific information available'*. If there is no scientific evidence available, it may be difficult for a doctor to satisfy themselves that the treatment serves the patient's needs, as paragraph 16a of *Good medical practice* requires.

(E) New section on 'Time and resource constraints'

'Time and resource constraints' is a new section. It acknowledges the reality that competing demands and pressures on a doctor's time can make it difficult for them to spend more time with their patients and support their patients in making decisions about their care and treatment.

Paragraph 22 includes two suggestions: that doctors consider how other members of the clinical and care teams could be involved in helping them gather and give information to the patient; as well as the use of information leaflets and support groups for people with specific conditions (and for any family/whānau/caregivers supporting the patient).

Paragraph 23 notes that patients with additional needs such as those with disabilities or for whom English is not their first language may need more time and support in making a decision about their care and treatment.

It is proposed that paragraphs 22 and 23 read as:

> 22. Time pressures and/or limited resources can make it difficult to give patients as much information or support to make a decision as you, or they need. To help, you should consider:
> (a) the role other members of the clinical and care team might play, for example in gathering and giving information and answering questions before or after your contact with the patient.
> (b) what other sources of information and support are available to the patient (and to any family/whānau/caregivers supporting the patient). For example, patient information leaflets or support groups for people with specific conditions.
>
> 23. You must ensure patients with additional needs, such as those with disabilities or for whom English is not their first language, have the time, support and any reasonable adjustments they need to make a decision about their care and treatment.

7. Do you agree with including a section about time and resource constraints, and how that impacts on doctors when communicating with patients about their care and treatment?

Yes

8. What other changes, if any, should Council include in the section on 'Time and resource constraints'?

We would also recommend including guidance on what doctors can do if they feel that time and resource constraints seriously constrains their patients' ability to make an informed decision. At paragraph 25 of our Consent guidance we say 'If you think that limits on your ability to give patients the time or information they need is seriously compromising their ability to make an informed decision, you should raise your concerns with your employing or contracting authority.
See paragraph 25b of *Good medical practice* and the explanatory guidance *Raising and acting on concerns about patient safety*.'

(F) New section 'When a patient is anaesthetised'

'When a patient is anaesthetised' is a new section that addresses instances where the patient's clinical presentation is such that it warrants further investigation or intervention but because the patient has been anaesthetised, the patient is unable to make an informed decision at that moment. Because each clinical situation is different, it would be impractical to adopt the same approach about whether a doctor should/should not proceed further without the patient's consent. As such, paragraph 30 provides general guidance by saying:

> (30) There may be occasions when the clinical presentation of an anaesthetised patient is such that it warrants further investigation or intervention which the patient has not consented for. Good clinical judgement is needed as to whether to proceed, or to defer that additional investigation/intervention until you have discussed it with the patient and obtained the patient's consent. You should discuss any unexpected intraoperative findings with a peer, a clinical head or your Chief Medical Officer, and must document any advice given. You must also document your discussion(s) with the patient including any decisions that are made about proceeding with or deferring the additional investigation or intervention.

9. **Please provide any feedback you would like us to consider in relation to the proposed section 'When a patient is anaesthetised'.**

Whilst we do not provide specific reference to what doctors need to do with regard to patient anaesthesia we do have a number of provisions concerning the scope of decisions which doctors must consider (see paragraphs 37-40 in our Consent guidance). Specifically, doctors must explain the scope of any decisions to be made, particularly where uncertainty about the diagnosis or the options might only be resolved when the investigation or treatment has started, when the patient may be unable to make decisions (see paragraph 37). Doctors should discuss how decisions will be made about whether changes should be made to the investigation or treatment plan (paragraph 38), and mustn't exceed the scope of authority they are given (paragraph 39). Paragraph 40 is also of particular relevance in these circumstances. We write that doctors should discuss the possibility of additional problems which could come to light during an investigation or treatment when patients might be unable to make a decision about how to proceed. Where there is a significant

risk of a particular problem doctors should ask ahead of time as to what the patient would like to be done and whether there are procedures to which they would object or which they would like more time to think about.

(G) Additional paragraph in 'Informed choice and consent in treatment that is part of education'
Paragraph 37 of the draft retains the same wording as what is in the March 2011 statement about medical students' involvement in the care of patients.

Paragraph 38 is new. It is similar to paragraph 37 but concerns instances where an observer attends a consultation in a clinical setting. It is proposed that paragraph 38 reads as:

> (38) You must also obtain the patient's consent if an observer attends the consultation. This is especially important if sensitive issues are discussed and/or intimate examinations are conducted. Inform the patient about the observer's role and what is expected of an observer.

10. Please provide any feedback you would like us to consider about obtaining the patient's consent if an observer attends the consultation.
We think it would be useful to provide additional clarity to patients that they have a right to refuse to take part in teaching (see paragraph 9h in our Consent guidance).

(H) New section on 'Advance directives'
Doctors are obliged to adhere to an advance directive if the patient has one in place. The draft includes a short paragraph on advance directives that says:

> (39) An advance directive is an oral or written instruction that outlines or describes the patient's wishes in a specific situation. Under Right 7(5) of the Code, 'Every consumer may use an advance directive in accordance with the common law'. If a patient has an advance directive, you are obliged to follow it unless there is reason to question its validity.[Footnote 16]
>
> [Footnote 16]
> See also the section on 'Advance directives' in *Good medical practice* and *Cole's medical practice in New Zealand*.

11. Please provide any feedback you would like us to consider in relation to the section on 'Advance directives'.

Consultation process
Enclosed with this consultation paper are copies of the Council's draft statement on *Information, choice of treatment and informed consent* (Appendix 1) and the existing March 2011 statement

(Appendix 2). We have circulated our consultation paper widely to the profession and to other relevant stakeholders. Please review the draft statement, and give us your views on our proposed changes. You are welcome to respond to some or all of the questions in the consultation paper by completing this form, or by forwarding your feedback in a separate document. If there are any other comments you would like Council to consider, please include them with your response. Submissions and suggestions can be sent to:

Kanny Ooi
Senior Policy Adviser and Researcher
Medical Council of New Zealand
PO Box 10509
The Terrace
Wellington 6143

Or via e-mail at kooi@mcnz.org.nz

If you have any queries, please contact Kanny on direct dial +64 4 381 6793.

Thank you in advance for your input on our consultation. We look forward to receiving your comments by **31 May 2019.**