Submitted via online form 22 September 2023

Medical Council of New Zealand
Consultation – *Disclosure of harm following an adverse event*

Key points at the outset of the statement
We have added a summary box at the beginning of the statement which contains the following key points:

- When harm occurs as a direct result of medical care, the patient and/or their family/whānau should be informed. We call this 'disclosure of harm.' In some jurisdictions, it is called duty of candour.

- You should be prompt, honest and transparent when informing the patient and/or their family/whānau about the harm.

- You should also reflect on what led to the harm, and put measures in place to prevent a similar incident occurring in the future.

- When disclosing harm to the patient and/or their family/whānau:
  - ensure that a senior doctor is present
  - consider the patient's needs and preferences for information and support
  - document details of the harm, and any disclosures that have been made, in the patient's records
  - consider whether there are third parties that should also be informed of the harm.

1. Do these key points provide an accurate overview of the statement? What changes (if any) should we make to the key points?

Yes.
One small change could be the addition of '/family/whānau' to the second bullet point *consider the patient's and/or family/whānau's needs and preferences for information and support*.

Terms we use in this statement
We define the following terms in our statement:
- Adverse event
- Harm
- Disclosure of harm
- Near-miss
- Open disclosure
- Risk.

2. Are there any changes we should make to any of our definitions?

No. The change from 'treatment' to 'care' is clearer and more encompassing.
The glossary is very helpful.

The phrasing, particularly around open disclosure, is much improved on the previous version.

Point 2 – b: If open disclosure is part of the discussion of something unplanned that went wrong, then is it not part of informed consent. The informed consent process would have included the discussion of the 'risk' of complications or that harm may arise, but not that it has happened. Informed consent should include all discussion of risk and potential harm, but that is not informing of open disclosure unless you are saying that the consent process should include advice that open disclosure will occur in the event of unexpected harm.

Factors to consider before disclosing harm to the patient
Similar to the existing statement, the draft statement states the importance of disclosing harm in a timely manner and giving the patient the opportunity to reflect and ask questions. In addition, the draft statement encourages taking a restorative approach to disclosing harm, and outlines the benefit of such an approach.

3. Is the guidance in 'Factors to consider before disclosing harm to the patient' clear, appropriate and practical? What changes (if any) should we make?

Yes.
The change in the steps for the clinical team from 'how it happened' to 'what led to the harm' shifts possible interpretations from blame or one resulting factor to a wider view of the scenario and possible multiple resulting factors that could have led to the harm.

A small grammatical error - missing a 'the' in 13: In some situations, it may be more effective to disclose the harm in stages. For example, you may be concerned that the patient could be overwhelmed if they were given full information within a single session. Consider whether a staged approach is the best way to inform your patient and/or their family/whānau about what has happened and the implications for them.

Factors to consider when disclosing harm to the patient and/or their family/whānau
We have re-organised this section so that we are clearer on what a doctor's obligations are, and what they should consider when disclosing harm.

We have also included a subsection that discusses situations where the doctor may have an obligation to disclose harm to other parties. For example, if the patient died as a result of a medical procedure and that death was medically unexpected, the Coroner must be informed.

4. Is the guidance in 'Factors to consider when disclosing harm to the patient and/or their family/whānau' informative and workable? What changes (if any) should we make?

More explicit provisions to appropriate Māori health providers for this mahi would make this a more useful tool to help doctors provide a Whanaungatanga approach.

The addition of considering whether a third party should be informed within the steps required aids to ensure this is considered as part of the process.

Point 10: We see benefit in expanding on '*an apology is appropriate without accepting liability*'. For example, you can offer an apology for the patient's experience or distress without accepting liability or apologising for the actual harm.

Could it be worth including with point 12 f *any third parties that should be notified, including what documents need to be completed:* the consideration of reporting the near miss or adverse event to specialty-based reporting systems, if there is one available and it meets employer policies?
This would be in line with the points*: (d) increases public understanding and awareness about the reality and risks of medical treatment* and *(e) can lead to a review of processes and contribute to a safety culture by taking steps to strengthen systems and prevent a similar incident*, of the document's purpose.
For example, in anaesthesia, the web-based anaesthetic reporting system (webAIRS) is available to all anaesthetic departments across Australia and New Zealand with the intention to capture, analyse and share information on incidents relative to the safety and quality of anaesthesia.

Any other feedback

5. Please provide any other comments you may have about *Disclosure of harm following an adverse event* that you would like us to consider.

It may be helpful to include links to the statements, guidelines, and referenced information for those that are available online. For example: See also our statement on Informed consent: Helping patients make informed decisions about their care.