Te Kaunihera Rata o Aotearoa | Medical Council of New Zealand

August 2023 www.mcnz.org.nz

Disclosure of harm following an adverse event

Key points

When harm occurs as a direct result of medical care,[1] 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.

About this statement

This statement outlines what is expected of doctors when harm to patients occurs as a direct result of medical care. In such situations, the patient and/or their family/whānau should be informed.[2] We call this 'disclosure of harm.' In some jurisdictions, it is called the duty of candour.

[1] In this statement, 'medical care' refers to the professional input of doctors and other health practitioners to maintain, improve or restore the physical, mental or emotional health and well-being of patients. 'Medical care' includes prescribing, assessing, diagnosing, treating, reporting and giving advice in a medical capacity.

[2] Because adverse events often affect those close to the patient, it can be helpful for family members/whānau to be present when open disclosure occurs. There will also be occasions where, owing to the patient's mental capacity, disability or death, the disclosure occurs only to family members/whānau.

This statement is intended to help doctors understand the purpose of open disclosure, why it matters to patients and/or their family/whānau, and to guide doctors on factors to consider when a situation requires that the harm is disclosed.

Terms we use in this statement

Adverse event
An incident, situation or occurrence where the patient has experienced a negative reaction or result that was unplanned, unexpected or unintended.

Harm
A situation where the patient has been injured as a direct result of receiving medical care even where that injury may be a recognised risk of treatment. Depending on the extent of the injury, the patient may require additional monitoring, treatment or hospitalisation. In some situations, the injury could result in disability or death.

Disclosure of harm
The process of informing the patient and/or their family/whānau that injury occurred to the patient as a direct result of the care provided.

Near-miss
A situation where something occurred during the patient's treatment that could have, but did not, result in harm to the patient.

Open disclosure
Open disclosure refers to an honest and transparent conversation about harm to the patient as a direct result of medical care. Open disclosure can include discussions about near-misses even though steps may have been taken to avoid harm to the patient.

Risk
Risk refers to the chance that a patient could be harmed when they receive care or treatment.

The purpose of open disclosure

1. Open disclosure refers to situations where doctors inform the patient (and/or their family/whānau) that something unplanned, unexpected or unintended happened to the patient as part of their medical care. Open disclosure is not about blaming someone or something. It is intended to facilitate honest communication, trust, accountability and transparency.

2. Open disclosure is ethically and legally the right response to an adverse event or a near-miss. It is recognised as such by the Code of Health and Disability Services Consumers' Rights.[3] Open disclosure also:

    a. encourages honesty and accountability which builds trust in the doctor-patient relationship

[3] See in particular Right 6 (right to be fully informed) and Right 7 (right to make an informed choice and give informed consent) of the Code of Health and Disability Services Consumers' Rights.

b. is a vital part of the informed consent process, especially if the risk of harm might mean the patient needs further treatment or care
c. facilitates a learning environment where clinical teams can discuss adverse events and near-misses openly
d. increases public understanding and awareness about the reality and risks of medical treatment
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.

Risk is unavoidable in medical care

3. Risk is an unavoidable part of medical care. No matter how skilled the clinician is or how carefully the treatment is provided, there is a risk that the patient could experience harm as a result of the treatment. However, the risk for each patient will differ depending on various factors such as the complexity or duration of the procedure, the patient's medical history, age, state of health, the skills and experience of the clinical team involved, and the facility in which the care or treatment is provided.

4. Before going ahead with any treatment, you should discuss recognised risks with the patient. This is an important part of helping the patient make an informed decision about their treatment.[4] As part of your discussion, you should:

   a. identify the risks and benefits for the treatment you are recommending, and what those risks and benefits mean for that particular patient
   b. explain what the possible effects and consequences are for the patient if harm occurs
   c. highlight the implications of consenting to or declining the treatment.

Communication after an adverse event has occurred

5. Following an adverse event, patients and doctors may have different concerns and expectations about how an adverse event should be addressed and disclosed. It is important that you are mindful of this difference when communicating with your patient and/or their family/whānau.

What matters to patients when harm is disclosed

6. Research indicates that when harm is disclosed, the patient is usually concerned about what and how that harm occurred, why it happened, and what the immediate and long-term consequences are for them.

7. Patients usually want to be reassured that steps have been taken (for example, by making changes to a process) to reduce the risk of the harm from happening again to the patient and/or to other patients, and that staff learn from the experience.

[4] See also our statement on *Informed consent: Helping patients make informed decisions about their care*.

What doctors are concerned about when disclosing harm

8. When disclosing harm, doctors are often concerned that the patient could be overwhelmed by technical details, and that the disclosure could cause further distress to a patient who is already unwell. These concerns may limit what doctors disclose even though those details could be informative for the patient.

9. The fear of liability, loss of professional reputation, damage to the doctor-patient relationship, and the possibility of a complaint can all contribute to doctors' reluctance to openly disclose harm. However, research shows that a patient is more likely to complain if communication is unsatisfactory, for example, if the doctor fails to disclose the harm, or is not open and transparent when disclosing the harm.[5]

10. You should consider whether an apology is appropriate without accepting liability especially if the cause of the harm has not been established or confirmed. Most literature about open disclosure recommends this approach.[6]

Factors to consider before disclosing harm to the patient

11. Harm should be disclosed in a timely manner. This means the initial disclosure should be made as soon as practical, followed by a detailed discussion with the patient once the clinical team has met and assessed how the patient was harmed. The patient should be given the opportunity to reflect on what has happened and to ask questions.

12. If the patient was harmed during a procedure carried out by a clinical team, the clinical team should discuss the incident to identify:
    a. what happened
    b. what led to the harm
    c. the consequences for the patient and their family/whānau, including the patient's ongoing care needs as a result of the harm
    d. what will be done to prevent a similar occurrence in the future
    e. who should be present when the harm is disclosed to the patient
    f. any third parties that should be notified, including what documents need to be completed.

    It may be helpful to seek input from the management or administrative team on how harm should be discussed with the patient, and on any changes that should be made to strengthen existing processes for delivering care. Where possible, seek to take a restorative approach.[7]

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

[5] See also the Health and Disability Commissioner's *Guidance on open disclosure policies*.

[6] The Health and Disability Commissioner's *Guidance on open disclosure policies* contains advice on how to apologise. See also the Health Quality & Safety Commission's *Healing, learning and improving from harm/Te whakaora, te ako me te whakapai ake i te kino* for guidance on extending a meaningful apology.

[7] A restorative approach is where those affected by a harmful event come together in a safe and supportive environment to talk openly about what happened and the impact it has had on their lives. The purpose is to heal and learn from harm, and to clarify responsibility for actions by focusing on participation, respectful communication, truthfulness, accountability, and empowerment. For more information, refer to the Health Quality & Safety Commission's website on 'restorative practice.'

given full information within a single session. Consider whether a staged approach is 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

Ensure a senior doctor is present when the harm is disclosed

14. Ensure that the senior doctor responsible for the patient's care is present when the harm is disclosed. In situations where the doctor providing the care is not the senior doctor, both doctors should attend. Avoid disclosure where only hospital administrative staff or management attend as that is often not well received by patients.

Consider the patient's needs and preferences

15. When preparing to disclose harm, you should consider your patient's needs and preferences (such as cultural needs, disability, language, and level of health literacy) and what support they may require. Where possible, that support should be arranged (for example, by involving the patient's family/whānau, a social worker, Māori health provider or interpreter) and/or the patient should be informed how to access further support.[8]

Document the harm in the patient's records

16. When the patient has been harmed by medical care, that harm should be documented. You should include the following details in the patient's records:
    a. the nature of the harm
    b. any subsequent action taken in response to the harm
    c. details of the disclosure such as what was disclosed, which staff attended when the disclosure occurred, and the patient's reaction to the disclosure
    d. any follow-up or ongoing care the patient may require as a result of the harm.

Consider whether you need to disclose the harm to other parties

17. If the harm occurred in a secondary or tertiary care facility (such as a private or public hospital), you must inform the patient's general practitioner, if they have one. You should also advise the general practitioner what follow-up or ongoing care the patient may require, and who is responsible for providing that.

18. In some situations, you may be required to disclose the harm to a third party. For example:
    a. when the patient has died
    b. when the patient has been severely injured or affected by the treatment for example, if it resulted in total and/or permanent disability
    c. when the patient has long-term diminished competence, or is incompetent to understand the information and to make their own decisions.

[8] Such as lodging a treatment injury claim with ACC. In situations where you lodge a treatment injury claim on the patient's behalf, ensure that you have the patient's consent to do so.

19. You should familiarise yourself with any legal requirement to report the harm and ensure that you comply with that. For example, you must report the death to the Coroner where the patient died as a result of a medical procedure and the death was medically unexpected.[9]

Support for doctors when an adverse event has occurred

20. Doctors involved in an adverse event and/or who have to disclose harm to a patient may find the experience stressful and challenging. There are agencies that can provide you with confidential support such as employee assistance programmes, doctor support agencies and medical indemnity insurers.

21. Medical indemnity providers can also provide you with advice and support on matters including law and ethics. In situations where a patient has been harmed, you may wish to contact your indemnity provider for advice on disclosing the harm.

[9] Refer to the Ministry of Health's website for guidance about what kind of deaths must be reported to the Coroner.