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 as soon as practicable. We call this 'disclosure of harm'.

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

Where possible, review 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 clinician is present (this should preferably be the doctor with lead responsibility for the patient's care)
- consider the needs of the patient and/or family/whānau 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 and complete relevant documentation
- ensure the patient and/or family/whānau are aware of complaints processes available to them.

About this statement

This statement outlines what is expected of doctors when harm to patients or a near-miss 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.

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

[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.

Terms we use in this statement

Adverse event
An incident or situation where the patient experienced an adverse outcome that was unplanned, unexpected or unintended.

Harm
An outcome that negatively affects a patient's health or quality of life. Sometimes, it could result in death. Harm may or may not relate to the risks discussed during the informed consent process.

Disclosure of harm
The process by which an adverse event is communicated to the patient and/or their family/whānau.

Near-miss
A situation where something occurred during the patient's treatment that could have, but did not, result in harm to the patient. A near-miss can be the result of an error or a deviation from normal practice.

Open disclosure
Open disclosure is the transparent communication and honest discussion with a patient and/or their family/whānau about an incident that resulted, or could have resulted, in harm or injury to the patient.

Risk
Risk refers to the chance that a patient could be harmed when they receive medical care. Risk can vary based on factors such as the type of procedure performed, the patient's medical history and characteristics, the skills and knowledge of the doctor and clinical team, and the setting in which the medical care is provided.

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.

2. Open disclosure is ethically and legally the right response to an adverse event. It is also an appropriate response to a near-miss where there are serious implications for the patient or where that incident may impact the patient's future decisions on care. Open disclosure is consistent with the patients' rights under 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

    b. can be healing for the patient and/or their family/whānau

[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.

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, discuss the benefits and recognised risks with the patient. This is an important part of helping the patient make an informed decision about their treatment. For further details, refer to our statement on *Informed consent: Helping patients make informed decisions about their care*.

Communication after an adverse event has occurred

5. Patients and doctors may have different expectations about how an adverse event should be disclosed and addressed. It can be a stressful and emotive situation for all concerned. Be mindful of your communication when disclosing harm to 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. They may also want to know whether they could be eligible for a treatment injury claim and such information should be given to the patient.

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 important and relevant to 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.[4]

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

10. You should consider whether an apology or an expression of regret 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.[5]

Factors to consider before disclosing harm to the patient

11. Harm should be disclosed as soon as practicable. The patient's mental and cognitive state should be considered when deciding when to disclose harm.[6]

12. Where there is uncertainty over the cause of an adverse event, an initial disclosure should be made as soon as practicable, followed by a more detailed discussion with the patient once additional information is available.[7] If the harm was the result of another practitioner's action or omission,[8] consider the most appropriate person to disclose the harm to the patient and/or their family/whānau. The patient should be given the opportunity to reflect on what has happened and encouraged to ask questions.

13. Managing adverse events in a team-based environment can be complex. If the patient was harmed during a procedure carried out by a clinical team, that team should discuss the incident to identify:

    a. what happened

    b. what led to the harm

    c. the consequences/implications for the patient and their family/whānau, including any ongoing care needs the patient may have as a result of the harm

    d. what the clinical team could do differently/changes they could make to their practice 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,[9] 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 disclosed to the patient, and on any changes that should be made to strengthen existing processes for delivery of care. Avoid blaming individuals and adopt a learning culture. Where possible, seek to take a restorative approach.[10]

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[5] 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 reporting, reviewing and learning from adverse events including extending a meaningful apology.

[6] Consider whether any recent medical procedures may have affected the patient's cognitive state, for example general anaesthesia.

[7] In situations where the doctor is a sole practitioner, consider discussing the incident with a peer and/or the practice manager (if applicable).

[8] See also our statement on *What to do when you have concerns about another doctor* if you are concerned that another doctor's actions may have contributed to the harm the patient experienced.

[9] Consider also whether to report a near-miss or an adverse event to a specialty-based reporting system if there is one available.

[10] 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.'

14. 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

Include a senior clinician when disclosing significant harm

15. A senior clinician (preferably the doctor with lead responsibility for the patient's care) should be present when disclosing significant harm to the patient and/or their family/whānau. This is important where the doctor who provided the care was not the senior doctor. Avoid disclosure where only administrative staff or management (non-clinical staff) attend as that is often not well received by patients. Where a senior clinician is unavailable, consider the impact of delaying the disclosure against the benefit of timely communication with the patient and/or their family/whānau.[11]

Consider the patient's needs and preferences

16. When preparing to disclose harm, you should consider your patient's specific needs and what support they may require[12] (for example, by involving the patient's family/whānau, a social worker, interpreter or Māori health provider). The patient and/or family/whānau should be informed of how to access further support.[13] You should also ensure the patient and/or family/whānau are aware of complaints processes available to them.

Document the harm in the patient's records

17. When the patient has been harmed by medical care, that harm should be accurately documented, as soon as practicable after the event. You should include the following details in the patient's records:
    a. the nature of the harm
    b. factors that contributed to the harm
    c. any subsequent action taken in response to the harm, including notifications to third parties
    d. details of the disclosure such as what was disclosed, which staff attended when the disclosure occurred, and the patient's reaction to the disclosure
    e. 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

18. 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. The general practitioner should be advised if a treatment injury claim has been lodged. You should also advise the general practitioner what follow-up or ongoing care the patient may require, and discuss who is responsible for providing that.

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[11] In instances where the senior clinician is unable to attend in person, consider scheduling an online session with the patient and/or the patient's family/whānau as an alternative.
[12] See also the right to effective communication under Right 5 of the Code of Health and Disability Services Consumers' Rights.
[13] In situations where you lodge a treatment injury claim on the patient's behalf with ACC, discuss the lodgement process with the patient and obtain their consent to do so.

19. 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.

20. 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.[14]

Support for doctors when an adverse event has occurred

21. Doctors need the opportunity to discuss adverse events in a safe environment, and for systems to be put in place to prevent a recurrence. The Council recommends that employers facilitate a supportive work environment by providing peer support and training on responding to adverse events.

22. 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.

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