Open Disclosure

The law concerning Open Disclosure is currently governed by the Civil Liability (Amendment) Act 2017. The Act provides the legal framework to support voluntary open disclosure; it applies to all patient safety incidents including near misses and no-harm events. It provides for an open and consistent approach to communicating with patients and their families allowing an apology, as appropriate, when things go wrong in healthcare. The approach is intended to create a positive voluntary climate for open disclosure. This factsheet is intended to guide you through the statutory process.

The Medical Council's Guide to Professional Conduct and Ethics for Registered Medical Practitioners, 9th Edition, 2024 ("The Guide") also provides guidance on Open Disclosure, which is considered further below.

At the outset, the principles of Open Disclosure can be usefully summarised as:

- a timely acknowledgement to the patient about what happened and what impact it had on the patient, physically, emotionally and socially.
- an apology or expression of regret, which includes the phrase 'I am sorry' or 'we are sorry'.
- a factual explanation of what happened without speculation or conjecture.
- providing an opportunity for the patient and their support persons to relate their experience/story.
- a discussion of the potential consequences of the adverse event.
- an explanation of the steps being taken to manage the adverse event and to minimise the likelihood of a recurrence of such an event.
- keeping the patient and their nominated support person(s) informed and involved in the review, learning and quality improvement process.
- providing ongoing practical support for patients to manage the effects of harm and agreeing on matters regarding their ongoing care and treatment.

What are patient safety incidents?

The Act defines a patient safety incident as one of the following:

- an incident that resulted in an unintended or unanticipated injury, or harm, to a patient during the course of provision of a health service
- an incident that has not resulted in actual injury or harm but where a clinician has reasonable grounds to believe a patient was placed at risk of unintended injury or harm
- the prevention, by timely intervention or chance, of an unanticipated injury or harm which the clinician has reasonable grounds to believe that, in the absence of the prevention, could have resulted in injury or harm to a patient.

What legal protection is offered?

When done correctly, the Act and Regulations state that your disclosure and apology made during an open disclosure meeting shall not:

- constitute or be used as evidence of an admission of fault or liability:
- invalidate any insurance or indemnity;
- constitute an express or implied admission of professional misconduct, poor professional performance or unfitness to practise in any regulatory Fitness to Practise proceedings; or
- be admissible as evidence of professional misconduct, poor professional performance or unfitness to practise.



Where possible, it is advisable to contact Medisec in advance of open disclosure so we can advise you how best to proceed.

To whom should patient safety incidents be disclosed?

You may disclose to:

- (a) The patient concerned
- (b) A relevant person where:
 - Having regard to the patient's age, capacity or health status, it is appropriate, in your opinion, to disclose the patient safety incident to a relevant person
 - The patient has died; or
 - The patient has requested that disclosure be made to the relevant person and not the patient.

or

- (c) Both the patient and a relevant person where:
 - Having regard to the patient's age, capacity or health status, it is appropriate, in your opinion, to disclose the patient safety incident to both the patient and a relevant person; or
 - The patient has requested that disclosure is also made to the relevant person.

You may, for example, form the opinion that it is appropriate to disclose the patient safety incident to a relevant person if the patient has cognitive impairment.

Who may disclose the information?

The patient's principal healthcare practitioner shall make the disclosure, unless:

- the principal healthcare practitioner is not available or not otherwise in a position to make the disclosure; or
- having regard to the circumstances of the patient safety incident, the principal healthcare practitioner is satisfied that Open Disclosure should be made by another health practitioner.

Medical Council Guide

The Guide acknowledges at paragraph 4 that "healthcare is complex, and sometimes things go wrong, which may result in harm to patients". The Guide goes further than the Civil Liability Act in expanding the definition of Open Disclosure to include a requirement to take an empathetic approach. It provides that the response to a patient safety incident from health service providers, including doctors, must be professional and empathetic and reiterates that a culture of open disclosure must be promoted and supported. Paragraph 4 states that:

4. Open Disclosure is an honest, open, compassionate, consistent and timely approach to communicating with patients, and, where appropriate, their family, carers and/or supporters, following patient safety incidents.

The Guide provides that disclosure can be made to a "patient, their family, carers and/ or supports following patient safety incidents." This new definition allows for inclusion of Decision Supporters under the Assisted Decision-Making (Capacity) Act 2015.



The Guide further states that a doctor must comply with any applicable legislation and national policies regarding Open Disclosure and makes specific reference to the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023, which was signed into law in April 2023.

Please do not hesitate to contact Medisec if you have any queries regarding the above.

"The contents of this publication are indicative of current developments and contain guidance on general medico legal queries. It does not constitute and should not be relied upon as definitive legal, clinical or other advice and if you have any specific queries, please contact Medisec for advice".