FACTSHEET

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Open Disclosure

In Medisec, we recognise that our members are diligent and caring GPs who know their patients very well, care about patient safety, and aim for excellent communication. We also know that communication skills, professionalism and ethical obligations are substantial components of GP Training in Ireland. However, the daily "*plate-spinning*" and a fear of litigation cause many GPs to feel anxious about next steps when a patient safety incident arises.

Chapter 1 Section 4 of the Irish Medical Council Guide to Professional Conduct and Ethics for Registered Medical Practitioners 2024 (9th Edition) outlines the Council's position on open disclosure as follows[1]:

"*Healthcare is complex, and sometimes things go wrong, which may result in harm to patients. 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. It includes acknowledging what has happened, expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to on-going care and treatment, how lessons will be learned from what happened, and the steps being taken by the health services provider to try to prevent a recurrence of the event*."

The Medical Council further outlines your responsibilities as medical practitioners as follows:

"4.1 When a patient safety incident occurs, the response from health service providers, including doctors, must be professional, and empathetic.
4.2 You must practise, promote and support a culture of open disclosure.
4.3 You must comply with any applicable legislation and any national policies"

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.

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.

Legislation and Policies

The applicable legislation and national policies referred to in paragraph 4.3 above include the Civil Liability Act 2017[2], the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023[3], the Department of Health Guidance on the Patient Safety Act 2023[4], the HSE Open Disclosure Policy 2025[5] and the HSE Notifiable Incident Guideline 2026.[6]

Voluntary Open Disclosure

Part 4 of the Civil Liability Act 2017 provides the legal framework to support voluntary open disclosure and applies to all patient safety incidents.[2] It provides for an open and consistent approach to communicating with patients and their families allowing for an apology, as appropriate, when things go wrong in healthcare. The approach is intended to create a positive climate for voluntary open disclosure. If you are considering making a voluntary open disclosure regarding a patient safety incident in practice, it is advisable to contact your indemnifier early in proceedings.

The 2017 Act provides that if the correct procedure for mandatory open disclosure is followed, any communication, documentation, information provided, or apology given in the process of open disclosure cannot be used as evidence against the healthcare provider in any subsequent legal proceedings.

It is advisable to contact Medisec in advance of making any 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.

Mandatory Open Disclosure

The Patient Safety Act 2023 introduced mandatory reporting for a list of notifiable patient safety incidents outlined in Schedule 1 of the Act.[3] These incidents are outlined below and are notifiable to the relevant health service provider and regulatory body "*as soon as practicable or in any event, not later than 7 days from the day on which the provider was satisfied the incident had occurred.*"

The current list of notifiable incidents includes:

- death where it is unanticipated and cannot wholly be attributed to an illness or disease
- death due to medication error, and
- death in a setting where healthcare services are provided, which is deemed to be directly attributable to medical care
- surgical patient safety incidents
- unanticipated death due to anaesthesia
- death to do with the administration of blood products
- unanticipated death in the antenatal, postnatal or neonatal period attributable to medical management
- suicide in a healthcare setting

While it appears that most of these incidents are unlikely to occur in GP and relate to secondary care, you are obliged to be aware of the list and to act accordingly. It is also worth noting that Section 8 of the Act allows for the Minister of Health to expand this list in the future, which may include more GP-related care.

Procedure for Mandatory Open Disclosure

The procedure for open disclosure for notifiable incidents is detailed in The Department of Health Guidance on the Patient Safety Act 2023[4], the HSE Open Disclosure Policy 2025[5] and HSE Notifiable Incident Guideline 2026.[6]

The steps can be helpfully summarised as follows:

- 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.

The 2023 Act provides that if the correct procedure for mandatory open disclosure is followed, any communication, documentation, information provided, or apology given in the process of open disclosure cannot be used as evidence against the healthcare provider in any subsequent legal proceedings.

In summary GPs are advised to:

- Contact your indemnifier early for guidance or advice regarding voluntary open disclosure in practice.
- In the unlikely event that a notifiable incident occurs in practice, contact your indemnifier early, given the short-time frame for reporting.
- Be familiar with the Medical Council Ethical Guide including the section on open disclosure.
- Have processes in place for dealing with patient safety incidents and near misses in practice.
- Be familiar with the list of notifiable incidents in the Patient Safety Act 2023.

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References:

1. Irish Medical Council Guide to Professional Conduct and Ethics for Registered Medical Practitioners 2024 (9th Edition)
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2. The Civil Liability (Amendment) Act 2017
https://www.irishstatutebook.ie/eli/2017/act/30/section/8/enacted/en/html
3. The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023
https://www.irishstatutebook.ie/eli/2023/act/10/enacted/en/html
4. Department of Health Patient Safety Act 2023 Guidance
https://assets.hse.ie/media/documents/Department_of_Health_Patient_Safety_Act_2023_guidance.pdf
5. HSE Open Disclosure Policy 2025 https://www2.healthservice.hse.ie/organisation/nqpsd/featured-articles/hse-open-disclosure-policy-2025/
6. HSE Notifiable Incident Guideline 2026
https://assets.hse.ie/media/documents/HSE_Notifiable_Incident_Guideline_2026.pdf
7. Medisec Factsheet on Open Disclosure
https://medisec.ie/gp-resources/open-disclosure-2/
8. Medical Independent Article December 2025 Kate Noone
www.medicalindependent.ie/comment/medico-legal/from-voluntary-to-mandatory-the-new-era-of-open-disclosure-in-ireland/

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.

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