



Opinion Medico-Legal

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From voluntary to mandatory: The new era of open disclosure in Ireland

Ms Kate Noone on what the updated HSE policy on open disclosure means for healthcare staff

The law on open disclosure has undergone many notable changes over the past number of years. Once a voluntary process based on HSE policy, it is currently governed by the Civil Liability (Amendment) Act 2017 as amended. The signing into law of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 in April 2023, amended the 2017 Act, introducing mandatory open disclosure for specified serious patient safety incidents. In June of this year, the HSE released its updated policy on open disclosure, to provide clarity and alignment with the legislative updates.

Voluntary open disclosure

Prior to the current legislative framework, open disclosure was voluntary. The 2013 *HSE Open Disclosure Policy* initially laid the groundwork for open disclosure in the Irish health service. This policy only applied to the HSE and HSE-funded organisations.

Part 4 of the Civil Liability (Amendment) Act 2017 ('the 2017 Act') introduced the legal framework to support voluntary open disclosure. The 2017 Act applies to all patient safety incidents including near misses and no-harm events. It provides that where a patient safety incident occurred during the provision of healthcare, the health services provider may make an open disclosure of the incident to the patient. The 2017 Act provides that any apology offered cannot then be used in litigation.

Mandatory disclosure

The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (the 'Act') came into effect on 26 September 2024. The Act introduced the mandatory open disclosure of specified adverse incidents that occur during the provision of healthcare services. The intention was to ensure that patients and their families have access to comprehensive and timely information, including an apology where appropriate, in relation to serious patient safety incidents. It applies to both public and private healthcare providers. This Act was introduced in order to create a shift towards a culture of openness and transparency in healthcare in Ireland.

The Act also focused on the ability to learn from serious patient safety incidents, with the aim of supporting health service-wide improvements, in turn preventing harm to other patients. This would be achieved through the obligation on health service providers to report notifiable incidents to the relevant regulatory body.

In addition to mandatory open disclosure, the Act also provides for the expansion of HIQA's remit into private hospital services to allow it to set standards for the operation of private hospitals, to monitor compliance with these standards, and to undertake inspections as required.

Notifiable patient safety incidents

A patient safety incident can be described as an instance of preventable harm or injury which occurs to a patient during their care. Schedule 1 to the Act sets out a list of specific serious patient safety incidents that must be disclosed under the mandatory open disclosure process. These incidents are described as 'notifiable patient safety incidents' and include the following:

1. Patient death associated with a medication error.
2. Wrong site surgery or wrong surgery resulting in unintended and unanticipated death.
3. Unintended and unanticipated death occurring in an otherwise healthy patient undergoing elective surgery.
4. Unintended and unanticipated death occurring in any place where a health services provider provides a health

service that is directly related to any medical treatment and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.

5. Unanticipated and unintended perinatal death where a child born with, or having achieved, a prescribed gestational age and a prescribed birthweight was alive at the onset of care in labour.

6. Unanticipated death of a woman while pregnant, or within 42 days of the end of the pregnancy.

7. Unanticipated and unintended stillbirth.

8. A baby who was considered for, requires, or is referred for therapeutic hypothermia.

9. A death believed to be caused by the suicide of a patient within a health service setting.

As can be seen from the above list, currently all of the notifiable incidents involve the death of a patient. However, provision has been included under Section 8 of the Act for the Minister for Health to add additional notifiable incidents to the above list.

Notification to the health service provider

Where one of the notifiable incidents set out in the Act occurs, there is now an obligation on a health practitioner to notify the health services provider that was providing the service to the patient as soon as practicable. The health services provider is obliged to notify the incident to HIQA, the Chief Inspector of Social Services or the Mental Health Commission, dependent on the types of health services provider involved, within seven days.

Notification to the patient

Where a health services provider is satisfied that a notifiable incident has occurred, there is also an obligation to hold a notifiable incident disclosure meeting to disclose the incident to the patient concerned and/or a 'relevant person'. A 'relevant person' may be notified instead of the patient where:

1. Having regard to the patient's age, capacity or health status, it is appropriate, in the opinion of the principal health practitioner, to disclose the incident to a relevant person. For example, if the patient has significant cognitive impairment;
2. The patient has died; or
3. The patient has requested that disclosure be made to the relevant person as well as themselves or alternatively has requested disclosure is made solely to the relevant person.

Who discloses the information?

Under the Act, the patient's principal health practitioner should make the disclosure on behalf of the health services provider, unless they are not available or not otherwise in a position to make the disclosure; or having regard to the circumstances of the notifiable incident, the health service provider or the principal health practitioner is satisfied that open disclosure should be made by another health practitioner.

The open disclosure meeting for notifiable incidents

The Act sets out specific requirements about how the notifiable incident disclosure meeting ('the meeting') should take place and what information should be provided during and after the meeting. It states that the meeting should generally be held in person unless requested otherwise by the patient or relevant person.

A description of the incident concerned together with the date on which it occurred, the date it came to the attention of the health services provider, and the manner in which it came to the attention of the provider should

be disclosed. In addition, where, in the opinion of the health services provider, physical or psychological consequences of the notifiable incident are present or have developed, the patient and/or relevant person should be informed in respect of those consequences, and of any other physical or psychological consequences the health services provider believes are likely to develop at any time after the meeting.

If the health services provider has determined that an apology is warranted, this can also be provided at the meeting together with the details of any actions being taken or proposed to be taken as a result of the notifiable incident. There are also specific requirements for the maintenance of records and the provision of statements during and following the meeting within specified timelines.

Legal protection during the open disclosure process

It is important to remember that there are a number of legal protections under both the 2017 and 2023 Acts. Any disclosure and apology made during the open disclosure process shall not:

1. Constitute or be used as evidence of an admission of fault or liability;
2. Invalidate an insurance or indemnity;
3. Constitute an express or implied admission of professional misconduct, poor performance, or unfitness to practise in any regulatory fitness to practise proceedings; or
4. Be admissible as evidence of professional misconduct, poor professional performance, or unfitness to practise.

Non-compliance

Given its mandatory nature, non-compliance with the legislation can result in serious consequences including prosecution and/or a fine of up to €5,000.

The 2025 policy

Following on from the recent legislative changes, the HSE launched its updated policy on open disclosure on 17 June 2025. The updated policy replaces the 2019 policy and sets out the open disclosure requirements in HSE and HSE-funded services. It serves as a useful tool for all healthcare professionals, providing clarity on the legal position as well as a step-by-step guide to the disclosure process.

Key takeaways for healthcare practitioners

1. All healthcare practitioners will be required to comply with the open disclosure requirements for notifiable incidents and therefore must have processes in place to identify and disclose these incidents to patients and/or relevant persons in a timely manner.

2. Healthcare practitioners should remember that there may also be an obligation to notify relevant regulatory bodies of notifiable incidents as per the Act.

3. Resources:

► The HSE provides an e-learning programme, accessible through the HSeLanD website. This includes a helpful quick reference guide and toolkit. Although provided for those working in the HSE and HSE-funded services, the HSE Open Disclosure Policy 2025, provides up-to-date, easy to follow guidance on the open disclosure process.

► Paragraph 4 of the Medical Council's *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (ninth edition) also provides helpful guidance for practitioners.

► In light of statutory timelines to notify relevant regulatory bodies, healthcare practitioners should act promptly and seek advice from their indemnifier if they have any concerns or questions in relation to their legal obligations.