The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

The Act provides a legal framework for:

- the mandatory open disclosure, by health services providers, of certain incidents occurring in the course of the provision of a health service to a person. Specifically, the Act describes 13[1] different incidents, termed notifiable incidents, whereby open disclosure must take place in line with the legislation. The notifiable incidents are listed below (Figure 1);
- the mandatory open disclosure, by health services providers, of reviews carried out in relation to cancer screening that were requested by the patient (breast, bowel and cervical screening);
- legal protection in relation to the information shared at the time of open disclosure and any apologies made in the course of such disclosures;
- procedures in respect of clinical audit, and the data obtained in clinical audits;
- organisations will be required to report notifiable incidents to regulators, specifically the Health Information and Quality Authority, Chief Inspector of Social Services and the Mental Health Commission, and it requires such notifications to be made via the National Incident Management System (NIMS);
- amendments to the Health Act 2007 to provide for the application of standards set by the Health Information and Quality Authority to private hospitals;
- the review by the Chief Inspector of certain incidents (termed specified incidents) where some or all of the care of a patient/service user was carried out in a nursing home, and
- amendments to Part 4 of the Civil Liability (Amendment) Act 2017.

What does the Act mean for you?

It is important for staff to continue to comply with the HSE Open Disclosure Policy which outlines the principles, responsibilities and processes regarding open disclosure. The bottom line is that where patients are harmed or harm is suspected following a patient safety incident, staff and organisations must be open and honest in relation to what happened and provide a meaningful apology irrespective of whether or not it will be deemed a Notifiable Incident as set out in the Act. Staff should engage with all those impacted compassionately and with empathy.

There will be new reporting requirements to regulators through the National Incident Management System (NIMS), and specific requirements concerning the process of open disclosure including the provision of written communication to the patient/service user/relevant person following an open disclosure meeting. Admittedly, in the current list of notifiable incidents the patient/service user is deceased but the Minister can add to the list of Notifiable Incidents and the legislation refers to the patient/service user regularly throughout.

There are provisions in the legislation for clinical audit and a particular section relevant to cancer screening programmes where a patient requests a clinical review of their screening history. The legislation describes the requirement to be open and transparent with those patients and outlines similar steps to those that need to be followed for notifiable incidents. One key difference is that the reviews as described in Part 5 of the legislation in relation to cancer screening programmes do not need to be notified to the regulators.

Exemptions to open disclosure are clearly described as only applying where the patient/service user/relevant person cannot be contacted or the patient/service user/relevant person does not

[1] Please note that NI 13 has an a) and b) section to it

want to engage with open disclosure at that time. Non-compliance with the Act, without reasonable excuse, will be deemed an offence and subject to a financial penalty.

Aside from the financial penalty and potential reputational damage, it is well recognised that the purpose of open disclosure is to be open and transparent and that non-compliance can lead to mistrust in services and a poor patient/service user experience.

Schedule 1 of the Act - Notifiable Incidents:

1. **Surgery performed on the wrong patient** resulting in unintended and **unanticipated patient death** which did not arise from/was a consequence of an illness/underlying condition
2. **Surgery performed on the wrong site** resulting in unintended and **unanticipated patient death** which did not arise from/was a consequence of an illness/underlying condition
3. **Wrong surgical procedure** performed on a patient resulting in unintended and **unanticipated patient death** which did not arise from/was a consequence of an illness/underlying condition
4. **Unintended retention of a foreign object** in a patient after surgery resulting in unintended and **unanticipated patient death** which did not arise from/was a consequence of an illness/underlying condition
5. Any unintended and **unanticipated death** occurring in an otherwise healthy patient **undergoing elective surgery** in any place or premises in which a health services provider provides a health service where the death is directly related to a surgical operation or anaesthesia…
6. Any unintended and **unanticipated death** occurring in any place or premises in which 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.
7. Patient death due to **transfusion of ABO incompatible blood or blood components** and the death was unintended and **unanticipated** and which 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
8. **Patient death associated with a medication error** and the death was unintended and unanticipated as it 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.
9. **An unanticipated death of a woman while pregnant or within 42 days of the end of the pregnancy** from any cause related to, or aggravated by, the management of the pregnancy, and which 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.
10. **An unanticipated and unintended stillborn child** where the child was born without a fatal foetal abnormality and with a prescribed birthweight or has achieved a prescribed gestational age and who shows no sign of life at birth, from any cause related to or aggravated by the management of the pregnancy, 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 child.
11. **An unanticipated and unintended perinatal death** where a child born with, or having achieved, a prescribed gestational age and a prescribed birthweight who was alive at the onset of care in labour, from any cause related to, or aggravated by, the management of the pregnancy, and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the child or an underlying condition of the child.
12. **An unintended death where the cause is believed to be the suicide** of a patient while being cared for in or at a place or premises in which a health services provider provides a health service …
13. **A baby who—**
    - **(a) in the clinical judgment of the treating health practitioner requires, or is referred for, therapeutic hypothermia,**
    - **(b)** or (b) **has been considered for, but did not undergo therapeutic hypothermia** as, in the clinical judgment of the health practitioner, such therapy was contraindicated due to the severity of the presenting condition.

The Act is published here: gov.ie - [Patient Safety Legislation and Advocacy (www.gov.ie)]

The National Open Disclosure Framework (2023)

The Department of Health's National Open Disclosure Framework (2023) (Framework) provides a unified and consistent approach to open disclosure across public and private health and social care service providers, service regulators, and health and social care professional regulators, health and social care educators and other relevant bodies and organisations.

The ethos of this Framework is to ensure that the rights of all patients/service users and health and social care staff involved in and affected by patient safety incidents and adverse events are met and respected and that they are communicated in an honest, open, timely, compassionate, and empathic manner and that they are treated with dignity and respect.

The Framework outlines its six principles that it is based on, namely:

- **Principle 1**: Open, honest, compassionate and timely communication;
- **Principle 2**: Patient/service user and support person's entitlement in open disclosure
- **Principle 3**: Supporting health and social care staff
- **Principle 4:** Promoting a culture of open disclosure
- **Principle 5**: Open disclosure for improving policy and practice in health and social care
- **Principle 6**: Clinical and corporate governance for Open Disclosure.

What does the Framework mean for you?

The Framework builds on the HSE Open Disclosure Policy 2019 but clearly has a much broader scope as it incorporates regulators and health and social care providers and other agencies outside of the public sector. Each relevant organisation will be required to submit an annual report to the Minister for Health regarding their implementation of open disclosure and compliance with the Framework. For health care providers this includes reporting on the number of open disclosure events initiated and closed.

The Framework is published here: gov.ie - Patient Safety Legislation and Advocacy (www.gov.ie)