An Roinn Sláinte
Department of Health

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

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

Patient Safety Legislation, Advocacy & Policy Unit
National Patient Safety Office
Date: 14th June 2023

Background to the development of the Patient Safety Act 2023

Civil Liability (Amendment) Act 2017

(Part 4)

Patient Safety (Notifiable Patient Safety Incidents) Bill 2019

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Background to the development of the Patient Safety Act 2023

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

- The Act provides a legislative framework for a number of important patient safety issues, including the mandatory open disclosure of a list of specified serious patient safety incidents that must be disclosed to the patient and/or their family and the notification of the same to the Health Information and Quality Authority, Chief Inspector of Social Services and the Mental Health Commission.

Background to the development of the Patient Safety Act 2023

- Part 4 of the Civil Liability (Amendment) Act 2017 provides for voluntary open disclosure and was commenced on the 22nd of September 2018.
- During Report Stage of the 2017 Act in the Dáil, the Minister committed to progress legislation on the mandatory open disclosure for a defined set or list of serious events.

Background to the development of the Patient Safety Act 2023

- This Bill forms part of a broader programme of legislative and policy initiatives, including the Civil Liability (Amendment) Act 2017, that seek to embed a culture of open disclosure across the Irish Health Sector.

- The legislation was informed by the Report of the Commission on Patient Safety and Quality Assurance (Madden 2008).

- HSE Open Disclosure Policy 2013 laid the groundwork for open disclosure in the Irish health service

Background to the development of the Patient Safety Act 2023

- Draft Heads for open disclosure and clinical audit were provided for in the General Scheme of the Health Information and Patient Safety Bill (HIPS) November 2015.

- On the 5 July 2018 the Government agreed to separate the provisions for open disclosure and clinical audit from the HIPS Bill and approved the general scheme of the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 which provided the legislative framework for a number of important patient safety issues including, for the first time in Irish law, a legislative framework for the mandatory open disclosure of specified patient safety incidents. The Bill also provided for the extension of the Health Information Quality Authority's regulatory remit to private hospitals and for certain provisions related to the conduct of clinical audit against explicit clinical standards on a national basis.

Background to the development of the Patient Safety Act 2023

TIMELINES

- General Scheme of the Bill - approved on **5 July 2018**
- Oireachtas Committee on Health pre-legislative scrutiny on **26 September 2018**.
- Government approved text and authorised the Minister to introduce it to Dáil Éireann **3 December 2019 including three amendments**
- Progressed through the first and second stages on **12 December 2019**
- Dáil Committee Stage **March 2022**
- Dáil Report Stage **December 2022**
- Dáil (resumed) Report Stage **February 2023**
- Seanad 1st and 2nd Stage – **March 2023**
- Seanad Committee Stage – **March 2023**
- Seanad Report and Final Stage – **April 2023**
  - (back to Dáil Committee Stage - technical amendment)
- Presidential signature **Tuesday 2 May 2023**

Background to the development of the Patient Safety Act 2023

Important Amendments introduced at Committee and Report Stages in the Dáil

- Review of Act Mechanism
- Screening – Open Disclosure of Patient Requested Screening Reviews
- Nursing Home Incident Review

Review of Act Mechanism

- Section 80 of the Act provides that the Minister shall initiate a review of the operation of the Act no later than 2 years from the date of commencement. These provisions closely mirror those in other existing pieces of health legislation but in this case, require that the review be commenced sooner.

- 2 years is required to allow sufficient time for the provisions of the Act to become embedded within the health sector, allowing for initial learnings to be assimilated from the experience of the various organisations who are carrying out its implementation.

- The amendment will also make provision for the Minister to consult widely when carrying out a review, engaging with any person, body or organisation – including any appropriate Minister of the Government – having regard to their work or functions. This enshrines in statute a robust basis for ensuring that any review is carried out extensively and widely.

- The scope of the review will be the operation of the Act throughout the health sector.

Screening – Open Disclosure of Patient Requested Screening Reviews

- The Minister flagged an amendment at Committee Stage of the Bill for introduction at Report Stage to provide for mandatory open disclosure of completed individual patient requested reviews of their cancer screening by the Health Service Executive's National Screening Service.

- The new amendment provides patients with the full assurance that, should a patient requested review of their screening be completed, the full disclosure of the results of that review will be legally mandated, regardless of what the result is.

Screening – Open Disclosure of Patient Requested Screening Reviews

- A Part 5 patient requested review in respect of CervicalCheck, Breast Check and Bowel Screen screening programmes was therefore included in Section 5 of the Act. This Part 5 patient requested review will be subject to mandatory Open Disclosure of all the relevant information related to that part 5 patient requested review, in a similar manner to a notifiable patient safety incident elsewhere in the Act.

- In line with the Minister's commitments in the Dáil at Report Stage another amendment was prepared to ensure that the health services provider shall inform the patient of their right to a *Part 5 review* before or at the time the cancer screening is carried out.

- The legislation also requires that a health services provider shall establish and implement procedures for the further provision of information to patients with regard to their right to make a request for a review.

Screening – Open Disclosure of Patient Requested Screening Reviews

- In Summary:

- A new Patient Requested Review (PRR) process has been developed for cancer screening, following the guidelines from the Expert Reference Group, and (in the case of Cervical Check) designed in conjunction with patients, including the 221+ Group.

- It will be mandatory to fully disclose the results of these reviews to patients.

- Before a patient participates in the screening programme, or has a test, the legislation provides that they will be fully informed that reviews are available in the future.

- The choice of whether or not to get a review will be for patients to decide. Not all patients want a review; that will be their choice. The patient must, and will be, empowered to make informed choice.

Review of Nursing Home Incident

- The PSA 2023 also gives HIQA's Chief Inspector of Social Services a discretionary power to carry out a review of certain serious patient safety incidents ("specified incidents" in the amendment) occurring during the provision of health care, where some or all of the care of a patient was carried out in a nursing home.
- The amendment will allow for the implementation in a timely manner of the recommendation in the report of the COVID-19 Nursing Home Expert Panel that "*the Department of Health should explore a suitable structure and process for external oversight of individual care concerns arising in nursing homes, once internal processes have been exhausted without satisfaction*."
- This power will not replace the responsibility of nursing homes' services to address concerns that are raised by patients and families but will put in place an appropriate pathway to ensure these concerns are addressed in a way that will provide answers to families and patients when something has gone wrong.

Stakeholders during the Houses of the Oireachtas Process of the Bill/Act

- **BILLS OFFICE**
- **WHIPS OFFICE**
- **PROOFING**

Next Steps

- Project Manager for NIMS notification project

- Interviews, successful candidate, start date to be identified

- Commencement Timeline - The Patient Safety Act was enacted on 2nd May 2023. Prior to commencement of the Act, there are a number of preparatory steps required. The intention is to commence the Act at the earliest possible date and the Department will provide practical guidance as soon as matters develop.

- In progress: significant multi-stakeholder engagement, is now taking place across the health system. HSE KPI Development Group and HSE Implementation Group - The NPSO is a member of Work Stream 1 of the HSE National Open Disclosure Performance Measurement Project which is working on the Development of a KPI for Open Disclosure for the HSE Service Plan.

- Director NSPO to attend next meeting of the HSE Implementation Group.

Thank You

- The Patient Safety (Notifiable Incidents and Open Disclosure Act) 2023 is available at https://data.oireachtas.ie/ie/oireachtas/act/2023/10/eng/enacted/a1023.pdf

An Roinn Sláinte
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The National Open Disclosure Framework

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Patient Safety Legislation, Advocacy & Policy
National Patient Safety Office
Date: 14th June 2023

Background to the development of the National Open Disclosure Framework

Independent Patient Safety Council - Appointed in **2019** by the then-Minister for Health, Simon Harris T.D.

- Development of recommendations in respect of a national policy framework on open disclosure in health and social care.

The Crowe Report (2021) – Provided the evidence base that informed the Independent Patient Safety Council (IPSC) recommendations and the development and implementation of the Framework.

The IPSC Recommendations (2021) – Provide a road map for the development and implementation of the Framework for different stakeholders.

- *6 Principles of Open Disclosure*

Background to the development of the National Open Disclosure Framework

HSE Open Disclosure Policy

This policy applies to patient safety incidents and reflects the primacy of the right of patients to have full knowledge about their healthcare as and when they so wish and to be informed about any failings in that care process, however, and whenever they may arise.

- *This policy only covers the HSE and HSE-funded organisations.*

Background to the development of the Open Disclosure Framework

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

- The Act provides a legislative framework for a number of important patient safety issues, including the mandatory open disclosure of a list of specified serious patient safety incidents that must be disclosed to the patient and/or their family and the notification of the same to the Health Information and Quality Authority, Chief Inspector of Social Services and the Mental Health Commission.

- *This Act only covers specified notifiable incidences.*

Background to the development of the National Open Disclosure Framework

The National Open Disclosure Framework (2023)

Aims to provide a unified and consistent approach to open disclosure across public and private health and social care service providers, service regulators, health and social care professional regulators, health and social care educators, and other relevant bodies and organisations.

The Framework intends to make open disclosure the norm, not merely the focus of mandatory disclosures.

- Keeping the focus on the concepts of humanity, empathy, and open communication.
- Recognising the importance of the timeliness of the first early communications, in reducing any further possible harm or trauma.

Background to the development of the National Open Disclosure Framework

Consultation (2022)

- Focused consultation with relevant stakeholders.
- Public Consultation.

Feedback

The results of the public consultation on the Framework show that **97%** *of the respondents are in favour (69% strongly agree and 28% agree) of an open disclosure policy to be in place in all health and social care services in Ireland.*

(Framework Public Consultation 2022)

97% *of the respondents to the public consultation either agree or strongly agree (15% agree and 82% strongly agree) that organisations should promote a "just culture".*

(Framework Public Consultation 2022)

Contents of the National Open Disclosure Framework (2023)

- **7 Chapters with specific subsections:**

Chapter 1 - Introduction

Chapter 2 – Context – Legislative and Policy

Chapter 3 - Principles of Open Disclosure: (IPSC Recommendations)

- Open, Honest, Compassionate, and Timely Communication
- Patient/Service User and Support Persons' Entitlements in Open Disclosure
- Supporting Health and Social Care Staff
- **Promoting a Culture of Open Disclosure**
- Open Disclosure for Improving Health and Social Care Policy and Practice
- The Importance of Good Clinical and Corporate Governance for Open Disclosure

Contents of the National Open Disclosure Framework (2023)

Chapter 4 - Open Disclosure in Practice (Health Service Providers)

- Health and social care service providers must have a policy on open disclosure in place that aligns with the provisions of the Framework.

- Health and social care service providers must include mechanisms in their open disclosure policies empowering staff to report patient safety incidents and adverse events and to communicate with patients/service users and their support persons openly in relation to these incidents.

Contents of the National Open Disclosure Framework (2023)

Chapter 5 - Open Disclosure in Practice (Non-Health Service Providers)

- ***Health and Social Care Service Regulators***
- Embed the Principles of Open Disclosure into their standards and guidelines. for health and social care services.
- Ensure that inspections of services assess compliance with the Framework.

- ***Professional Regulators***
- Include Open Disclosure in all Policies and Codes of Conduct.
- Ensure Open Disclosure Policy in all Education Bodies and Clinical Training Sites are in place.
- Embedding of the Framework in all approved undergraduate and postgraduate education and training with a clinical component.
- Approval of professional development courses on Open Disclosure.

Contents of the National Open Disclosure Framework (2023)

- ***Education Bodies***

- Embed Open Disclosure in all their undergraduate and postgraduate education and training programmes with a clinical component.
- Ensure that all sites for Clinical and Practice Placements have a policy on Open Disclosure.

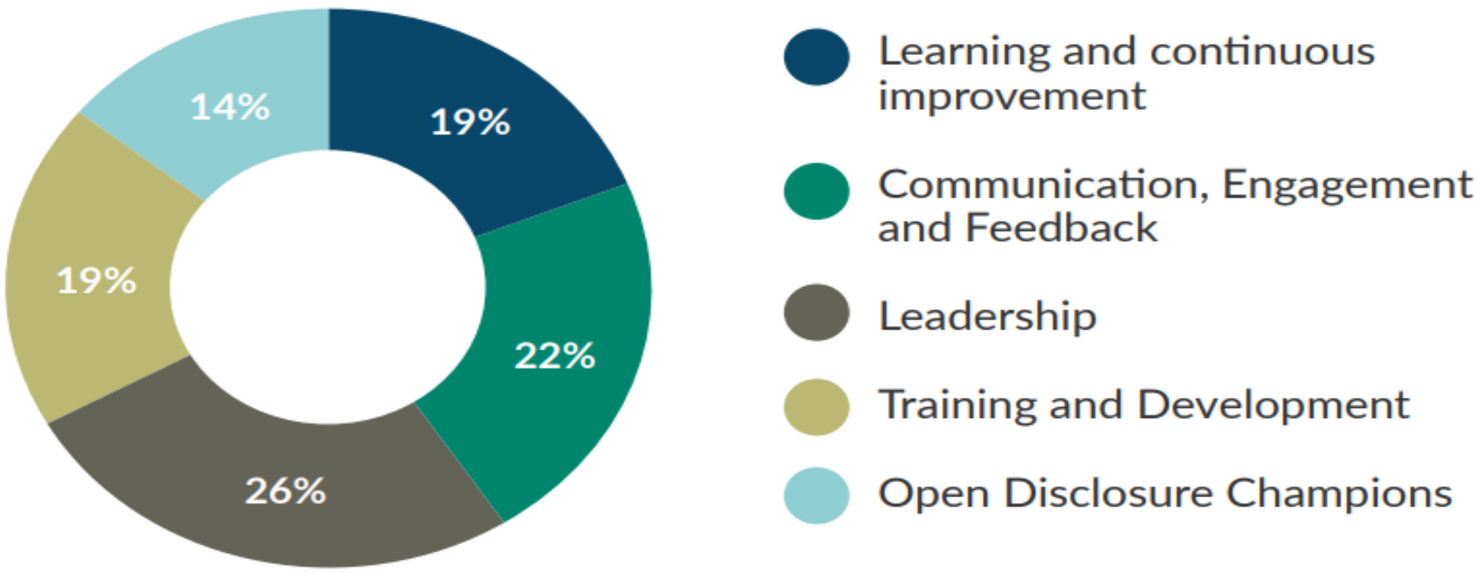
The majority of the respondents (95 %) to the public consultation believed (71% Strongly Agree and 24% Agree) that it is important to embed open disclosure in all undergraduate and postgraduate training programmes.
They also identified two benefits of this approach:

1. *Higher compliance with Open Disclosure principles as a result of the approval, accreditation, and monitoring of undergraduate and postgraduate education, and;*
2. *Better preparation of new entrants to the health sector workforce as a result of such training.*

Contents of the National Open Disclosure Framework (2023)

Chapter 6 - Drivers for Change

- Learning and Continuous Improvement
- Communication, Engagement, and Feedback
- Leadership
- Training and Development
- Open Disclosure Champions



Contents of the National Open Disclosure Framework (2023)

Chapter 7 – Monitoring and Evaluation of the Requirements of the Framework

- Annual Report to the Minister for Health
- Specific reporting requirements for stakeholders
- Example: "*Requirements for Health and Social Care Service Providers*"

a. Development and implementation of open disclosure policy.

b. Development and implementation of open disclosure training for all clinical and non-clinical staff including agency staff.

c. Evidence of the availability of support structure for all staff clinical and non-clinical including agency staff.

d. The number of trained clinical and non-clinical staff including agency staff.

e. The number of appointed and trained clinical and managerial open disclosure champions.

f. The number of open disclosure events initiated and closed.

What is the team's current focus and next steps?

1. Publication and implementation of the Framework

- Framework will be circulated to all relevant stakeholders.

2. Official launch of the Framework

- Working with the HSE and other stakeholders for the launch.

The results of the public consultation on the Framework show that **95%** *of the respondents highly support (62% strongly agree and 33% agree) that all relevant organisations and individuals should promote and support the embedding of the Open Disclosure Framework.*

(Framework Public Consultation 2022)