Open Disclosure Policy 2025

NATIONAL
OPEN DISCLOSURE
PROGRAMME

HSE Open Disclosure Policy 2025:
Communicating with Patients and Relevant Persons following Patient Safety or Notifiable Incidents

Policy ☒ Procedure ☐ Protocol ☐ Guideline ☐ Clinical Guideline ☐

DOCUMENT GOVERNANCE	
Document Owner (post holder title):	Chief Clinical Officer (CCO)
Document Owner name:	Dr Colm Henry
Document Owner email contact:	opendisclosure.office@hse.ie on behalf of the CCO
Document Commissioner(s):	Dr Colm Henry, Chief Clinical Officer
Document Approver(s):	Dr Colm Henry, Chief Clinical Officer
Lead responsibility for national implementation:	Dr Colm Henry, Chief Clinical Officer
Lead responsibility for national monitoring and audit:	Dr Colm Henry, Chief Clinical Officer
Development Group Name:	HSE National Open Disclosure Steering Committee
Development Group Chairperson:	Dr Orla Healy, National Clinical Lead, National Quality and Patient Safety
DOCUMENT MANAGEMENT	
Date effective from:	17/06/2025
Date set for next review:	17/06/2028
Your Reference No:	NATOD-POL-001-03
Current version no: 3	Archived version no: 2

PUBLICATION INFORMATION	
Title:	HSE Open Disclosure Policy 2025: Communicating with Patients and Relevant Persons following Patient Safety or Notifiable Incidents
Topic:	This policy document sets out the requirements for open disclosure in the HSE and HSE-funded services where a patient safety or notifiable incident occurred. It is aligned to the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 and guided by the Department of Health National Open Disclosure Framework 2023.
National Group:	The HSE National Open Disclosure Steering Committee
Short summary:	It is the policy of the HSE to communicate with patients and relevant persons in an open, honest, timely and compassionate manner when a patient safety or notifiable incident occurs. The HSE has set out the requirements for open disclosure and the process to follow in such instances. This policy document reflects the importance of the rights of patients to be fully informed about their care, including when things go wrong and an incident occurs. It emphasises the importance to treat others with dignity and respect. The policy supports those involved in incident management and the open disclosure process, in particular patients/relevant persons and staff, by providing clear information about the important elements of the process and what supports are available to them.

PUBLICATION INFORMATION	
Description:	The purpose of this policy, which applies across HSE and HSE-funded services, is to: ▶ Clearly state and inform staff and the public of the open disclosure requirements. ▶ Recognise the importance of governance and leadership in open disclosure at all levels. ▶ Help drive and embed a culture of openness, transparency and learning. ▶ Describe the underlying principles, process steps, roles and responsibilities, governance requirements and supports available in relation to open disclosure. ▶ Outline the importance of open, honest, timely and compassionate communication following a patient safety or notifiable incident to prevent compounded harm to those affected by it. ▶ Enable implementation of (i) The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (ii) the Department of Health National Open Disclosure Framework (2023) across the HSE and HSE-funded services whilst maintaining an emphasis on empathy and compassion throughout the open disclosure process. ▶ Describe the legal protections available to staff in relation to the Civil Liability (Amendment) Act 2017 and the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 to encourage open disclosure.

VERSION CONTROL

Version No.	Date reviewed	Sections changed	Approved by
3	2025	All sections revised and updated in line with the (i) The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (ii) Department of Health National Open Disclosure Framework 2023 (iii) Dr Gabriel Scally review 2023 (iv) HSE Enterprise Risk Management Policy and Procedures 2023, (v) World Health Organisation Global Patient Safety Action Plan 2021-2030 (vi) Incident Management Framework 2020 (vii) HSE Patient Safety Strategy 2019-2024 and (viii) Assisted-Decision Making Act 2015.	HSE Senior Leadership Team
2	2019	All sections revised and updated in line with the (i) commencement of Part 4 of the Civil Liability (Amendment) Act 2017 and (ii) recommendations of the 'Scoping Enquiry into the Cervical Check screening Programme Report' 2018.	HSE Directorate Team
1	2013	New Policy.	HSE Directorate Team

Document management notes:

The title of the policy has been updated to incorporate notifiable incidents as described in the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Foreword

As someone who has followed the progress of establishing a culture of open disclosure in healthcare for many years, I believe open disclosure is the right thing to do.

Patients trust healthcare professionals to do their best to deliver safe care and part of that care includes honesty throughout the patient's healthcare journey. This is particularly important when patient safety incidents occur. Sometimes these are difficult situations, resulting in difficult conversations, which require robust supports for everyone involved. People who work in healthcare are the frontline of patient care and advocacy. Their wellbeing and right to be supported to do their work in the security of a just and fair culture is essential to successful open disclosure processes. Open disclosure is the right of every patient. Where the patient has died or is unable to receive disclosure information that right passes to their loved ones/relevant persons.

Everyone owns their own honesty and many apply it without question as a natural part of themselves. When faced with situations involving others, pauses are created where we acknowledge events to ourselves, view human challenges, and decide our actions. That is where open disclosure choices are made.

Everyone owns their own honesty and whether to share it with others.

Bernie O'Reilly
Chair, Patients for Patient Safety Ireland

Foreword HSE

Health and social care staff and services strive to deliver the best care possible for patients. When an incident occurs, our staff and services continue on this path to support those impacted. Open disclosure is a means of approaching a difficult situation in the most ethical and person-centred way. It embodies the importance of good communication, listening and providing information that is accessible.

Honesty builds confidence. Open disclosure instils trust in our services and helps reduce the likelihood of compounded harm to those affected by the incident. Patients and their family must always remain at the forefront of our approach to delivering care. We must approach open disclosure from the view of the patient. What is it that patients reasonably expect and we would expect if we were a patient harmed due to an incident? It simply is the right thing to do.

We must all lead by example and be open and honest in all matters of care to support patients in their understanding and decision making. National developments, such as the enactment of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 and the Department of Health National Open Disclosure Framework 2023, further highlight the importance placed on open disclosure across the wider healthcare system. This policy incorporates the requirements of both.

The essence of this open disclosure policy lies not merely in compliance with regulatory frameworks but in a proactive commitment to honesty and openness. It is a cornerstone of ethical conduct, guiding interactions between staff, patients and their family. This approach acknowledges that transparency is not a choice but a moral imperative, essential for nurturing robust relationships built on mutual respect and informed decision-making.

Acknowledging the requirement placed on us all, it is clear that open disclosure is not always easy and staff need to know that they will be supported by the system. I am pleased that this policy focuses on the importance of supporting patients, their family and staff. When our staff feel confident and assured about doing the right thing it will ensure open disclosure, on-going communication and support is delivered. Such support and power will be transformative and demonstrate the positive and pro-active approach the HSE and HSE-funded services take when an incident occurs. Transparency builds credibility, demonstrating a commitment to ethical conduct that goes beyond mere compliance.

Critically, open disclosure promotes continuous improvement. By seeking feedback and actively listening to patients and their family, services can better understand the events surrounding an incident and make the necessary recommendations to respond to them. This iterative process not only strengthens internal practices but also enhances the quality of service delivery, ensuring that patient's needs and expectations are met with diligence and responsiveness.

I would like to thank all who contributed in the development of this open disclosure policy in particular our patient representatives.

Dr Colm Henry
Chief Clinical Officer, HSE

Table of Contents

1

Introduction, Aim and Objectives

1.0 Introduction

Health and social care services aim to provide safe, high-quality care that results in good outcomes, both for those receiving and for those providing these services. However, health and social care is complex and sometimes, despite best efforts, things can go wrong and an incident occurs whereby a patient may experience harm. It is crucial that, in such instances, their immediate healthcare needs are addressed; that they experience open, honest, compassionate and timely communication about the incident; and that all those affected are supported.

Communicating effectively with persons affected is an important part of the therapeutic relationship and if done well following an incident can mitigate anxiety and enhance trust in staff, the organisation and the health and social care system. Sadly, patients and their family can experience compounded harm (in addition to the harm already reported due to the incident) where open disclosure does not occur and they encounter defensive and/or closed communication from health or social care service providers (Wailing *et al*, 2022). Nurturing a culture of openness and trust when an incident occurs is important in health and social care services and aligns with the HSE values of care, compassion, trust and learning. Open disclosure is a key requirement to achieving this.

1.0.1 What is Open Disclosure?

Open disclosure is defined as the open, honest, compassionate and timely approach to communicating with patients or, where appropriate, their relevant person (or both of them) following patient safety incidents or notifiable incidents.

It includes apologising and expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to ongoing care and treatment, learning and the steps being taken by the health or social care service providers to try to prevent a recurrence of a similar incident.

It is an integral part of the incident management process.

Open disclosure improves patient safety through improved understanding of what has happened from the patient/relevant person's perspective and through the learning acquired from the review of an incident.

1.0.2 Use of the term "patient" in this policy

Different terms are used for people who attend HSE and HSE-funded health and social care services in different settings. The terms "patient", "service-user", "client", "resident", "person supported by healthcare services", "consumer", "the public" and "people who use healthcare services" are used across health and social care services. The term "patient" is used throughout this document, and refers to people who use, or are supported by healthcare services, their personal support network, communities and anyone who may use healthcare services in the future. When reading this document, please substitute the word "patient" with the term most appropriate for your healthcare setting (HSE "Better Together", 2022).

'Patients' include persons to whom a health or social care service is, or has been, provided.

1.0.3 Use of the term "relevant person" in this policy

The term "relevant person" has different definitions in different legislation[1].

In the context of this policy, the term "relevant person" aligns with the definition of a relevant person in both the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 and the Civil Liability (Amendment) Act 2017. In both Acts, the relevant person relates to the individual, other than the patient, to whom the disclosure is disclosed to, for example, a family member, a cohabitant, a decision supporter, or a power of attorney. The definition of a relevant person as per the Patient Safety Act 2023 is included in the Glossary.

1.1 HSE Open Disclosure Policy Statement

It is the policy of the HSE and HSE-funded services that patients are communicated with in an open, honest, transparent and empathic manner following a patient safety or notifiable incident; that they are provided with a sincere and meaningful apology, especially when they are harmed as a result of such incidents; and that this communication process is initiated in a timely manner.

Open disclosure is a feature of high-quality health and social care, and is an important contributor to patient safety.

1.2 Purpose

The purpose of this policy document **[hereafter shortened to "policy"]** is to:

1.2.1 Recognise the importance of governance and leadership in open disclosure at all levels of the HSE and HSE-funded services.

1.2.2 Help drive and embed a culture of openness, transparency and learning across the HSE and HSE-funded services.

1.2.3 Clearly state and inform staff and the public of the open disclosure requirements in HSE and HSE-funded services.

1.2.4 Describe the underlying principles, process steps, roles and responsibilities, governance requirements and supports available in relation to open disclosure.

1.2.5 Outline the importance of open, honest, timely and compassionate communication following a patient safety or notifiable incident to prevent compounded harm to those affected by it.

1.2.6 Enable implementation of (i) The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 **[hereafter referred to as "Patient Safety Act 2023"]** and (ii) the Department of Health National Open Disclosure Framework 2023 [**hereafter referred to as "DoH National Open Disclosure Framework 2023"]** across the HSE and HSE-funded services whilst maintaining an emphasis on empathy and compassion throughout the open disclosure process.

1 For example, under the Assisted Decision-Making (Capacity) Act 2015, the "relevant person" is the person whose capacity is in question, may shortly be in question or who lacks capacity in relation to a decision

1.2.7 Describe the legal protections available to staff in relation to the Civil Liability (Amendment) Act 2017 and the Patient Safety Act 2023 designed to encourage open disclosure.

1.3 Scope

This policy applies to all HSE and HSE-funded health and social care services.

1.4 Objectives

The objectives of this policy are:

1.4.1 To outline the requirements for effective communication of open disclosure that is timely, empathic, compassionate and informed. It includes an expectation that patients are provided with a sincere and meaningful apology when they experience harm as a result of a patient safety or notifiable incident.

1.4.2 To demonstrate that open, honest and transparent communication with patients and/or their relevant persons occurs following a patient safety or notifiable incident using a standardised approach in a manner that they understand across all health and social care service providers.

1.4.3 To inform staff, in particular managers (clinical and corporate), on how they can support patients, their relevant persons and staff/peers immediately following a patient safety or notifiable incident and thereafter, as required, including the provision of support throughout the open disclosure and incident review process.

1.4.4 To promote a fair and just culture that drives openness, transparency and learning across all health and social care service providers.

1.4.5 To embed open disclosure as an integral part of incident management and support staff in implementing the requirements of the DoH National Open Disclosure Framework 2023 and the Patient Safety Act 2023.

1.4.6 To support and enable staff and services to engage in effective and meaningful open disclosure where a positive experience for patients/ their relevant person is reported whilst recognising the difficulties of being impacted by a patient safety or notifiable incident.

1.4.7 To outline the required governance processes in place to include accountability and assurance arrangements to support effective and meaningful open disclosure.

1.5 Outcomes

The expected outcomes of this policy are as follows:

1.5.1 A positive, open and transparent patient safety culture within the HSE and HSE-funded services.

1.5.2 Timely, informed, compassionate and empathic open disclosure.

1.5.3 Patients, their relevant persons and health and social care staff involved in and/or affected by patient safety or notifiable incidents are provided with immediate and ongoing support, as required and relevant to their individual needs, following such incidents.

1.5.4 All health and social care services follow a consistent process for the management of open disclosure.

1.5.5 All health and social care services have clear governance arrangements and assurance processes in place in relation to this policy.

1.5.6 Staff receive standardised open disclosure training designed and delivered by the HSE for HSE and HSE-funded staff.

1.6 Principles for the management of open disclosure

1.6.1 The image below outlines ten principles for the management of open disclosure in health and social care services. These have been adopted from the former UK National Patient Safety Agency (now incorporated into NHS England):

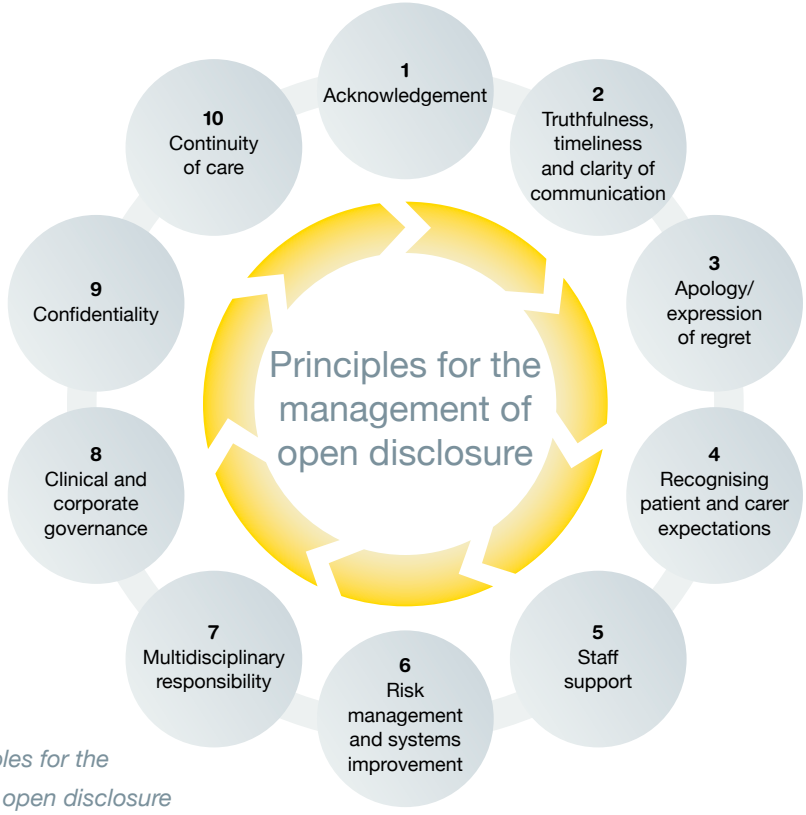

Figure 1: Principles for the management of open disclosure

1.7 Communication and open disclosure

Effective communication with patients is essential from initial consultation and throughout their journey of care including where an incident occurs. In fact, good communication is fundamental to open disclosure. This includes active listening and being responsive to a person's communication needs (for example organising interpreters for persons where English is not their first language, or organising assistive technology for persons with a disability who use such tools).

Key elements of open disclosure communication include:

a) Open, honest, compassionate and timely communication with patients and/or their relevant persons following a patient safety or notifiable incident.

b) Acknowledging to the patient/relevant person that a patient safety or notifiable incident has occurred and listening to them in regards to the impact of the incident on the patient.

c) Explaining what open disclosure is and maintaining ongoing communication as part of the open disclosure process described in Section 5.

d) Providing a factual explanation in relation to what has happened, when it happened and how/why it happened, as and when this information becomes known.

e) Listening to and hearing the patient's story (their understanding of what has happened and their description of the impact of the patient safety or notifiable incident on them) and responding to this information in an appropriate manner.

f) Demonstrating empathy, kindness and compassion towards all those involved in and/or affected by the incident that has occurred to include the patient, their relevant person and staff.

g) Apologising and expressing regret to the patient/relevant person, as appropriate to the situation. This must be sincere, meaningful and personal to the patient and/or their relevant person and to the given situation.

h) Shared decision making in relation to ongoing care and treatment, and meaningful involvement in the review of the patient safety or notifiable incident that has occurred.

i) Affording the patient and/or their relevant person the opportunity to ask questions and responding honestly and factually to any questions or concerns arising.

j) Providing immediate and ongoing support for the patient and/or their relevant person, as appropriate, including access to patient advocacy services.

k) Providing immediate and ongoing support for staff involved in and/or affected by the patient safety or notifiable incident, as appropriate.

l) Reassuring the patient and/or their relevant person in relation to any learning that has occurred as a result of the management and review of the patient safety or notifiable incident including sharing the incident review findings.

m) Providing information on the steps being taken or planned by the health and social care service provider to reduce the likelihood of a similar incident occurring in the future.

2

Imperative for Open Disclosure

2.0 Overview

This section sets out the imperative for open disclosure in the HSE and HSE-funded services, based on moral, policy, professional regulation, health service regulation, and legislative obligations.

2.1 Moral

Open disclosure is the right thing to do. Nurturing a culture of openness and trust when an incident occurs is important in health and social care and aligns with the HSE values of care, compassion, trust and learning. Whilst open disclosure is the right thing to do, the patient/relevant person's wishes must be respected when they decline open disclosure.

2.2 Policy

As per the HSE Open Disclosure Policy Statement in Section 1 of this document:

It is the policy of the HSE and HSE-funded services that patients are communicated with in an open, honest, transparent and empathic manner following a patient safety or notifiable incident, that they are provided with a sincere and meaningful apology especially when they are harmed as a result of such incidents and that this communication process is initiated in a timely manner.

Open disclosure is a feature of high-quality health and social care and is an important contributor to patient safety and safety improvement.

This policy has been informed by the Department of Health National Open Disclosure Framework 2023 which applies to all public and private health service providers. Section 3.4.3 of the framework sets out the requirement for an open disclosure policy by health and social care service providers.

2.3 Professional regulation

Professional healthcare regulators such as the Irish Medical Council, Nursing and Midwifery Board of Ireland (NMBI) and CORU, amongst others, have incorporated the requirement for open disclosure in their codes of conduct, ethics and practice.

2.4 Health and social care regulation

Healthcare regulators such as the Health Information and Quality Authority (HIQA), the Chief Inspector for Social Services, and the Mental Health Commission (MHC) require health and social care service providers to be open and fully inform patients/ their relevant person of an incident.

Reporting notifiable incidents to the relevant regulator is also a legal requirement of the Patient Safety Act 2023. The relevant regulator must be notified within seven (7) calendar days from when a health or social care services provider is satisfied that a notifiable incident has occurred.

HSE and HSE-funded (section 38s only) health and social care service providers must report notifiable incidents to the relevant regulator using the National Incident Management System (NIMS) incident management module. Section 39s and private providers report such incidents to the relevant regulator using a reporting portal on the regulators' website pages. See the Open disclosure webpage.

2.5 Legislation

In Ireland, there are two specific pieces of legislation that set out requirements for open disclosure and the relevant processes to follow.

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

Whilst open disclosure is a HSE requirement for patient safety incidents, the Patient Safety Act 2023 makes open disclosure a legal requirement for a sub-set of incidents, called notifiable incidents. These are defined in Schedule 1 of the Patient Safety Act 2023 and listed in Section 4 of this policy.

The Patient Safety Act 2023 was enacted into law in May 2023 and commenced on 26 September 2024. It provides a legal framework for patient safety, in particular as it relates to open disclosure. The legislation is applicable to public and private health and social care service providers, and sets out:

- the legally mandatory requirement for open disclosure, by health and social care service providers, of certain incidents occurring in the course of the provision of a health service to a person. Specifically, the Act describes 13 notifiable incidents, whereby open disclosure must take place in line with the legislation;
- the requirement for organisations to report notifiable incidents to regulators, specifically HIQA, the Chief Inspector of Social Services and the Mental Health Commission (as appropriate), and it requires such notifications to be made via NIMS as described in section 2.4;

- legal protections in relation to the information shared at the time of open disclosure and any apologies made in the course of such disclosures where the incident is a notifiable incident;
- provisions for procedures in respect of clinical audit, and the data obtained in clinical audits;
- amendments to the Health Act 2007 to adapt the threshold for HIQA to carry out statutory investigations and expansion of monitoring into private hospitals;
- amendments to Part 4 of the Civil Liability (Amendment) Act 2017 which relates to all patient safety incidents;
- the mandatory communication by health or social care service providers of results following patient requested cancer screening reviews (specific to breast, bowel and cervical national cancer screening programmes);
- non-compliance with the reporting of a notifiable incident to the relevant regulator or not holding the required open disclosure meeting(s) can result in a Class A fine. It is a defence to demonstrate all reasonable efforts were made to ensure compliance.

2.5.2 The Civil Liability (Amendment) Act 2017

The Civil Liability (Amendment) Act 2017 **[hereafter referred to as "CLA Act 2017"]** amended pre-existing legislation that was specific to claims/compensation management and the courts. The CLA Act 2017 includes a section on open disclosure in healthcare (namely Part 4 of the Act). The Patient Safety Act 2023 further amended the CLA Act 2017, and aligns the open disclosure process described in both pieces of legislation.

Importantly, and in contrast to the Patient Safety Act 2023, the CLA Act 2017 applies to all patient safety incidents that are **not notifiable incidents**. Additionally, it is described as "voluntary" because staff can choose to apply the CLA Act 2017 where they wish to seek the protections of the Act for any patient safety incident that is not a notifiable incident.

2.5.3 Legislation and legal protections

The open disclosure process, as described in Section 5 of this policy, incorporates the requirements of the Patient Safety Act 2023 as it relates to notifiable incidents, and the CLA Act 2017 as it relates to open disclosure of patient safety incidents. This policy highlights any key requirements that must be specifically met for both pieces of legislation and for the legal protections to apply.

Legal protections were introduced as part of the CLA Act 2017 and the Patient Safety Act 2023 to encourage and support healthcare staff in being honest about patient safety and notifiable incidents. In short, it means that, information shared by healthcare staff cannot be used in certain circumstances.

Legal protections apply to information provided and any apology given at an open disclosure meeting where the processes outlined in the CLA Act 2017 and the Patient Safety Act 2023 (as applicable) are followed, those processes are reflected in this policy. The legal protections of both Acts broadly include provisions that the information and apology:

- shall not constitute an express or implied admission of fault or liability in relation to the incident or any clinical negligence action arising from the consequences of that incident.
- will not be admissible as evidence of fault or liability in Court in relation to the incident or clinical negligence action arising from the consequences of that incident.
- will not invalidate the indemnity or insurance cover of the health service provider.
- shall not constitute an express or implied admission of fault, professional misconduct, poor professional performance or unfitness to practice or other failure or omission in relation to any complaint which arises from the consequences of the incident made to a regulatory body subsequently.
- shall not be admissible as evidence of fault, professional misconduct, poor professional performance, unfitness to practice a health service, or other failure or omission, in proceedings to determine a complaint, application or allegation.

Remit	Open Disclosure Policy	CLA Act 2017	PSA 2023
When does this apply?	Patient safety and notifiable incidents	All patient safety incidents excluding notifiable incidents	Notifiable incidents
Is it optional or mandatory?	HSE policy requirement	This is optional to follow	This is legally mandated hence a requirement in law
Is the content and apology of the open disclosure protected?	Not applicable – protections do not stem from the policy	Yes, as long as the process described in this Act (and this policy) is followed	Yes, as long as the process described in this Act (and this policy) is followed
Are there any specific requirements to be mindful of?	All requirements are clearly outlined in this policy	Prescribed process including the need for written communication following open disclosure which must reference the CLA and be shared within five calendar days of open disclosure meetings	Prescribed process including the need for written communication following open disclosure which must reference the PSA and be shared within five calendar days of open disclosure meetings

Figure 2: Policy and legal considerations

3

Roles and Responsibilities

3.0 Overview of roles and responsibilities

The patient is front and centre of this policy. Clarity in relation to the roles and responsibilities of staff at all organisational levels is a fundamental governance and leadership requirement for effective incident management. Open disclosure is an integral component of the incident management process.

The HSE Performance and Accountability Framework sets out the accountability structure for the HSE and clarifies the named individuals who have delegated responsibility and accountability for all aspects of service delivery in their service. They are therefore fully responsible and accountable for the services they lead and deliver. That includes the quality and safety of services incorporating compliance with incident management and open disclosure requirements and enabling services and staff to deliver in these areas. It is the role and responsibility of the Senior Accountable Officer (SAO) of a service to have overall accountability within their area of responsibility for the management of incidents which includes compliance with the HSE Open Disclosure Policy. This includes ensuring that the management arrangements and the roles of all staff in relation to open disclosure are clear. Failure to comply with the provisions of the HSE Open Disclosure Policy may lead to consideration of action under the Disciplinary Procedure.

3.1 Chief Executive Officer (CEO)

The CEO has overarching accountability and responsibility, so far as is reasonably practicable, for a high-quality and safe health service. The CEO is accountable to the HSE Board. In relation to open disclosure, the CEO:

- Ensures the development of and compliance with this policy.
- Delegates operational responsibility for the day-to-day running of the organisation to HSE Senior Leadership Team (SLT), senior managers and line managers for all matters within their control.
- Ensures that the required HSE Open Disclosure Annual Report is submitted in April of each year to the Minister/Department of Health as described in the DoH National Open Disclosure Framework 2023.
- Seeks assurance from the relevant SAOs about the implementation of the policy as demonstrated in the annual reports.

3.2 Chief Clinical Officer (CCO)

The CCO holds responsibility for the development of HSE Open Disclosure Policy and the implementation and monitoring of the policy at the HSE Centre. This activity is delivered by a dedicated open disclosure and incident management function within the quality and patient safety structure. The National Open Disclosure Office of the Quality and Patient Safety Incident Management Team, National Quality and Patient Safety, will collate the regional and national service annual open disclosure compliance reports and include them with the HSE Open Disclosure Annual Report. This will be submitted to the CCO and SLT for approval and is due with the Minister for Health in April of each year.

3.3 Senior Accountable Officer (SAO)

In all instances, the Senior Accountable Officer (SAO) in relation to open disclosure is the person taking on the SAO role as described in the HSE Performance and Accountability Framework in place at the time (it may be subject to change). Responsibility and accountability for the services provided within the six HSE Health Regions lies with the respective Regional Executive Officers (REOs). In addition, a range of nationally delivered services are the responsibility of the National Director for National Services and Schemes and the Chief Clinical Officer. The relevant SAO of a service has delegated responsibility and accountability for the area or service they manage and oversees, for example this will include Health Region/National Service (such as the National Ambulance Service, National Screening Service)/an Integrated Health Area, a hospital or a community health and social care service.

The SAO is accountable for compliance with this policy within their area/service of responsibility. The SAO must:

- establish governance and management arrangements for incident management, including open disclosure, in a manner that is consistent with the approach outlined in the HSE Incident Management Framework and this policy;
- provide assurance to the CEO that they and staff reporting to them are aware of their obligations in respect of the policy and that they are compliant with this policy;
- promote a culture of openness, honesty and transparency that is just and fair in the workplace;
- provide relevant resources required to support the implementation of this policy and related legislation;
- assure the HSE that they and the staff reporting to them participate in open disclosure training relevant to their role, attend refresher training every three years and provide assurance to the CEO in relation to meeting mandatory training requirements;
- support staff to enable them to participate in the incident management and the open disclosure process;
- identify clinical and/or managerial champions for open disclosure in each service (hospital, community, or national service, e.g. the National Ambulance Service, National Screening Service) to promote, lead and oversee open disclosure policy and practice;
- commit to improving learning from incidents by commissioning reviews that are open and transparent and includes meaningful engagement with those affected by the incident;
- have clear systems of governance in place to implement learning from the open disclosure process and include it in quality improvement initiatives;

- develop robust systems that enable staff to adhere to legislative and regulatory open disclosure reporting requirements within their area/service of responsibility;
- participate in open disclosure meetings as required and communicate with patients and relevant persons involved in or affected by patient safety or notifiable incidents in a manner that is honest, compassionate, caring and empathic;
- ensure that, throughout the incident management and open disclosure process, there are systems and structures in place to address the support needs of persons affected (patients, relevant persons and staff) as a consequence of the incident;
- must have systems in place to monitor compliance with this policy and the Patient Safety Act 2023. They must complete an annual report to be submitted to the SAO to whom they are accountable as demonstrated in figure 3 overleaf. The compliance reports are required as set out in the DoH National Open Disclosure Framework 2023, and include information on:
    - Development and implementation of open disclosure policy.
    - Development and implementation of open disclosure training for all clinical and non-clinical staff including agency staff.
    - Evidence of the availability of support structures for all staff clinical and non-clinical including agency staff.
    - The number of trained clinical and non-clinical staff including agency staff.
    - The number of appointed and trained clinical and managerial open disclosure champions.
    - The number of open disclosure events initiated and closed (in the preceding year).

The compliance reports will be included in the HSE Open Disclosure Annual Report completed by the National Open Disclosure Office, Quality and Patient Safety Incident Management Team, National Quality and Patient Safety, leading out on open disclosure. The annual report must be submitted to the Department of Health in April of each year.

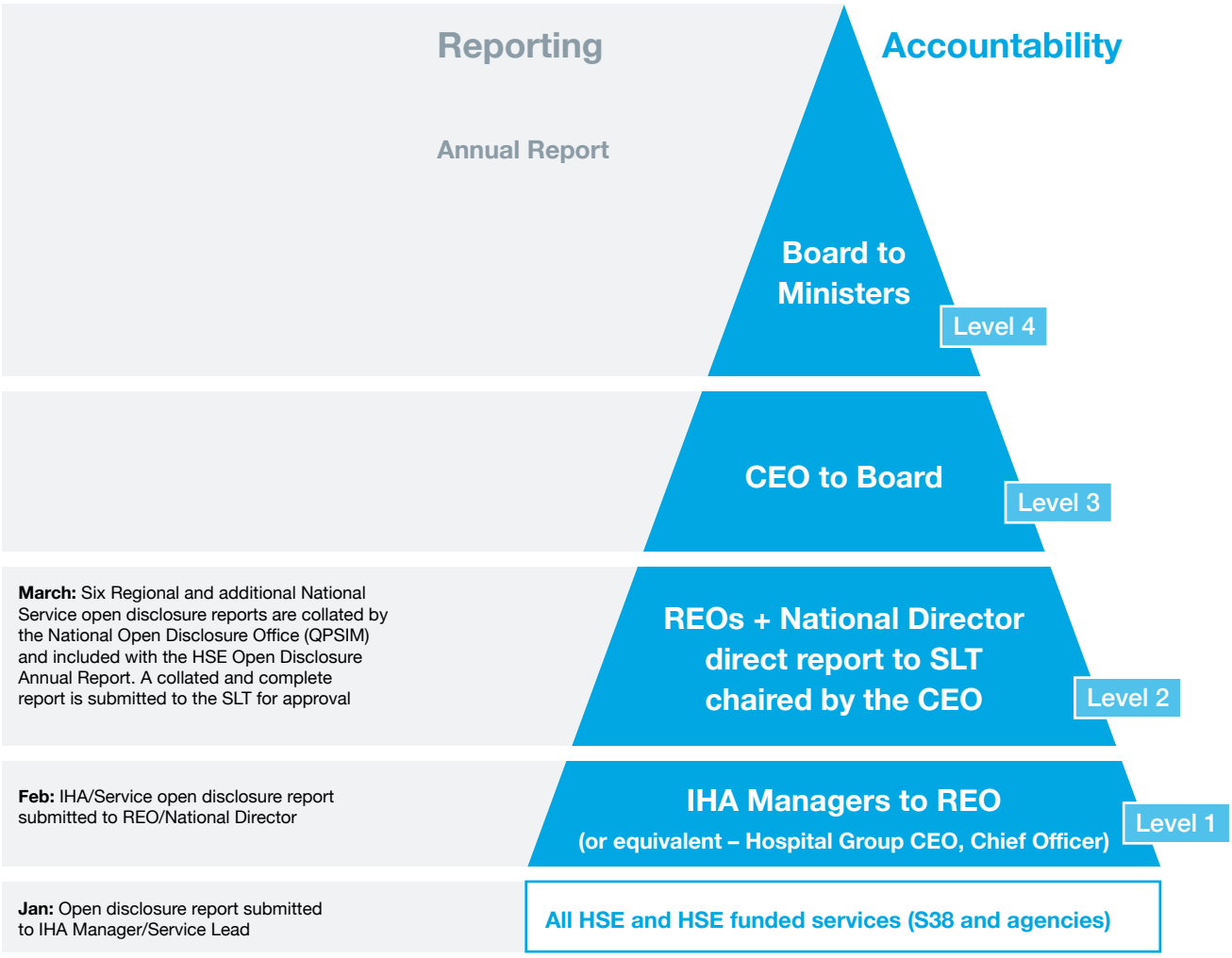

Figure 3: Reporting flow for Open Disclosure compliance reporting, aligned with the HSE Performance and Accountability Framework and the DoH National Open Disclosure Framework 2023

3.4 Local Accountable Officer (LAO)

Reporting to the SAO, it is the role and responsibility of all Local Accountable Officers (LAO) to promote compliance with the HSE Open Disclosure Policy by ensuring that, within their area of responsibility:

- they are accountable for the management of incidents including requirements in relation to open disclosure;
- they and the staff reporting to them are clear as to their professional, moral, regulatory and legal responsibilities and obligations in relation to open disclosure;
- clinical and managerial champions are identified to promote, lead and oversee open disclosure policy and practice;
- a culture of openness, honesty and transparency in the workplace is promoted that is just and fair;

- patient safety incidents are reported, managed and disclosed in line with the requirements of the HSE Incident Management Framework and this policy;
- notifiable incidents occurring are reported, managed and disclosed in line with the requirements of the Patient Safety Act 2023 and this policy;
- they and the staff reporting to them participate in HSE delivered open disclosure training relevant to their role and attend refresher training every three years;
- they participate in open disclosure meetings as required and communicate with patients and relevant persons involved in or affected by patient safety or notifiable incidents in a manner which is honest, compassionate, caring and empathic;
- staff are supported and enabled to participate in the incident management and the open disclosure process;
- there are systems and structures in place throughout the incident management and open disclosure process to address the support needs of persons affected (patients, their relevant persons and staff) as a consequence of patient safety or notifiable incidents;
- services have a clearly defined process in place for the management and recording of open disclosure including the recording of open disclosure on the NIMS and in the clinical/care record;
- implementation of the HSE Open Disclosure Policy is overseen at service level – the implementation plan must consider (i) accountability arrangements for open disclosure at every level in the organisation and (ii) any specific requirements of the service and patients accessing that service, i.e. any specific support(s) required by patients to enable them to participate in open disclosure meetings, e.g. communication supports or independent advocacy;
- compliance with this policy is monitored and audited;
- incidences of non-compliance and underperformance are identified and proactively managed and escalated to the SAO, as necessary;
- open disclosure is embedded in the service's governance programme/ framework and the learning from the open disclosure process is shared and included in the service quality improvement initiatives;
- performance and learning reports are provided to the SAO in relation to incident reporting, incident management and open disclosure within their area of responsibility.

3.5 Line Managers

It is the role and duty of line managers at all levels in the organisation to:

- ensure that they and the staff reporting to them are aware of their obligations in respect of this policy and comply with it;
- ensure that they and the staff reporting to them are clear as to their professional, moral, regulatory and legal responsibilities and obligations in relation to open disclosure;

- promote a culture of openness, honesty and transparency in the workplace that is just and fair;
- report, manage and disclose patient safety incidents occurring in line with the requirements of the HSE Incident Management Framework and this policy;
- report, manage and disclose notifiable incidents in line with the requirements of the Patient Safety Act 2023 and this policy;
- ensure that they and the staff reporting to them participate in HSE delivered open disclosure training relevant to their role, attend refresher training every three years and provide assurance that mandatory training requirements are being met through the maintenance of training records at local level;
- participate in open disclosure meetings as required and communicate with patients and relevant persons involved in or affected by patient safety or notifiable incidents in a manner which is honest, compassionate, caring and empathic;
- support and enable staff to participate in the incident management and open disclosure process;
- ensure that there are systems and structures in place throughout the incident management and open disclosure process to address the support needs of persons affected (patients, their relevant persons and staff) as a consequence of patient safety or notifiable incidents;
- learn and apply the ASSIST ME model for staff support following an incident;
- ensure that there are clearly defined processes in place for the management and recording of open disclosure to include recording of open disclosure on NIMS and in the clinical/care record;
- fully co-operate with the implementation of the HSE Open Disclosure Policy at service level. The implementation plan must consider (i) accountability arrangements for open disclosure at every level in the organisation, (ii) the specific requirements of the service and patients accessing that service, i.e. the relevant support(s) required by those patients to enable them to participate in open disclosure meetings, for example communication supports or independent advocacy;
- monitor and audit compliance with this policy;
- identify and proactively manage incidences of non-compliance and underperformance and escalate to the LAO, as necessary;
- ensure that learning from the open disclosure process is included in the service quality improvement initiatives;
- enable staff who take on the role as designated person to attend training and provide ongoing support to help them develop in this critical role.

3.6 All staff

It is the role and duty of all staff of HSE and HSE funded services to:

- read this policy and understand their professional, ethical, regulatory and legal responsibilities and obligations in relation to open disclosure;
- comply with this policy;
- attend role appropriate HSE-delivered training on this policy and attend refresher training every three years;
- report all patient safety and notifiable incidents to facilitate timely open disclosure;
- record patient safety and notifiable incidents on the national incident report form (NIRF) or directly onto NIMS; it is a legal requirement that all staff report notifiable incidents to the local health or social care service providers via locally agreed processes;
- document open disclosure in the health care record. See Section 5.5 Step 3: Documentation and written follow-up;
- participate in open disclosure, as required;
- promote a culture of openness, honesty and transparency in the workplace;
- communicate with patients and relevant persons involved in or affected by patient safety or notifiable incidents in a manner which is compassionate, caring, kind and empathic;
- provide support to all those involved in or affected by patient safety or notifiable incidents to include patients, their relevant persons and staff;
- notify non-compliance of this policy to their line manager;
- assume capacity when partaking in open disclosure. A person whose capacity to make decisions is in question is entitled to open disclosure on an equal basis with others and to be supported through this process, using resources where necessary.

3.7 The Principal Health Practitioner

The patient's principal health practitioner is the health practitioner who has principal clinical responsibility for the care and treatment of the patient [see definition in Glossary]. This may be the General Practitioner or Lead Consultant caring for the patient in a multidisciplinary team, senior social worker in a community setting, senior psychologist etc. The principal health practitioner may be part of a team or work autonomously in providing care. In a setting where there is no health practitioner with responsibility for the patient, then a suitably qualified senior manager should lead out on open disclosure. For notifiable incidents it must be a health practitioner. Whilst the aforementioned requirements for all staff apply as well as clinical duties, the principal health practitioner will:

- lead the open disclosure process and disclose the incident, in particular for category 1 incidents and notifiable incidents. Other suitable staff may take on this role for category 2 incidents or minor harm incidents;

- document a record of open disclosure and sign the letter that follows an open disclosure meeting;
- role model a positive safety culture that is open and transparent;
- support and enable staff to participate in the incident management and open disclosure process.

3.8 The Designated Person

Service users who have suffered harm will need practical, emotional and psychological support and this should arrive seamlessly. The designated person is the key point of contact for the patient/relevant person and may be able to advise on available supports where required.

The Patient Safety Act 2023 made the role of the designated person a legal requirement for notifiable incidents. The early assignment of a named designated person is essential to ensure that the person affected/their relevant persons and staff do not feel isolated and that their communication needs in respect of the plans for the management of the incident (including review) are met.

The designated person:

- Acts as the liaison person between the health or social care service providers and the patient/relevant person;
- Assists the patient /relevant person in preparing for and attending open disclosure meetings;
- Facilitates feedback during the incident review and open disclosure process;
- Advises the patient/relevant person on support services available;
- Acts as the point of contact for any clarifications sought, and liaises with relevant health and social care staff in relation to any clarification requests by the patient/relevant person;
- Is impartial and sufficiently removed from the incident or its management, where possible, to avoid any conflict of interest; although it is acknowledged this may not always be possible in smaller services;
- Attends HSE-delivered training on the role of the designated person, for example, the eLearning modules on HSeLanD "The Role of the Designated Person in Incident Management and Open Disclosure", and has the necessary skills and experience required to fulfil their role.

Where possible, the designated person should be the same person for the duration of the open disclosure and incident management process through to completion as patients and relevant persons will build a rapport with them.

Note: The designated person referred to in this policy will be the same person as the designated support person referred to in the HSE Incident Management Framework 2020. A more detailed description of the role and function of the designated person is available by accessing the following HSE document: The Role of the Designated Person in Incident Management and Open Disclosure (2024) and the Designated Person Checklist.

3.9 Open Disclosure Clinical and Managerial Champions

Leadership and "champions" are required to drive a culture of open disclosure. A peer-led approach is critical as it is acknowledged that, for example, junior doctors learn from senior doctors whom they respect and emulate[2]. Champions of open disclosure are equally important in non-clinical settings, thus necessitating the identification of managerial open disclosure champions, where there are no clinicians employed, to lead and promote open disclosure policy.

Each service (hospital, community, or national service, e.g. the National Ambulance Service, National Screening Service) should have an Open Disclosure Clinical Champion. In services where there are no clinicians working, this may be an Open Disclosure Managerial Champion.

Open disclosure champions:

- Promote open disclosure policy, education, training, and practice in a service;
- Provide peer support for colleagues and role model best practice;
- Take a leadership role in open disclosure within their service by championing open disclosure as the right thing to do;
- Signpost staff to resources available to them to guide them through the open disclosure process.

3.10 Open Disclosure Leads

Across the HSE, there are Open Disclosure Leads who take on a key role in driving, embedding and updating their services on open disclosure developments. Such staff can be contacted for support locally by their service(s). A full list of Open Disclosure Leads can be found here.

3.11 Open Disclosure Trainers

The HSE has a network of open disclosure trainers who provide training on open disclosure locally. In particular, they support face-to-face training which offers an opportunity to practice communication skills. They have been trained on the HSE requirements for open disclosure. For assurance purposes and quality control, it is essential that HSE staff deliver the required training; this maintains uniformity across training content, ensuring high-quality standards. Open Disclosure Trainers can be contacted through the relevant Open Disclosure Lead.

2 Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland (2021) Independent Patient Safety Council https://assets.gov.ie/127396/af15e335-2c88-40a9-9571-371a978409ca.pdf

4

When does open disclosure apply?

4.0 Ethos of open disclosure

Open disclosure must be regarded as part of standard health and social care and is a critical element of continuous effective communication with patients/ their relevant person. Open disclosure is a requirement for both patient safety and notifiable incidents. As stated, it is the policy of the HSE and HSE-funded services that patients are communicated with in an open, honest, transparent and empathic manner following a patient safety or notifiable incident, that they are provided with a sincere and meaningful apology in particular when they are harmed as a result of such incidents and that this communication process is initiated in a timely manner. Open disclosure provides an opportunity for learning and preventing reoccurrence of patient safety and notifiable incidents wherever possible.

It must be proportionate in response. The required level of response is set out in this section of the policy, which is informed by the requirements of the Patient Safety Act 2023 for notifiable incidents, the degree of harm the patient has experienced due to a patient safety incident and/or the expectations and needs of the patient or their relevant person. The response may range from a single conversation to a number of meetings.

4.1 Incidents triggering open disclosure: Notifiable Incidents

Notifiable incidents are a defined list of incidents that are captured in Schedule 1 of the Patient Safety Act 2023. When a notifiable incident is identified, the requirements of the Patient Safety Act 2023 apply and it must be reported to the relevant regulator (HIQA, the Mental Health Commission or the Chief Inspector). Importantly, it is a legal requirement to disclose the notifiable incident to the patient, their relevant person, or both depending on the patient's wishes[3].

For all notifiable incidents, the open disclosure process must be followed as described in Section 5 of this policy.

Notifiable incidents are currently as follows [*note: numbering below as per the Patient Safety Act 2023*]:

1.1 Surgery performed on the wrong patient resulting in unintended and unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.

1.2 Surgery performed on the wrong site resulting in unintended and unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.

3 With regards the current list of notifiable incidents listed in the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023, it is acknowledged that the patient will be deceased. Should the Minister for Health add to the current list of notifiable incidents, however, the patient may not be deceased and obligations are to them primarily.

1.3 Wrong surgical procedure performed on a patient resulting in an unintended and unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.

1.4 Unintended retention of a foreign object in a patient after surgery resulting in an unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.

1.5 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 (including recovery from the effects of anaesthesia) 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.

1.6 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.

1.7 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

1.8 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.

1.9 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

1.10 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.

1.11 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.

1.12 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 whether or not the death was anticipated or arose from, or was wholly or partially attributable to, the illness or underlying condition of the patient.

2.1 A baby who—

(a) in the clinical judgment of the treating health practitioner requires, or is referred for, therapeutic hypothermia, 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.

Additionally, Regulation S.I. No. 501/2024 – Patient Safety (Notifiable Incidents and Open Disclosure) Regulations 2024 describes that for the purposes of Schedule 1 of the Patient Safety Act 2023 (No. 10 of 2023) and notifiable incident—

(a) 1.10 and 1.11 thereof—

(i) "prescribed birthweight" means a birthweight of not less than 2500 grammes; and

(ii) "prescribed gestational age" means a gestational age of at least 37 weeks, commencing on the first day of the 37th week

(b) 1.11 thereof, a "perinatal death" means a death which occurred within 7 days of birth.

4.2 Incidents triggering open disclosure: Patient Safety Incidents

A patient safety incident requires open disclosure, in particular where there is harm. A patient safety incident is defined in the CLA Act 2017 as:

(a) an incident, other than a notifiable incident, which has caused an unintended or unanticipated injury, or harm, to the patient and which occurred in the course of the provision of a health service to that patient,

(b) an incident, other than a notifiable incident, —

(i) which has occurred in the course of the provision of a health service to the patient and did not result in actual injury or harm, and

(ii) in respect of which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm,

or

(c) the prevention, whether by timely intervention or by chance, of an unintended or unanticipated injury, or harm, to the patient in the course of the provision, to him or her, of a health service, and in respect of which the health services provider has reasonable grounds for believing that, in the absence of such prevention, could have resulted in such injury, or harm, to the patient.

Patient safety incidents are categorised by their level of harm to the patient in line with the HSE Incident Management Framework 2020 and the HSE Enterprise Risk Management Policy and Procedures 2023, which includes examples in its risk impact table as to how the different levels of harm are assessed.

See the Open Disclosure Requirements Table below for further detail on when open disclosure process is required for each relevant event.

4.3 Incidents triggering open disclosure: Adverse Events

An adverse event is defined as "an incident which resulted in harm to a patient" (WHO Global Patient Safety Action Plan 2021-2030). There must, therefore, be a patient safety incident that occurred that led to harm for it to be understood as an adverse event. As stated, the required open disclosure must be proportionate in response depending on the level of harm experienced. Principally, for any type of incident, the common thread is good communication that is compassionate, timely and honest.

4.4 Open disclosure requirements table

Type of incident	Open disclosure requirement
Notifiable Incident as defined in the Patient Safety Act 2023	Disclose, as set out under the Open Disclosure Process described in Section 5
Major/Extreme harm (severe harm, permanent disability or death) defined as Category 1 Incidents in the Incident Management Framework, and as per examples in the HSE Enterprise Risk Management Policy and Procedures 2023 Risk Impact Table	Disclose, as set out under the Open Disclosure Process described in Section 5
Moderate harm defined as Category 2 Incidents in the Incident Management Framework, and as per examples in the HSE Enterprise Risk Management Policy and Procedures 2023 Risk Impact Table	Disclose, as set out under the Open Disclosure Process described in Section 5

Type of incident	Open disclosure requirement
Minor harm defined as Category 3 incidents in the Incident Management Framework, and as per examples in the HSE Enterprise Risk Management Policy and Procedures 2023 Risk Impact Table	Disclose, as set out under Section 5.8.1: Managing the response to minor or no harm incidents
No harm Examples may include, with all of the following resulting in no patient harm: medication incident, absconscion, wrong test performed, multi-patient incident (e.g. ICT failure), patient fall	There should be honest, clear, timely communication with patients involved in no harm patient safety incidents if the incident involved a patient directly (for example a bedside conversation where there was a no harm medication administration incident) which in this instance constitutes open disclosure. Good communication embodies the principles of open disclosure and fosters trust within a service. A practical, reasonable and person-centred approach should be taken. In particular, if, after consideration of the no harm incident, it is determined that: (i) there is a risk of/potential for future harm (ii) that informing the patient would assist in the prevention of future harm, Then the incident must be discussed with the patient/relevant person as set out under Section 5.8.1: Managing the response to minor or no harm incidents
Near Miss Examples may include: patient attending for treatment in which the wrong product is nearly administered; a near miss of wrong medication/ test that is not needed; patient was consented for wrong-site surgery and mistake identified pre-operatively.	Near miss incidents do not require open disclosure, but must be assessed on a case-by-case basis. This approach is recommended to encourage incident reporting and ensure open disclosure requirements are not a deterrent. If after consideration of the near miss incident, it is determined that: (i) there is a risk of/potential for future harm, i.e. there is potential for the “near miss” incident to become a “harm” incident in the future, and/or (ii) that informing the patient would assist in the prevention of future harm, Then the near miss must be discussed with the patient/relevant person as set out under Section 5.8.1: Managing the response to minor or no harm incidents

Type of incident	Open disclosure requirement
Unknown Patient Harm	Where there are patient safety incidents where harm is unknown, they are often rare and complex. Health and social care staff must assess such instances on a case by case basis. Decisions not to disclose must be discussed with and agreed by the Senior Accountable Officer and must have input and agreement from a minimum of two independent patient representatives/advocates and the National Open Disclosure Office.

4.5 Assessing the level of response required

4.5.1 Notifiable Incidents

The Patient Safety Act 2023 requires that where a health or social care services provider is "satisfied" that a notifiable incident has occurred, it shall notify the relevant regulator of that notifiable incident and open disclosure requirements are then also mandated. The Act does not define what "satisfied" means. The Act provides that the health or social care services provider can be "satisfied" that a notifiable incident occurred even if all of the information is not available. This means that it is not necessary to establish the cause of the injury or death with absolute certainty. In the interests of openness and transparency, the HSE has interpreted the word "satisfied" as a requirement to make reasonable efforts to establish if a notifiable incident occurred. A clinical assessment should be made with the information available on the likelihood that a notifiable incident occurred. Where it is deemed that a notifiable incident likely occurred, the health care practitioner and health or social care services provider must take the required actions.

4.5.2 Patient Safety Incidents (other than Notifiable Incidents)

For patient safety incidents, the level of harm will be assessed by staff using the risk impact table in the HSE Enterprise Risk Management Policy and Procedures 2023. It includes examples of different levels of harm to a patient. This list is not exhaustive and must be considered depending on the specific patient/incident, for example a patient may have suffered moderate harm due to a patient safety incident but they may not have had their hospital stay extended up to 72 hours in the acute setting because they were suitable for transfer to their residential care setting. At their place of residence they would still receive ongoing care in relation to the incident.

Categories	Negligible	Minor	Moderate	Major	Extreme
Harm to a person (Service User, Patient, Staff and Public)	No harm. No need for treatment. No impairment of ability to manage normal daily routines. No impaired psychosocial functioning. No time off work	Adverse event/incident leading to **minor harm** needing minimal additional intervention. (e.g. first aid, extra observation or minor treatment) Requiring first aid/ extended hospital stay for treatment of ≤ 72 hours. Recovery of ability to manage daily routines within 72 hours. Impaired psychosocial functioning (> 72 hours ≤ 1 month) ≤ 72 hours absence from work.	Adverse event/incident leading to **moderate harm** (significant, but not permanent harm) requiring a moderate increase in treatment. (e.g. an unplanned return to surgery, an unplanned re-admission, cancelling of treatment leading to prolonged symptoms/disease, or transfer to another treatment area (such as short stay in intensive care with good recovery) Extended hospital stay for treatment of (> 72 hours to ≤ 8 days) Recovery of ability to manage daily routine within a month and without significant complication or significant permanent disability. Impaired psychosocial functioning (> 1 month ≤ 6 months) > 72 hours absence from work to ≤ 6 months. Agency reportable, e.g. Gardaí (violent and aggressive acts), Tusla, HIQA, MHC and HSA.	Adverse event/incident leading to **severe harm** such as permanent lessening of bodily, sensory, motor, physiologic or intellectual functions resulting in long-term incapacity or disability (e.g. loss of limb, blindness, brain damage/ HIE, shortening of life expectancy) Extended length of stay in hospital (> 8 days) Significant complication/ significant permanent disability impacting ability to manage normal daily routine in the same manner as before. Impaired psychosocial functioning (> 6 months) Absence > 6 months Agency reportable, e.g. Gardaí (violent and aggressive acts), Tusla, HIQA, MHC and HSA.	Adverse event/incident leading to death or permanent total disability. (e.g. unanticipated death that 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 occurring while receiving care) Permanent psychosocial functioning incapacity. Agency reportable, e.g. Gardaí (violent and aggressive acts), Tusla, HIQA, MHC and HSA.

HSE Risk Impact table – HSE Enterprise Risk Management Policy and Procedures 2023

It is important to be confident that harm has not occurred as a result of a patient safety incident and the best way to ensure this, aside from any diagnostic findings, is to discuss the incident with the patient/relevant person. It is also important to establish if there are any ongoing risks to patient safety. Trust can be lost in staff and health or social care service providers if an incident is not discussed with a patient and/or their relevant persons.

It is acknowledged that the communication of **all** no harm incidents to patients is not practicable. If there is an opportunity to learn from a suspected but unproven incident, or a potential risk of harm, and sharing this information with other healthcare professionals could help prevent recurrence, it should also be disclosed to those involved or their families. The following questions will assist staff when determining a decision in relation to communicating such events.

- Is there potential for the event to become a “harm” event in the future?
- Is there any ongoing patient safety risk?
- Will disclosure reduce the risk of future harm events?

4.6 Complications in healthcare and patient outcomes

Complications are a recognised risk in healthcare, and it is important to take a proportionate response where complications arise. In situations where the outcome of the care and treatment provided was not as expected by the patient/relevant person and the health and social care service provider, but a patient safety or notifiable incident has **not** occurred, the open disclosure process does not apply. Principles of good communication and follow-up with the patient, however, are essential. This may be, for example, where a patient's condition fails to improve or continues to deteriorate despite the best care and treatment (e.g. cancer spreads to another organ); or the inherent risk of an investigation materialises, which was discussed as part of consent and mitigated against as best as possible.

All patients who experience harm, regardless of whether this was caused by deficiencies in care or not, must be communicated with clearly and compassionately. Although a patient safety incident may not have occurred, it is important that the outcome is acknowledged and discussed with the patient/relevant person to ensure their understanding, discuss ongoing care and treatment, and prevent misconceptions in relation to care and treatment. This allows the patient to ask questions and have their queries acknowledged and addressed in an informal but supportive setting.

Good clinical communication is important at the time of consenting for the procedure or treatment, where risks are explained and discussed, and in discussing any materialised complication with the patient/relevant person after the procedure. This must be supported with good documentation. Refer to the HSE National Consent Policy (2024) for more information.

The open disclosure process set out in Section 5 of this document does not apply unless it meets the definition of one of the notifiable incidents or it is found that there was an underlying patient safety incident, for example a medical device used was faulty, the procedure was not in line with best practice due to lack of training, or the patient was not properly prepped for the procedure, e.g. did not receive required anti-coagulant and developed a pulmonary embolism. Where a notifiable incident or patient safety incident is identified, then it must be reported and open disclosure initiated.

4.7 Open disclosure and clinical audit

"Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit specific clinical standards or clinical guidelines and acting to improve care when clinical standards or clinical guidelines are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit specific clinical standards or clinical guidelines." (Patient Safety Act 2023)

Following clinical audit, improvements, if required, should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements. (DOH 2008, p. 152) (HSE National Centre for Clinical Audit – Nomenclature – Glossary of Terms for Clinical Audit 2025). In this way, clinical audit makes a key contribution to patient safety. It should not, however, become confused with other patient safety processes in healthcare such as incident management and open disclosure. The Nomenclature sets out clearly the definitions of each process.

Clinical audit ensures patient care is not only delivered at certain standards but that improvements to the quality of that care are put in place wherever possible. Recommendations from a clinical audit are designed to further improve processes and outcomes, in line with expected standards and best practice. As a patient, it can be reassuring to know that healthcare professionals are engaged with clinical audit as a means to improve patient care.

The purpose of clinical audit is to measure performance and identify variance from standards or guidelines and therefore opportunities for improvement. It does not review the context of decision-making in patient management and as such cannot comment on the standard of care relating to an individual patient.

The Patient Safety Act 2023 encourages health and social care professionals to carry out clinical audit, and it provides additional protections for the conduct of clinical audits provided they meet the definition of clinical audit and are carried out in line with best practice guidance. The National Centre for Clinical Audit- 'Clinical Audit- A Practical Guide' is a resource outlining best practice in clinical audit. Under the Patient Safety Act 2023, clinical audits will now be afforded protections in how information from clinical audits can be used.

Under the Patient Safety Act 2023, for these protections to apply, the data obtained from that clinical audit by a health service provider or health service practitioner (or both of them) must have been:

- collected solely for the purpose of improving patient safety and quality improvement in healthcare of patients,
- collected and analysed by the health services provider or the health practitioner (or both of them) or more than one health services provider or practitioner.
- published as aggregated information, and
- used by that health services provider or health practitioner for the purpose of improving patient safety and quality improvement in healthcare of patients or for sharing with another health services provider or health practitioner solely for the purpose of improving patient safety and quality improvement in healthcare of patients.

"Aggregated information", in relation to data, means data obtained from a clinical audit, which excludes information that identifies or could reasonably lead to the identification of a person in that clinical audit. National and international practice guidance documents on clinical audit state that clinical audit data should be anonymised. This is for a number of reasons, including the need to maintain and protect patient confidentiality. Clinical audit should only use the minimum, relevant data needed, and this does not typically extend to patient specific or personal data as clinical audit is aimed at assessing care against specific standards to identify areas for improvement in the provision of the service.

If during the collection of audit data and before information is anonymised and aggregated, the audit data collector discovers information that indicates an incident that caused harm has occurred, it is their responsibility to raise this matter as soon as possible through local clinical/executive governance reporting lines. This information must then be reviewed and managed under any or all of the relevant HSE policies and procedures e.g. the HSE Incident Management Framework 2020, Look Back Review Guidelines and Open Disclosure Policy. Such follow up actions are not carried out under the auspices of clinical audit. Once complete, the information from the clinical audit itself will not provide information on any individual case. Any incident management process will be completely separate.

Clinical audit findings of non-conformance do not necessarily signify that harm has occurred to a patient. For example, the Irish Hip Fracture Standard 6 states that a patient with a hip fracture should have a specialist falls assessment during their hospital stay. Where this does not occur, it does not cause harm to a patient; however, it is not good practice and if it systematically occurs, it should be identified as an area for improvement.

For further information and guidance on Clinical Audit, see links below:

- HSE National Centre for Clinical Audit Webpage
- HSE National Centre for Clinical Audit – A Practical Guide to Clinical Audit 2023
- HSE National Centre for Clinical Audit – Nomenclature – Glossary of Terms for Clinical Audit 2022
- HSE National Centre for Clinical Audit Information for the Patient Safety Act – Clinical Audit Part VI

4.8 Open disclosure and research

Patient safety or notifiable incidents can occur in the course of clinical trials. The obligation to disclose remains as it would for all other healthcare being provided. There may be additional obligations in relation to reporting the incident to the trial sponsor and other applicable safety monitoring bodies including the research ethics committee as per the research ethics committee approval process. The basic requirements for open disclosure remain.

4.9 Open disclosure and improvement

Quality improvement and service improvement initiatives in health and social care are driven by the desire to enhance patient experience, service performance, efficiency, and/or safety. There have, however, been occasions where improvement initiatives inadvertently lead to patient safety incidents. This can happen, for example, where there is an unbalanced emphasis on efficiency over safety, or where there is an over-reliance on new technology which has not been thoroughly tested. If an improvement initiative results in a patient safety incident, the obligation to disclose remains as it would for all other healthcare being provided.

4.10 Open disclosure and HSE's personal data breach reporting obligations

In line with the GDPR and the Data Protection Act, Article 34(1), the HSE has an obligation to communicate any personal data breaches to the affected individuals when it is likely to result in a high risk to the rights and freedoms of those individuals e.g. service users. The HSE's Data Breach Process Guidance and the Data Protection Commission (DPC) Personal Data Breach Notification Guide should be used to support the determination.

5 The Open Disclosure Process

5.0 Introduction to the open disclosure process

The open disclosure process described in this section applies to notifiable incidents as well as Category 1 and 2 patient safety incidents (i.e. where there was moderate harm, severe harm, permanent disability, or death). It is referred to as a process because open disclosure may require more than one meeting or conversation. Importantly, it is a requirement of the open disclosure process that there is:

- An open disclosure meeting which is documented.
- That the meeting is followed up in writing.
- That the incident finding (report where available) is shared with the patient/relevant person.

The duration of the open disclosure process will depend on the incident that has occurred, the number of patients involved, the progress of the incident review and the immediate and ongoing needs of the patient/relevant person.

To note, communication in response to minor or no harm incidents is described later in this Section, in 5.8.1: Managing the response to minor or no harm incidents.

5.1 Timing of open disclosure

Open disclosure must commence as soon as practicable. This means initiating the open disclosure process within 24-48 hours of the service becoming aware of an incident, which includes considerations and planning for the open disclosure meeting.

The timing of the open disclosure meeting may be influenced by:

- the ability/readiness of the patient/relevant person, both physically and emotionally, to take part in the open disclosure meeting, which should be determined in consultation with the patient/relevant person;
- the patient's/relevant person's ask and need for a support person (e.g. independent advocate) to be present at any meeting;
- the immediate availability of the principal healthcare practitioner or other suitable healthcare practitioner.

5.2 Key steps in the open disclosure process

There are five (5) key steps in the open disclosure process, outlined in the figure below:

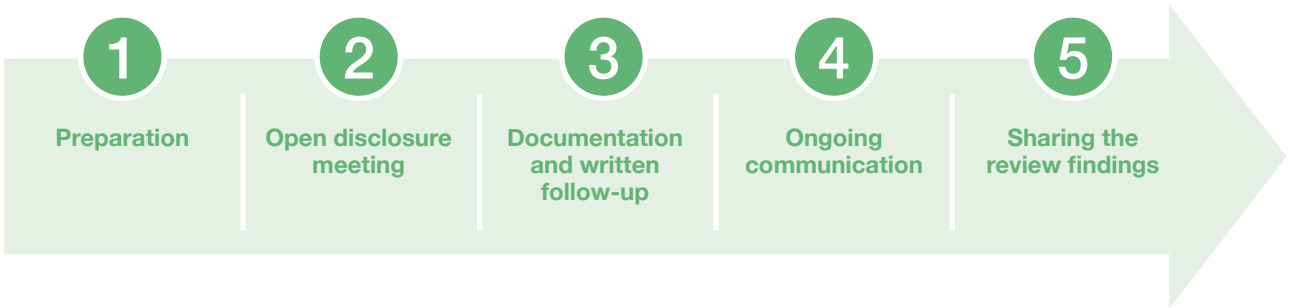

Figure 5 Key steps of the open disclosure process

In this policy, the open disclosure process for a patient safety incident where there has been moderate harm, severe harm, permanent disability or death reported (Category 1 or 2) has been aligned, insofar as possible, with the requirements of the Patient Safety Act 2023 for notifiable incidents. Some minor differences apply, which are highlighted in the process steps below. This is intended to limit the risk of confusion for staff due to variation in processes for different incidents and to address any inequitable responses for patients where the incident led to severe harm but was not a notifiable incident as described in the Act requiring the response described in the legislation.

5.3 Step 1: Preparation

Preparation for the open disclosure process is important. A well-planned open disclosure meeting will have a more positive outcome for the patient/relevant person and also for the staff members involved. This must be balanced with the need to undertake timely open disclosure, recognising that not all facts must be established and not all likely consequences must have developed to proceed with the process. Where there is clear evidence of an incident that caused harm, this must be disclosed whilst all facts are being established and even if consequences are still developing. Health and social care service providers should prepare for an open disclosure meeting by giving due consideration to the following:

5.3.1 Appointment of the designated person

It is a legal requirement for notifiable incidents that each patient/relevant person has a designated person assigned to them to communicate with them throughout the open disclosure process. This requirement also applies where staff seek the protections of the Civil Liability (Amendment) Act 2017.

Additionally, it is also a requirement of the HSE that where a patient safety incident resulted in severe harm, permanent disability or a reported death of a patient receiving care (described as category 1 incident in the Incident Management Framework) that each patient/relevant person has a designated person assigned to them to support them throughout the open disclosure process. It is acknowledged that this may not always be possible for moderate harm incidents (described as Category 2 incidents in the Incident Management Framework) due to limited staffing resources; a local staff member or manager should still offer support and ongoing communication as needed in such instances.

The name of the designated person must be documented in the local Incident Management/Open Disclosure file and a direct telephone line number and contact arrangements provided to the patient/relevant person and staff members involved (see further information on the designated person in Section 3 of this policy).

5.3.2 Planning for the open disclosure meeting

In preparation for an open disclosure meeting, planning should include relevant members of the health or social care team who were involved in the delivery of care to the patient when the incident occurred, and any others (e.g. quality and patient safety staff) who are involved in the open disclosure process.

In preparation for open disclosure, health and social care service providers must:

1) assess the patient's circumstances and the nature of the patient safety or notifiable incident;
2) consider the requirements of the open disclosure process, including the need for written follow-up, and make preparations for this;
3) consult with appropriate persons/staff prior to the open disclosure meeting to establish the facts available at the time of the open disclosure meeting. Reasonable efforts should be made and it is not expected that all facts or learning points will be known at the initial stages of disclosure;
4) determine who the open disclosure will be made to, i.e. the patient and/or their relevant person;
5) consider the information relating to the patient safety or notifiable incident and, having regard to the complexity of that information, take reasonable steps to present that information in as clear a manner as is possible;
6) determine the apology that is required and the wording of such an apology; and
7) ensure that a designated person has been appointed and their name and role is documented.

Further planning considerations include:

- confirming everyone's role and being clear on who will make the open disclosure, e.g. the patient's principal healthcare practitioner;
- consider potential questions the patient/relevant person may have and appropriate responses, e.g. questions in relation to the patient's condition, care/treatment plan and options available, questions regarding what has happened and how or why it happened, any learning established and proposed next steps;
- information already provided and available to the patient/relevant person at the time of the meeting;
- the need to express sincere condolences to the family/relevant person in the situation when the patient is deceased;
- making sure that staff are aware that legal protections apply to the apology and content of the open disclosure meeting for notifiable incidents once the requirements of the Patient Safety Act 2023 are met. The Act needs to be referenced in written follow-up communication to the patient/relevant person after the open disclosure meeting. It is therefore helpful to inform the patient/relevant person of the healthcare provider's responsibilities to engage with open disclosure (moral, professional, policy, legal) so that the written follow-up does not read insensitive and so they are informed of the health or social care service provider's obligations.

- making sure that staff are aware that legal protections apply to the apology and content of the open disclosure meeting for patient safety incidents once the requirements of the CLA Act 2017 are met. Where staff want to avail of these protections, the CLA Act 2017 needs to be referenced in written follow-up communication to the patient/relevant person after the open disclosure meeting. It is therefore helpful to inform the patient/relevant person of the healthcare provider's responsibilities to engage with open disclosure (moral, professional, policy, legal) so that the written follow-up does not read insensitive and so they are informed of the health or social care service provider's obligations;
- consider seeking the support of the health or social care service's Open Disclosure Lead or Open Disclosure Trainer to guide and support the open disclosure team, if required;
- review the Open Disclosure Quick Reference Guide and Toolkit which can be accessed on the HSE Open Disclosure webpage.
- direct the open disclosure team to Module 2 of the eLearning module "*Open Disclosure: Applying Principles to Practice*" on HSeLanD, which provides guidance on how to prepare for and manage an open disclosure meeting including practical examples;
- consider the mental health and wellbeing of the staff engaging in open disclosure and the wider team, where necessary, both following the incident and following the open disclosure meeting. Further information on supporting staff in such circumstances can be found on the HSE Open Disclosure webpage.

5.3.3 Preparing the patient/relevant person for the open disclosure meeting

It is important that the patient's perspective and needs are taken into account when organising an open disclosure meeting. Health and social care service providers must consider:

- the patient/relevant person and their needs;
- the requirement to provide support to the patient and/or relevant person to assist them in preparing for and attending an open disclosure meeting through the appointment of a designated person and providing information on patient advocacy services;
- that it is important that the patient/relevant person is informed of the patient safety or notifiable incident and the purpose of the meeting, including explaining open disclosure;
- the availability and willingness of the patient/relevant person to attend the open disclosure meeting and the availability of their relevant person/ independent advocate;
- the clinical condition of the patient and other circumstances that may affect their physical and emotional wellbeing at the time;

- the preference of the patient/relevant person as to the venue of the meeting, ensuring their privacy and comfort, consideration if they are still an inpatient, consideration of an off-site location away from where the incident occurred if preferred by the patient/relevant person and providing a suitable, confidential environment where interruptions will be minimal, preference to having the open disclosure meeting held other than in person (for example by phone or video conferencee) should also be facilitated in reference to section 17 of the Patient Safety Act 2023 and this policy;
- provide any other practical support such as assistance with portering or parking arrangements as appropriate, or linking with any other department to arrange support;
- the grieving process that relevant persons may be undergoing following the death of a patient.

Information and resources to prepare the patient/relevant person for the open disclosure meeting are available on the HSE Open Disclosure webpage.

5.3.4 Establishing the open disclosure team

The principal healthcare practitioner must undertake the open disclosure unless they are unavailable; they are not in a position to make the open disclosure; or an alternative health practitioner is deemed more appropriate by the health or social care service provider. The principal health practitioner will generally always be part of the open disclosure team. They should also be available for any potential follow-up meetings required or requested. Other suitable staff may take on this role for category 2 incidents (for example a Clinical Nurse Manager 2).

It is generally acknowledged that the greater the reported level of harm, the more senior the person leading the open disclosure meeting will be, e.g. Clinical Director, another clinician involved in the care of the patient, Service Manager, Director of Nursing.

Where the delivery of care is multifaceted and collaborative, the open disclosure process should reflect this. Where appropriate, staff who have been involved in the care of the patient will be made aware by the health or social care service provider that a patient safety or notifiable incident has occurred and that it is intended that an open disclosure will be made. In determining the members of the open disclosure team, consideration must also be given to non-clinical contributory factors identified in any review of the incident and who should be present at the meeting to respond to the factors identified.

It is important that the number of staff involved in the open disclosure meeting is kept to a minimum, as a large group of staff in the meeting may appear defensive and may cause discomfort for the patient/relevant person. Health and social care service providers should consider the balance in relation to the number of staff members and patients/relevant persons attending as well as the preference and expectations of the patient/relevant person. In particular, where it is a category 2 patient safety incident then the persons undertaking open disclosure may involve the principal health practitioner (or other i.e. Clinical Nurse Manager) and one other person only.

An example of an open disclosure team is outlined in figure 6 overleaf.

Example of an Open Disclosure Team

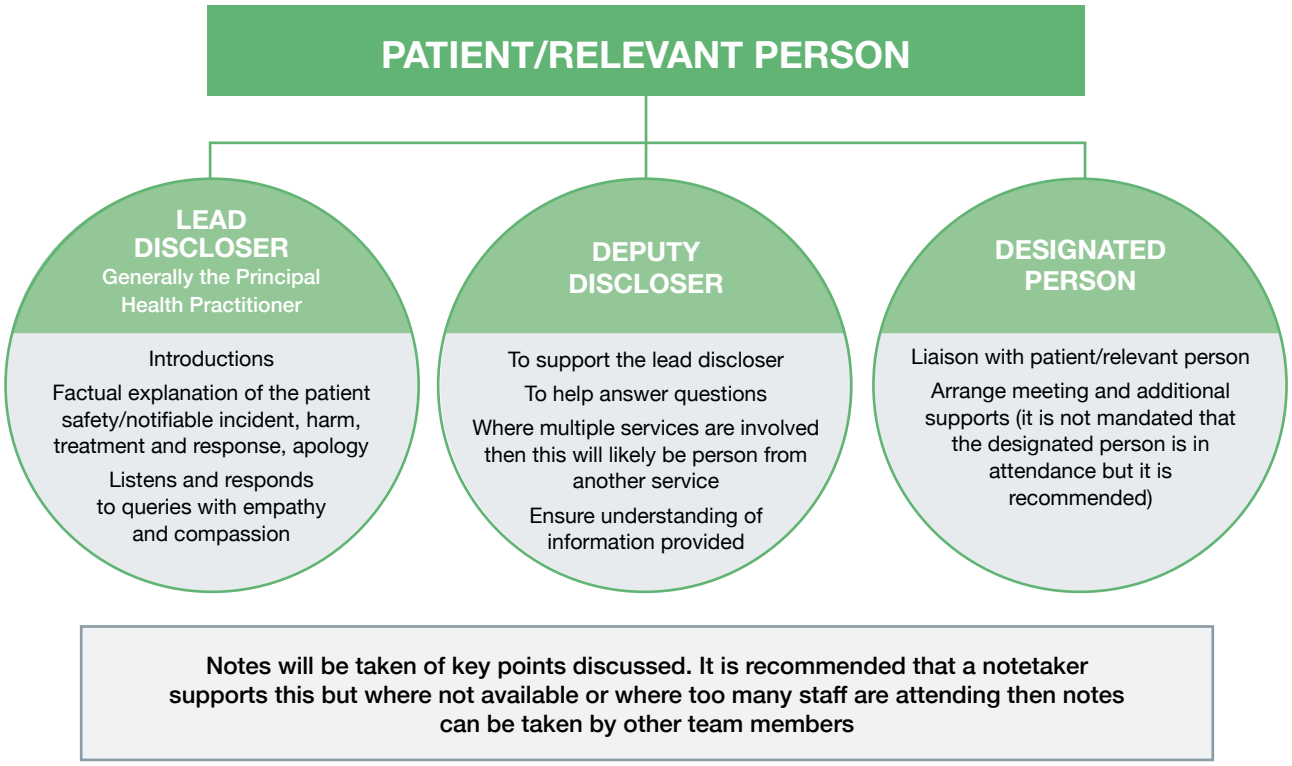

Figure 6: Open disclosure team example

5.4 Step 2: The open disclosure meeting

The requirements of each Act must be met for the meeting to be deemed an open disclosure meeting or a notifiable incident disclosure meeting. For ease, when the term 'open disclosure meeting' is used in this document it is intended to cover either an open disclosure meeting as defined in the CLA Act 2017 or a notifiable incident disclosure meeting as defined in the Patient Safety Act 2023, unless the context requires otherwise. The requirements are important to patients/their relevant person, and will further encourage an open and transparent culture. The requirements below are aligned to the Patient Safety Act 2023 and the CLA Act 2017, and once the requirements of the Acts are complied with then the legal protections of the relevant legislation apply. The open disclosure meeting may take place, following the incident, whilst the patient is an inpatient, at their residential setting or alternative venue as agreed with them.

5.4.1 Information provided at an open disclosure meeting

Information at an open disclosure meeting must be provided in a manner which demonstrates understanding, empathy and compassion. Such meetings must be in-person unless the patient/relevant person wishes otherwise in which case alternative means should be facilitated where possible and documented.

The following points **must** be discussed with the patient/relevant person:

1) An introduction must be made, sharing the names and roles of the persons present at the open disclosure meeting. It is advisable to explain that notes will be taken.

2) The opportunity for the patient/relevant person to talk about their understanding of what happened, the impact of the patient safety or notifiable incident; and their expectations regarding the meeting. The open disclosure team must listen and respond appropriately.

3) A sincere and meaningful apology must be made.

4) A description of the incident concerned including date of the incident, where known. The patient must be informed of the facts available to the health and social care service provider at the time of the open disclosure meeting in relation to the patient safety or notifiable incident. It is not necessary to know **all** of the facts pertaining to the incident to commence the communication process with the patient; in those circumstances, additional information can be provided to the patient/relevant person at a later stage as it becomes available.

5) When and how the health or social care service providers became aware of the incident.

6) If the health or social care service provider is aware of whether or not the incident led to any harm (physical or psychological) for the patient and, if so, information in respect of that harm.

7) Where the health or social care service provider has reasonable grounds for believing that, in addition to the consequences referred to already, future harm may develop (physical or psychological) or not, and, if so, information in respect of that future harm.

8) At the time of the open disclosure meeting, where there was harm identified (physical or psychological), the health or social care service provider shall inform the patient/relevant person of the treatment and relevant clinical care that the service is providing (or proposes to provide) to the patient to address those consequences.

9) The actions the provider has taken or proposes to take, and procedures or processes to be implemented, in order to address any learning the provider has obtained from its consideration of that incident and the circumstances giving rise to it.

It is important that staff involved in the open disclosure meeting explain that a written record of the meeting and letter will be shared with the patient/relevant person following the meeting. The written record will include a summary of the discussion; the contact details for the designated person, if not already provided; and that it is a requirement to reference the relevant legislation (the Patient Safety Act 2023 or the CLA Act 2017). The designated person should determine who the point of contact will be from the family (patient/relevant person) for this purpose, and agree frequency of contact (i.e. 6-weekly, whenever there are significant new developments, etc.) and means of contact (i.e. phone call, e-mail, etc.) with them.

In line with good communication practices, staff should provide information in small amounts with intervals and check if the information is understood before moving on. Respond to any emotions arising with understanding, empathy and compassion.

Staff should provide factual responses to questions/clarifications sought by the patient/relevant person. Staff must not speculate or attribute blame to individuals, teams or services. If all information requested is not yet available to provide factual answers, then the patient/relevant person should be informed of this including how additional information will be provided when available.

5.4.2 The apology

An apology in relation to the open disclosure of an incident means a genuine expression of being sorry for what has happened. It is important that health practitioners take the time to understand the impact of the incident on a person to be able to provide a genuine apology. Each incident is unique affecting the patient/relevant persons in different ways.

When a patient safety or notifiable incident occurs, then the patient/relevant persons must be provided with a sincere and meaningful apology in a timely manner. This apology must be personal to the patient/relevant person and to the given situation. The exact words used in an apology will be dependent on what has happened and the circumstances; the level of harm experienced; and the relationship between the health and social care service provider and the patient/relevant person.

An apology must be given at the open disclosure meeting, even if all the information relating to the incident is not yet available. The underlying contributory factors and learning may not be known, but it is appropriate in this situation to apologise that the incident occurred.

An apology should always contain:

- an acknowledgement of what has happened and the impact on the patient/relevant person;
- an explanation as to how or why it happened, where this is known;
- the words “I am sorry” which conveys a personal approach and genuine compassion and concern;
- reassurance in relation to the ongoing situation and care; and

- an outline of how the incident and its outcomes will be managed and the service improved to prevent such an incident happening again.

Whilst the Patient Safety Act 2023 does not mandate an apology, it is the right thing to do. It is consistent with the core values of the HSE and with a person-centred approach to care. A genuine apology delivered in a manner which is honest, sincere and empathic is always appropriate; fosters trust and respect; improves relationships; validates the situation; and may lead to quicker emotional recovery and closure from the incident.

It is important to highlight that notifiable incident 2.1 (a) and (b) are notifiable incidents relating to a type of treatment (therapeutic hypothermia) that is potentially life-saving. All Patient Safety Act 2023 requirements must be adhered to. However, in such incidents, it may be more appropriate to express regret for what has happened. If a service is aware that a patient safety incident occurred, however, then an apology must be provided.

5.4.3 Closing the open disclosure meeting

In closing the open disclosure meeting, staff should:

- summarise the salient points discussed and recap on any agreed actions;
- check with the patient/relevant person if they have any outstanding concerns or questions and close the meeting, with their agreement, when all matters have been addressed and next steps have been agreed;
- check that the patient/relevant person is aware that they can contact the designated person directly should they require further information or clarification of any information provided;
- where deemed of benefit, signal to the patient/relevant person the need for a further open disclosure meeting;
- provide details of the relevant support services available to the patient and/or their relevant person, e.g. independent advocacy;
- advise the patient/relevant person that a written letter will follow the meeting (see further detail below).

5.5 Step 3: Documentation and written follow-up

The open disclosure meeting must be followed up in writing with the patient/relevant person as part of the open disclosure process. This is in line with previous version of the HSE Open Disclosure Policy, and is mandated in the Patient Safety Act 2023 for notifiable incidents.

A written record of the open disclosure meeting is imperative for patients/their relevant person as part of good communication. It is essential correspondence for capturing the salient points discussed at the meeting, including an apology, and providing the health service providers' relevant contact details.

The written record can take the form of a letter, which is more personable. The importance of good documentation must be balanced with the need for empathetic communications.

The following points must be captured in the written record shared with the patient/relevant person following an open disclosure meeting:

1) Date of the meeting;
2) Summary information provided to the patient/relevant person at the open disclosure meeting, as set out earlier in this policy;
3) Sincere and meaningful apology in line with the apology offered at the meeting;
4) Details of the designated person/point of contact for follow-up by the patient/relevant person, if they wish to;
5) Signed by the (principal) health practitioner who undertook the open disclosure.

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Where the incident is a notifiable incident then the written record must be shared within **five (5) calendar days** of the meeting. It must state that the open disclosure was made pursuant to and in compliance with section 5(1) of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023.

Civil Liability (Amendment) Act 2017

Where the incident is a patient safety incident other than a notifiable incident, and the protections of the Civil Liability (Amendment) Act 2017 are being sought by the health or social care service provider, then the written record must be shared within **five (5) calendar days** of the meeting. It must state that the open disclosure was made pursuant to and in compliance with Part 4 of the Civil Liability (Amendment) Act 2017.

A copy of the letter must be retained by the health or social care service provider as described in section 5.6.3.

The HSE Open Disclosure webpage has a range of resources to support staff and organisations in undertaking open disclosure, designed in consultation with patient partners. For example, sample letters for all written correspondence are available in the resource: Example letters to support services during open disclosure following notifiable incidents or patient safety incidents (category 1 and 2). Importantly, the templates are intended to be compassionate, sensitive and should be adapted to the specific patient or their relevant person.

5.6 Step 4: Ongoing communication

Communication will continue following on from the open disclosure meeting. Agreed actions must be followed up, and communication maintained with the patient/relevant person through the designated person.

In particular, the designated person will liaise with the patient/relevant person and in many instances the patient will still be under the care of the health and social care service provider. Where new information comes to light during the course of a review of the incident, it is important that the patient/relevant person is kept informed of new information that emerges.

5.6.1 Additional open disclosure meetings

Additional open disclosure meetings are essentially follow-up open disclosure meetings as part of the open disclosure process where new information is disclosed to the patient/relevant person, where required. All additional information obtained subsequent to the first or preceding open disclosure meeting, including the findings and recommendations of any reviews undertaken by the health and social care service provider as a result of the incident, must be provided to the patient and/or their relevant person.

The sharing of additional information which has become available will be undertaken ideally in a face-to-face meeting and led by the principal healthcare practitioner involved in the care of the patient or a health practitioner deemed appropriate by the service provider. It is important that the same health care staff participate in these meetings, if possible, to maintain trust and rapport with the patient/relevant person; to demonstrate continuity in respect of the information provided; and to give due consideration and respect to the patient's/relevant person's experience. If it is too difficult for the patient/relevant person or staff due to the nature of the incident or additional information and there is a complete breakdown in the relationship, then the service provider may allocate a suitable alternative person to support additional open disclosure meetings.

If it is not practicable for the patient/relevant person to attend a meeting, they can be contacted by telephone or similar method of communication depending on their preferences.

At the additional open disclosure meetings, the following points must be discussed:

1) An introduction must be made, sharing the names and roles of the persons present at the meeting.
2) A description as to what the additional information relates to following on from the points discussed at prior open disclosure meeting(s).
3) Having regard to the additional information provided, where the health or social care service provider has reasonable grounds to believe that further physical or psychological consequences are likely or unlikely, the service provider must provide further information in respect of what is likely to develop (physical or psychological) or not.
4) Where, at the time of the additional meeting, there was harm identified (physical or psychological) or has since developed, the health or social care services provider must inform the patient of any changes in treatment and relevant clinical care that the service is providing (or proposes to provide) to the patient to address those consequences.
5) The information on the actions the provider has taken or proposes to take, and procedures or processes to be implemented, in order to address the knowledge the provider has obtained from its consideration of the additional information.
6) Where a health or social care services provider has determined that an apology is to be made to the patient, their relevant person or both, then this should be made at the meeting.

The same requirements as set out in Step 3: Documentation and written follow-up apply following an additional open disclosure meeting, i.e. an open disclosure letter with a summary record of the discussion must be sent after the meeting, whether held in person or by telephone, including the additional information that was highlighted at the meeting. If it is a notifiable incident or patient safety incident where the CLA Act 2017 is being applied then the relevant legislation must be referenced and the letter sent within five (5) calendar days of the meeting. Written correspondence must always be personalised.

5.6.2 Managing requests for clarifications of information

Following an open disclosure meeting or additional open disclosure meeting(s), the patient/relevant person may seek clarification of certain information. All requests received by the health and social care service provider in relation to the clarification of information provided at an open disclosure meeting must be referred to the designated person and responded to factually and in a timely manner.

The designated person will liaise with the health practitioner who disclosed the information at the relevant meeting which the query relates to. If they are not available, then the service provider must identify another suitable health practitioner to respond to the clarification sought. The health practitioner responding to the request can provide the clarifications verbally, and should make a note of this in the patient's healthcare record.

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Where a clarification is sought for a notifiable incident as per the Patient Safety Act 2023 and the clarification has been provided verbally, then it must be followed up in writing by the person providing it to the patient/relevant person. This communication must set out the information provided in the clarification, specify the date on which the clarification was provided, and be signed by the person who provided clarification. This must be shared within **five (5) calendar days** of providing the clarification. It must be forwarded to the designated person capturing what was discussed, including the date of the discussion.

Civil Liability (Amendment) Act 2017

Where the incident is a patient safety incident other than a notifiable incident, and the protections of the Civil Liability (Amendment) Act 2017 are being sought by the health or social care service provider and clarifications are sought in relation to the open disclosure or additional disclosure meeting then the same requirements described above as per the Patient Safety Act 2023 apply.

A record of the request for clarification and the response must be retained by the health services provider.

Sample letters for all written correspondence and other similar resources for staff and organisations are available on the HSE Open Disclosure webpage.

5.6.3 Record keeping

Good record keeping is important in relation to open disclosure. The patient safety or notifiable incident must be recorded in the patient's healthcare record. That includes the salient points discussed as part of open disclosure with the patient/relevant person during the open disclosure meeting. Therefore:

- The open disclosure letter with a summary record shared with the patient/relevant person must be retained in the patient's healthcare record, similarly to other patient letters. Where a patient has multiple records or files because they are cared for by multiple providers, i.e. in the community setting, then the letter should be retained in the records used by the principal health practitioner who made the open disclosure.
- Where services use electronic health records, then the service can develop electronic template letters as described in this policy to ensure they are stored in the patient's healthcare record.
- If a patient/relevant person requests that a copy of the letter is not kept in their healthcare record, then this must be respected and it should be retained in an incident management/open disclosure file used by the health or social care services provider.

- Similarly, for incidents of a sensitive nature (e.g. where the incident relates to an allegation of abuse or actual abuse) then it may not be suitable to retain such letters in the healthcare record. A copy must be retained in the incident management/open disclosure file maintained by relevant staff, e.g. quality and patient safety manager.
- The incident record and open disclosure fields in relation to the incident must be completed on NIMS. The incident entry on NIMS should be reviewed and updated as required to ensure all relevant fields are completed.
- For notifiable incidents, the content of the written record is mandated and cannot be deviated from if the protections of the Patient Safety Act 2023 should apply. The CLA Act 2017 is also prescriptive in relation to the content of the letter where this is invoked by a staff member. The requirements have been confirmed earlier in this policy.
- Other documents compiled as part of managing the open disclosure, for example open disclosure checklists, should be kept on record in a file separate to the healthcare record, e.g. open disclosure file or incident management file, as these are working documents to support staff.

5.7 Step 5: Sharing the review findings and closing the open disclosure process

Closure of the open disclosure process occurs following honest and complete open disclosure, and after incident review findings (report where available) is shared with the patient/relevant person in line with the requirements set out in the HSE Incident Management Framework. To help manage expectations, it is advisable to outline this to the patient/relevant person at the outset.

Whilst the open disclosure process has reached a point of closure, however, the patient/relevant person may still require ongoing support.

Health and social care service providers should try to understand what supports might be required, and help the patient/relevant persons in accessing them where possible. Consider ways in which the patient/relevant person could be involved in or have input to quality improvement initiatives, as appropriate. Where appropriate, keep the patient/relevant person informed in relation to any actions or improvement initiatives undertaken by the service to reduce the likelihood of a recurrence of a similar incident.

Psychological closure for the patient/relevant person does not usually occur until they have experienced the following:

(i) an acknowledgement by the health and social care service provider of the patient safety or notifiable incident, and of the impact of the incident on the patient;

(ii) a satisfactory explanation in relation to what happened and how/why it happened;

(iii) a sincere and meaningful apology;

(iv) honest and factual answers to their questions;

(v) reassurance in relation to their ongoing care/treatment; and

(vi) reassurance that learning has occurred and that actions are being taken by the service provider to try to prevent a recurrence of the incident.

Feedback from patients, their relevant persons and the staff involved in the open disclosure process should be sought and any learning incorporated into improving the process going forward.

When a satisfactory conclusion cannot be reached for the patient/relevant person, they should be advised of alternative courses of action which are open to them, e.g. escalation through the line of management (governance), the complaints process, and/or litigation process.

5.8 Additional considerations

5.8.1 Managing the response to minor or no harm incidents

A low level response to minor harm incidents, or in some instances no harm incidents, may involve one face-to-face conversation with the patient/relevant person. In the event that the patient has been discharged or has indicated a preference for same, the patient may be contacted by telephone or alternative method of communication.

While the completion of open disclosure of an incident with minor harm or no harm might seem an involved process with an additional resource requirement, the outcome can be invaluable to patients, their family and friends, staff, the service and the HSE. It is the right thing to do. It is also important that such incidents are reported and monitored by the health and social care service provider, that learning occurs, and that actions are taken to mitigate any risks identified.

Low level response for minor or no-harm incidents

The conversation with the patient /relevant person should address, as appropriate:

- acknowledging what happened and any resulting impact or consequences for the patient;
- listening to and hearing the patient's story/understanding of what has happened and its impact;
- providing an objective explanation of the incident;
- responding to questions openly, honestly and factually;
- providing a meaningful apology;
- providing reassurance in relation to ongoing care and treatment and the steps being taken to try to prevent a recurrence of the incident going forward to the patient involved and to others.

Contact details will be provided should the patient/relevant person have any further questions/concerns that they would like addressed at a later stage. This may be the only discussion that is required and, with the agreement of the patient/relevant person, open disclosure may be concluded at this stage.

The staff member most directly involved in the incident or the person who first identified the incident, e.g. nurse, midwife, doctor, health and social care professional, may be the most appropriate person to speak with the patient/relevant person, and should discuss this with their line manager/person in charge. It is recommended that another member of the team is present also, as a support to the member of staff and to the patient/relevant person. Consideration must also be given as to the patient's preference to have their relevant person or other support person (e.g. independent advocate) present.

Where it is determined that it is not appropriate for the individual involved in the incident to carry out open disclosure, for example where they are very distressed following the incident, then the management of the open disclosure conversation will be agreed with their line manager or person in charge and open disclosure may be led or facilitated by the line manager/person in charge/other appropriate person.

The open disclosure must be documented in the healthcare record.

5.8.2 Open disclosure to the relevant person

Disclosure of information to an adult patient's relevant person (see definition of relevant person in Glossary) must only be undertaken, where possible, with the consent of the patient. The decision by a health and social care service provider to disclose to the patient's relevant person must take into consideration:

- the known will and preference or any instruction provided by the patient in relation to the sharing of their information, e.g. advance healthcare directive or information/instruction provided by the patient in their healthcare record;
- who the disclosure should be made to, e.g. information provided by the patient in their healthcare record or in an advance healthcare directive, i.e. establish if the person has appointed a designated healthcare representative;
- legally mandated requirements as per the Patient Safety Act 2023 for notifiable incidents
- what information is deemed appropriate and justifiable for the service provider to share, i.e. the information provided to the relevant person must include only the necessary information relating to the incident.
- in the case of a deceased patient, the readiness of their relevant person emotionally to take part in the open disclosure meeting should be determined in consultation with that person or persons.

The patient must be informed at a later stage of any open disclosure made to the relevant person and the details of what was disclosed. This must be recorded in the patient's healthcare record.

5.8.3 Managing open disclosure of a patient safety incident which occurred while the patient was under the care of another team/provider

A health and social care service provider may suspect or identify that a patient safety or notifiable incident occurred whilst a patient was in the care of another team, service or organisation. This can be a challenging situation and may raise questions such as:

- what actions have been taken to date?
- has open disclosure occurred already?
- which professionals carry the responsibilities in relation to open disclosure?
- how to initiate the open disclosure process?
- what are the obligations?

The open and transparent disclosure of patient safety and notifiable incidents is a shared professional responsibility; the appropriate response is to turn towards, rather than away from, all those involved. In particular, where incidents span different services, e.g. a medical speciality and a diagnostic speciality, it is recommended that both specialities are represented at the open disclosure meeting to speak to their relevant area of expertise and answer questions accordingly. Making the effort to understand what happened and ensure appropriate communication with the patient/relevant person is the priority. It is an ethical duty and professional responsibility to ensure that the rights of the patient come first. Only a collective approach to accountability can fully meet the needs of patients and families after patient safety or notifiable incidents.

The team/service whose care the patient is under at the time the incident becomes known will initiate open disclosure. They will inform the patient/relevant person that an incident was identified and reported, and that the relevant service/organisation will be informed of the incident, with the patient's/their relevant person's consent. At this stage, very limited information may be available but the patient/relevant person will likely want to understand how the incident will impact their ongoing care and treatment, if at all. Ultimately, however, the responsibility for the ongoing open disclosure process and open disclosure meeting lies with the team or service whose care the patient was under at the time the incident occurred, as they will be best placed to explain the facts and answer specific queries.

How the open disclosure process is managed and by whom should be discussed between the services/organisations involved, in line with the patient's/relevant person's wishes. These will be in keeping with the principles of open disclosure as outlined in this policy. Any challenges in decision making or in progressing open disclosure must be escalated to the relevant SAO(s) and ultimately the REO/National Director, where necessary.

If multiple health and social care service providers contributed to the patient safety or notifiable incident, they should work together on the incident review and open disclosure process. Each provider still has its own responsibilities in relation to open disclosure; they must assure themselves that these have been met.

Important : Notifiable Incidents

The Patient Safety Act 2023 describes that where a health or social care services provider is satisfied that a notifiable incident has occurred **in the course of the provision by it of a health service to a patient (whether the notifiable incident occurred when that provider was providing that service or another health services provider was providing a health service to that patient)** the health or social care services provider shall hold a notifiable incident disclosure meeting in order to make the open disclosure of that notifiable incident to the patient or relevant person (or both of them), notwithstanding the absence of knowing some or all of the consequences of the notifiable incident or some or all of the information related to the notifiable incident. It shall notify the relevant regulator of that notifiable incident.

The HSE is the overarching health and social care service provider, and can determine if an alternative health practitioner is more suited to undertake open disclosure. It is the intention of this policy to outline that: whilst a service where the incident is identified will inform the patient/relevant person and other service of the incident, the service where the incident occurred must take a lead on the open disclosure and such communication must be supported by staff caring for the patient at the time the notifiable incident is identified. Communication and information exchange between services will be important and staff must seek the patient's/relevant person's wishes, and work to implement these as far as reasonably possible, as well as adhering to information governance requirements.

Where the HSE is satisfied that a notifiable incident occurred and the incident occurred whilst the patient was receiving health and social care from a non-HSE nor HSE-funded service provider, then HSE staff must lead out on the open disclosure as required in the legislation for notifiable incidents. It is recognised that information may be limited, and for the patient/relevant person's benefit it would be important that the HSE engages with the non-HSE service provider and that open disclosure is planned and considered between the services/organisations.

If the notifiable incident is notifiable incident 2.1a or 2.1b and occurs at a referring site (where the baby is born) but the baby is then transferred to another hospital for therapeutic hypothermia then the referring hospital site will lead out on the open disclosure and notify the incident to the relevant regulator.

5.8.4 Managing open disclosure where a patient's decision-making capacity may require support

People may be vulnerable in terms of their ability to understand and to be fully informed, and also in their ability to communicate their wishes and decisions with regard to their ongoing care and treatment. Staff must work on the presumption that every adult person has the capacity to make decisions about their care. A person whose decision-making capacity is in question is entitled to open disclosure on an equal basis with others, and to be provided with all the necessary supports to facilitate their involvement in the open disclosure process.

In preparation for an open disclosure meeting with a patient, it is important that staff find out how the person communicates and what they understand. Information should be gathered on the supports that the person uses to communicate, e.g. Lámh, objects of reference or pictures. It is important to use these resources to support the patient to understand as fully as possible the apology and the message conveyed to them.

There is no 'one size-fits all' way to support a person who has decision-making capacity challenges. The support required by a vulnerable person will depend on the following factors:

- The nature and complexity of the incident, taking account of the person's individual circumstances and needs;
- The person's ability to understand the information about the incident, the consequences of the incident, and options available in relation to the management of the incident including their care/treatment plan;
- The person's ability to communicate their understanding and preferences;
- Whether the person is accustomed to making their own decisions and dealing with such situations.

In circumstances where a patient/relevant person has a Co-Decision Making Arrangement or a Decision Making Representation Order in place, these individuals should be present with the patient/relevant person when open disclosure is taking place. The purpose of their presence is:

- Co-Decision Maker: To support the relevant person to make any necessary decisions arising from the open disclosure
- Decision Making Representative: To make/action any decisions on behalf of the relevant person arising from the open disclosure

To ascertain if a patient has an arrangement in place under the Assisted Decision Making Act 2015, staff can access the Decision Support Services (DSS) register. More information about accessing the DSS register can be found at https://www.decisionsupportservice.ie/services/search-register.

5.8.5 Managing open disclosure where a patient is a child

When a patient safety or notifiable incident involves a child then the team involved, in conjunction with the parent(s)/legal guardians of the child, will make an informed decision as to what the child is told. This will take into consideration the child's age, comprehension and emotional maturity. The child's best interests are of paramount importance, and the child's wishes will be taken into account and given weight according to their maturity.

5.8.6 Managing open disclosure following patient safety incidents affecting multiple patients

Open disclosure requirements for Look-back Reviews (LBR) require special consideration:

- As is the case with all harm events, once it is identified that a patient has been harmed due to an incident there must be open disclosure as soon as reasonably practicable.
- Neither is it given that all patients whose records were screened as part of the LBR require individual communication. This should be assessed on a case by case basis, bearing in mind legal obligations must be met if there is a notifiable incident.
- All patients who are known to have been harmed require open disclosure, and those who require recall should receive the appropriate communication reflective of their involvement in the LBR and the level of harm associated.
- A database tracking the status of all patients whose care is encompassed by the LBR should be maintained.
- In such circumstances, it may be necessary to establish a helpline as per HSE Guidance for Conducting a Look-back Review (2022) and/or write to those potentially affected.
- In the event that the public is aware of the LBR in advance of its completion, a comprehensive database allows for clear communication with those who are affected and assurance for those who are not.
- Findings in relation to the LBR should not be released into the public domain until the LBR is complete, all the findings are known, and all persons affected are informed of the implications for them. It is not necessary to conduct open disclosure with all patients whose records were reviewed over the course of the LBR.
- See the HSE Guidance for Conducting a Look-back Review (2022) for more information on conducting LBRs. Where additional support is required for serious incidents or multiple patient incidents, the National Open Disclosure Office can be contacted at email: opendisclosure.office@hse.ie for support and coaching prior to the disclosure.

5.9 Circumstances where open disclosure cannot be facilitated

There are two circumstances when open disclosure cannot be facilitated that apply to open disclosure in the HSE and HSE-funded services. This is in line with the Patient Safety Act 2023. The two circumstances when open disclosure cannot be facilitated are outlined in the sub-sections below.

The rationale for not carrying out open disclosure must be documented in the healthcare record and on NIMS. A notifiable incident must still be reported to the relevant regulator, even if a circumstance where open disclosure cannot be facilitated applies.

Where a patient has requested it, has died, is incapacitated, or there are concerns that open disclosure may put them or others at risk of harm, open disclosure must occur with the patient's relevant person. It must take into consideration any stated will and preference of the patient in relation to data sharing and matters relating to patient confidentiality. Open disclosure must be undertaken with the patient when they are able to participate, e.g. when their condition improves. The patient must be informed that their relevant person was informed of the incident initially.

Where a patient does not have a relevant person who can initially participate in the open disclosure process, then the open disclosure will be deferred until the patient's condition improves. This must be documented in the patient's healthcare record.

5.9.1 Unsuccessful attempts to contact a patient/relevant person for the purpose of open disclosure

The health and social care service provider may not be able to contact the patient/relevant person based on the contact information available. In this instance, the services provider must take all reasonable steps to establish contact, e.g. try their General Practitioner for contact details and attempt to contact the patient/relevant person multiple times by different means.

The health or social care services provider must document the efforts made to contact the patient/relevant person in the patient's healthcare record.

At any time after making the unsuccessful attempts to contact the patient/relevant person initially, if contact is later established by the service provider then an open disclosure meeting must be held.

5.9.2 Patient/relevant person declined to participate in open disclosure

If a patient/relevant person is contacted but declines to participate in open disclosure, the service provider must document the patient's/relevant person's decision to not participate at that time; sign and date the document; provide the patient/relevant person with a copy; and retain a copy in the patient's healthcare record. In this record, they must also advise the patient/relevant person of their right to request open disclosure verbally or in writing at a later date, ideally within a five (5) year period.

Where the health and social care service provider receives a request subsequently for open disclosure, the service provider must keep a note of the request in writing specifying the date of the request and the person who made it. Where the service provider receives a request, they must hold a disclosure meeting.

5.10 Open disclosure and complaints

Patients/relevant persons have the right to make a complaint or escalate a complaint or concern about the open disclosure process or the patient safety incident itself through any and all mechanisms available, and should be supported in doing so through the provision of information on the HSE complaints procedure and on patient advocacy services. This includes the right to appeal, seek legal or other redress. Patients and/or their relevant persons exercising these rights must not be treated differently.

The HSE Policy Your Service Your Say: the Management of Service User Feedback for Comments, Compliments and Complaints (2017) and accompanying Staff Guidance Manual adopts all relevant principles to promote a culture of openness, transparency and learning. For those dealing with formal written complaints, i.e. Complaints Officers, Review Officers and relevant parties, e.g. QPS/Clinical Director (for matters relating to clinical judgment), the relevant principles of open disclosure must be adopted. The principles of open disclosure form the basis of an ethical response and promote a fair and just culture within the HSE, and when employed effectively in the feedback process can lead to improved service user and staff acceptance of the outcomes and all recommendations.

When a patient safety incident is identified through the complaints process, the incident will be managed in line with the provisions of the HSE Incident Management Framework and this HSE Open Disclosure Policy. This must be acknowledged to the complainant/patient.

For more information on complaints concerns and feedback see, the HSE Complaints and Feedback webpage.

6

Supporting patients/ relevant persons and staff

6.0 Support following a patient safety or notifiable incident

Patient safety and notifiable incidents can have a significant impact on all those involved. Where a patient is harmed, in particular, this can have a negative impact on all. It is recognised that this can be a difficult time and supporting patients, their relevant person and staff is essential. All persons may be affected differently, and the response may require different supports.

6.1 Supporting patients/relevant persons

Following an incident, it is important to address the clinical needs of the patient as a priority and to ensure they receive the care needed. Equally, they may also require emotional support due to the impact of the incident. There are a number of different supports and resources available to patients/relevant persons, including bereavement supports.

A list of available supports can be accessed on the HSE Open Disclosure webpage.

6.1.1 The designated person

The role of the designated person is outlined in Section 3 of this policy, and a more detailed description of the role and function of the designated person is available by accessing the following HSE documents: The Role of the Designated Person in Incident Management and Open Disclosure (2024) and the Designated Person Checklist.

The early assignment of a named designated person by the health and social care service provider helps maintain personal contact between the patient/relevant person and the service provider. The designated person can also sign-post the patient/relevant person to support services available to them. This will ensure that the patient/relevant person does not feel isolated; that their support and communication needs in respect of the plans for the management of the incident (including review) are met; and also that they are supported in preparing for and attending open disclosure meetings. The designated person can further advise the patient/relevant person on advocacy service and other supports available to them.

Following an open disclosure meeting, the designated person should contact the patient or relevant person on a mutually agreed date and time to establish their experience of the open disclosure meeting in relation to the following:

- Did the patient/relevant person feel that they were treated with dignity and respect during the open disclosure meeting?
- Did the patient/relevant person feel that they were listened to and heard during the open disclosure meeting?
- Did the patient/relevant person receive an appropriate and meaningful apology?
- Did the patient/relevant person receive answers to their questions?
- Does the patient/relevant person have any further questions or clarifications which require response? As noted, clarifications concerning open disclosure meetings need to be followed-up with the relevant health practitioner.

Early on in the process, the designated person seeks to agree with the patient/relevant person how often they want to have contact with the designated person (i.e. 6-weekly, whenever there are significant new developments, etc.) and by what means (i.e. phone call, e-mail, etc.)

Their role will include receiving updates from the review team on the review process as it progresses. They will keep the patient/relevant person up to date on progress and will report on any clarifications the patient/relevant person is seeking or address any relevant issues that may arise. They will liaise with the patient/relevant person directly in relation to the report of the review team when it is completed and agree arrangements for the provision of the report to them.

6.1.2 Independent advocacy

Information should be provided by the designated person to the patient/relevant person on the availability of access to independent advocacy services. Independent advocates can assist the patient/relevant person in (i) accessing information, (ii) providing information, (iii) exploring options and outcomes, (iv) writing letters and in making a complaint, (v) providing support following a patient safety or notifiable incident, (vi) attending meetings and (vii) empowering the person to represent themselves. The role of the advocate is to provide additional independent support and ensure that people can exercise their rights with dignity, autonomy, equality and independence at the core.

A list of Advocacy Services can be found here.

6.1.3 Meaningful involvement of patient/relevant person in the review process

The first open disclosure meeting may be the first time a patient/relevant person will learn about the incident and about open disclosure and incident review processes. This will likely be very new to them.

When a review is undertaken, it is important that it is in line with the HSE Incident Management Framework, and that the patient/relevant person experiences meaningful involvement in the review process, if they so wish. The patient/relevant person should receive information on the incident review process; staff should describe how the patient/relevant person will be included in the review process; and indicate anticipated timelines for the review to be undertaken.

The patient/relevant person should be informed that:

- The Terms of Reference of the incident review will seek to include any key issues or questions raised by the patient/relevant persons in the aftermath of the incident (see the HSE Incident Management Framework 2020 section 11). If possible, the patient/relevant persons should have an opportunity to review the draft Terms of Reference of the incident review before they are finalised and add any questions to be addressed as part of the review. If the queries fall outside the incident review process, then the health and social care service provider should follow-up on those with the patient/relevant person outside of the review process.

- They will be able to share their recollection of events if they so wish and meet with the review team and therefore contribute to the review.
- They will be able to determine how and when they want to be kept abreast of progress of the review which will generally be through the designated person.
- They will be able to review a draft report to check for factual accuracy from the perspective of their involvement in the incident.

Being informed and sharing their account is important to patients and/or their relevant persons.

6.1.4 Restorative practice

Restorative practice is a social science field concerned with improving and repairing relationships and social connections among people. It is based on a set of core values and the explicit promotion and enhancement of particular skills such as the ability to empathise and to find solutions to specific problems. In some instances, patients/relevant persons will have had a negative experience in relation to the incident review or open disclosure process. This can lead to compounded harm. Communication with the health and social care service provider may not have addressed outstanding concerns, or may have broken down altogether. In such instances, restorative practice, may help bridge such communication and support patients'/their relevant persons' healing.

6.2 Supporting staff

Staff can experience trauma in relation to an incident they have witnessed or were involved in. It is widely recognised that staff do not go to work to do harm and that incidents primarily occur due to system failings with multiple contributory factors. Providing support to staff is essential to support them and their well-being and to ensure they are empowered to do the right thing and be open and transparent about incidents. A list of available supports can be found here.

6.2.1 The ASSIST Model

The ASSIST model of communication was developed by the Medical Protection Society (MPS). It was developed to support all staff in the discussion of patient safety incidents with patients/relevant persons. It is a useful communication tool to help staff communicate clearly and compassionately.

6.2.2 The ASSIST ME Model

The importance of support for staff from line managers, colleagues and peers in the aftermath of a patient safety or notifiable incident should not be underestimated. Being available for staff and hearing/acknowledging their story surrounding the event is crucial. Staff require a safe and confidential space in which to discuss the incident. The intention is not to be investigative at this stage. The "Assist Me" model of staff support has been developed to assist managers and staff during this process. This has been adapted from the Medical Protection Society's ASSIST model of communication.

The tool can be accessed here.

6.2.3 Staff Liaison Person

A named staff member should be identified to act as a single point of contact for staff directly impacted by the incident. The role of this person is to ensure that staff affected do not feel isolated and that their support and communication needs are met throughout the incident management process including any review of the incident that may be required. The person identified should have the necessary skills and experience required to fulfil their role.

6.2.4 Debriefing and After Action Review (AAR)

After Action Review (AAR) supports debriefing in the aftermath of an incident, and can be a useful first step in supporting staff following an incident. The AAR is facilitated in a supportive, learning environment where all staff can contribute to the process equally. The HSE Incident Management Framework supports the application of AAR as a debriefing tool and as an incident review tool. All health and social care service providers should have trained AAR facilitators in place who can support debriefing following an incident.

Information on accessing HSE AAR training can be found here.

6.2.5 Employee Assistance Programme (EAP)

The HSE Employee Assistance Programme (EAP) is a work-based support service for staff and the organisation. It supports employees with psychosocial issues (psychological and social factors that influence mental health) which includes supports following an incident if the staff feel they would like to avail of this. The service is free and available to all HSE employees.

Supports provided by the EAP Service include:

- Counselling
- Consultation to managers on staff wellbeing and psychosocial issues
- Workshops on staff wellbeing issues
- Critical Incident Stress Management (CISM) Response – individual and group support and pre-incident training to reduce risk associated with traumatic incidents in the workplace

6.2.6 Just Culture

Commitment 2 of the HSE Patient Safety Strategy (2019-2024) outlines the HSE's ambition for a compassionate, just, fair and open culture in the HSE and states that "Staff must be actively encouraged to speak up for safety, feel psychologically safe, be involved in decisions which affect the safe delivery of care and be provided with the skills, support and time to engage in patient safety improvement initiatives".

The HSE is committed to a Just Culture as outlined in the HSE Incident Management Framework. The Framework defines Just Culture as one which refers to a values based supportive model of shared accountability. It states that individual staff should not be held accountable for system failings over which they have no control. Instead, organisations need to encourage staff to report such incidents and near-misses and apply system-learning to improve patient safety.

Further information on Just Culture in the HSE can be found here.

6.2.7 Managerial and Clinical Open Disclosure Champions

Open Disclosure Champions and Open Disclosure Leads are available in services to support staff and offer guidance in relation to the policy, legal requirements and training. The HSE is also working to develop and embed clinical/managerial champions in services for clinical peer support and as required as part of the DoH National Open Disclosure Framework.

7 Policy Development

7.0 Overview of Policy Development

This section outlines the steps taken to review and update the revised HSE Open Disclosure Policy for publication in 2025.

To note, this policy document builds on previous Open Disclosure Policies from 2013 (V1) and 2019 (V2). All sections have been revised and updated in line with the most up-to-date legislation, regulation, evidence, and internal/external review, as outlined in this section. Whilst every effort has been made to ensure the accuracy and completeness of the information outlined in this document, the process may change with the passage of time and, in particular, the law and practice are constantly changing and can be interpreted only in light of particular factual situations. For questions about the policy and process outlined herein, particularly as it may relate to local circumstances, please contact the local Open Disclosure Lead or the HSE National Open Disclosure Office on opendisclosure.office@hse.ie for advice and guidance.

This policy describes the specific open disclosure response required to patient safety and notifiable incidents aligned with the HSE Incident Management Framework. The HSE Incident Management Framework addresses the incident review process in detail and provides guidance on alternative review processes for other scenarios. Open disclosure may still be applicable for different approaches described. Please see figure 7 overleaf.

Source						
Confidential Recipient	Protected Disclosure	HSA/ Dangerous Occurrences	Complaint	Audit	Incident	Regulatory
Identify the Dominant Concern to Determine Appropriate Route for Management (see examples below)						

Concern related to individual competence, behaviour or accountability?	Consult Human Resources
Concern related to the need to identify any/all individuals potentially harmed by a hazard	Consider the need for the conduct of a Look-back Review
Concern related to a hazard or risk that could, if not managed result in an incident occurring	Consider as part of the service's Risk Management Process
Allegations or concerns of abuse of vulnerable adults (including elder abuse)	Refer to line manager/head of discipline to deal with allegation or concern in line with relevant policy and procedures, e.g. Trust in Care (2005), HSE Safeguarding Vulnerable Persons at risk of Abuse National Policy and Procedures (2014)
Concern related to an incident of intentional harm of a service user not related to abuse	Apply the Just Culture Guide described in the Incident Management Framework
Concern related to whether the care provided to a service user was appropriate and timely	Consider requesting an independent opinion in relation to the standard of care provided, e.g. a Healthcare Record Review
Concern related to a formal complaint as defined by the Your Service Your Say Policy	Refer to Complaints Officer for management in line with Your Service Your Say Policy
Suspected incidents of unauthorised disclosure of data	Refer to line manager to deal with in accordance with the HSE's Data Breach Policy and GDPR. Report the breach to Consumer Affairs (or equivalent immediately so that the timeline of 72 hours can be adhered to. https://www.hse.ie/eng/services/publications/pp/ict/data-protection-breach-management-policy.pdf
Suspected incidents relating to Theft/Fraud	Refer to line manager to deal with in accordance with the HSE Policy Statement on Fraud and Corruption https://www.hse.ie/eng/staff/resources/hrppg/policy-statement-on-fraud-and-corruption.html

Figure 7: Alternative review processes

7.1 Stakeholder engagement

The first HSE Open Disclosure Policy was published in 2013, and was revised in 2019.

In 2021, the HSE undertook an extensive consultation of the 2019 HSE Open Disclosure Policy. Its revision was paused, however, due to a number of national developments led by the Department of Health.

This third revision of the HSE Open Disclosure Policy has aligned it with the DoH National Open Disclosure Framework and the Patient Safety Act 2023. The Policy was disseminated for open consultation through end September 2024, and feedback was reviewed and incorporated into this updated Policy document.

7.2 External review

A legal review of this policy has been undertaken to ensure the requirements stated are correct and in line with the Patient Safety Act 2023 and CLA Act 2017.

7.3 Disclosure of interests

No conflicts of interest were declared as part of the HSE Open Disclosure Policy revision.

7.4 Rationale/alignment with HSE national priorities

The HSE Open Disclosure Policy is an essential policy required to describe clearly the expectations and requirements regarding open disclosure when a patient safety or notifiable incident occurs. It underpins the importance the HSE places on the need for a compassionate, honest, open and transparent response when things go wrong. This is crucial in the health and social care setting to prevent compounded harm to those affected by a patient safety or notifiable incident. Being open and transparent enables the organisation to maintain a relationship of trust.

The HSE Open Disclosure Policy incorporates multiple sources that set out the requirements for open disclosure across the wider health care system. The sources that have influenced this policy include:

- HSE Core Values which include care, compassion, trust and learning.
- The Department of Health National Open Disclosure Framework (2023) section 3.4.3 requires the development of an Open Disclosure Policy by health and social care service providers to support a culture of open disclosure, and states that:

  "Local policies must recognise and address the role of a supportive culture in effective open disclosure. The Open Disclosure Framework provides a flexible framework designed to be used by organisations, health and social care professionals, and managers when developing or amending policies and procedures for open disclosure." It further states in section 4.1 that: "Health and social care service providers must have a policy on open disclosure in place that aligns with the provisions of the Framework... Providers must communicate this policy clearly to all clinical and non-clinical staff including agency staff and patients/service user and their support persons."

- The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023
  The Patient Safety Act 2023 includes provisions for open disclosure/ communication as part of a patient requested review of their cancer screening history and includes provisions for data obtained as part of clinical audit. The Patient Safety Act 2023 further sets out a legal framework for the mandatory open disclosure of Notifiable Incidents that are defined in the legislation.

- The Civil Liability (Amendment) Act 2017 [CLA Act 2017] Part 4
  Legal protections are available to the health and social care service providers for the content of an open disclosure meeting and the apology following a patient safety incident. The protections are set out under the provisions of Part 4 of the CLA Act 2017 and can be availed of whenever the open disclosure process is followed as described in the CLA Act 2017.

- Sláintecare Implementation Strategy & Action Plan 2021-2023, section 5.3 Patient Safety and Quality Initiatives states that:

  "Embedding of Open Disclosure – … It is imperative that a culture prevails where patients are treated the way that they would most like when things go wrong, that they receive a sincere and genuine apology, are afforded the opportunity to understand what has happened, and can be sure that what happened to them will not happen to other patients."

- National Service Plan 2025, section 2.3 Clinical, Quality and Patient Safety states that the HSE should implement patient safety improvements through the following: "Monitoring the HSE's implementation plan for the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 with the Health Regions… [and] Open Disclosure policy and the National Open Disclosure Framework."

- The WHO Patient Safety Rights Charter 2024
  It is the first Charter to outline patients' rights in the context of safety. The Charter aims to outline patients' rights in the context of safety and promotes the upholding of these rights, as established by international human rights standards, for everyone, everywhere, at all times. It includes:

  1) Right to timely, effective and appropriate care
  2) Right to safe health care processes and practices
  3) Right to qualified and competent health workers
  4) Right to safe medical products and their safe and rational use
  5) Right to safe and secure health care facilities
  6) Right to dignity, respect, non-discrimination, privacy and confidentiality
  7) Right to information, education and supported decision making
  8) Right to access to medical records
  9) Right to be heard and fair resolution
  10) Right to patient and family engagement

- The WHO Global Patient Safety Action Plan 2021-2030
  Patient engagement and empowerment is at the core of the Global Patient Safety Action Plan 2021–2030. The purpose of the action plan is to provide strategic direction for all stakeholders for eliminating avoidable harm in health care and improving patient safety in different practice domains through policy actions on safety and quality of health services, as well as for implementation of recommendations at the point of care.
- The HSE Incident Management Framework 2020 outlines that incident management should be:
  - person centred
  - fair and just
  - open and transparent
  - responsive
  - improvement focused and
  - inform learning
- The Department of Health Code of Conduct for Health and Social Service Providers (May 2018) states: "Openness and transparency, honest communication, learning and accountability – we will communicate honestly and ensure learning when a service user has suffered harm as a result of care and accept full responsibility for our actions."
- The HIQA National Standards for Safer Better Healthcare 2024 standard 3.5 states: "Service providers fully and openly inform and support service users as soon as possible after an adverse event affecting them has occurred, or becomes known and continue to provide information and support as needed."

Other related HIQA standards include:

- National Standards for Adult Safeguarding (2019)
- National Standards for the Conduct of Reviews of Patient Safety Incidents (2017)
- National Standards for Residential Care Settings for Older People in Ireland (2016)
- National Standards for Safer Better Maternity Services (2016)
- National Standards for Residential Services for Children and Adults with Disabilities (2013)

Professional regulators describe the requirement for open disclosure in the various codes of conduct, including but not exclusively:

- Medical Council's Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2024)
- The Nursing and Midwifery Board of Ireland: Code of Professional Conduct and Ethics for Registered Nurses and Midwives (May 2021)
- Dieticians Registration Board Code of Professional Conduct and Ethics for Dieticians (2019)
- Medical Scientists Registration Board Code of Professional Conduct and Ethics for Dispensing Opticians (2019)
- Optometrists Registration Board Code of Professional Conduct and Ethics for Dispensing Opticians (2019)
- Optometrists Registration Board Code of Professional Conduct and Ethics for Optometrists (2019)
- Occupational Therapists Registration Board Code of Profession Conduct and Ethics for Occupational Therapists (2019)
- Podiatrists Registration Board Code of Professional Conduct and Ethics for Podiatrists (2021)
- Physiotherapists Registration Board Code of Professional Conduct and Ethics for Physiotherapists (2019)
- Radiographers and Radiation Therapists Registration Board of Professional Conduct and Ethics for Radiographers and Radiation Therapists (2019)
- Social Care Workers Registration Board Code of Professional Conduct and Ethics for Social Care Workers (2019)
- Speech and Language Therapist Registration Board Code of Professional Conduct and Ethics for Speech and Language Therapists (2019)
- Social Workers Registration Board Code of Professional Conduct and Ethics for Social Workers (2019)
- Pharmaceutical Society of Ireland Code of Conduct for Pharmacists (2019)

7.5 Supporting evidence

The following legislations are pertinent and were referred to during the revision of this Policy:

- Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023
- Civil Liability (Amendment) Act 2017
- The Children's First Act 2015
- The Assisted Decision-Making (Capacity) Act 2015
- National Treasury Management Agency (Amendment) 2000
- The Health Act 2004
- The Health Act 2007
- Mental Health Act 2001
- Interpretation Act 2005

The following strategy, frameworks, reports and PPGS were referred to during the revision of this Policy:

- HSE National Consent Policy 2024
- DoH National Open Disclosure Framework 2023
- HSE Performance and Accountability Framework 2023
- HSE "Better Together" The Heath Services Patient Engagement Roadmap 2023
- HSE Enterprise Risk Management Policy and Procedure 2023
- HSE National Policy on the Prevention and Management of Work-Related Stress 2023
- HSE Guideline for Conducting a Look-back Review 2022
- HSE National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death 2022
- HSE Incident Management Framework 2020
- HSE Patient Safety Strategy 2019-2024
- HSE National Review of Clinical Audit Report November 2019
- HSE Your Service Your Say: The Management of Patient Feedback for Comments, Compliments and Complaints 2017
- Disciplinary Procedure for Employees of the HSE 2007
- HSE Trust in Care Policy 2005
- HSE Grievance and Disciplinary Procedures for the Health Service 2004

Further Information and Resources are available at the HSE Open Disclosure website

7.6 Literature review

A wider literature review and findings informed the revised HSE Open Disclosure Policy.

7.6.1 Methodology

A literature review was undertaken by HSE Library Services on published literature over the last decade using key search terms:

- Open Disclosure or Duty of Candour
- Open Disclosure or Duty of Candour Policy/Frameworks
- Open Disclosure or Duty of Candour Implementation
- Open Disclosure or Duty of Candour Patient or Staff Experience
- Open Disclosure or Duty of Candour as it applies to different incident categories or levels of harm

The literature search was completed in January 2024. HSE library databases were searched as well as grey literature resources and 48 relevant articles were identified as relevant in informing the revision of the HSE Open Disclosure Policy.

7.6.2 Key findings

- Ramsey *et al* (2022) found in their study on patient and family involvement in serious incident investigations that most patients and families valued being involved; however, it was important that investigations were flexible and sensitive to both clinical and emotional aspects of care to avoid compounding harm. This included the following: early active listening with empathy for trauma, sincere and timely apology, fostering trust and transparency, making realistic timelines clear, and establishing effective non-adversarial communication. Most staff perceived that patient and family involvement could improve investigation quality, promote an open culture, and help ensure future safety. However, it was made difficult when multidisciplinary input was absent, workload and staff turnover were high, training and support needs were unmet, and fears surrounded litigation. Potential solutions included enhancing the clarity of roles and responsibilities, adequately training staff, and providing long and short-term support to stakeholders.
- Martin *et al* (2022) identified four features that appear to be necessary conditions for sustained progress in improving openness: (1) authentic integration into organisational mission is crucial in making openness a day-to-day concern; (2) functional and effective administrative systems are vital; (3) these systems must allow for flexibility and sensitivity in implementation and (4) a spirit of continuous inquiry, learning and improvement is required to avoid the fallacy that advancing openness can be reduced to a time-limited project.

- Case *et al* (2021) found that patients involved in a patient safety incident that did not receive an apology or expression of regret in the incident disclosure process were significantly more likely to make a complaint.
- Dijkstra *et al* (2022) showed that there are three main domains that patients considered essential in the aftermath of a health care incident namely interpersonal communication, organisation around disclosure and support, and desired outcomes.
- Carrillo *et al* (2021) found that: The willingness of the professionals to fully disclose an incident was greater among those who were backed by their institution and who had experience with that type of communication.
- Sattar *et al* (2020) found that there is a difference in attitudes and expectations between patients and health care professionals regarding the disclosure conversation. Patients/family members expressed a need for information, the importance of sincere regret and a promise of improvement. However, health care professionals faced several barriers, which hindered appropriate disclosure practices. These included difficulty of disclosure in a blame culture, avoidance of litigation, lack of skills on how to conduct disclosure and inconsistent guidance.
- Donaghy *et al* (2018) reported that the safety of patients and staff are inextricably linked. When healthcare staff are supported by their organization, they are more confident and able to deliver high-quality, safe and compassionate care for their patients. Rather than simply 'firefighting' problems they have time for reflection, and the energy and resources to prevent problems from recurring. Confident supported staff are more likely to learn from an incident. Promoting a culture of openness and learning from mistakes within an organisation, rather than a culture of blame and punishment, is of vital importance in allowing this.

8 National Implementation Plan

8.0 National Implementation Team

The Quality and Patient Safety Incident Management Team, National Quality and Patient Safety, is responsible for the revision of this policy, training and education programmes, and the development of resources and engagement to support its rollout.

SAOs/LAOs are accountable for the implementation of this policy, and all staff are responsible for implementation of it in line with their roles and responsibilities.

8.1 Open Disclosure Training Requirements

8.1.1 Training requirements

HSE designed and delivered open disclosure training is mandatory for all staff working in HSE and in HSE-funded services, with refresher training required every three (3) years. All staff must complete the open disclosure eLearning Module 1 "Communicating Effectively through Open Disclosure" which is available on HSeLanD.

Staff who may be involved in the open disclosure process, e.g. senior managers, senior health and social care professionals, medical staff, QPS staff and staff fulfilling the role of the designated person must also complete the following:

- Module 2 "Open Disclosure: Applying Principles to Practice", available as eLearning on HSeLanD; and
- Module 3 Face to Face Skills Workshop (3 hours) on the management of the open disclosure process, delivered in person by HSE staff. This training can be accessed by contacting the Open Disclosure Lead for the relevant health and social care service provider.

Additional eLearning modules on The Patient Safety Act 2023 and Role of the designated person are also available on HSeLanD.

Staff can enhance their communication skills by enrolling in training delivered by the HSE National Healthcare Communications Programme. The HSE National Healthcare Communication Programme is designed to support healthcare staff to learn, develop and maintain their communication skills with patients, their families and with colleagues.

For further information and queries, contact the National Open Disclosure Office at email: opendisclosure.office@hse.ie

8.1.2 Training accountability

It is the responsibility of each service to ensure that their staff (including agency staff) are trained in HSE facilitated training in open disclosure and to maintain local training records to provide assurance that the service is meeting mandatory training requirements.

8.2 Expected date of full implementation

Whist this is a significant revision of the HSE Open Disclosure Policy in line with the DoH National Open Disclosure Framework and the Patient Safety Act 2023, there is already an expectation that open disclosure is undertaken. Full implementation will be effective within a short timeframe of six months of launching the revised Policy to allow the system-wide awareness and embedding of the requirements of the Policy. Legal requirements must already be met and adhered to as the Patient Safety Act 2023 has commenced.

8.3 Governance and approval

This policy was produced by the Quality and Patient Safety Incident Management Team overseen by the HSE National Open Disclosure Steering Committee and approved by the Senior Leadership Team of the HSE.

8.4 Communication and dissemination plan

The Policy will be disseminated by the Chief Clinical Officer for immediate implementation by relevant services, and will be available on the HSE National Central Repository.

Additionally it will be shared with Open Disclosure leads and trainers via the National Open Disclosure Office as part of the Quality and Patient Safety Incident Management Team.

8.5 Sustainability

8.5.1 National monitoring and audit

The **HSE National Open Disclosure Steering Committee** was established to strengthen corporate oversight, strategic leadership and accountability for the ongoing implementation of the national open disclosure programme and policy. The primary objective of the steering committee is to build the capacity and capability of HSE staff and services to improve the implementation and practice of open disclosure for all patients and their relevant persons. This is delivered by working in collaboration with services and patient representatives. The committee further reviews HSE training compliance data with open disclosure and the annual report on open disclosure. It has overseen the developments of the HSE open disclosure performance and assurance programme of work which is focusing on measuring compliance with the Patient Safety Act 2023, national and local audit, training compliance and importantly patient experience of the open disclosure process.

8.5.2 National Audit Tool

- The HSE has developed “The Incident Management Framework and Open Disclosure Audit Tool” for services to self-assess compliance with this Policy and legislation. It includes elements of incident management and open disclosure.

- Reporting and oversight tools using NIMS data are under development and will be made available within six months of publication.
- A policy implementation checklist is available for services to use.
- The HSE annual open disclosure report developed by the National Open Disclosure Office incorporates updates and information on the implementation of this policy and is a requirement following on from the Gabriel Scally review.
- The DoH National Open Disclosure Framework requires health and social care service providers to prepare an annual report on open disclosure which must be submitted to the Department of Health to demonstrate how they are meeting the requirements of the Framework. For the HSE, there is one collated annual report by the National Open Disclosure Office which incorporates information on the developments of the programme. It further includes summary compliance reports from each Health Region and National Service as stipulated in the Framework. Specifically, each compliance report will include information regarding:

    a. the development and implementation of open disclosure policy.

    b. the 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.

8.6 National Service Plan Key Performance Indicator (KPI)

The HSE will be developing national KPIs to measure compliance with the key steps of the open disclosure process for notifiable incidents. This will include measuring if a notifiable incident meeting has taken place for notifiable incidents, and if the written record was shared after the meeting.

8.7 Measuring experience

The HSE is developing a tool to measure and encourage patient/relevant person feedback on their experience. It is intended that this feedback will be collated by the National Open Disclosure Office and learning from this will translate into policy and training programme developments.

8.8 Policy Review

This policy was reviewed and updated as of June 2025.

It is scheduled for next review in three-year's time (June 2028) or sooner if there is a requirement to do so.

9 References

References

Note: *Relevant legislation as well as publications and resources published by the HSE and Department of Health have been hyperlinked throughout this document for immediate access to the source documentation. The following are external references which contributed to the revision of this Policy for 2025 publication.*

Australian Commission on Safety and Quality in Health Care (2014). Australian Open Disclosure Framework – Better communication, a better way to care. ACSQHC, Sydney. Available at: https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework

Carrillo I, Mira JJ, Guilabert M, Lorenzo S; Second and Third Victim Research Group. Why an Open Disclosure Procedure Is and Is not Followed After an Avoidable Adverse Event. J Patient Saf. 2021 Sep 1;17(6):e529-e533. doi: 10.1097/PTS.0000000000000405

Case J, Walton M, Harrison R, Manias E, Iedema R, Smith-Merry J. What Drives Patients' Complaints About Adverse Events in Their Hospital Care? A Data Linkage Study of Australian Adults 45 Years and Older. J Patient Saf. 2021 Dec 1;17(8):e1622-e1632. doi: 10.1097/PTS.0000000000000813

Dijkstra RI, Roodbeen R, Bouwman R, Pemberton A, Friele R. Patients at the centre after a health care incident: A scoping review of hospital strategies targeting communication and nonmaterial restoration. Health Expect. 2022;25(1):264-275. doi: 10.1111/hex.13376

Donaghy C, Doherty R, Irwin R. Patient safety: a culture of openness and supporting staff. Surgery (Oxford), 2018 36(9): 509-514. doi: 10.1016/j.mpsur.2018.07.005

Martin G, Chew S, McCarthy I, Dawson J, Dixon-Woods M. Encouraging openness in health care: Policy and practice implications of a mixed-methods study in the English National Health Service. Journal of Health Services Research & Policy. 2023;28(1):14-24. doi: 10.1177/13558196221109053

Ramsey L, McHugh S, Simms-Ellis R, Perfetto K, O'Hara JK. Patient and Family Involvement in Serious Incident Investigations From the Perspectives of Key Stakeholders: A Review of the Qualitative Evidence. J Patient Saf. 2022 Dec 1;18(8):e1203-e1210. doi: 10.1097/PTS.0000000000001054

Sattar R, Johnson J, Lawton R. The views and experiences of patients and health-care professionals on the disclosure of adverse events: A systematic review and qualitative meta-ethnographic synthesis. Health Expectations. 2020;23(3):571-583. doi:10.1111/hex.13029

Wailling J, Kooijman A, Hughes J, O'Hara JK. Humanizing harm: Using a restorative approach to heal and learn from adverse events. Health Expect. 2022 Aug;25(4):1192-1199. doi: 10.1111/hex.13478

Appendices

Appendix 1: Glossary of Terms

Term/Abbreviation	Definition
Acknowledgement	An acceptance of the truth or existence of something.
Adverse Event	An incident which resulted in harm to a patient (WHO Global Patient Safety Strategy 2021-2030)
Advocacy	A person nominated by an individual adult to speak on their behalf and represent their views. Advocacy comes in different forms. This may include informal support or independent advocacy services. Advocacy should always be independent from the service providing care or support (HSE National Consent Policy 2022). Advocacy is a means of empowering people by supporting them to assert their views and exercise their rights and where necessary representing and negotiating on their behalf. Advocacy helps to ensure that the person's voice, will and preferences are heard and given due consideration. Advocacy can also help people to understand options, weigh up factors and make an informed decision. Advocacy empowers people to make up their own minds in a difficult situation (Patient Advocacy Service 2022). Advocacy is about supporting and empowering people to communicate their will and preference, secure their human rights, or represent their interests. Staff have a responsibility to make people aware of independent advocacy services. Where appropriate and with consent, they can support a person to contact an independent advocacy service. (HIQA, 2023).
Apology	An apology in relation to an open disclosure of a notifiable incident/patient safety incident means an expression of sympathy or regret (Patient Safety [Notifiable Incidents and Open Disclosure] Act 2023/Civil Liability [Amendment] Act 2017 respectively). It is a genuine expression of being sorry for what has happened. Further guidance can be found in the DoH National Open Disclosure Framework (2023).
Category 1 Incident	**Category 1 Major/Extreme** – Clinical and non-clinical incidents rated as major or extreme as per the HSE's Risk Impact Table (HSE Incident Management Framework 2020).
Category 2 Incident	**Category 2 Moderate** – Clinical and non-clinical incidents rated as moderate as per the HSE's Risk Impact Table (HSE Incident Management Framework 2020).
Category 3 Incident	**Category 3 Minor/Negligible** – Clinical and non-clinical incidents rated as Minor or Negligible as per the HSE's Risk Impact Table (HSE Incident Management Framework 2020).
Child	The Child Care Act 1991, the Children Act 2001 and the Mental Health Act 2001, and the Children First Act 2015 define a child as a service user under the age of 18 years of age, other than a service user who is or has been married.
CLA Act 2017 (Civil Liability [Amendment] Act 2017 Open Disclosure)	Open disclosure is where a health and social care service provider discloses, at an open disclosure meeting, to— (a) a patient that a patient safety incident has occurred in the course of the provision of a health service to him or her, (b) a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient concerned, or (c) a patient and a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient. (Civil Liability [Amendment] Act 2017)

Term/Abbreviation	Definition
Clinical Audit	Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements, Following clinical audit, improvements, if required should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements. (DOHC 2008, p. 152) It is noted that clinically-led includes the breadth of clinical professionals working in health and social care services. (Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023, Part VI, P 82) and (Department of Health and Children (DOHC) (2008) Building a culture of patient safety: Report of the Commission on Patient Safety and Quality Assurance: Dublin: Stationery Office. Available from: https://health.gov.ie/wpcontent/uploads/2014/03/en_patientsafety.pdf)
Designated Person	A person to liaise with the health and social care service provider and the patient or relevant person (or both of them) in relation to the open disclosure of the patient safety incident (Civil Liability [Amendment] Act 2017) or the open disclosure of a notifiable incident (Patient Safety Act 2023) Note: This definition is distinct from the definition of the Designated Healthcare Representative in the Assisted Decision Making Capacity Act 2015.
DoH	Department of Health
Error	The failure of a planned action to be completed as intended or use of a wrong inappropriate or incorrect plan to achieve an aim. (HSE Incident Management Framework 2020)
'Fatal foetal abnormality' (Patient Safety [Notifiable Incident and Open Disclosure] Act 2023) or **'fatal fetal anomaly'** (Pregnancy Loss Research Group, commissioned by the Department of Children, Equality, Disability, Integration and Youth)	The terms fatal foetal abnormality, in the Act, and fatal foetal anomaly (Pregnancy Loss Research Group, commissioned by the Department of Children, Equality, Disability, Integration and Youth) are used to describe anomalies that will lead to fetal or neonatal death and are sometimes used interchangeably with lethal and life-limiting terms. While fatal fetal anomaly is not a medical term, it has been used by the media and in the political sphere.
Harm	Harm to a person: Impairment of structure or function of the body and or any detrimental effect arising from this, including disease, injury, suffering, disability and death. Harm may be physical or psychological. The degree of harm relates to the severity and duration of harm and the treatment implications that result from an incident. Reference should be taken for examples of harm from the HSE Risk Impact table of the HSE Enterprise Risk Management Policy and Procedures 2023.

Term/Abbreviation	Definition
Health Services Provider – definition as provided in the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023	(1) In this Act, "health services provider" means (a) a person, other than a health practitioner, who provides one or more health services and for that purpose: (i) employs a health practitioner for the provision (whether for, or on behalf of, that person) by that practitioner, of a health service, (ii) enters into a contract for services with a health practitioner for the provision (whether for, or on behalf of, that person) by that health practitioner of a health service, (iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, that person, (iv) enters into an arrangement with a health practitioner: (I) for the provision by that health practitioner of a health service (whether for, or on behalf of, that person, or through or in connection with that person), (II) for the provision by that health practitioner of a health service on his or her own behalf (whether through or in connection with, or by or on behalf of, that person or otherwise), or (III) without prejudice to the generality of clause (II), to provide that health practitioner with privileges commonly known as practising privileges (whether such privileges are to operate through or in connection with, or by or on behalf of, the person or otherwise), or (v) insofar as it relates to the carrying on of the business of providing a health service: (I) employs one or more persons, (II) enters into a contract for services with one or more persons, (III) enters into an agency contract for the assignment of an agency worker, or (IV) enters into an arrangement with one or more persons, in respect of the carrying on of that business, (b) a health practitioner who provides a health service and does not provide that health service for, or on behalf of, or through or in connection with (whether by reason of employment or otherwise), a person referred to in *paragraph (a)* and includes a health practitioner who— (i) employs another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner) by that other health practitioner of a health service, (ii) enters into a contract for services with another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner) by that other health practitioner, of a health service, (iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, the first-mentioned health practitioner, or

Term/Abbreviation	Definition
Health *(continued)* Services Provider – definition as provided in the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023	(iv) insofar as it relates to the carrying on of the business of providing a health service— (I) employs one or more persons, (II) enters into a contract for services with one or more persons, (III) enters into an agency contract for the assignment of an agency worker, or (IV) enters into an arrangement with one or more persons, in respect of the carrying on of that business, (c) a partnership of 2 or more health practitioners who provide a health service in common which does not provide that health service for, or on behalf of, or through or in connection with (whether by reason of employment or otherwise), a person referred to in *paragraph (a)* and includes a partnership which— (i) employs another health practitioner for the provision (whether by or on behalf of, the partnership) by that other health practitioner of a health service, (ii) enters into a contract for services with another health practitioner for the provision (whether for, or on behalf of, the partnership) by that other health practitioner of a health service, (iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, the partnership, or (iv) insofar as it relates to the carrying on of the business of providing a health service— (I) employs one or more persons, (II) enters into a contract for services with one or more persons, (III) enters into an agency contract for the assignment of an agency worker, or (IV) enters into an arrangement with one or more persons, in respect of the carrying on of that business, or (d) in the case of a cancer screening service, the Executive or, in respect of the cancer screening service referred to in *paragraph (b)* of the definition of "cancer screening service", a provider referred to in *paragraph (b)* or *(c)*. (2) For the purposes of *paragraphs (b)* and *(c)* of the definition of "health services provider", references in each such paragraph to "through or in connection with" do not include the use by a health services provider referred to in each such paragraph of a health service (or processes related to a health service) provided— (a) by a health services provider referred to in *paragraph (a)* of that definition, and (b) for the purpose of the provision, by a health services provider— (i) referred to in *paragraph (b)* of that definition, of a health service on its own behalf, or (ii) referred to in *paragraph (c)* of that definition, of a health service on behalf of a partnership.
HSE	Health Service Executive

Term/Abbreviation	Definition
Incident	An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service user complaints which are associated with harm. Incidents can be clinical or non-clinical and include incidents associated with harm to: ▶ patients, service users, staff and visitors ▶ the attainment of HSE objectives ▶ ICT systems ▶ data security, e.g. data protection breaches ▶ the environment (HSE Incident Management Framework 2020) See also the definition of a Patient Safety Incident below.
Just Culture	Just culture refers to a values based supportive model of shared accountability (HSE Incident Management Framework 2020).
Local Accountable Officer	This is the local manager who is responsible for the service in which the incident occurred, e.g. ADON, Person In Charge, Business Manager, Clinical Lead (HSE Incident Management Framework 2020).
Look-back review	Review where a number of people may have been exposed to a specific hazard in order to identify if any of those exposed have been harmed and how to take care of them (HSE Incident Management Framework 2020).
Medical treatment (a definition for the use in relation to the term as used in Notifiable Incident 1.6)	Whilst medical treatment is not defined in the Patient Safety Act – the HSE definition is interpreted in line with healthcare treatment as stated in the HSE Consent Policy: Healthcare treatment means an intervention that is or may be done for a therapeutic, preventative, diagnostic, palliative or other purpose related to the physical or mental health of the person and includes life-sustaining treatment. (HSE Consent Policy 2022)
Near Miss	An incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user (National Standards for the Conduct of Reviews of Patient Safety Incidents 2017).
National Incident Management System (NIMS)	The National Incident Management System is a web-based database which facilitates direct reporting of patient and staff incidents by state authorities such as the HSE. It is the single designated system for reporting of all incidents in the public healthcare system, i.e. for HSE and HSE funded services.
No Harm Incident	An incident occurs which reaches the patient but results in no injury to the patient. Harm is avoided by chance or because of mitigating circumstances (HSE Incident Management Framework/Guidance 2020).
Notifiable Incidents	Notifiable Incidents are pre-defined as such by the Department of Health and are listed in Schedule 1 of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023.

Term/Abbreviation	Definition
Open Disclosure HSE definition	Open disclosure is defined as an open, honest, compassionate and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety or notifiable incidents. It includes apologising and expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to ongoing care and treatment, learning and the steps being taken by the health or social care service providers to try to prevent a recurrence of a similar incident. It is an integral part of the incident management process (HSE 2025).
Patient	'Patient' means, in relation to a health and social care service provider, a person to whom a health service is, or has been, provided; (Patient Safety [Notifiable Incidents and Open Disclosure] Act 2023) **Note:** Please note the use of the word patient as described in the Policy Introduction.
Patient Safety Incident	A patient safety incident is defined by the Civil Liability (Amendment) Act 2017), which was amended by the 2024 Patient Safety [Notifiable Incidents and Open Disclosure] Act 2023. It is defined by Part 4, Section 7 of the Civil Liability (Amendment) Act 2017) as follows: In this Part, 'patient safety incident', in relation to the provision of a health service to a patient by a health services provider, means— (a) an incident, other than a notifiable incident, which has caused an unintended or unanticipated injury, or harm, to the patient and which occurred in the course of the provision of a health service to that patient, (b) an incident, other than a notifiable incident,— (i) which has occurred in the course of the provision of a health service to the patient and did not result in actual injury or harm, and (ii) in respect of which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm, Or (c) the prevention, whether by timely intervention or by chance, of an unintended or unanticipated injury, or harm, to the patient in the course of the provision, to him or her, of a health service, and in respect of which the health services provider has reasonable grounds for believing that, in the absence of such prevention, could have resulted in such injury, or harm, to the patient. (Civil Liability (Amendment) Act 2017) revised 2024
Perinatal death	For the purposes of Notifiable Incidents 1.11: "perinatal death" means a death which occurred within 7 days of birth *S.I. No. 501/2024 – Patient Safety (Notifiable Incidents and Open Disclosure) Regulations 2024*
Prescribed birthweight	For the purposes of Notifiable Incidents 1.10 and 1.11: "prescribed birthweight" means a birthweight of not less than 2500 grammes *S.I. No. 501/2024 – Patient Safety (Notifiable Incidents and Open Disclosure) Regulations 2024*
Prescribed gestational age	For the purposes of Notifiable Incidents 1.10 and 1.11: "prescribed gestational age" means a gestational age of at least 37 weeks, commencing on the first day of the 37th week *S.I. No. 501/2024 – Patient Safety (Notifiable Incidents and Open Disclosure) Regulations 2024*

Term/Abbreviation	Definition
Principal Health Practitioner	A principal health practitioner in relation to a patient, means a health practitioner who has the principal clinical responsibility for the clinical care and treatment of the patient and, in the case of a cancer screening service, means the health practitioner who has the principal clinical responsibility for the cancer screening service (Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023).
Relevant Person	"Relevant person", in relation to a patient and in the context of a notifiable incident, means a person— (a) where an appointment has been made under Part 3, 4, 5, 7 or 8 of the Assisted Decision-Making (Capacity) Act 2015 in relation to health matters, to the person appointed, (b) where the patient has, under the Powers of Attorney Act 1996 , made an enduring power of attorney (within the meaning of that Act) which includes a personal care decision (within the meaning of that Act), to the attorney appointed pursuant to that Act, (c) where the patient is a ward of court, to the Committee of the Person of that ward, duly authorised in that behalf, (d) where the patient has nominated, in writing, a person to whom his or her clinical information may be disclosed, to that person, (e) where the patient is a child, to the parent or guardian of that child or where— (i) an order in respect of the child has been made under section 18 of the Act of 1991, (ii) the child has been taken into the care of the Agency under section 4 of the Act of 1991, or (iii) an order in respect of the child has been made under section 13, 17 or 20 of the Act of 1991, to the parents or guardian of the child and the Child and Family Agency (or an authorised person) or, where an order under section 23H of the Act of 1991 has been made in respect of the child, to the parents or guardian of the child and that Agency (or the social worker assigned responsibility for the child by the Agency), or (f) where the patient does not fall within the categories specified in paragraphs (a) to (e), to— (i) the spouse, civil partner or cohabitant of the patient, (ii) an adult son or daughter of the patient, or (iii) the mother, father, brother or sister of the patient. *Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023, Paragraphs (a) – (f) of Section 7 (2)* **Note:** This definition is distinct from the definition of the "relevant person" in the Assisted Decision Making Capacity Act 2015.
Restorative Practice	Restorative practice is based primarily on a set of core values and the explicit promotion and enhancement of particular skills such as the ability to empathise and to find solutions to specific problems. This practice allows for building trust between and with people.
Senior Accountable Officer	In the context of the management of an incident, the Senior Accountable Officer is the person who has ultimate accountability and responsibility for the services within the area where the incident occurred. In a hospital setting it would be a person with delegated responsibility for a service and reporting directly to the Regional Executive Officer, e.g. a hospital manager or the person delegated with overall responsibility for the management of a clinical directorate or service. In a community setting it could be the Head of Service and in the case of the NAS, it could be the NAS corporate area manager. (HSE Incident Management Framework 2020 – updated to align with the new health regions structure)

Term/Abbreviation	Definition
Serious Reportable Event	Serious Reportable Events (SREs) are a defined subset of incidents which are either serious or that should not occur if the available preventative measures have been effectively implemented by healthcare providers. Serious reportable events are mandatorily reportable by services to the Senior Accountable Officer (SAO). (HSE Incident Management Framework 2020)
Service	Please note that the term "service" as used throughout this policy refers to services provided by a health and social care service provider (as defined in the Civil Liability (Amendment) Act 2017).
Surgery	Surgery is referenced in the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 as a 'health service' provided to a person for 'the performance or surgery, or a surgical intervention, in respect of aesthetic purposes, or other non-medical purposes, that involves instruments or equipment being inserted into the body of the person'. Therefore references to surgery in the notifiable incident list includes surgical interventions such as endoscopy, interventional radiology, cardiac cath lab, oro-dental surgery, etc.
Suspected Harm Event	A suspected harm event is an incident which is an event or circumstance which could have or did lead to unintended and/or unnecessary harm (HSE Incident Management Framework 2020).
Therapeutic Hypothermia	Therapeutic Hypothermia is a therapy during which the infant is cooled within six hours of birth to a targeted core body temperature of between 33°C to 34°C for a duration of 72 hours. Following the 72-hour period, the infant is rewarmed to normal body temperature over a 6-12 hour period (Neonatal Therapeutic Hypothermia Audit, Health Information and Quality Authority, 2016).
Unanticipated death	Unanticipated death is where there was a death other than an anticipated or expected death, or a death where there was no expectation that the person was likely to die in the manner or at the time in which they did.
Unintended death	Unintended, in relation to a death, means a death arising from an unintended event occurring, or arising from, the provision of a health service. (Patient Safety [Notifiable Incidents and Open Disclosure] Act 2023)
Vulnerable Person	The National Vetting Bureau (Children and Vulnerable Persons) Act 2012, states: " vulnerable person " means a person, other than a child, who— (a) is suffering from a disorder of the mind, whether as a result of mental illness or dementia, (b) has an intellectual disability, (c) is suffering from a physical impairment, whether as a result of injury, illness or age, or (d) has a physical disability, which is of such a nature or degree— (i) as to restrict the capacity of the person to guard himself or herself against harm by another person, or (ii) that results in the person requiring assistance with the activities of daily living including dressing, eating, walking, washing and bathing. https://www.irishstatutebook.ie/eli/2012/act/47/section/2/enacted/en/html

Appendix 2: Membership of Policy Development Group

The Policy Development Group is the National Open Disclosure Steering Committee*

Membership of National Open Disclosure Steering Committee*	
Name	**Role and position**
Dr Orla Healy *(Chairperson)*	National Clinical Lead, Quality and Patient Safety, HSE
Lorraine Schwanberg	Assistant National Director, Incident Management, Open Disclosure and NIMS, HSE National Quality and Patient Safety
Bernadette O'Reilly	Patient Representative, Patients for Patient Safety Ireland
Stephen Teap	Patient Representative
Ciaran McCullagh	General Manager, Quality and Patient Safety, HSE National Ambulance Service
Irene O'Hanlon	General Manager, Quality and Patient Safety, HSE National Access and Integration
Anne Gallen	Area Director of Nursing and Midwifery, Office of Nursing and Midwifery Services Director, HSE
Dr Cathal O'Keeffe	Deputy Director and Head of Clinical Risk, State Claims Agency
Colette Brett	Head of Quality, Safety and Risk, National Screening Service
Prof Nóirín Russell	Consultant Obstetrician and Gynaecologist, Clinical Director of CervicalCheck
Dr Jack McCarthy	NCHD representative (Medical BST SHO Wexford), HSE National Doctors Training and Planning
Aoife O'Riordan	Employee Relations Executive, HSE National Human Resources Advisory Team

To note, staff members of the National Open Disclosure Office were vital to the review and revision of this policy, and coordinated much of the research, engagement, and improvements made to the policy. These include:

- Lorraine Schwanberg, AND QPS Incident Management
- Róisín Egenton, General Manager, Incident Management (Open Disclosure)
- Eleanor Southgate, National Open Disclosure Manager
- Mary Friel, Open Disclosure Trainer and Educator
- Kelly McDyer, Open Disclosure Trainer and Educator

* ***Please note:*** *Members included in the above listing attended at least one Steering Committee meeting between July 2024 and January 2025, when the Policy development was subject to Steering Committee discussion and feedback. Further to ongoing reconfiguration of the HSE throughout 2024, members of the Steering Committee may have changed roles during the course of the year; the membership above reflects names and titles of Steering Committee members as relevant to the policy development.*

Appendix 3: Membership of Approval Governance Group

The following lists all members of the Approval Governance Group who gave final approval of the document.

Membership of Senior Leadership Team	
Name	**Role and position**
Bernard Gloster	Chief Executive Officer, Health Service Executive
Sandra Broderick	Regional Executive Officer, HSE Midwest
Martina Queally	Regional Executive Officer, HSE Dublin & South East
Kate Killeen White	Regional Executive Officer, HSE Dublin & Midlands
Sara Long	Regional Executive Officer, HSE Dublin & North East
Tony Canavan	Regional Executive Officer, HSE West North West
Andy Philips*	Regional Executive Officer, HSE South-West
Stephen Mulvany	Chief Financial Officer, Health Service Executive
Joseph Duggan	Chief Internal Auditor, Health Service Executive
Anne Marie Hoey	Chief People Officer, Health Service Executive
Dr Colm Henry	Chief Clinical Officer, Health Service Executive
Damien McCallion	Chief Technology & Transformation Officer, Health Service Executive
Patrick Lynch	National Director, Planning & Performance, Health Service Executive
Mark Brennock	National Director, Communications & Public Affairs, Health Service Executive
Pat Healy	National Director, National Services & Schemes, Health Service Executive
Grace Rothwell	National Director, Access & Integration, Health Service Executive
David Walsh	National Director, Access & Integration, Health Service Executive
Brian O'Connell	National Director, Head of Strategic Infrastructure & Capital Delivery, Health Service Executive
Joe Ryan	National Director, Public Involvement, Culture & Risk, Health Service Executive

** Andy Philips was absent for the presentation and approvals meeting but received the policy for review.*

Sign-off by Chair of Approval Governance Group

The HSE Open Disclosure Policy (2025) was formally ratified and recorded in the minutes of the Approval Governance Group on 18/02/2025.

Name:	Bernard Gloster
Title:	Chief Executive Officer, Health Service Executive
Signature: *(e-signatures accepted)*	
Registration number: *(if applicable)*	

Appendix 4: HSE Open Disclosure Policy Signature Sheet

This is a tool for line managers to print off and have staff sign as part of good record keeping/audit trail.

I have read, understand and agree to adhere to this Policy.

Document Title: HSE Open Disclosure Policy 2025

Print Name	Signature	Job Title	Date

Quality and Patient Safety Incident Management,
National Quality and Patient Safety,
HSE,
Dr Steeven's Hospital,
Dr Steeven's Lane,
Dublin 8,
D08 W2A8

Email: opendisclosure.office@hse.ie