



Cáilíocht Náisiúnta agus Sábháilteacht Othar

Oifig an Phríomhoifigigh Clínicíúil

National Quality and Patient Safety

Office of the Chief Clinical Officer



NATIONAL
OPEN DISCLOSURE
PROGRAMME



Patient Safety Together:
learning, sharing and improving



NIMS

Córas Náisiúnta um Bainistíocht Teagmhais
National Incident Management System

Open Disclosure in Pharmacy: What the Latest Requirements Mean for Practice

Irish Institute of Pharmacy Webinar

Wednesday 27 May 2026





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Agenda

- What is open disclosure?
- What governs the open disclosure requirement?
- The National Open Disclosure Framework
- The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023
- The HSE Open Disclosure Policy 2025
- The HSE National Open Disclosure Programme

 NIMS

Córas Náisiúnta um Bainistíocht Teagmhais
National Incident Management System



HSE What is open disclosure?

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



www.hse.ie/opendisclosure





The impact of open disclosure...



Everyone owns their own honesty and many apply it without question as a natural part of themselves. When faced with situations involving others, we pause to acknowledge what has happened, reflect on the human realities before us, and choose how to act. That is where open disclosure choices are made.

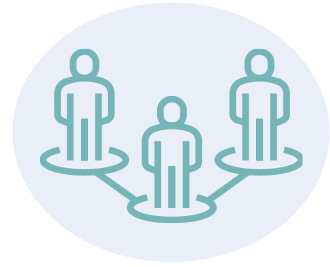
*Bernie O'Reilly - Patients for Patient Safety
Ireland*

*From her foreword to the HSE Open Disclosure
Policy 2025*



Context of the National Open Disclosure Programme

The HSE National Open Disclosure Office is part of the Quality Patient Safety Incident Management Team, NQPS. We work with individuals and teams to design and deliver national policies, programmes and resources aimed at building individuals' skills, knowledge and confidence in undertaking open disclosure.



Our work is aligned to:

Legislation

Healthcare
Regulation

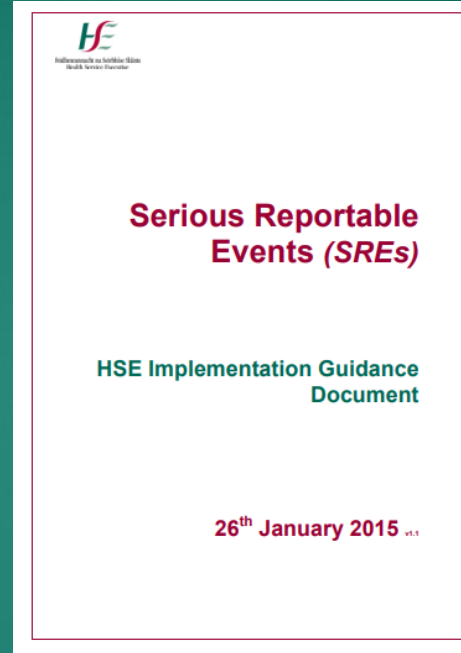
National Open
Disclosure
Framework

Professional
Regulation

National reports
and
recommendations

Incident
Management
Framework

Key Policy Documents

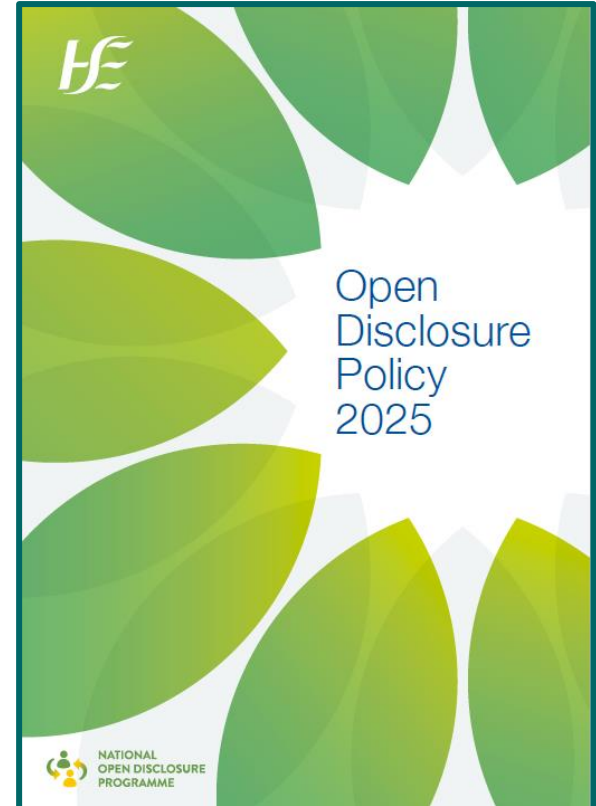




HSE Open Disclosure Policy 2025 (Revision)

Formally launched by HSE Chief Clinical Officer, Dr Colm Henry on 17th June 2025

- Section 1: Introduction, Aims and Objectives
- Section 2: Imperative for Open Disclosure
- Section 3: Roles and Responsibilities
- Section 4: When does open disclosure apply
- Section 5: The open disclosure process
- Section 6: Supporting patients, relevant persons and staff
- Section 7: Policy development





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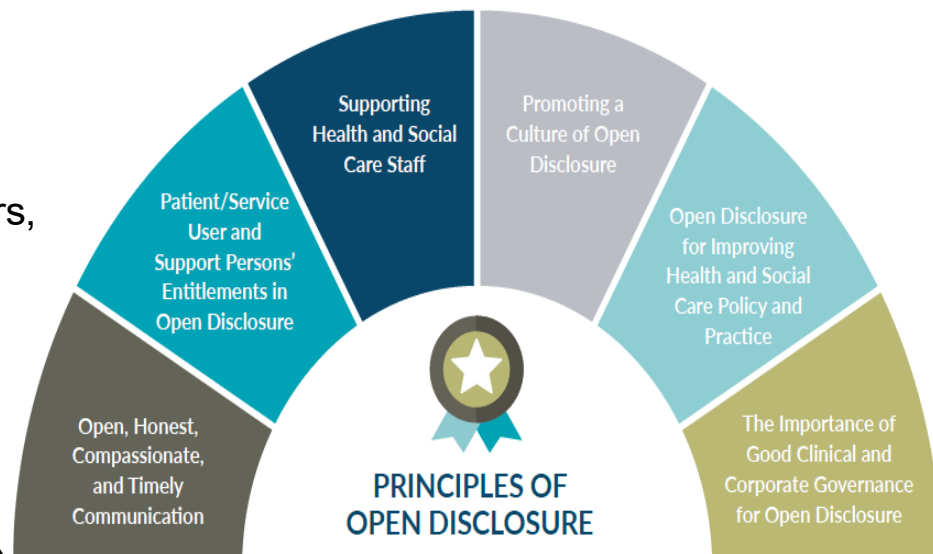
Office of the Chief Clinical Officer

The Department of Health National Open Disclosure Framework 2023



DOH National Open Disclosure Framework (2023)

- Launched by the Department of Health in October 2023
- Promotes open disclosure across all health and social care services
- Applies to public and private providers, regulators, and educators
- Key drivers: leadership, champions, training, engagement, and feedback
- Annual reporting requirement
- Reports from HSE and HSE-funded (Section 38) services feed into the national report



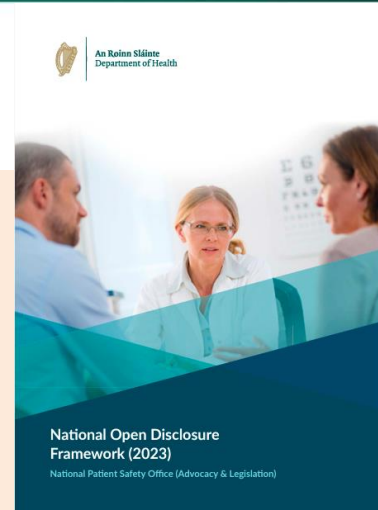


DoH National Open Disclosure Framework (2023)

Chapter 6

The drivers for change to help embed an open disclosure culture

- **Clinical and managerial champions must be identified** and appointed by health and social care service providers
- **Strong clinical leadership is necessary** to build a just culture of open disclosure and reporting within health and social care organisations.
- Health and Social Care providers should **appoint clinical leaders** tasked with ensuring open disclosure practice is embedded across the organisation.





Annual reporting requirements

Chapter 7 – Monitoring and Evaluation of Open Disclosure

- Health and social care service providers, regulators, and professional regulators will be required to submit an annual report by the first week of April each year to the Minister for Health outlining compliance.
- The health and social care service providers' annual report will include information regarding:
 - a. Development and implementation of open disclosure policy.
 - b. Development and implementation of open disclosure training for all clinical and non-clinical staff including agency staff.
 - c. Evidence of the availability of support structure for all staff clinical and non-clinical including agency staff.
 - d. The number of trained clinical and non-clinical staff including agency staff.
 - e. The number of appointed and trained clinical and managerial open disclosure champions.
 - f. The number of open disclosure events initiated and closed.





DOH Annual Open Disclosure Framework Report

Service providers

- *Non-HSE service providers are also making progress in adopting and implementing the requirements of the Framework. However, the response rate from these providers was low. **NPSO contacted 258 organisations that offer a variety of services, including pharmacy services, but only 32 (12%) responded.***
- *Among those who responded, most indicated that they have established policies and guidance documents and are actively working on implementing open disclosure practices.*

Regulators

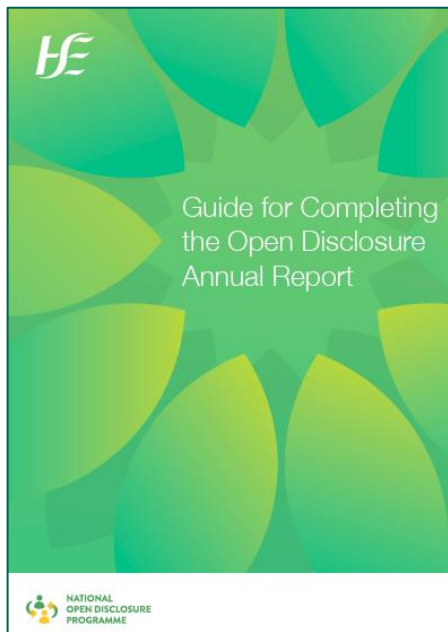
- *The NPSO will continue to work with the regulators to ensure that the requirements of the Framework are fully implemented in the services/professions that they regulate.*
- ***The Pharmaceutical Society of Ireland (PSI) intend to review the need for a static policy document in 2025.***





2024 Annual Report and Supporting Resources

- The 2024 report is available to access on the HSE website.
- Additional resources are designed to support services with the preparation of their own report to feed into the national annual report.



Visit the HSE Open Disclosure Website to access these resources



SCAN ME



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



The Patient Safety Act provides a legal framework for:

- Mandatory open disclosure of specified incidents by health service providers.
- 13 defined notifiable incidents requiring disclosure.
- Mandatory reporting via NIMS to HIQA, Chief Inspector of Social Services, and Mental Health Commission.
- Legal protections for information shared and apologies given during open disclosure.
- Provisions governing clinical audit and audit data.
- Amendments to the Health Act 2007 (HIQA investigation threshold and oversight of private hospitals).
- Amendments to the Civil Liability (Amendment) Act 2017.
- Mandatory disclosure of patient-requested cancer screening reviews (breast, bowel, cervical).
- Chief Inspector's discretionary review powers in designated centre.

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Schedule 1

Notifiable Incidents Part 1 and 2

Item	Notifiable Incident
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.
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— <ul style="list-style-type: none"> (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.



Notifiable Incidents

List of Current Notifiable Incidents (13 in total) in PSA



Unintended and unanticipated patient death which did not arise from/was a consequence of an illness/underlying condition, including:

- Surgery performed on the wrong patient
- Surgery performed on the wrong site
- Wrong surgical procedure
- After unintended retention of foreign object after surgery
- Undergoing elective surgery where the death is directly related to the surgical operation or anaesthesia (including recovery from the effects of anaesthesia) in otherwise well patient
- Directly related to any medical treatment
- Due to transfusion of ABO incompatible blood or blood components
- Associated with a medication error



Notifiable Incidents (continued)

List of Current Notifiable Incidents (13 in total) in PSA



NOTE: The Minister has reserved the right to make further regulations (additions to the list)

- Unanticipated death of a woman while pregnant or within 42 days of the end of pregnancy from any cause related to, or aggravated by, the management of the pregnancy
- Stillborn child born without fatal foetal abnormality and with a prescribed gestational age or birth weight, and who shows no sign of life at birth, from any cause related to or aggravated by the management of the pregnancy, not related to underlying condition of the child
- Perinatal death of 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, not related to an underlying condition
- 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
- A baby who, in the clinical judgement of the health practitioner:
 - a) requires or is referred for therapeutic hypothermia,
 - b) or has been considered for, but did not undergo therapeutic hypothermia as such therapy was contraindicated due to the severity of the presenting condition.



Open Disclosure of a Notifiable Incident: compliance with legislation

HSE Open Disclosure Policy (2025) aligns with the Act and patient safety incident processes.

There are some additional requirements under the legislation as follows:

- Notifiable incidents reported via NIMS within 7 days
- Legally mandated appointment of a designated person (Policy = category 1 incidents)
- Written record of disclosure meeting within 5 days
- Statutory record-keeping at all stages
- Offences and penalties for non-compliance



Amendment to the Civil Liability (Amendment) Act 2017 (CLA)

- Part 4 of the Civil Liability (Amendment) Act 2017 has been amended to align with the Patient Safety Act.
- Prescriptive open disclosure process written into law applies. Written communication must reference compliance with Part 4 of the Civil Liability (Amendment) Act and be shared within 5 calendar days of the meeting
- **Amendments are effective from 26 September 2024 onwards (hence incidents reported after this date).** For any patient safety incident which occurred before 26 September 2024, the previous process and the Civil Liability Regulations 2018 (Prescribed Statements) applies, if staff involved wish to seek the protections.



Where do I find more information on the Act?



Visit **HSeLand** for e-learning modules on:

1. An Overview of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023
2. The Role of the Designated Person in Incident Management and Open Disclosure

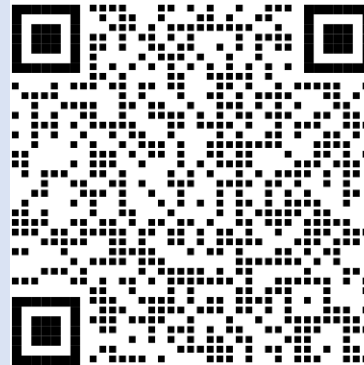
hseland.ie

Visit the dedicated **webpage** with information on the Patient Safety Act



Notifiable Incidents Guideline:

Guidance on the interpretation the Act and key responsibilities in responding to a notifiable incident.



Watch back on previous **webinars** focusing on the Patient Safety Act



Contact the National Open Disclosure Office: OpenDisclosure.Office@hse.ie



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The HSE Open Disclosure Policy 2025

Managing the response to minor or no harm incidents (Cat 3)

A low level response to minor harm incidents, or in some instances no harm incidents, may involve one face-to-face conversation with the service user / relevant person whilst receiving care.

Low level response for minor or no-harm incidents

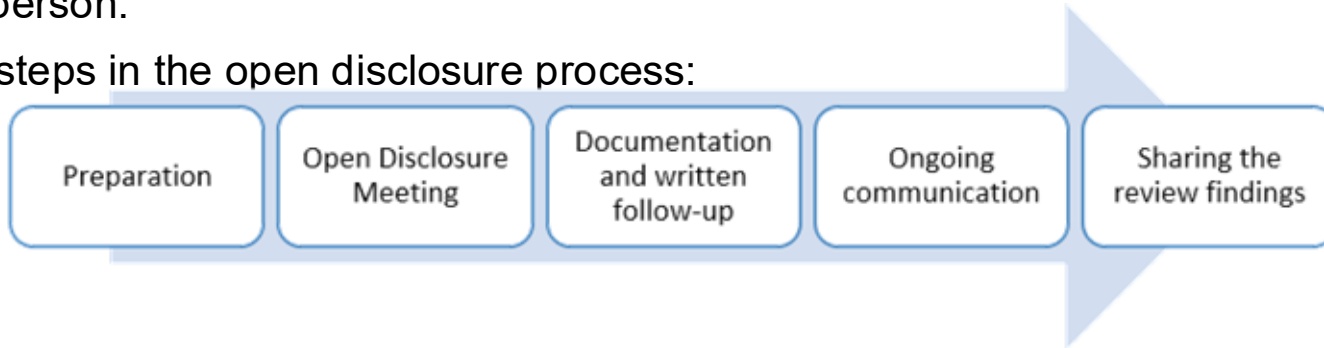
The conversation with the patient /relevant person should address, as appropriate:

- acknowledging what happened and any resulting impact or consequences for the service user;
- listening to and hearing the their 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.

The conversation must be documented in the healthcare record.

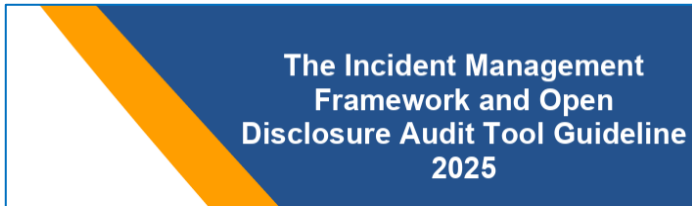
Managing the response to a Patient Safety Incident (Cat 1 and Cat 2) and Notifiable Incident

- The **open disclosure process** applies to notifiable incidents (as per Patient Safety Act 2023) and Category 1 and 2 patient safety incidents (i.e. moderate harm, severe harm, permanent disability, or death).
- It's called a "process" as more than one meeting or conversation may be required.
- Commence as soon as practicable – initiate within 24-48 hrs of becoming aware of incident.
- Duration of process will depend on the incident that occurred, the number of service users involved, the progress of incident review, immediate and ongoing needs of the service users / relevant person.
- Five key steps in the open disclosure process:



Compliance in incident management and open disclosure

- Implementing the HSE Open Disclosure Policy/an organisation's own open disclosure policy requires clear governance and a development of an approach for service-wide operationalisation.
- The [Checklist for the Implementation of the HSE Open Disclosure Policy 2025](#) was developed to support services to self-assess their implementation and ongoing compliance with the HSE Open Disclosure Policy.
- The [Incident Management Framework \(IMF\) Audit Tool](#) supports staff to assess compliance with the management of Category 1 and Category 2 incidents to ensure adherence to the open disclosure process as part of the wider Incident Management Framework. It has been aligned with national developments (the PSA, NODF and HSE OD Policy).



Roles and responsibilities in the management of patient safety and notifiable incidents

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.

The HSE model

- It is the role and responsibility of the Senior Accountable Officer (SAO) or Person-in-Charge (PIC) of a service to have overall accountability within their area for the management of incidents. This includes ensuring that the operational arrangements and the roles of all staff in relation to notifiable incident management are clearly defined.

A universal model of governance

- Any model for the management of incidents requires that all staff are aware of their responsibilities, including:
 - Clearly defined responsibilities of all staff
 - Line manager responsibilities
 - Lead healthcare practitioner
 - Lead discloser
 - Designated Person
 - Incident Management Team
 - Review Team, plus Chair/Commissioner
 - Individual with legal responsibility for the provider
 - Quality and Patient Safety Responsibility Holder/Committee



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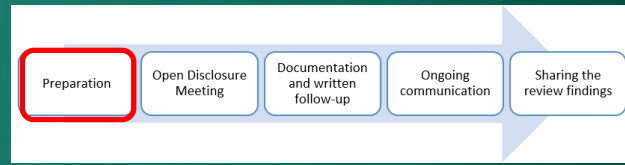
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The open disclosure process – an overview

The Open Disclosure Process: Preparation



Who makes the Open Disclosure?

- The service user's principal healthcare practitioner leads the open disclosure process and discloses the incident, in particular for category 1 incidents and notifiable incidents. Other suitable staff may take this role for category 2 incidents or minor harm incidents.

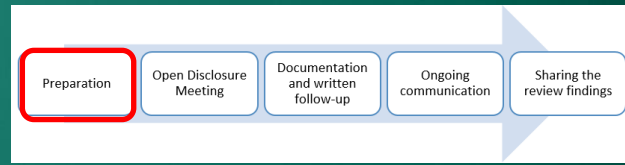
Who is the open disclosure made to?

- The service user
- Their Relevant Person, or
- Service user and their Relevant Person

When (Timing of Open Disclosure)?

- As soon as practicable and as deemed appropriate by health services provider
- It is not necessary to know all of the information relating to the incident to initiate this meeting.

The Open Disclosure Process: Preparation



Prepare for Open Disclosure:

- Assess circumstances of the service user and nature of the incident
- Consult with any person as appropriate.
- Consider who the open disclosure will be made to.
- Discuss the apology to be provided
- Consider how the information can be relayed → clear and understandable

Appoint a Designated Person:



- Designate a person to liaise with the service user and/or relevant person
- The designation must be made in writing and kept on record
- The designated person assists service user person in preparing for and attending the open disclosure meeting

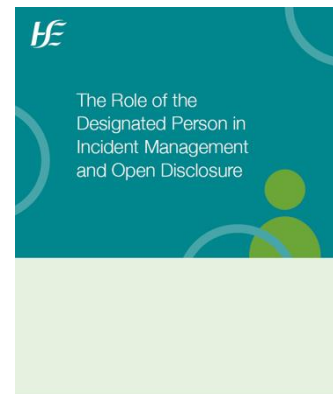
HSE The Designated Person

- The **Designated Person** (DP) is a **key point of contact** for the service user /relevant person.
- The DP acts as a liaison between the service user / relevant person and the service ensuring the service user / relevant person is **supported** and **kept up to date** in a timely manner.
- The DP assists the service user / relevant person in **preparing for and attending** open disclosure meetings
- Details of the DP must be included in written communication and **kept on record**. This record is a legal requirement for all notifiable incidents.

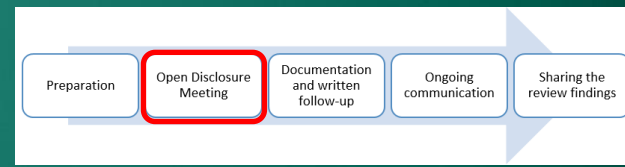


Resources to support the role of the Designated Person

- [The Role of the Designated Person in Incident Management & Open Disclosure](#) 
- [Designated Person Checklist](#) 
- HSeLanD e-learning module
- Designated person network (contact OpenDisclosure.Office@hse.ie for more information)

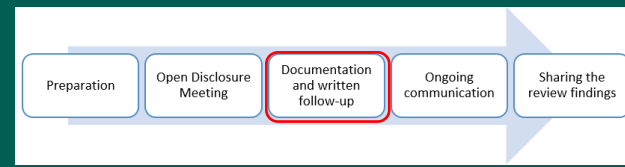


The Open Disclosure Process: Open Disclosure Meeting



- Open disclosure meeting normally held in person with the service user /relevant person.
- The service user /relevant person can request (orally) to have the meeting other than in person e.g. telephone, virtual - this request must be recorded in writing by the health services provider and kept on record.
- Provide information in small amounts with intervals and check if the information is understood before moving on - “chunk and check”
- Provide factual responses to questions/clarifications sought by the service user / relevant person
- Points for discussion and closing an open disclosure meeting are outlined in Open Disclosure Policy (2025)

HSE The Open Disclosure Process: Documentation & Written follow-up



- Open disclosure meetings must be followed up in writing with the patient or relevant person
- A written record supports clear, compassionate communication (e.g. a summary letter)
- Where disclosure is under legislation, the written record must be issued within 5 calendar days and reference the relevant Act
- Sample documentation templates are available on the HSE website
- Sample templates to support documentation and the written record can be accessed on the HSE website [here](#).





Why written communication following open disclosure is important

Reduced retention of verbal information

- Modern studies find service user freely recall ~49% of key points.
- Approximately less than 50% of what is remembered may be inaccurate.
- Under emotional strain, people retain far less information than in routine conversations.

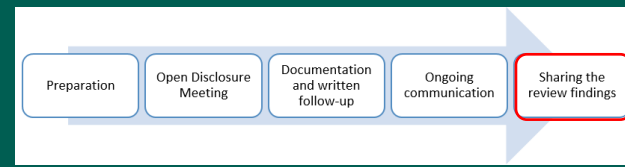
Outcomes of reduced recall

- Reduced adherence to treatment plans.
- Increased need for follow-up calls and repeated explanations.
- Higher likelihood of misunderstandings and errors in self-care.
- Lower confidence and satisfaction in the service.

Recommendations for practice

- Provide written summaries following meetings.
- Use clear, plain language and highlight the salient points.
- Use follow-up written communication to reinforce the next steps.
- Given the evidence, written follow-up should be considered an essential standard in health and social care provider communication with service users.

The Open Disclosure Process: Sharing Review Findings



- Closure of the open disclosure process occurs following honest and complete open disclosure, and after an objective final incident review report is shared with the service user / relevant person in line with the requirements set out in the HSE Incident Management Framework.
- Closure of the process but may not be closure for the person impacted.
- Health and social care service providers should try to understand what supports might be required, and help the service user / relevant person in accessing them where possible.
- Feedback from service user, their relevant person(s) and the staff involved in the open disclosure process should be sought and any learning incorporated into improving the process going forward.



The MPS Assist Model of Communication

Open Disclosure using the MPS ASSIST Model of Communication

A – Acknowledge – what has happened and the impact

S – Sorry – express regret – provide meaningful apology

S – Story – hear their story and summarise back to them

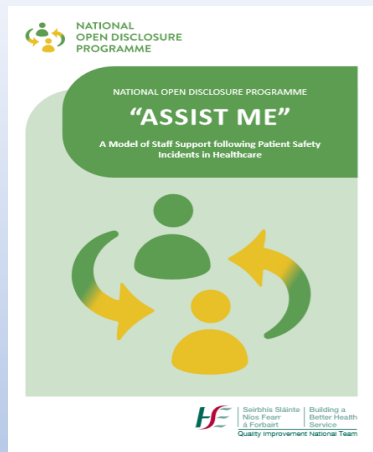
I – Inquire – encourage questions to be answered, provide factual answers

S – Solution – seek their agreement for the way forward - agree a plan together

T – Travel – avoid abandonment – outline plan for their continued care and contact arrangements



Care for Staff



- Provide a safe, supportive and caring environment for staff involved in or affected by patient safety incidents
- Ensure that the impact of patient safety incidents on staff is recognised and managed in a caring, supportive and compassionate manner
- Provide information on services and resources that may support staff involved in and/or affected by a patient safety incident
- Ensure that staff have access to training on the Open Disclosure Policy relevant to their role



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The HSE Open Disclosure Programme



Open Disclosure Mandatory Training Programmes

Training Programme	Delivery	Description	Target Audience	CPD
Module 1: Communicating Effectively through Open Disclosure	eLearning via HSeLanD	This module is mandatory for all staff and provides an overview of Open Disclosure, the principles for the management of the process, and the role of staff in open disclosure.	All staff working in HSE and HSE funded services	NMBI: 2 CEUs RCPI: 2 external CPD Points
Module 2: Open Disclosure: Applying Principles to Practice	eLearning via HSeLanD	This module aims to assist staff in preparing for and managing open disclosure meetings, following a patient safety incident or notifiable incident. This includes exploring some of the complexities that may arise.	All staff working in HSE and HSE funded services, who may be involved in the open disclosure process	NMBI: 3 CEUs RCPI: 3 external CPD Points
Module 3: Face to Face Skills Workshop	In-person Workshop: Half Day Available by booking through Open Disclosure leads /trainers in services	The workshop aims to equip staff who are involved in the open disclosure process with the skills required to engage in effective and meaningful open disclosure. It aims to build the capacity of staff to prepare for and manage the open disclosure process, exploring policy and legislative requirements.	All staff working in HSE and HSE funded services, who may be involved in the open disclosure process	NMBI: 3 CEUs RCPI: 3 external CPD Points

- *HSE National HR Guidance states that all staff must complete Open Disclosure e-learning Module 1 “Communicating Effectively through Open Disclosure”. Staff who may be involved in formal open disclosure meetings e.g. senior managers and medical staff, must also complete Module 2 “Open Disclosure: Applying Principles to Practice” and Module 3 Face to Face Skills Workshop.*
- *Refresher training must be undertaken by all staff every 3 years.*



Open Disclosure Additional Training Programmes

Training Programme	Delivery	Description	Target Audience	CPD
An Overview of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023	eLearning via HSeLanD	This module provides an overview of the main provisions of the Patient Safety Act, and the legislative requirements within. Through case studies, it outlines the requirement for mandatory open disclosure and the roles and responsibilities of staff to ensure compliance.	All staff as relevant working in health and social care services	NMBI: 3 CEUs RCPI: 3 external CPD Points
The Role of the Designated Person in Incident Management and Open Disclosure	eLearning via HSeLanD	This e-learning supports the role of the Designated Person in supporting patients and their relevant person(s) after an incident. It aims to provide clear guidance on legislation, policy, practice and the importance of self-care as it applies to incident management and open disclosure.	Staff who currently undertake the role of Designated Person, and those who may fulfil the role in the future	NMBI: 2 CEUs RCPI: 2 external CPD Points
Open Disclosure Train the Trainer Programme	Hybrid: Half day virtual + Full day in-person Available by booking through the National Open Disclosure Office	The aim of the Open Disclosure Train the Trainer programme is to provide attendees with the appropriate skills to deliver open disclosure training and to support staff, as relevant, in their service. The programme is split into 2 parts: Part A (3 hour virtual) & Part B (full day workshop).	Nominated Staff through relevant governance structures	NMBI: 11 CEUs RCPI: 9 external CPD Points