







Open Disclosure:

Policy, procedures and legislative requirements for pharmacists

Irish Institute of Pharmacy Webinar

12 March 2025



What is Open Disclosure?

- Open disclosure is defined as an open, honest, compassionate and timely approach to communicating with patients or, where appropriate, their relevant person (or both of them) following <u>patient safety incidents</u> or <u>notifiable incidents</u>.
- 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 Open Disclosure Policy & Procedures 2025 (to be published soon)



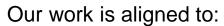




Context of the National Open Disclosure Programme

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.





Legislation

Healthcare Regulation National Open Disclosure Framework

Professional Regulation

National reports and recommendations

Incident
Management
Framework







Bernie O'Reilly is a patient advocate and member of Patients for Patient Safety Ireland.



Medication Incidents – Pharmacy National Medication Safety Programme / iSimpathy

Adverse Drug Events (ADE)

- 10% of emergency admissions in people aged ≥65 associated with an ADE, 71% potentially avoidable.
- Mean length of stay for an ADE admission is 10.8 days at a cost of €9,538.
- Healthcare utilisation costs also increase by additional €2,047 in the 3 months following ADE admission

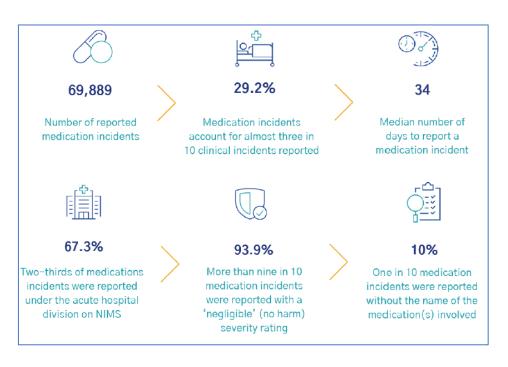
Polypharmacy

- Polypharmacy increases with age and deprivation
- 22% of those aged ≥65 and 8% aged 45-64 were prescribed ≥10 medicines in 2012 (most recent figures available).
- Potentially inappropriate prescribing (PIP)
 - Affects 70% of older adults resident in long term care facilities and 51% of community-dwelling older adults
 - Associated with harm, healthcare utilisation and cost.
 - Expenditure on PIP accounted for over €45 million or 9% of overall pharmaceutical expenditure in those aged ≥70.



Medication Incidents Reported on NIMS (2019 – 2022)

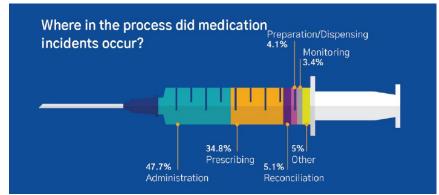
Analysis from State Claims Agency





What was the most common medication incident category chosen on NIMS?

The most common incident category (problem/cause on NIMS) was 'Omitted/Delayed Dose', which accounted for 22.7% of medication incidents by category.





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



The Patient Safety Act provides a legal framework for:

- mandatory open disclosure, by health services providers, of certain incidents occurring in the course of the provision of a health service to a person. Specifically, the Act describes 13 "notifiable incidents" where open disclosure must take place in line with the legislation;
- organisations to **report notifiable incidents to regulators**, specifically the Health Information and Quality Authority, Chief Inspector of Social Services and the Mental Health Commission, and it requires such notifications to be made via the National Incident Management System (NIMS) (portal on regulator website for s. 39s and NIMS incident module for s. 38s);
- **legal protection** in relation to the information shared at the time of open disclosure and any apologies made in the course of such disclosures;
- 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 Health information and Quality Authority (HIQA) to carry out statutory investigations and expansion of monitoring into private hospitals.
- Not commencing at this time the discretionary power of the Chief Inspector to conduct a review of specified incidents that may have resulted in death or serious injury where some or all of the care was delivered in a designated centre such as a nursing home.
- amendments to Part 4 of the Civil Liability (Amendment) Act 2017.
- the mandatory (communication/open disclosure), by health services providers, of reviews carried out in relation to **cancer screening** that were requested by the patient (breast, bowel and cervical screening);

Patient Safety (Notifiable Incidents and Open	1.7
Disclosure) Act 2023	
Schedule 1	1.8

Notifiable Incident

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.

Notifiable Incidents Part 1 and 2

Item

1.1

1.5

1.6

patient.

1.2	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.

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

wholly attributable to) the illness of the patient or an underlying condition of the

Item	Notifiable Incident
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

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

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.

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.

arise from, or was a consequence of (or wholly attributable to) the illness of the

	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						
	consequence of (or wholly attributable to) the illness of the child or an underlying					
	condition of the child.					

patient or an underlying condition of the child.

underlying condition of the patient.

1.9

1.12

prescribed birthweight who was alive related to, or aggravated by, the did not arise from, or was a e illness of the child or an underlying An unintended death where the cause is believed to be the suicide of a patient

was contraindicated due to the severity of the presenting condition.

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 Item Notifiable Incident

	on or anaesthesia (including recovery from the effects of anaesthesia) and	recin	1 total more increase.
the death did not arise from, or was a consequence of (or wholly attributable to) the		2.1	A baby who—
	illness of the patient or an underlying condition of the patient.		(a) in the clinical judgment of the treating health practitioner requires, or
	Any unintended and unanticipated death occurring in any place or premises in		is referred for, therapeutic hypothermia, or
	which a health services provider provides a health service that is directly related to		(b) has been considered for, but did not undergo therapeutic hypothermia
	any medical treatment and the death did not arise from, or was a consequence of (or		, , , , , , , , , , , , , , , , , , , ,
	wholly attributable to) the illness of the nationt or an underlying condition of the	I	as, in the clinical judgment of the health practitioner, such therapy



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

Key definitions/interpretations:

- 'Unintended' defined in the Act 'in relation to a death, means a death arising from an unintended event occurring, or arising from, the provision of a health service...
- 'Unanticipated death' not defined in the Act, but understood to mean that 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 (to be finalised as part of the NI Guidance/Policy).
- Where a death 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.'
 - not defined in the Act, this reference in the Notifiable Incident description is closely linked to the
 explanation of an unintended and unanticipated death. It distinguishes between when a patient dies
 because of their underlying disease, illness or injury or the death likely occurred or was contributed to
 because of the facts of the Notifiable Incidents.



- In the Act it states that 'where the health service provider is satisfied that a NI has occurred', then...
 - In the spirit of the legislation (openness and transparency), the HSE is interpreting this in the following way:
 - Whilst there is a determination to be made if a Notifiable Incident occurred, it is not a requirement to establish this with absolute certainty in the legal sense or to determine a cause of death. Rather a reasonable clinical assessment should be made with the information available at that time on the likelihood that a Notifiable Incident occurred. Where it is deemed that a Notifiable Incident likely occurred the health care practitioner and health services provider must take the required actions



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.

Patient Safety (Notifiable Incidents and Open Disclosure) Regulation – Statutory Instrument 501/2024

- These Regulations define "prescribed birthweight" and "prescribed gestational age" for the purposes of Notifiable Incident 1.10 and 1.11 in Schedule 1 of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023, only.
 - For the purposes of Schedule 1 of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (No. 10 of 2023) and Notifiable Incident—
 - (a) 1.10 and 1.11 thereof—
 - "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.



Notification Requirements of the Patient Safety Act 2023

- The provisions of the Act define the reporting obligations of health, mental health, and social care services.
- From commencement, community mental health services will no longer be required to submit notifications to the MHC through CIS.
- The 2023 Act requires community mental health services to submit the notification of a notifiable to HIQA.

Health and care services provider	Regulator to notify
Approved centre	Mental Health Commission
Designated Centre	The Chief Inspector of Social Services
All other health and care settings (including community mental health services)	HIQA

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

- Part 4 of the Civil Liability (Amendment) Act 2017 has been revised to align it with the provisions of the Patient Safety Act and the legal protections provided within that Act.
- A similarly prescriptive process applies and a key difference is that the written communication following open disclosure must reference that the open disclosure meeting was held in compliance with Part 4 of the Civil Liability Amendment Act and the HSE Open Disclosure Policy 2024. Similar to the Patient Safety Act this must be shared within 5 calendar days, following the meeting.
- Amendments are effective from 26 September 2024 onwards.
- 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.



Open Disclosure of a Notifiable Incident: compliance with legislation

The draft HSE Open Disclosure Policy (2025) aligns the Open Disclosure process in the Act for Notifiable Incidents with the Open Disclosure Policy for Patient Safety Incidents.

There are some additional requirements under the legislation as follows:

- Notification of Notifiable Incident to the relevant regulatory body within <u>7 days</u>
 from when the health services provider is satisfied that a notifiable incident has
 occurred in the course of the provision of health services via NIMS (portal for s.39
 and NIMS incident module s.38)
- Legal requirement for appointment of a designated person.
- Written statement/record of the open disclosure meeting to be provided at the meeting or <u>within 5 days</u> of the meeting happening.
- Record keeping legal requirements throughout all stages of the process.
- Offences and Penalties apply for non compliance.



- Where do I find more information on the Act?



Visit **HSeLanD** for elearning 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



Access resources for staff available on the Open Disclosure website



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



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

Introduction to the Open Disclosure Process



- 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 patients involved, the progress of incident review, immediate and ongoing needs of the patient / relevant person.
- Five key steps in the open disclosure process:





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 patient / 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 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.

The conversation must be documented in the healthcare record.



Who makes the Open Disclosure?

 The patient'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?

- Patient
- Their Relevant Person, or
- Patient 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.



Prepare for Open Disclosure:

- Assess circumstances of the patient 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 patient and/or relevant person
- The designation must be made in writing and kept on record
- The designated person assists patient/relevant person in preparing for and attending the open disclosure meeting

The Open Disclosure Process: Open Disclosure Meeting



- Open disclosure meeting normally held in person with the patient/relevant person.
- The patient/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 patient / relevant person
- Points for discussion and closing an open disclosure meeting are outlined in Open Disclosure Policy (2025)



The Open Disclosure Process: Documentation & Written follow-up

- Open disclosure meeting must be followed up in writing with the patient / relevant person as part of the open disclosure process.
- A written record of the open disclosure meeting is imperative for patients/their relevant person as part of good communication. This can take the form of a compassionate summary letter, which is more personable.
- If managing open disclosure under legislation, this written record must be sent within **five** (**5**) **calendar days** of the open disclosure meeting, and must state that the meeting was held pursuant to the legislation (Patient Safety Act or Civil Liability Amendment Act)
- Sample templates to support documentation and the written record can be accessed on the HSE website here.







- Communication will continue following on from the open disclosure meeting
- Designated person will liaise with the patient / relevant person
- Additional open disclosure meetings may be required where new information is disclosed to the patient / relevant person, when it emerges – same requirements as for "Documentation and written follow-up" step
- Requests for clarification may be sought and must be followed up on. Where
 managing open disclosure under legislation, if provided verbally, it must always be
 followed up on in writing within <u>five (5) calendar days</u> of providing the clarification.
- Good record keeping is important in relation to open disclosure.



H Managing Clarification Requests

Request for clari	fication following an oper	n disclosure meeting/a	dditional information	meeting		
Date:		Incident Reference Number (NIMS):			An Southermood on Androphysholin National Code And Southermood on Androphysholin National Code American Code America	
Add patient sticker		I	.L		Documentation template examp to support services during open disclosure following	
Name of Patient / Service User:		Contact details Patient/Service User:	Address:		disclosure following notifiable incidents or patient safety incident (Category 1 & 2)	
Detail of request made (by whom and date):						
Type of clarification response sought (please note that the written letter summarising the response must be shared by the						
making the clarification even if a verbal response is provided that is for the PSA and CLA only):						
Face to Face / Telephone ,	/ Written			gar gar		
Action taken (i.e. principa	l health practitioner contact	ed who held the open di	sclosure meeting. They w	vill phone and write to the		
patient's wife, Mrs Smith,	who sought the clarification	1):				
					4	
Date on which the clarific	ation requested was provide	ed:				





- 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 patient / 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 patient / relevant person(s) in accessing them where possible.
- Feedback from patients, 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 Open Disclosure Process: Additional considerations

- Draft HSE Open Disclosure Policy 2025 Managing open disclosure of a patient safety incident which occurred while the patient was under the care of another team / provider:
 - Generally shared professional responsibility
 - Collective approach to accountability
 - The team/service whose care the patient is under at the time the incident becomes known will inform the patient and initiate the open disclosure process. Inform patient/relevant person and other service with the patient's/their relevant person's consent.
 - Ultimately, the responsibility for the 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.

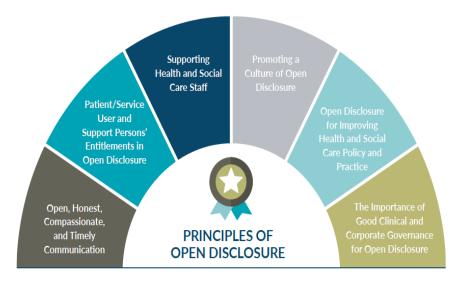


The DoH National Open Disclosure Framework 2023



DoH National Open Disclosure Framework (2023)

- Launched by the Department of Health in Oct 2023.
- Aims to further embed a culture of Open Disclosure across all health & social care services and in the practice of all health & social care professionals.
- Applies to all public and private health and social care providers, regulators, health and social care educators.
- Drivers for Change including clinical and managerial open disclosure champions, leadership, engagement and feedback, induction, training and development.



Annual reporting requirements

The DoH National Open Disclosure Framework requires each Health Service Provider to submit an annual report the first week of April starting in 2025 to the Minister of Health reporting on;

- a. 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 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.

The HSE is currently working on developing these reports to supplement the annual report already produced previously. Key consideration as part of this is in relation to including HSE-funded services

Open Disclosure Training Programmes



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

Shared Learning





A sharing learning component of the patient safety programme to support the HSE Patient Safety Strategy

Outputs:

- Are shared via an open access HSE webbased platform
- Are co-developed to ensure that information is accurate, valid and informative and where possible solutions driven

Features:

- HSE National Patient Safety Alerts (NPSAs)
- Patient Safety Supplements (PSS)
- Patient Safety Stories
- HSE Patient Safety Digest
- Spotlight Series
- Patient Safety Community



HSE NPSAs







PSS







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OpenDisclosure.Office@hse.ie



HSE National QPS

