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National Quality and Patient Safety Directorate
Office of the Chief Clinical Officer

Update on the National Open Disclosure Programme

Presentation to Irish Institute of Pharmacy (IIOP)

Wednesday 05 June 2024

Presentation Agenda

Learning objectives

At the end of this presentation attendees will be briefed on:

- the importance of Open Disclosure following patient safety incidents;
- the National Open Disclosure Framework, and
- the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023.

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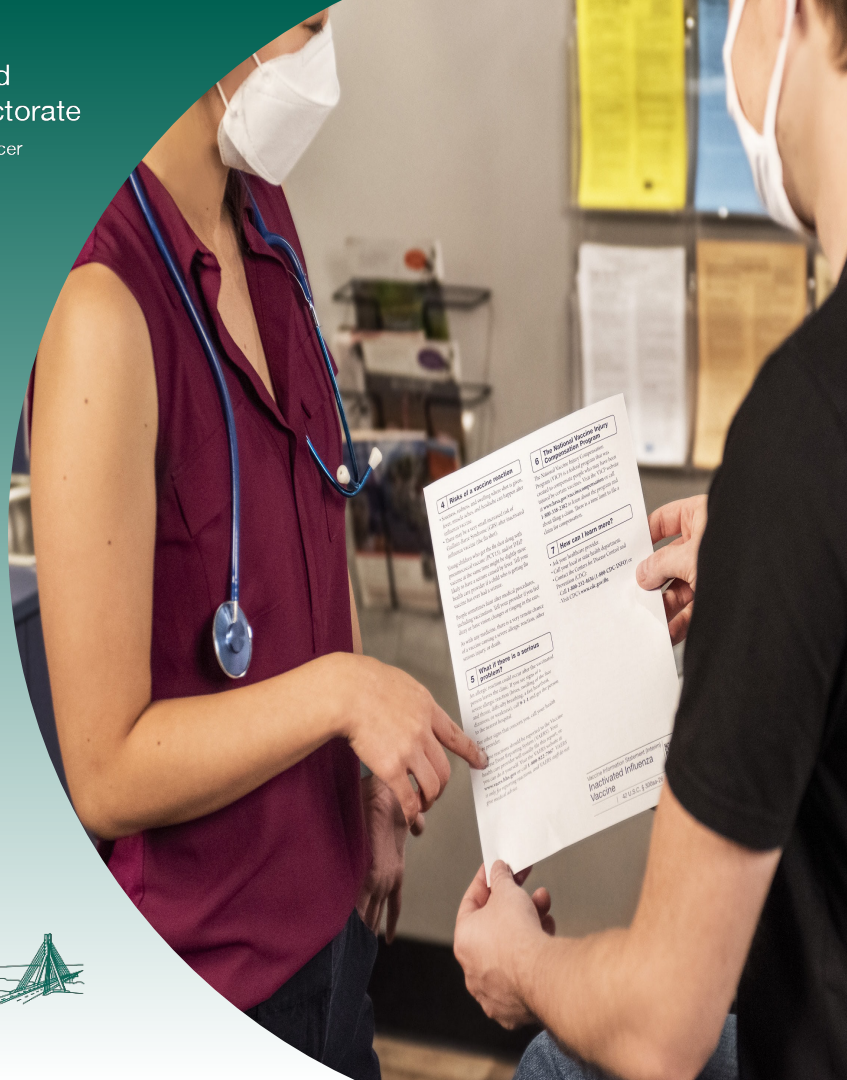
Open Disclosure: An overview



Open Disclosure: A definition

Open disclosure is defined as an open, consistent, compassionate and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents.

It includes:

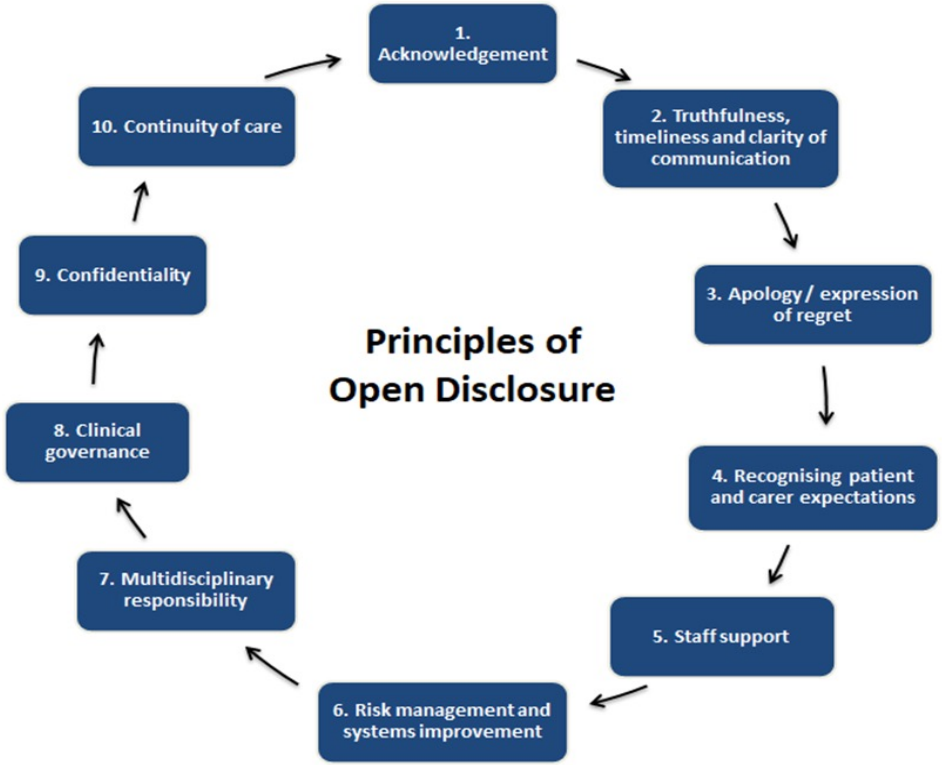
- expressing regret for what has happened,
- keeping the patient informed and providing reassurance in relation to on-going care and treatment,
- learning about the incident and sharing that learning, and
- the steps being taken by the health services provider to try to prevent a recurrence of the incident. (HSE 2019)

Open disclosure is a discussion and an exchange of information that may take place in one conversation or over one or more meetings.

Open Disclosure: A definition

- Acknowledgement
- Truthfulness, timeliness and clarity of communication
- Apology/Expression of Regret
- Recognise Patient and Carer expectations
- Staff Support
- Risk Management and Systems Improvement
- Multidisciplinary Approach
- Clinical Governance
- Confidentiality
- Continuity of Care

CARE - COMPASSIONATE - EMPATHY



Open Disclosure: the statutory and legislative impetus

- HSE Open Disclosure Policy/Incident Management Framework/YSYS
- Department of Health: National Open Disclosure Policy Framework
- Professional and Regulatory
  - NMBI/Medical Council/CORU codes of conduct and professional ethics
  - HIQA - standards
  - Mental Health Commission
  - Pre Hospital Emergency Care Council
  - **Pharmaceutical Society of Ireland (PSI)**

Open Disclosure: the statutory and legislative impetus

Legislation:

- Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023, which amends Part 4 of the Civil Liability Amendment Act 2017

Indemnifying Bodies:

- SCA/MPS/MEDISEC

Royal Colleges, professional representative, educational and CPD management bodies:

- RCSI, RCPI, ICO, ICGP, IIOP

WHO

Media

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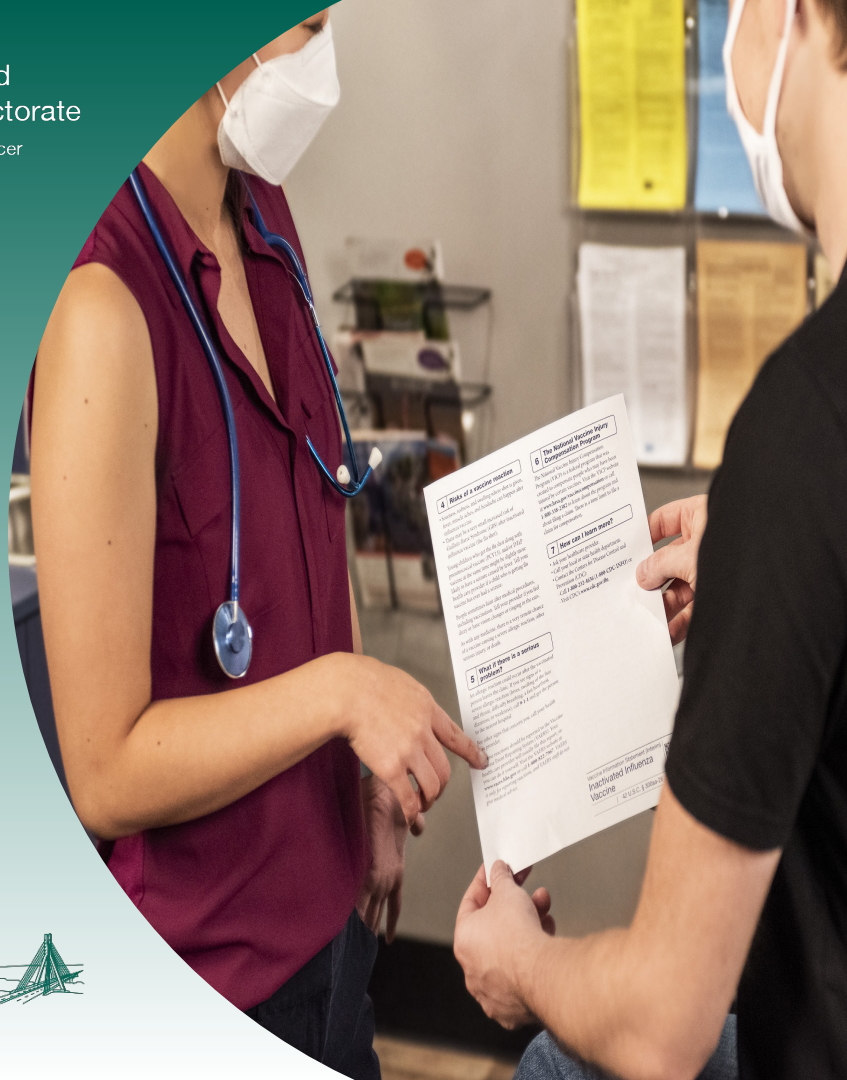
Open Disclosure

How it relates to Pharmacists



The Pharmaceutical Society of Ireland: Code of Conduct for Pharmacists

Code of Conduct for Pharmacists – The 7 Principles:

1. Put the Patient First
2. Act professionally
3. Communicate effectively
4. Work with others
5. Show leadership
6. Maintain Competence
7. **Be Open and Honest**

Principles Seven – Be Open and Honest

'Promote patient safety through open and honest communication with patients , colleagues and other healthcare professionals. Raise any concerns you have about patient safety. Be honest when something goes wrong and learn from incidents. Improve existing pharmacy practice and always foster a culture of patient safety'.

Pharmacy incidents and how to act in response to them

Pharmacy incidents

- Prescribing
- Interactions
- Input error
- Directions
- Limited counselling opportunities
- Overlooking
- Miscalculation
- Failure to question or act on concerns
- Mix-up
- Equipment
- Expired drugs
- Storage
- Pharmacy services error
- OTC

What to know and what to do-

- Pharmaceutical incidents can and do happen.
- Incidents can be hard to admit - punitive environment – fear of losing licence, reputational damage, fitness to practice, litigation, professional advancement, patient response.
- Not disclosing an incident can have disastrous consequences.
- Reviewing and learning from incidents leads to safer better systems, quality improvement and improved patient safety.
- Anyone can report an incident – any member of the pharmacy/management team
- PIERS (Pharmacy Incident and Events Reporting System).
- Share the learning.

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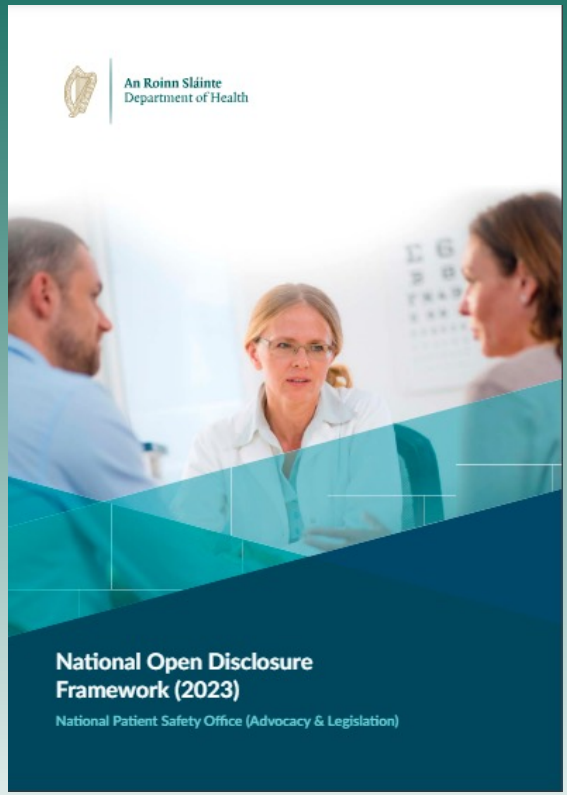
National Open Disclosure Framework



National Policy and National OD Framework

National Open Disclosure Framework:

- The Framework was prepared by the National Patient Safety Office of the Department of Health and informed by recommendations from the Independent Patient Safety Council.
- Launched 19th October 2023
- The framework will inform open disclosure policy in all organisations identified.
- The framework has been informed by the HSE Policy “The HSE has a well-developed open disclosure policy upon which this Framework is built”.

HSE Open Disclosure Policy:

- Initial HSE Open Disclosure Policy launched in 2013.
- Updated in 2019 with further significant revisions due to launch later this year to align with Patient Safety Act

National Open Disclosure Framework for Irish health and social care services

Aim of the Framework:

1. to provide a unified and consistent approach to open disclosure across public and private health and social care service providers, service regulators, and health and social care professional regulators, health and social care educators, and other relevant bodies and organisations.
2. to further embed a culture of open disclosure across the entirety of health and social care services and in the practice of all health and social care professionals.

All stakeholders should adopt the Framework and identify mechanisms and initiatives that will support the embedding of a culture of openness, and the consistent, coherent, and sustainable implementation of open disclosure in their organisations.

The Framework applies to……

- Health Service Executive
- Voluntary Hospitals
- Private Hospitals
- Nursing Homes
- Residential Care Settings
- Outpatient Health Services
- Primary Care Health Services
- National Ambulance Service
- Health Information and Quality Authority
- Mental Health Commission

- Irish Medical Council
- CORU
- Nursing and Midwifery Board of Ireland
- Dental Council of Ireland
- Pharmaceutical Society of Ireland
- Pre-hospital Emergency Care Council
- Education and Training Bodies
- Providers of Health Service Workers
- All other providers of health and social care services, including private practitioners regulated by any of the professional and service regulators listed above

Overview of Framework content

- Principles of Open Disclosure
  - Open, Honest, Compassionate, and Timely Communication
  - Patient/Service User and Support Persons' Entitlements in Open Disclosure
  - Supporting Health and Social Care Staff
  - Promoting a Culture of Open Disclosure
  - Open Disclosure for Improving Health and Social Care Policy and Practice
  - The Importance of Good Clinical and Corporate Governance for Open Disclosure.
- Open Disclosure in Practice (Health Service Providers)
- Open Disclosure in Practice (Non-Health Service Providers) – regulators, training and education bodies, clinical placement sites, undergraduate and postgraduate education including continuing professional development training, professional practice, workplace policies and procedures, and regulatory standards and guidance.
- Drivers for Change
- Monitoring and Evaluation

Overview of Framework content

- **Chapter 6 – outlines the drivers for change to help embed an open disclosure culture**
- Learning & Continuous Improvement, Communication, Engagement & Feedback, Leadership, Training & Development, Open Disclosure Champions
- Open Disclosure Champions: **Clinical and managerial champions must be identified** and appointed by health and social care service providers to lead and promote open disclosure policy, education, and training, and monitor practice.
- **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.
- **Clinical leaders should have protected time** outside of their clinical duties to undertake this work. Championing of open disclosure is equally important in non-clinical settings and champions must be identified and appointed to lead and promote open disclosure policy.

Overview of Framework content

- **Chapter 7 – Monitoring and Evaluation of Open Disclosure**
- Health and social care service providers, health and social care service 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.

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

The aim of the Act is to further embed openness and transparency…

The Act provides a legal framework for:

- the mandatory open disclosure, by health services providers, of certain incidents occurring in the course of the provision of a health service to a person. Specifically, the Act describes 13 different incidents, termed notifiable incidents, whereby 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);
- 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 provide for the application of standards set by the Health Information and Quality Authority to private hospitals;
- the review by the Chief Inspector of certain incidents (termed specified incidents) where some or all of the care of a patient/service user was carried out in a nursing home,
- 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);

PART 1
OPEN DISCLOSURE OF NOTIFIABLE INCIDENT

- Short title and commencement
- Interpretation (definitions)
- Not exhaustive:
  - Patient
  - relevant person
  - designated person
  - Partnership
  - principal health practitioner
  - health practitioner
  - agency health practitioner
  - Health service
  - Health services provider
  - Apology
  - notifiable incident
  - Part 5 review
  - Prescribed
  - Unintended

PART 2
OPEN DISCLOSURE OF NOTIFIABLE INCIDENT

CHAPTER 1
Obligations for making an open disclosure:

- Of the Health practitioner to inform health services provider
- Regarding the persons to whom open disclosure of notifiable incident is made
- Regulations specifying notifiable incident
- Information and apology not to invalidate
- insurance; constitute admission of liability or fault; or not to be admissible in proceedings
- Statement issued following the open disclosure of notifiable incident

CHAPTER 2
Open disclosure: openness and transparency

- Disclosure of information by health services provider and health practitioner

PART 3
PROCEDURE FOR MAKING OPEN DISCLOSURE OF NOTIFIABLE INCIDENT

- Making of open disclosure of notifiable incident – timing, matters to be addressed prior to he making open disclosure of notifiable incident
- Designated person
- Notifiable incident disclosure meeting
- Refusal to participate in open disclosure of notifiable incident
- Failure to contact patient or relevant person (or both)
- Additional notifiable information, its provision at an additional notifiable information
- Meeting and clarifications
- Statements specifying information given at certain meetings
- Records relating to open disclosure of notifiable incident

PART 4
NOTIFICATION TO CERTAIN BODIES OF NOTIFIABLE INCIDENTS

- Notification to HIQA, the Chief Inspector of Social Services and the Mental Health Commission by (certain) health services providers of notifiable incident
- Method of making notifications
- Provision of additional and further information by health services provider
- Sharing information
- Notification under Part 4: information not to invalidate insurance; constitute admission
- of liability or fault; or not to be admissible in proceedings
- Restriction of Act of 2014 in respect of notification made under this Part

PART 5 COMMUNICATION OF PATIENT REQUESTED SCREENING REVIEWS	PART 6 CLINICAL AUDIT	PART 7 AMENDMENTS TO LEGISLATION PERTINENT TO HIQA AND THE CHIEF INSPECTOR	Part 8 OFFENCES AND PENALTIES
• Obligation to communicate the results of patient requested screening review and to inform a patient of the right to request a review • Communication of patient requested screening review results: information and apology not to invalidate insurance etc • Communication of patient requested screening review by health services provider: timing and planning • Designated person • Refusal, by patient or relevant person, to participate in the review • Failure to contact patient or relevant person • Clarification of information provided at patient requested screening review meetings • Statements specifying information given at certain meetings	• Describes a definition of clinical Audit • Describes a definition of clinical guideline • Outlines specific type of clinical audit it relates to • Audit data used cannot be used to invalidate insurance, constitute admission of liability or fault, or not to be admissible in proceedings	• Service provider includes private hospitals • to set standards on safety and quality in relation to services (including private services) and may undertake an investigation as to the safety, quality and standards of any of the services • Powers to the Minister of Health and Minister for Children & Youth Affairs to require the Authority (HIQA) to undertake investigations in relation to serious risk of safety including private services • Amendments with regards to standards set by HIQA • Provision of information to HIQA • Review of specified incident by chief inspector	• Class A Fine • A person fails to make an open disclosure of NI • A person fails follow process re the two exemptions that apply (refusal/contact) • A person fails follow process re notification to regulator • A person fails follow process re obligation to make an open disclosure of Part 5 review • Demonstrating reasonable efforts made to comply may be a defence • Applicable where there was an offence by corporate entity and senior persons PART 9 MISCELLANEOUS • Act will be reviewed 2 years post commencement • Amendment of Act of 2000 SCHEDULE 1 – List of NI SCHEDULE 2 – CLA Act Amendment

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Schedule 1 – Notifiable Incidents

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.

Part 2

Item	Notifiable Incident
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.

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 .

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

Key definitions/interpretations:

- 'Surgery' is referred to in the Act in relation to its provision as part of a health service, and includes the 'performance or surgery, or a surgical intervention', that may be done outside a surgical environment 'in respect of aesthetic purposes, or other non-medical purposes, that involves instruments or equipment being inserted into the body of the patient'.
  - for example, wrong site block (including blocks for pain relief), biopsy, interventional radiology procedure, cardiology procedure, drain insertion and line insertion (e.g. peripherally inserted central catheter (PICC)/ Hickman lines), gastroenterological stents, scoping, aesthetic procedures oral dental surgery.
- 'In any place or premises in which a health services provider provides a health service' – not defined in the Act, but the DoH have provided feedback that outlines that this does not include death occurring in patient's home for example.
  - To be read in line with SRE list description – example given specifically was in relation to SRE 3c

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

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/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.

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

Provisions in relation to:

(1) The management of Open Disclosure (Part 2)
(2) The notification of Notifiable Incidents (Parts 3 and 4), **and**
(3) Offences and Penalties (Part 8)

Managing the Open Disclosure of a Notifiable Incident (NI)

Responsibilities:

Inform health services provider of the NI:

- A health practitioner must inform the health services provider as soon as practicable if, in their opinion, a NI has occurred, including if that NI has occurred while the patient was under the care of another health services provider.

Notification to Regulator (Part 4 of the Act):

- The health service provider must notify the relevant regulator as soon as practicable and no later than 7 days from when the health services provider was satisfied that a notifiable incident occurred in the course of the provision of a health service (**Mental Health Commission, HIQA or Chief Inspector, as relevant)**

- The regulator shall acknowledge receipt in writing no later than 21 days following receipt of the notification
- Information to be provided to the regulator is captured in the Act and will be reflected on the NIMS.

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

Managing the Open Disclosure of a Notifiable Incident (NI)

Arrange for the Open Disclosure of the NI to the relevant person:

- **Who makes the Open Disclosure?** The patient's principal healthcare practitioner or another healthcare practitioner deemed appropriate

- **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.

Preparation for Open Disclosure:

Preparation: Make an assessment of all the circumstances of the patient and nature of the incident
Consult with any person as appropriate.
Consider who the open disclosure will be made to.
Determine whether it is appropriate for an apology is to be made
Consider how the information can be relayed in a manner that is clear and understandable
Appoint a Designated Person

Managing the Open Disclosure of a Notifiable Incident

Preparation for Open Disclosure (continued)

- **Appointment of a Designated Person:**
  - Designate a person to liaise with the patient and/or relevant person
  - This designation must be made in writing and kept on record
  - The designated person will assist the patient/relevant person in preparing for and attending the notifiable incident open disclosure meeting

- **How an Open Disclosure is made:**
  - Generally the open disclosure meeting is to be 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.

Managing the Open Disclosure of a Notifiable Incident

Management of the Open Disclosure meeting
Information to be provided at the meeting includes:

- An introduction and the names of the persons present at the open disclosure meeting;
- A description of the incident concerned (including date of the incident where known);
- When and how the health services provider became aware of the incident;
- If the health service provider is aware of whether or not the incident led to any physical or psychological harm for the patient/service user (acknowledging that predominantly for the current list of NIs the patient is deceased);
- Where the health services provider has reasonable grounds for believing that in addition to the consequences referred to already, that future harm might develop (physical or psychological) or not, this must be described;
- Where, at the time of the NI disclosure meeting there was harm identified (physical or psychological), the health service provider shall inform the patient of the treatment, and relevant clinical care, that the provider is providing (or proposes to provide) to the patient / service user to address those consequences;
- 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 that incident and the circumstances giving rise to it, and
- Where a health 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.

Managing the Open Disclosure of a Notifiable Incident

Written record of the Open Disclosure Meeting (referred to as a statement in the Act)

- Must be given to patient/relevant person at the open disclosure meeting or within **5 days** of the meeting happening;
- Must include the information provided at the open disclosure meeting, as above
- Must contain details of any apology provided;
- Must state that the open disclosure was made pursuant to and in compliance with section 5(1) of the Act;
- Must be signed by principal healthcare practitioner, and
- Must be kept on record by the health services provider.

Part 3 (19) Refusal by Patient/Relevant Person to participate in Open Disclosure meeting

Patient and/or relevant person can refuse to engage in Open Disclosure
A patient may authorise a relevant person to attend the meeting and where they refuse to attend the patient can specify another relevant person to attend.

Where an open disclosure meeting is refused the patient/relevant person shall inform the health services provider that they:

- will not attend OD meeting and
- do not want to receive the information to be provided at this meeting and
- do not want to receive any additional notifiable information or apology that may be made.

Record keeping obligations: The health services provider must set out a statement in writing to the patient, relevant person or patient and relevant person indicating:

- their refusal to attend an open disclosure meeting,
- their rights to make a later request (up to 5 years after the date the meeting was refused).

The patient/relevant person must be provided a copy of this and the health services provider must keep a copy of this on record.
An OD meeting will not be held.

Part 3 (19) Refusal by Patient/Relevant Person to participate in Open Disclosure meeting

Where a patient/relevant person or both refuse to accept this statement, the health service provider must:

- make a note of this refusal outlining the incident to be disclosed and the date of incident,
- sign and date the note and
- maintain the note on record.

Where a patient/relevant person make a later request (within 5 years from the date of refusal) this request must be managed as follows:

- The health services provider will make a note of the request and the person who made it;
- They will keep this note on record, and
- Hold a notifiable incident open disclosure meeting.

Part 3 (20) Failure to contact patient or relevant person

Responsibilities of the health services provider

- Take all reasonable steps taken to establish contact with patient/relevant person
- Set out in writing those step taken and contact information
- Sign and date this written record (statement)
- Maintain on record
- Notify the regulator of the NI
- Where contact is established at a later stage with the patient/relevant person proceed to hold a notifiable incident open disclosure meeting.

Additional Information Meeting

Where additional information becomes available after the NI Open Disclosure meeting, an additional NI Open Disclosure meeting will be held to:

- Provide that additional information
  Based on additional information discuss:
- If the health service provider is aware of whether or not the incident led to any physical or psychological harm for the patient/service user (acknowledging that predominantly for the current list of NIs the patient is deceased)
- Where the health services provider has reasonable grounds for believing that in addition to the consequences referred to already, what future harm might develop (physical or psychological) or not.
- Where, at the time of the NI disclosure meeting there was harm identified (physical or psychological), the health service provider shall inform the patient of the treatment, and relevant clinical care, that the provider is providing (or proposes to provide) to the patient / service user to address those consequences
- Provide an apology as determined by the provider and as deemed necessary based on additional information
- Provide 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.

Provide a written statement at the meeting or **within 5 days** of the meeting containing the information provided.

Managing Clarification Requests

- Relates to clarification of information provided at NI Open Disclosure Meeting or Additional NI Open Disclosure Meeting.
- Request to be submitted to designated person
- May request that the clarification is made other than in person.

Management of Clarification request by health services provider

- The Designated Person will make a record of the clarification request in writing and include the date that the clarification request was received.
- Designated Person will inform the health care practitioner who conducted the open disclosure meeting of the request and liaise with them in relation to a response to the request.
- The health care practitioner who conducted the meeting or another practitioner deemed suitable will provide a response to the clarification request
- This clarification may be made orally and also must be set out in writing to the Designated Person and to the patient/relevant person.
- The response must be signed by the healthcare practitioner providing the response to the clarification
- All records must be kept on file by the health services provider.

Open Disclosure of a Notifiable Incident: Legal Protections

Information provided and an apology given at an open disclosure meeting:

- 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 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 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 made by the patient to a regulatory body subsequently.
- shall not be admissible as evidence of fault, professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission, in proceedings to determine a complaint, application or allegation

Protections apply only when Open Disclosure is managed in accordance with the provisions of the Act and completion of documentation as set out in the Act.

The Civil Liability Amendment Act (2017) is also being amended by this Act.

Part 8: Offences and Penalties

A person (health services provider) who fails to comply without reasonable excuse shall be guilty of an offence and shall be liable on summary conviction to a Class A fine

Failure to comply relates to

(1) Failure to notify the relevant authority (regulatory body) **(Sections 27, 28 and 29)**

(2) Failure to hold an open disclosure meeting which includes as follows

Non-compliance to hold a NI OD Meeting **Section 5(1)**	Non-compliance to hold requested NI OD meeting following an initial refusal by patient/relevant person **Section 19(9)**	Non-compliance to hold a NI OD meeting when there was an initial challenge to contact the patient/relevant person and where contact is later established. **Section 20(5)**	Non-compliance to hold a Part 5 Review Meeting **Section 37(1)**	Non-compliance to hold requested Part 5 review meeting following an initial refusal by patient/relevant person **Section 50(9)**	Non-compliance to hold a Part 5 review meeting when there was an initial challenge to contact patient/relevant person and where contact is later established **Section 51(5)**

Defence - able to demonstrate all reasonable efforts were made to ensure compliance 77(8)(9)

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National Quality and Patient Safety Directorate
Office of the Chief Clinical Officer

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

NIMS

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

Part 4 s(30) Method of making notifications under sections 27, 28 and 29 (notifying the relevant regulator)

30. For the purposes of making a notification under section 27, 28 or 29, the health services provider shall make the notification by means of the National Treasury Management Agency incident management system.

Part 9 Amendment of the National Treasury Amendment Act of 2000

81. The Act of 2000 is amended by the insertion of the following section after section 11:
“Notifications under Act of 2023
11A.
(1) The Agency may provide the National Treasury Management Agency incident management system (within the meaning of the Act of 2023) as the means for making a notification under section 27, 28 or 29 of the Act of 2023.
(2) Subsection (1) shall apply whether the health services provider (within the meaning of the Act of 2023) making a notification referred to in that subsection is a State authority or otherwise.
(3) In this section, ‘Act of 2023’ means the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023.”

NIMS

Currently:

Has open disclosure Happened?

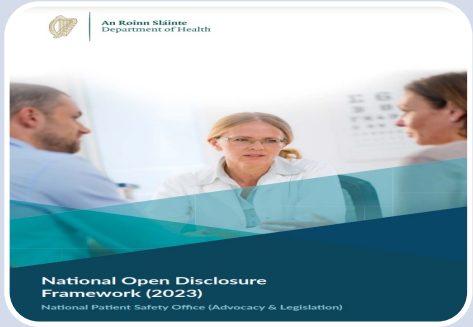
Reason for non open disclosure (Incident Review Screen)

PSA:

Classifying an incident is a NI

Reporting NI to the Regulator via NIMS

Timely reporting to



NODF:

The reporting of the number of open disclosure events initiated and closed by a health and social care service

days)

annual report to the

The Patient Safety Act: Notifying the Regulator on NIMS

Notifiable Incident Report Form

Is this incident notifiable? Yes

Regulator to be informed 2- HIQA

Health Service Provider and Hospital/Centre details

Please enter the name of the Health Service Provider HSE

Name of Hospital/Centre where the incident happened? Rotunda Hospital

ROTHHQ

Point of Contact Nominee details

Please enter the Point of Contact Nominee - Name Jim O'Leary

Please enter the Notifiable Incident Details below

Click here for a full description of Notifiable incidents

Type Of Notifiable Incident 1.6 Unintended, unanticipated death directly related to any p

Date the Notifiable Incident Occurred 19/08/2023

Date the Notifiable Incident came to the notice of the Health Service Provider 2/4/2024

Please do not enter Private Personal Information (PPI) in the following fields

Description Of Notifiable Incident

Patient had a central line inserted post-op for inotrope administration. The patient obtain ... the following day by the reporting radiologist. At 01:00 the patient had a cardiac arre...

Mitigating Actions Taken

Family informed. Audits of future surgeries to be commenced to recog... gular training sessions included into surgeons schedule.

Actions taken of due to be taken to share learning

For discussion at next department meeting. Review team set up as per IMF. Learnings from review and coroners report will be disseminated to relevant staff.

Open Disclosure (at the time of notification to the Regulator)

(At the time of notification) has the Open Disclosure meeting happened?

If No, please indicate plan for Open Disclosure including intended timeframe

Acknowledgement

I confirm, using the acknowledgement below, that all details provided are accurat... o PPI (Personally Identifiable Information) on the parties involved have been added to this incident...

Confirmation

Patient Safety Notification Status Notification...

Under Development

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Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Part 5 Patient Requested Screening Review

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

Key messages for healthcare professionals

1. Anyone who has developed cancer after screening and requests a review of their screening will be given a dedicated point of contact [designated person] to support them through the review process.
   a) Patient-requested review processes are in place for CervicalCheck and BreastCheck
   b) A patient-requested review process is being designed for BowelScreen
2. Reviews are patient-requested and designed around needs of patients (ie, timing, support, etc).
3. If your patient has developed cancer after screening and would like a review of their cancer screening they can contact review.request@screeningservice.ie to learn more about the process.

Work is ongoing to identify gaps, and relevant resources and supports for staff, patients and organisations, for the implementation of patient-requested reviews as set out in the Act.

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

Provisions in relation to Clinical Audit (Part 6)

Part 6 – Clinical Audit

- With regards to clinical audit, the Patient Safety Act will mean that there is now a specific law that limits the way in which information from clinical audits can be used.
- This new law will mean that information created during a clinical audit cannot be used:

❑ as an admission of fault by a healthcare organisation or professional.

❑ as evidence in legal cases (civil proceedings) against healthcare professionals or healthcare organisations

❑ as evidence to cancel a healthcare professionals' insurance; or

❑ as evidence of fault, professional misconduct, poor professional performance or any other failure or omission

❑ as evidence in disciplinary or fitness to practice procedures against healthcare professionals

- Also, the new law will mean that Freedom of Information legislation will not apply to information that is produced in clinical audit.

Part 6 – Clinical Audit

- Patient Safety Act does not seek to alter the current way in which clinical audits are conducted
- Important to note that these legal protections will only apply if the clinical audit is conducted in line with the definition of clinical audit and conditions set out by the Act.
- Other QI methodologies are not included in or effected by the Act.
- These other methodologies should continue as before.
- A more detailed FAQ for staff will be available soon.

Take Home Messages in relation to Open Disclosure

- The HSE Open Disclosure Policy requires that all harm events are disclosed
- The provisions of the Patient Safety Act build on current HSE Policy and relate to the mandatory requirement to notify and disclose the notifiable incidents as set out in the Act.
- The Minister reserves the right to add to the current list of notifiable incidents.
- Legal protections apply automatically when open disclosure is managed in accordance with the legislation.
- Open Disclosure is the right thing to do and it is important that we do it right.
- Empathy and Compassion are key.
- Open Disclosure when managed well assists emotional recovery and prevention of second harm or compounded harm
- Good documentation of Open Disclosure is critical - NIMS, patient record, records of meetings to patients/relevant persons.

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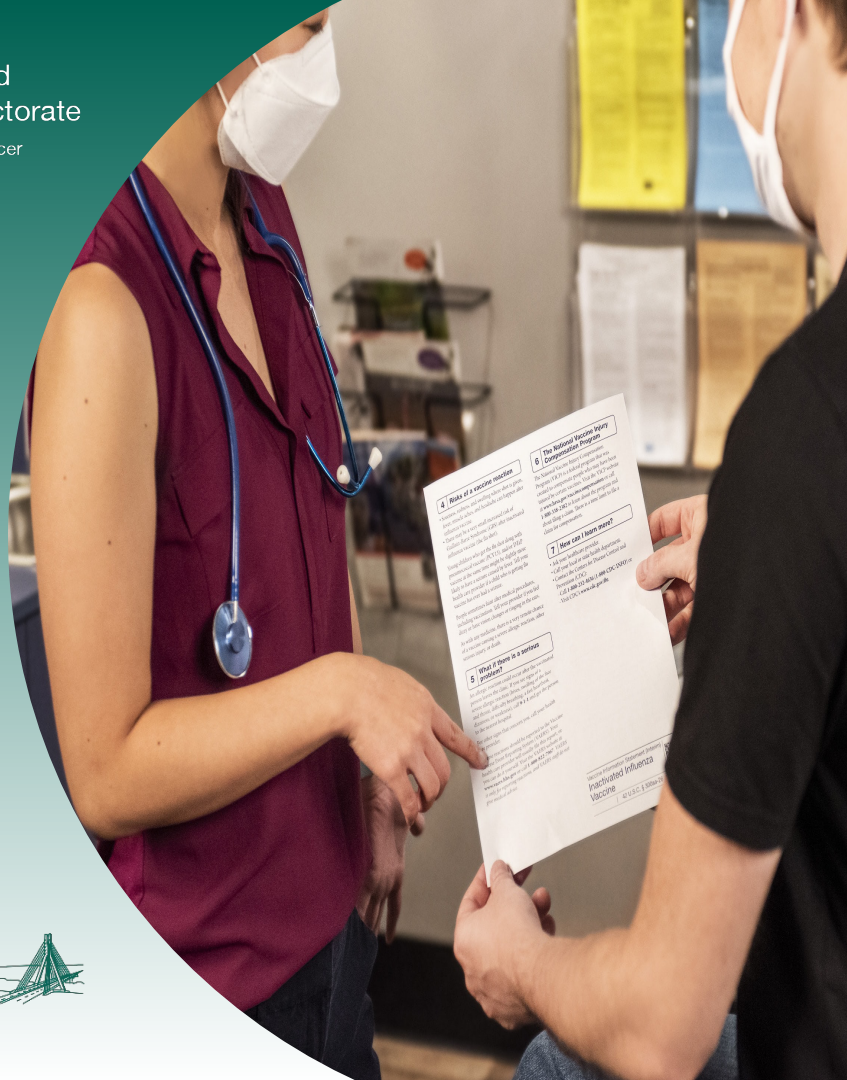
Embedding Open Disclosure



Staff Support

Providing a safe, supportive environment 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 services to support staff who are involved in and/or affected by patient safety incidents-use ASSIST Me resource on open disclosure website which includes contact lists.
- Lifeworks Staff Support Service
- Ensure that staff have access to training on the open disclosure policy relevant to their role.

Open Disclosure Training

Memo re Mandatory Training issued by National HR July 2022

Module 1: Communicating effectively through Open Disclosure (2CPD, 2 CEUs)

Module 2: Open Disclosure: Applying Principles to Practice (3 CPD, 3 CEUs)

Module 3: Face to Face Skills Workshop (3 hours. 3CPD, 3 CEUs)

Train the Trainer: 1 day workshop and 3 hrs virtual training. (3CPD, 3 CEUs)

Mandatory Training:

Module 1 is mandatory for all staff.

For staff who may , as part of their role, have to engage in formal OD meetings they must also complete Module 2 and the face to face skills programme.

Refresher Training:

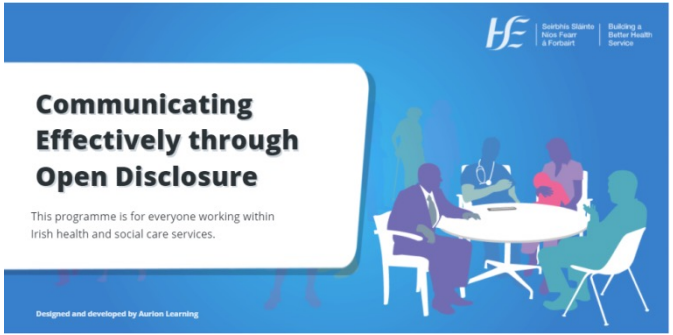
Required every 3 years; Module 1 for most staff or completion of Module 2 or 3 will also suffice

For staff who may , as part of their role, have to engage in formal OD meetings they should refresh by completing Module 2 or Module 3

E-Learning Module 1

E-Learning Programme Module 1 –
“Communicating Effectively through Open Disclosure”

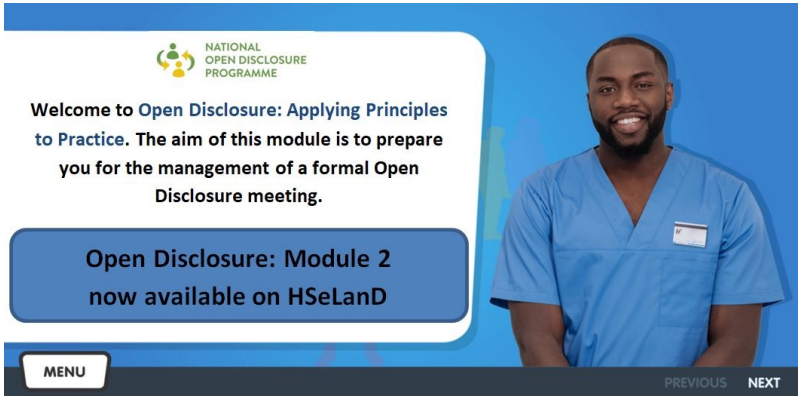
https://www.hseland.ie/dash/Account/Login



E-Learning Module 2

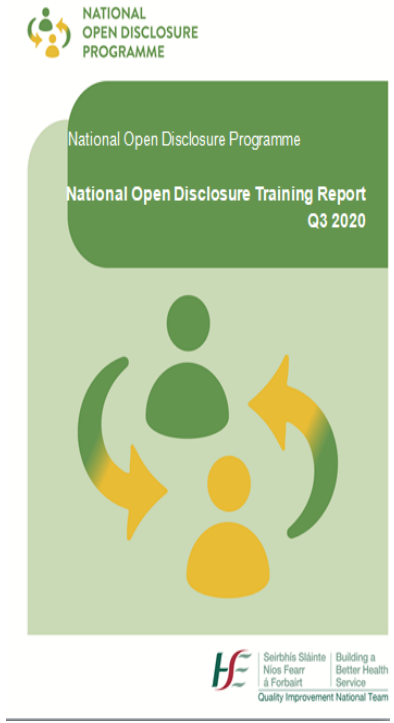
E-Learning Programme Module 2 –
“Open Disclosure: Applying Principles to Practice”

https://www.hseland.ie/dash/Account/Login



Open Disclosure Actions: Embedding ethos of Open Disclosure

- Promote a just culture
- Staff support
- Include OD in local training events/study days/conferences
- Promote resources especially Quick Reference Guide
- Ensure OD is agenda item QPS/Governance Meetings
- Promote good documentation of OD
- Share the learning



Maintaining Ethos of Open Disclosure

- **Open Disclosure: Maintaining our Values:** Care, Compassion, Trust and Learning
- **Open Disclosure: The right thing to do.**
- Open Disclosure : What we would expect for ourselves or for a loved one.
- Open Disclosure: The professional, ethical and humane response.
- Open Disclosure: The empathic response to all those involved in and/or affected by patient safety incidents .

Further Information

QR Code

- www.opendisclosure.ie
- National documents
- Resources for clinicians, organisations and trainers
- Open disclosure site leads/group leads/CHO leads/NAS
- National Open Disclosure Office

  Email: opendisclosure.office@hse.ie

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@NationalQPS
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