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HSE guideline for the identification and reporting of notifiable incidents

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HSE Guideline for the Identification and Reporting of Notifiable Incidents

Policy Procedure Protocol Guideline Clinical Guideline

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HSE Guideline for the identification and reporting of notifiable incidents

Topic:

This guideline sets out the requirements for the identification of notifiable incidents, describing key terms and obligations of their management and other aspects of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 for HSE and HSE-funded services.

It should be read in conjunction with the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 and the HSE Open Disclosure Policy (2025).

National Group:

HSE Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 Implementation Working Group

Short summary:

Notifiable incidents are defined by Schedule 1 of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023. Clear understanding of the notifiable incidents, and further provisions of the Act, is required for their identification and management. This document sets out to support the attainment of this understanding and its practical application.

VERSION CONTROL			
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I. Introduction

Notifiable incidents are incidents that are listed in Schedule 1 of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (referred to as 'the Patient Safety Act 2023' hereafter). They require notification to the relevant regulator via the National Incident Management System (NIMS) and mandatory open disclosure, following the procedure outlined in the Act. Clear understanding of the notifiable incidents and further provisions of the Act are required for their identification and management.

This guideline is aligned with the [HSE Open Disclosure Policy \(2025\)](#), which itself is aligned with the Patient Safety Act 2023, the Civil Liability (Amendment) Act 2017 and the Department of Health National Open Disclosure Framework 2023. This guideline is intended to further support staff in determining if an incident is a notifiable incident or not. It must be read in conjunction with the HSE Open Disclosure Policy 2025 and the HSE Incident Management Framework.

1. Purpose

- a- This guideline has been developed to provide health and social care staff with guidance on the notifiable incidents and how to interpret them.
- b- This guideline further describes key responsibilities in responding to a notifiable incident, including how they report a notifiable incident. Further detail is provided in the HSE Open Disclosure Policy (2025).

2. Scope

This guideline applies to all HSE and HSE-funded health and social care services. All staff and services are required to implement the legislation.

3. Objectives

The objectives of this guideline are:

- 1.4.1 To describe the notifiable incidents as defined in the Patient Safety Act 2023 and clearly outline the specific requirements that make it a notifiable incident;
- 1.4.2 To support staff to report notifiable incidents confidently and consistently across the HSE and HSE-funded services, and
- 1.4.3 To provide guidance for staff on the specific legal requirements concerning notifiable incidents and practical implementation of those requirements.

4. Outcomes

The expected outcomes of this guideline are as follows:

- a. That staff are informed and guided in their understanding of the notifiable incidents, and
- b. That notifiable incidents are reported as set out in the Patient Safety Act 2023 and the HSE Open Disclosure Policy (2025).

5. Aim of the Patient Safety Act 2023

A key purpose of the Patient Safety Act 2023 is to provide a legal framework for the mandatory open disclosure of notifiable incidents and to clearly set out regulatory reporting requirements of notifiable incidents. It is intended that this will further enhance a culture of openness and transparency across Irish healthcare as the Act applies to the public and private health and social care service provider settings.

The current list of 13 notifiable incidents all relate to events where there was a serious outcome for the patient or service user, and in the majority of instances the patient or service user died. The Patient Safety Act 2023 requires the health services provider to be responsive, open and transparent when a notifiable incident is identified.

The purpose of categorising events such as these as notifiable incidents in line with the law must not lead to blame within the health care setting but rather is must lead to good, open and compassionate communication with those affected and be aligned with the Incident Management Framework which requires incident management to be just and fair.

Reporting and identifying any learning from individual notifiable incidents or trends in relation to reported notifiable incidents is an added benefit for the health and social care service provider. Such insight can help identify risks and improve patient safety. Whilst in some instances a notifiable incident might not be a patient safety incident, they predominantly are and should be reviewed in line with the HSE Incident Management Framework. For others, such as an unintended/unanticipated death following medical treatment for example where the death was not related to the underlying disease, would warrant at a minimum a thorough and robust morbidity and mortality review.

Supporting staff to recognise a notifiable incident is essential so that the opportunity can be taken to disclose, learn and improve in a timely way and trust with the patient or their relevant person¹ is maintained.

6. Governance of notifiable incidents

Application across the HSE and HSE-funded services

Given the nature of the current list of notifiable incidents, most are likely to occur in the hospital setting (public or private). However, a notifiable incident could also occur in any health or social care service setting, such as notifiable incidents arising from medication incidents, medical treatment, management of a pregnancy, or suspected suicide of a patient. It is therefore important for all health and social care service providers to have appropriate governance structures in place to identify and report notifiable incidents, and undertake open disclosure as outlined the HSE Open Disclosure Policy (2025) which aligns with the Patient Safety Act 2023.

The Patient Safety Act 2023 refers to “health service providers”. The definition of health services providers in the Act indicates that social care services fall within this heading. There are a few relevant points to this:

1. The definition of health services provider makes reference to ‘health practitioners’. Health practitioners are defined in the Act and include registrants within the meaning of section 3 of the Act of 2005 (The Health and Social Care Professionals Act 2005). This explicitly includes allied health professionals such as social care workers.

¹ The term “relevant person” aligns with the definition of a relevant person in both the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 and the Civil Liability (Amendment) Act 2017. In both Acts, the relevant person relates to the individual, other than the patient, to whom the disclosure is made.

By contrast, under the Assisted Decision-Making (Capacity) Act 2015 “relevant person” has a different meaning, referring to the person whose capacity is in question; may shortly be in question, or who lacks capacity in relation to a decision.

2. The definition of a health services provider is also reliant on the definition of ‘health service’ within the Act. This includes the “the prevention, diagnosis, treatment or care of an illness, injury or health condition of the patient”. Many social care services would fall within this definition.

Accountability

Ultimately, the Senior Accountable Officer (SAO) is accountable for the notification of a notifiable incident and crucially for the health services providers’ response to a notifiable incident. This is in line with the HSE Performance and Accountability Framework.

The SAO must be informed about notifiable incidents identified in their organisation within 24 hours, and view each as an opportunity for the service to engage in meaningful communication with those affected. Notifiable incidents will likely be shared with the leadership team in a service, as set out in their local governance structures. The SAO provides support and leadership to enable effective implementation of the Patient Safety Act 2023 and, importantly, support a compassionate response.

Compliance with key steps in the open disclosure process (for example open disclosure meeting and written follow-up) are measured for all reported notifiable incidents. The [Department of Health National Open Disclosure Framework \(2023\)](#) further outlines the annual reporting requirement to the Department of Health relating to open disclosure compliance.

To note, this guideline aligns with the HSE Open Disclosure Policy (2025) and the HSE Incident Management Framework. It reflects the most up-to-date legislation, regulation, evidence, and internal / external review. Whilst every effort has been made to ensure the accuracy and completeness of the information outlined in this document, the process in relation to open disclosure and notifiable incidents may change with the passage of time and, in particular, the law and clinical practice.

If you have any questions about this guideline outlined herein, particularly as it may relate to local circumstances, please contact your service’s local [Open Disclosure Lead](#) or the HSE National Open Disclosure Office on opendisclosure.office@hse.ie for advice and guidance.

II. Managing notifiable incidents

The process for managing open disclosure is outlined in the HSE Open Disclosure Policy 2025. The policy was revised to include the management of both notifiable incidents and patient safety incidents.

This section outlines some specific requirements and detail in relation to managing notifiable incidents. The current number of notifiable incidents is 13, but the Minister for Health can update this list through regulation.

There are some general requirements that apply to all notifiable incidents:

- All staff (nurse, midwife, doctor, health and social care professional, manager, administrator, catering staff, etc.) have a responsibility to report notifiable incidents on a National Incident Reporting Form or the National Incident Management System (NIMS) as they would report any other patient or staff incident and to escalate them within their service as stipulated locally. If staff are aware and have confirmed that a notifiable incident has already been reported in their health service, then it does not need to be reported again.
- The notification and disclosure process should take place as soon as practicable, as outlined in the Patient Safety Act 2023 and HSE Open Disclosure Policy 2025.
- The notification and disclosure process must adhere to other relevant HSE policies and legislation as relevant, such as the [HSE National Consent Policy](#) (2024).
- The Patient Safety Act 2023 requires that where a health services provider is “satisfied” that a notifiable incident has occurred, it shall notify the relevant regulator of that notifiable incident and open disclosure requirements are then also mandated. The Act does not define what “satisfied” means. The Act provides that the health or social care services provider can be ‘satisfied’ that a notifiable incident occurred even if all of the information is not available. This means that it is not necessary to establish the cause of the injury or death with absolute certainty. In the interests of openness and transparency, the HSE has interpreted the word “satisfied” as a requirement to make reasonable efforts to establish if a notifiable incident occurred. A clinical assessment should be made with the information available on the likelihood that a notifiable incident occurred. Where it is deemed that a notifiable incident likely occurred, the health care practitioner and health or social care services provider must take the required actions. See the below section [Roles and responsibilities in the management of a notifiable incident](#) for further information in relation to this.
- The SAO makes the final decision based on the facts known and the clinical assessment, all of which must be clearly documented. The National Open Disclosure Office can be contacted for advice, if required.
- Once the health services provider is satisfied that a notifiable incident occurred, the health service provider must report it to the relevant regulator via NIMS within **7 calendar days**.
- If an incident was not deemed to be a notifiable incident initially, but information comes to light that clarifies it is a notifiable incident at a later date, then the required actions need to be initiated and progressed; that is to hold a notifiable incident disclosure meeting and report the notifiable incident to the relevant regulator via NIMS.
- NIMS must be used to notify the relevant regulator of the notifiable incident. The steps required for the notification on NIMS to the relevant regulator have been described in detail in the guideline entitled '[HSE Recording Open Disclosure on NIMS and reporting Notifiable Incidents to the Relevant Regulator](#)'. The notification on NIMS is made by a senior manager in the organisation who has been identified for this purpose locally, for example a Quality and Patient Safety Manager. The relevant regulator is either HIQA, the Mental Health Commission or the Chief Inspector. All HSE and

HSE-funded services (S.38s) must use the incident management module on NIMS to make the notification. A portal for reporting to the regulator is available for S. 39 services and private entities on the relevant healthcare regulator's website pages.

- The Patient Safety Act 2023 describes that where a health or social care services provider is satisfied that a notifiable incident has occurred in the course of its provision of a health service to a patient, (whether the notifiable incident occurred when that provider was providing that service, or another health services provider was providing a health service to that patient) the health services provider shall hold a notifiable incident disclosure meeting in order to make the open disclosure of that notifiable incident to the patient or relevant person or both of them, notwithstanding the absence of knowing some or all of the consequences of the notifiable incident or some or all of the information related to the notifiable incident.
- The HSE is the overarching health and social care service provider, and can determine if an alternative health practitioner is more suited to undertake open disclosure. It is the intention of this policy to outline that: whilst a service where the incident is identified will inform the patient/relevant person and other service of the incident, the service where the incident occurred must take a lead on the open disclosure and such communication must be supported by staff caring for the patient at the time the notifiable incident is identified. Communication and information exchange between services will be important and staff must seek the patient's/relevant person's wishes, and work to implement these as far as reasonably possible, as well as adhering to information governance requirements and the requirements of the Patient Safety Act 2023.
- Where the HSE is satisfied that a notifiable incident occurred and the incident occurred whilst the patient was receiving health and social care from a non-HSE nor HSE-funded service provider, then HSE staff must lead out on the open disclosure as required in the legislation for notifiable incidents. It is recognised that information may be limited, and for the patient/relevant person's benefit it would be important that the HSE engages with the non-HSE service provider and that open disclosure is planned and considered between the services/organisations.
- In particular for notifiable incident 2.1, where the infant is referred for therapeutic hypothermia to a different site, it will be the referring site (where it is necessary for a baby to be transferred for treatment from one site to another) who will lead out on notifying the relevant regulator on NIMS and open disclosure of the incident. Sites should support one another in the interest of the family involved to ensure good communication. See [Notifiable Incidents: definitions and explanations](#) below for more information and guidance relating to Therapeutic Hypothermia.
- When a notifiable incident occurs and there are multiple health services providers involved in the care of the patient then a joined approach to open disclosure must be arranged wherever this is possible. This is for the benefit of the patient or their relevant person to ensure any of their questions raised can be responded to where possible.
- Should the health or social care provider form the view, on further investigation or based on additional clinical information, that the original notification did not constitute a notifiable incident, this can be addressed by emailing the relevant regulator (HIQA and the Chief Inspector of Social Services: patientsafetyactincidents@hiqa.ie or the Director of Regulation at the Mental Health Commission: compliance@mhcirl.ie). The provider must also email nims@hse.ie who will log a request with the State Claims Agency to update the record so that that it is not logged as a notifiable incident on NIMS and the incident record is updated accordingly. The regulator will maintain such records outside of NIMS.
- The HSE Open Disclosure Policy 2025 outlines the open disclosure requirements for patient safety incidents and highlights any specific legal requirements if the incident is a notifiable incident. Specifically, the Patient Safety Act 2023 is prescriptive as to what must be covered at the notifiable

incident disclosure meeting it is a notifiable incident. It also outlines that the notifiable incident disclosure meeting must be followed-up in writing within 5 calendar days after the notifiable incident disclosure meeting. The Open Disclosure Policy 2025 incorporates and describes the process for on-going communication as set out in the Act be that at additional open disclosure meetings or where clarifications are sought. Staff must follow those processes.

III. Notifiable incidents: definitions and explanations

Notifiable incidents have been defined in the Patient Safety Act 2023. There is some key terminology used for a number of notifiable incidents that is explained here.

1. Unintended and Unanticipated Death

The majority of notifiable incidents refer to events where there was an unintended or unanticipated death.

Unintended, as defined in the Patient Safety Act 2023 as follows:

‘in relation to a death, means a death arising from an unintended event occurring, or arising from, the provision of a health service.’ (Part 1, Section 2 [1], p.13)

This means that the actual event that led to the death was not anticipated or in line with the patient’s or service user’s planned health care provision

Unanticipated death is where there was a death other than an anticipated or expected death, or a death where there was no expectation that the person was likely to die in the manner or at the time in which they did.

- That means that the death was not expected given the patient’s underlying health condition. It includes deaths where a persons’ life was shortened even if they were unwell or had a poor prognosis.
- It may not necessarily include incidents where clinical staff are undertaking life-saving and high risk procedures or treatment, that carry a high risk of mortality, in an attempt to save a person’s life or their bodily function and the risk materialises. This is with the clear exception of notifiable incident 2.1 (a), which relates to therapeutic hypothermia. In this circumstance, the therapeutic hypothermia is a potentially life-saving intervention, and is a notifiable incident.
- This definition of an unanticipated death includes deaths from complications that are known to occur but are rare, for example a pulmonary embolism or unexpected surgical injury leading to hypovolemic shock. Such incidents should be reported as notifiable incidents and at minimum require a mortality review.

None of the notifiable incidents outline a timeframes during which the death must have occurred for it to be deemed a notifiable incident. This means the proximity of time of the death to the incident that potentially caused it is not relevant in determining if it is a notifiable incident. This is particularly important to consider when making a determination regarding, for example, an unintended and unanticipated death occurring in an otherwise health patient undergoing elective surgery.

2. 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 (or an underlying condition of the child for NI1.10 and 1.11).

This description of circumstances, listed in certain notifiable incidents, 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, and when the death likely occurred or was contributed to because of the facts of the notifiable incident. In every case, the healthcare professionals involved must use their judgement to assess whether anything occurred during the provision of the care

or treatment that was unexpected or unintended where the death was not related to their underlying illness and/or condition.

As stated, it is important to note that the purpose of reporting a notifiable incident is not to determine a cause of death but rather to notify the relevant regulator that a notifiable incident is likely to have occurred and to initiate open and transparent communication.

Examples of events in scope:

- The death of a deteriorating patient who had sepsis and inadvertently received a higher than intended dose of antibiotics which led to renal failure, multi-organ failure and death of the patient.
- A patient was started on lithium by their psychiatrist. The patient was also taking herbal supplements which was recorded in their healthcare record but the clinician was unaware. The patient developed serotonin syndrome, which was left untreated and they died.

Examples of events out of scope:

- A patient death due to terminal cancer where there was a medication incident but the medication incident did not contribute to the patient's death.
- A patient who called emergency services due to severe chest pain and dizziness who was rushed to hospital pre-arrest and died during resuscitation from a likely cardiac event.

3. Surgery

Surgery is referred to in the Patient Safety Act 2023 in relation to its provision as part of a health service, and includes:

‘the performance or surgery, or a surgical intervention, in respect of aesthetic purposes, or other non-medical purposes, that involves instruments or equipment being inserted into the body of the patient’

Surgery incorporates surgical interventions that may be done outside a surgical environment, 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, other invasive procedures, aesthetic procedures or other non-medical intervention that involve instruments or equipment being inserted into the body of the patient.

It is also important to note that this notifiable incident can happen in a range of specialities, and their delivery environments, including maternity, paediatrics, Ear, Nose and Throat (ENT), cardiac, colorectal, emergency care, and many more.

4. Prescribed birthweight, prescribed gestational age and perinatal death

The Minister for Health published the following regulations which offer meanings to terms used in notifiable incident 1.10 and 1.11²:

For the purposes of Schedule 1 of the [Patient Safety \(Notifiable Incidents and Open Disclosure\) Act 2023](#) (No. 10 of 2023) and Notifiable Incident—

² <https://www.irishstatutebook.ie/eli/2024/si/501/made/en/print>

(a) 1.10 and 1.11 thereof—

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

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

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

5. Therapeutic hypothermia

Notifiable incident 2.1(a) is defined as a circumstance in which the principal health practitioner has determined through their clinical judgement ‘that therapeutic hypothermia is required or the baby should be referred for it’. Where there is no therapeutic hypothermia available at the service where the birth took place and the baby must be transferred to a service that can provide this intervention, then the notification to HIQA (of notifiable incident 2.1[a]) and the offer of a notifiable incident disclosure meetings should be made by the service where the birth took place. This service, which is referring and transferring the baby to another, is known as the ‘referring service’. It is more suitable for the referring service to complete the notification and the disclosure meeting because it will have the relevant information in relation to the mother’s pregnancy and labour to inform the open disclosure process.

A service that offers therapeutic hypothermia and receives transfers for this treatment is called the ‘receiving service’. If, following transfer of a baby to the receiving service, there is perinatal death of the baby in circumstances that meets the criteria of notifiable incident 1.11 then that receiving service will notify the relevant regulator of this notifiable incident. Where appropriate, and with the agreement and co-operation of both services, the receiving service can offer a notifiable incident disclosure meeting to the relevant person(s) to cover the open disclosure requirements of both of the relevant notifiable incidents, that is for the therapeutic hypothermia (notifiable incident 2.1[a]) and for the perinatal death (notifiable incident 1.11). This meeting should be led by the principal health practitioner. This meeting would need careful planning and communication between the two services, but is likely to offer the most compassionate solution for the relevant person(s).

Where a baby is born in the community (or ‘out of service’) and is transferred to a health care provider for immediate care, and subsequently the baby receives therapeutic cooling or is considered for cooling but not progressed as described in notifiable incident 2(1)b, then that health care provider must notify HIQA and carry out the notifiable incident disclosure meeting. This requirement also applies to the health care provider offering such treatment if the baby is initially cared for in emergency care and then transferred to the tertiary site.

Communication and information exchange between services is of benefit to the relevant persons and services involved. It is important to seek the wishes of the relevant person(s) and work to implement these as far as reasonably possible, as well as adhering to information governance requirements and the requirements of the Patient Safety Act 2023. For more information on this please see the [HSE Open Disclosure Policy 2025](#).

IV. Roles and responsibilities in the management of a notifiable incident

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 Performance and Accountability Framework 2023](#) sets out the accountability structure for the HSE and clarifies the named individuals who have delegated responsibility and accountability for all aspects of service delivery in their service. They are therefore fully responsible and accountable for the services they lead and deliver. That includes the quality and safety of services incorporating compliance with incident management and open disclosure requirements and enabling services and staff to deliver in these areas. It is the role and responsibility of the Senior Accountable Officer (SAO) of a service to have overall accountability within their area of responsibility for the management of incidents. This includes ensuring that the operational arrangements and the roles of all staff in relation to notifiable incident management are clearly defined.

Role	Responsibility
All staff	<ul style="list-style-type: none"> It is the responsibility and duty of all staff of HSE and HSE-funded services to report notifiable incidents to the local health or social care services providers via locally agreed processes. If staff are aware that a notifiable incident has already been reported in their health or care service, then it does not need to be reported again.
Non-consultant hospital doctor (NCHD)	<ul style="list-style-type: none"> If a non-consultant hospital doctor forms the opinion that a notifiable incident has occurred then they should report this to the leader of their clinical team.
Principal health practitioner	<p><u>Identification of the notifiable incident</u></p> <ul style="list-style-type: none"> The principal health practitioner must inform the individual with legal responsibility for the health and social care services provider (for example, the Senior Accountable Officer [SAO] or the Person-in-Charge [PIC]) if they have formed the opinion that a notifiable incident has occurred. They must do this as soon as practicable. This is required whether it is their belief that the notifiable incident took place in their health and social care services provider, or in another provider. <p><u>Open disclosure of the notifiable incident (the notifiable incident disclosure meeting)</u></p> <ul style="list-style-type: none"> The principal health practitioner must undertake open disclosure of the notifiable incident, unless they are unavailable; they are not in a position to make the open disclosure, or an alternative health practitioner is deemed more appropriate by the health or social care service provider. <p><u>The written record of the notifiable incident disclosure meeting</u></p> <ul style="list-style-type: none"> They must ensure that a good written record of open disclosure is made and they must sign the written record that is sent to the patient/relevant person following an open disclosure meeting. They should ensure that the letter is sent to the patient/relevant person within five calendar days of the meeting. They must make sure that the letter states that the open disclosure was made pursuant to and in compliance with section 5(1) of the Patient Safety (Notifiable Incidents and Disclosure) Act 2023. They must also ensure that a copy of the letter is retained in the patient's healthcare record. <p><u>Management of additional information and clarification of information</u></p> <ul style="list-style-type: none"> The principal health practitioner will lead on the delivery of further information at Additional Information meeting, as required. They will also respond to any requests for clarification of information received by the patient/relevant person.

<p>The senior incident management team (SIMT)</p>	<ul style="list-style-type: none"> • The senior incident management team (SIMT) will receive and review the information related to notifiable incident. • The SIMT will advise the individual with legal responsibility for the health and social care services provider of the conclusion of their consideration of the information related to the notifiable incident. This will support the final determination of this individual on whether the incident is a notifiable incident, or not.
<p>The individual with legal responsibility for the health and social care services provider – referred to as ‘the health services provider’ in the Patient Safety Act 2023 (for example, the Senior Accountable Officer [SAO] or the Person-in-Charge [PIC])</p>	<ul style="list-style-type: none"> • This individual will make the determination as to whether they are “satisfied” that a notifiable incident has occurred. • When they have determine that they are satisfied that a notifiable incident has occurred, they shall instruct the locally nominated individual with responsibility for making the notification on NIMS to notify the relevant regulator of that notifiable incident. • Once this individual is satisfied that a notifiable incident has occurred, the health service provider must report it to the relevant regulator within 7 calendar days. • This individual makes the final decision based on the facts known and the clinical assessment, all of which must be clearly documented.
<p>Designated person</p>	<ul style="list-style-type: none"> • It is a legal requirement of the Patient Safety Act 2023 that each patient / relevant person has a designated person assigned to them to support them throughout the notifiable incident disclosure process. • The nomination of the designated person must be documented in the local Incident Management/Open Disclosure file and a direct telephone line number and contact arrangements provided to the patient / relevant person and staff members involved. • The designated person will act as the liaison person between the health or social care services providers and the patient/relevant person. • They will assist the patient/relevant person in preparing for and attending open disclosure meetings. • They will facilitate feedback during the incident review and open disclosure process. • They will advise on support services available.³ • They will act as the point of contact for any clarifications sought, and liaises with relevant health and social care staff in relation to any clarification requests by the patient / relevant person.

³ A list of advocacy services can be found on the HSE website, here: <https://www.hse.ie/eng/services/yourhealthservice/feedback/services/>

V. List of notifiable incidents and criteria for their identification

Notifiable incidents are listed in Schedule 1, Part 1⁴ of the Patient Safety Act 2023. For each notifiable incident, certain criteria must be met and the requirements for each is described here:

Notifiable incident	Criteria to be deemed a NI	Example
<p>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.</p>	<ul style="list-style-type: none"> - A surgery/surgical intervention is performed. - Surgery is performed on the wrong patient. - It resulted in an unintended and unanticipated death. - The death was not attributable to the patient's underlying illness or condition. 	<ul style="list-style-type: none"> - The wrong patient had brain surgery to remove a blood clot instead of their intended brain aneurysm repair and died from the procedure. - The wrong patient had a liver biopsy. The patient experienced a bleed post-operatively and died. - The wrong patient had a cardiac-angiogram. The patient developed post-operative pulmonary embolism and died.
<p>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.</p>	<ul style="list-style-type: none"> - A surgery/surgical intervention is performed. - Surgery is performed on a wrong site. In the HSE this is defined as 'any surgery performed on a body part that is not consistent with that described in the correctly documented informed consent for that patient. This event is intended to capture wrong site surgery, even if corrected intra-operatively, as long as the surgery had begun.'⁵ - It resulted in an unintended and unanticipated death. - The death was not attributable to the patient's underlying illness or condition. 	<ul style="list-style-type: none"> - A patient was due to have a left hip replacement but surgery inadvertently commenced on the right hip. The patient developed bone cement syndrome intra-operatively, deteriorated and died.
<p>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,</p>	<ul style="list-style-type: none"> - A surgery/surgical intervention is performed. - In the HSE wrong surgical procedure is defined as 'any surgical procedure performed on a patient that is not consistent with that described in the correctly documented informed consent for that patient.'⁶ - It resulted in an unintended and unanticipated death. 	<ul style="list-style-type: none"> - A patient had a gastroscopy instead of a planned colonoscopy. The patient developed a serious lung infection due to vomit aspirated during the procedure and dies.

⁴ Irish Statute Book, S.I. No. 501/2024 - Patient Safety (Notifiable Incidents and Open Disclosure) Regulations 2024 <https://www.irishstatutebook.ie/eli/2024/si/501/made/en/print>, 2024

⁵ HSE, *Serious Reportable Events (SREs) HSE Implementation Guidance Document*, 2015

⁶ HSE, *Serious Reportable Events (SREs) HSE Implementation Guidance Document*, 2015

Notifiable incident	Criteria to be deemed a NI	Example
<p>was not wholly attributable to that illness.</p>	<ul style="list-style-type: none"> - The death was not attributable to the patient's underlying illness or condition. 	
<p>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.</p>	<ul style="list-style-type: none"> - A surgery/surgical intervention is performed - The surgery results in an unintentionally retained foreign object(s). - It resulted in an unanticipated death. - The death was not attributable to the patient's underlying illness or condition. 	<ul style="list-style-type: none"> - A road traffic accident patient has a central line inserted in the emergency department. The guidewire is inadvertently retained and it travels to the patient's heart causing internal damage and they die. - A patient had a maxillofacial surgical procedure and a throat pack was inserted to prevent fluids, particulate matter as well as foreign bodies from entering into the aero-digestive tract. On completion of the procedure the throat pack was inadvertently retained. After extubation the patient experienced respiratory difficulties because of the throat pack. They went into respiratory arrest and died.
<p>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.</p>	<ul style="list-style-type: none"> - It resulted in an unintended and unanticipated death. - The death was directly related to surgery/surgical intervention or anaesthesia, or recovery from the effects of the anaesthesia. - The HSE interpretation of 'an otherwise healthy patient' is that of a patient who had a pre-operative American Society of Anesthesiologists (ASA) physical status classification score (an 'ASA score') of 1 or 2 at the time of the elective surgery. It includes patients with an ASA score of 1 as this describes a healthy patient and an ASA score of 2 means that a patient has mild systemic disease.⁷ - The elective surgery took place at premises where a health services provider provides a health service. - The death was not attributable to the patient's underlying illness or condition. 	<ul style="list-style-type: none"> - A patient with an ASA score of 1 undergoes elective oro-dental surgery for tooth extraction. The patient received high dose sedation and goes into respiratory failure and dies. - A patient with an ASA score of 2 attends day surgery for an abdominal procedure. Hydrogen peroxide is used incorrectly to wash out the abdominal cavity. This produces an air embolism and the patient dies from the air embolism. - A service user with an ASA score of 2 is admitted to hospital for an elective colonoscopy. The service user returns to their care home of residence. The service user experiences extreme pain and shows signs of a bowel perforation and infection. The service user deteriorates rapidly and dies from sepsis whilst awaiting ambulance transfer. - A patient with an ASA score of 2 undergoing laparoscopic procedure to remove a liver lesion. The trocar enters a major blood vessel and the patient dies.

⁷ American Society of Anesthesiologist, *ASA Physical Status Classification System*, <https://www.asahq.org/standards-and-practice-parameters/statement-on-asa-physical-status-classification-system> (2020)

Notifiable incident	Criteria to be deemed a NI	Example
<p>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.</p>	<ul style="list-style-type: none"> - It resulted in an unintended and unanticipated death. - The death occurred in any place or premises where a health services provider provides a health service - The death was directly related to medical treatment. - The death was not attributable to the patient's underlying illness or condition. 	<ul style="list-style-type: none"> - A cardiac patient died from a head injury following a fall. The likelihood of the patient falling was increased due to a high dose of anti-hypertensive medicine leading to a sudden drop in blood pressure and syncope. - Inadvertent connection of a patient requiring oxygen to medical air via a flowmeter. The patient being oxygen dependent, desaturated and was in respiratory failure resulting in death.
<p>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.</p>	<ul style="list-style-type: none"> - The death was directly related to the transfusion of ABO incompatible blood or blood components. - It resulted in an unintended and unanticipated death. - The death was not attributable to the patient's underlying illness or condition. 	<ul style="list-style-type: none"> - A patient had wrong blood transfused inadvertently and had a serious haemolytic reaction and died. - A patient had an unintentional ABO mismatched solid organ transplant and had a serious haemolytic reaction and died.
<p>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</p>	<ul style="list-style-type: none"> - It resulted in an unintended and unanticipated death. - The death was directly related to a medication incident. - The death was not attributable to the patient's underlying illness or condition. 	<ul style="list-style-type: none"> - A service user received penicillin although it was documented in their healthcare record that they are allergic to it. The service user had an anaphylaxis and died. - A paediatric patient's parent was dispensed the incorrect drug. It sounded similar to the intended drug. The actual drug dispensed was lethal for a child and the patient died.
<p>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.</p>	<ul style="list-style-type: none"> - An unanticipated death of a woman while pregnant or within 42 days of the end of the pregnancy. - The death was related to, or aggravated by, the management of the pregnancy. This is interpreted by the HSE in line with the WHO definition of a 'direct obstetric death' as a 'death resulting from obstetric complications of the pregnancy state (pregnancy, labour and puerperium), 	<ul style="list-style-type: none"> - A woman who delivered her baby after a long labour and forceps delivery. She subsequently had a post-partum haemorrhage, developed a Disseminated Intravascular Coagulation (DIC) and died four hours after delivery. - A pregnant woman was brought to the emergency department seizing who later died. She had a history of epilepsy and her General Practitioner had stopped her anti-convulsant medicine with the start of her pregnancy.

Notifiable incident	Criteria to be deemed a NI	Example
	<p>from interventions, omissions, incorrect treatment or from a chain of events resulting from any of the above'.⁸</p> <ul style="list-style-type: none"> - The death was not attributable to the patient's underlying illness or condition <p>'The end of pregnancy' has been interpreted in line with the World Health Organisation's <i>Definition of maternal deaths</i> (WHO, 2022)⁹ which states: that 'the end of pregnancy includes termination, miscarriage or birth and ectopic pregnancies'.</p>	<ul style="list-style-type: none"> - A mother deteriorated and died from an undiagnosed postpartum haemorrhage (PPH) following a C-section. - A mother died by suicide two weeks following delivery. The concerns of the public health nurse and the GP were noted in the postpartum period, however, a referral to the perinatal mental health service was never completed. The woman was pronounced dead on arrival at ED.
<p>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.</p>	<ul style="list-style-type: none"> - It is an unanticipated and unintended stillborn child (up to the diagnosis of labour). - Fatal foetal abnormality is not defined in the Patient Safety Act 2023. This reference and the reference to the 'death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition' is interpreted that the child was born without major congenital abnormalities. - Where the child was born with a prescribed birthweight or has achieved a prescribed gestational age. The following definitions were published as regulations by the Minister for Health (Statutory Instrument 501/2024) to offer meaning to the terms: <ul style="list-style-type: none"> (i) "prescribed birthweight" means a birthweight of not less than 2500 grammes; and (ii) "prescribed gestational age" means a gestational age of at least 37 weeks, commencing on the first day of the 37th week;¹⁰ - The child shows no sign of life at birth. - It is a death from any cause related to, or aggravated by, the management of the pregnancy. 	<ul style="list-style-type: none"> - Omissions in regularly monitoring a mother with pre-eclampsia and recognising signs of deterioration leading to delayed treatment, placental abruption and stillbirth. - Woman admitted with reduced foetal movements at 39 weeks and 4 days. Appropriate monitoring did not take place nor was a plan for delivery made. An intra-uterine foetal death occurred after 24 hrs.

⁸ The World Health Organisation, *International statistical classification of diseases and related health problems (ICD): ICD-111, (2022)*

⁹ The World Health Organisation, *International statistical classification of diseases and related health problems (ICD): ICD-111, (2022)*

¹⁰ Irish Statute Book, *S.I. No. 501/2024 - Patient Safety (Notifiable Incidents and Open Disclosure) Regulations 2024*, <https://www.irishstatutebook.ie/eli/2024/si/501/made/en/print>, 2024

Notifiable incident	Criteria to be deemed a NI	Example
	<ul style="list-style-type: none"> - It is a death that did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the child. 	
<p>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.</p>	<ul style="list-style-type: none"> - The death is an unanticipated and unintended perinatal death. - Where a child born with, or having achieved, a prescribed gestational age and a prescribed birthweight. The following definitions were published as regulations by the Minister for Health (Statutory Instrument 501/2024) to offer meaning to the terms: <ul style="list-style-type: none"> (a) (i) “prescribed birthweight” means a birthweight of not less than 2500 grammes; and (ii) “prescribed gestational age” means a gestational age of at least 37 weeks, commencing on the first day of the 37th week; (b) 1.11 thereof, a “perinatal death” means a death which occurred within 7 days of birth. ¹¹ - The child was alive at the onset of care in labour. - It is a death from any cause related to, or aggravated by, the management of the pregnancy. - It is a death that 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. 	<ul style="list-style-type: none"> - Following induction labour commences. Foetal distress occurs and bradycardia develops. As a result of indecision there is an undue delay in performing a caesarean section, such that the baby was not delivered for an hour. The baby dies within seven days of birth. - Mother has group-B streptococcus (GBS) and maternal fever develops in labour. Ante-natal antibiotics are not prescribed and administered to the mother and the baby subsequently is born with GBS neonatal pneumonia and septicaemia. The baby dies within seven days of birth. - A baby is born in good condition at birth. Day 2 examination was apparently normal but imperforate anus was not detected. Post discharge from hospital the baby developed problems, including abdominal distension and, despite readmission, the baby dies due to complications of bowel perforation.
<p>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.</p>	<ul style="list-style-type: none"> - The death was unintended (as defined in the Patient Safety Act 2023) - The cause is suspected to be suicide (note comment above at page 8 regarding the determination of a notifiable incident). - The location of the suspected suicide outlined in this notifiable incident relates to a death which takes place in an HSE premise or the premise of a HSE-funded service in which a health services provider provides a health service. Interpretation of this notifiable incident should be in line with the current SRE Implementation Guidance for ‘SRE 	<ul style="list-style-type: none"> - Death of a patient by suspension from a height in an acute mental health outpatient facility. A note is found with the deceased addressed to loved ones. - Where a patient attempts suicide at a health services provider (A), is resuscitated and dies sometime later at another health services provider (B) due to the injuries from the attempted suicide then the site where the incident occurred (health services provider A) must take the required actions (report to the relevant regulator and lead out on open disclosure). For example, health services provider A may be a mental

¹¹ Irish Statute Book, S.I. No. 501/2024 - Patient Safety (Notifiable Incidents and Open Disclosure) Regulations 2024, <https://www.irishstatutebook.ie/eli/2024/si/501/made/en/print>, 2024

Notifiable incident	Criteria to be deemed a NI	Example
	<p>3C Patient Protection Events' and extends beyond mental healthcare facilities, which is outlined as:</p> <p>'All sudden unexplained deaths or injuries which result in serious disability of a person who is an inpatient / resident in a mental healthcare facility.</p> <p>This is defined as events that result from actions after the patient / resident has been admitted to an inpatient facility. Inpatient facility is a hospital or other facility for care and treatment of persons suffering from mental illness or mental disorder. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility. This event is not intended to capture patient suicide or attempted suicide when the patient is on approved leave from the mental health facility'.¹²</p> <p>This excludes death by suspected suicide that takes place in the community and an individual's home.</p>	<p>health facility (approved centre) and health services provider B might be an acute provider.</p>

¹² HSE, *Serious Reportable Events (SREs) HSE Implementation Guidance Document*, 2015

Schedule 1, Part 2¹³

Notifiable incident	Criteria to be deemed a NI	Example
<p>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</p>	<p>Criteria for 2.1(a)</p> <ul style="list-style-type: none"> - The clinical judgement of the principal health practitioner is that therapeutic hypothermia is required or refers the baby for therapeutic hypothermia - The HSE is interpreting this as - On completion of the Cooling Candidacy Assessment Checklist¹⁴ by the principal health practitioner and the result is that the infant is suitable for cooling. 	<p>Examples for 2.1(a)</p> <ul style="list-style-type: none"> - Complications during a difficult vaginal delivery, which required forceps assistance, resulting in the baby developing a sub-galeal haemorrhage. Following a traumatic delivery and intubation the Cooling Candidacy Assessment Checklist was completed. The treating clinician assessed the baby as requiring cooling. - Hypoxic-ischaemic encephalopathy (HIE) is diagnosed shortly after birth and the baby is referred for therapeutic hypothermia. - Following a complicated delivery, in which the baby's head was impacted following a prolonged second stage of labour, the baby was born flat, pale and poor tone. The attending Neonatologist completed the Cooling Candidacy Assessment Checklist and the baby fulfilled the criteria for cooling. Passive cooling was commenced by the referring site. Active cooling was commenced during transfer and continued on arrival at tertiary/receiving site. - Following a complicated delivery, in which the baby's head was impacted following a prolonged second stage of labour, the baby was born flat, pale and poor tone. The attending Neonatologist completed the Cooling Candidacy Assessment Checklist and the baby fulfilled the criteria for cooling. Passive cooling was commenced by the referring site. Active cooling was commenced during transfer. On arrival at the tertiary/receiving site the Consultant Neonatologist completed the checklist again and deemed that the baby did not fulfil the criteria for cooling. He acknowledged this was an unusual decision but was based on the specific clinical findings on arrival. No further cooling was administered and a different clinical course of action was undertaken <p>Exclusion:</p>

¹³ Irish Statute Book, S.I. No. 501/2024 - Patient Safety (Notifiable Incidents and Open Disclosure) Regulations 2024, <https://www.irishstatutebook.ie/eli/2024/si/501/made/en/print>, 2024

¹⁴ National Women and Infants Health Programme, Neonatal Therapeutic Hypothermia in Ireland Annual Report 2020, <https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/national-reports-on-womens-health/neonatal-therapeutic-hypothermia-in-ireland-annual-report-2020.pdf>, 2022

Notifiable incident	Criteria to be deemed a NI	Example
		<ul style="list-style-type: none"> - A baby was unexpectedly flat at birth. The paediatric team was paged and attended within 1 minute. The baby was transferred to the resuscitaire by the Paediatric Registrar. The baby responded well to resuscitation. The Consultant Paediatrician completed the Cooling Candidacy Assessment Checklist and the baby did not fulfil the criteria for cooling. The baby did not receive therapeutic hypothermia, and a different clinical course of action was undertaken.
	<p>Criteria for 2.1(b)</p> <ul style="list-style-type: none"> - The clinical judgement of the principal health practitioner is that therapeutic hypothermia is required or the baby should be referred for it. - Therapy was contraindicated due to the severity of the presenting condition. The HSE further defines this requirement for it to be deemed a notifiable incident that the Cooling Candidacy Assessment Checklist¹⁵ is completed by the principal health practitioner and the result of their assessment using the checklist is that the infant is suitable for cooling. However, due to the severity of the presentation it is determined that therapeutic hypothermia is contraindicated, and active cooling is not commenced. 	<p>Examples for 2.1(b)</p> <ul style="list-style-type: none"> - HIE is identified and Cooling Candidacy Assessment Checklist completed, but the baby's conditions worsens as a result of uncontrolled pulmonary hypertension. This is a contraindication for therapeutic hypothermia. - HIE is identified and Cooling Candidacy Assessment Checklist completed, but uncontrolled coagulopathy is identified as result of the oxygen deprivation. This is a contraindication for therapeutic hypothermia. - Following a complicated delivery, in which the baby's head was impacted following a prolonged second stage of labour, the baby was born flat, pale and poor tone. The attending Neonatologist completed the Cooling Candidacy Assessment Checklist and the baby fulfilled the criteria for cooling. However, following an additional diagnosis of persistent pulmonary hypertension of the newborn (PPHN), the Neonatologist deferred the planned therapeutic hypothermia and a different clinical course of action was followed. - Following an emergency c-section for reduced fetal movements a baby was delivered with Apgars of 2, 2 and 2. Seizure activity was noted. The neonatology team was present at delivery having been paged as part of the Obstetric Emergency protocol. The Neonatologist completed the Cooling Candidacy Assessment Checklist, and the baby fulfilled the criteria for cooling. However, it was the opinion of the Neonatologist that the injury was on the extreme end. Following full and open conversation with the parents a decision was made to

¹⁵ National Women and Infants Health Programme, Neonatal Therapeutic Hypothermia in Ireland Annual Report 2020, <https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/national-reports-on-womens-health/neonatal-therapeutic-hypothermia-in-ireland-annual-report-2020.pdf>, 2022

Notifiable incident	Criteria to be deemed a NI	Example
		redirect to comfort care. The baby died at 3 hours of life in mother's arms.

VI. Non-compliance with the Patient Safety Act 2023

Effective open disclosure can improve patient, staff, and community confidence in how the health and social care system responds to patient safety incidents, and is fundamental to maintaining or re-building the trust between health and social care staff, patients, and their relevant persons. Non-compliance with open disclosure and the Patient Safety Act 2023 can lead to emotional harm and a loss in trust in the health services provider by a patient or their relevant person.

Accountability for the implementation of the Patient Safety Act 2023 aligns with the HSE Accountability and Performance Framework 2025. However, in addition to this, the Patient Safety Act 2023 also prescribes fines for health services providers that are non-compliant with the Act.

Section 77(4) of the Act states that where someone fails to comply with the Act, without a reasonable explanation for same, they will be guilty of an offence and liable on summary conviction to a **Class A fine of up to €5,000**

Where a health service provider fails to comply with the Act, and it can be proven that the offence was committed with the consent or wilful neglect of a person who was a director, manager, secretary or other officer of the health service provider (body corporate), both will be guilty of an offence and liable as per the above (Part 8, s. (9) of the Patient Safety Act 2023).

Non-compliance relates specifically to:

- (1) Omitting to notify the relevant regulator
- (2) Not holding any of the following open disclosure meetings

In legal proceedings for an offence under the Act, it will be considered a valid defence to demonstrate that all reasonable efforts were made to ensure compliance (Part 8, s. (77) (8) of the Patient Safety Act 2023).

VII. Guideline Implementation

The Patient Safety Act 2023 commenced in September 2024. Any legal requirements relating to the Act must be met and adhered to. This guideline is intended to support staff and organisations with the implementation for the Act.

VIII. Review

This guideline will be reviewed six months following publication. Feedback will be sought to evaluate its practical application and to identify any gaps or challenges requiring attention. The review will be informed by input from services and, where appropriate, patients/service users; learning from reported notifiable incidents; and any emerging insights into reporting gaps or challenges.

Revised documents will be reviewed and approved by the National Open Disclosure Steering Committee and the Chief Clinical Officer (CCO) within a one-year timeframe; accordingly, the review date has been recorded as one year. Any subsequent editions will be reviewed on a three-yearly basis unless new developments necessitate an earlier review.

IX. Audit

A comprehensive [Checklist for the Implementation of the HSE Open Disclosure Policy 2025](#) was developed by the National Open Disclosure Office, QPS Incident Management, to support services in

implementing and auditing compliance with the HSE Open Disclosure Policy (2025) which incorporates requirements of the Patient Safety Act 2023.

As regards the audit of this guideline, services should consider same within a broader policy audit. A concise Notifiable Incident Guideline Audit Checklist has been included in [Appendix III](#), focused on specific elements relating to the identification and reporting of notifiable incidents, as well as staff training and awareness of this guideline.

X. Sustainability

The sustainability of this guideline requires integrating it into the culture, systems and daily operations of health and social care services. Key strategies to enable sustainability include:

- **Structural Embedding:** Ensure this guideline is referenced in local and national policies, SOPs, and clinical governance documentation.
- **Training:** Tenets of this guideline are included in training designed and delivered by the National Open Disclosure Office, using case studies and incident reviews in workshops to help staff recognise notifiable incidents in practice. Such training material is standardised and aligned across the HSE and HSE-funded services and cascaded across a network of HSE open disclosure trainers that apply this in line with their local organisational needs and scenarios.
- **Monitoring:** Local monitoring of incidents should be undertaken at least monthly, using global views¹⁶ on the National Incident Management System (NIMS). Any gaps should be addressed by follow-up until all required actions are completed.
- **Compliance Reporting:** The HSE will develop national KPIs to measure compliance with key steps of the open disclosure process for notifiable incidents. This will include measuring if a notifiable incident meeting has taken place for notifiable incidents, and if the written record was shared after the meeting. Compliance with key steps of the open disclosure process will be reported quarterly to the National Open Disclosure Steering Committee and the Audit and Risk Committee of the HSE Board.
- **Continuous Quality Improvement:** Services should develop and maintain local improvement plans based on notifiable incident reviews, audit findings, and routinely gathering insights from staff using the guideline.

XI. References

- American Society of Anesthesiologists 2020, *ASA Physical Status Classification System*, <https://www.asahq.org/standards-and-practice-parameters/statement-on-asa-physical-status-classification-system>
- HIQA 2024, *Guidance for health services providers on notifying HIQA of notifiable incidents under the Patient Safety Act*, <https://www.hiqa.ie/sites/default/files/2024-09/Guidance-on-Reporting-Notifiable-Incidents-to-HIQA.pdf>
- HSE 2015, *Serious Reportable Events (SREs) HSE Implementation Guidance Document*, <https://www.hse.ie/eng/services/publications/performance-reports/srejan15.pdf>
- National Women and Infants Health Programme, *Neonatal Therapeutic Hypothermia in Ireland Annual Report 2020 (2022)*, <https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/national-reports-on-womens-health/neonatal-therapeutic-hypothermia-in-ireland-annual-report-2020.pdf>

¹⁶ NIMS global views are available and pre-defined search criteria that can be accessed on the system by persons who have access rights. It enables staff to monitor and maintain oversight of reported notifiable incidents and track progress against essential steps. Please contact NIMS@hse.ie for any queries in relation to this.

- The World Health Organisation 2022, *International statistical classification of diseases and related health problems (ICD): ICD-11*, <https://www.who.int/standards/classifications/classification-of-diseases>

Appendix I - Membership of the Notifiable Incident Workstream (the Development Group)

Membership of the Notifiable Incident Workstream	
Name	Role and position
Lorraine Schwanberg	Assistant National Director Incident Management, Open Disclosure and NIMS, HSE National Quality and Patient Safety
Róisín Egenton	General Manager, Incident Management / Open Disclosure HSE National Quality and Patient Safety
Eleanor Southgate	National Open Disclosure Manager, HSE National Quality and Patient Safety
Aideen Quigley	Quality & Safety Manager, National Women and Infants Health Programme
Bernadette O'Reilly	Patients for Patient Safety Ireland
Ciaran McCullagh	General Manager, Quality & Patient Safety, HSE National Ambulance Service
Fiona Melia	HSCP Development Manager, HSE National Health & Social Care Professions Office
Irene O'Hanlon,	General Manager, Access and Integration, HSE National Quality Patient Safety
Dr John Fitzsimons	Consultant Paediatrician, Children's Health Ireland
Loretta Jenkins	General Manager (Incident Management), National Quality and Patient Safety
Dr Maureen Flynn	HSE Director of Nursing, QPS Lead, National Clinical Programmes Liaison CDI & ONMSD and National Lead Nurse Referral for Radiological Procedures
Rosaleen Cafferty	Deputy Quality & Patient Safety Manager, HSE Dublin & North East Acute Hospitals
Susan Moloney	Quality & Patient Safety Manager, HSE Dublin & North East Acute Hospitals

Appendix II - Sign-off by the Chair of the Approval Governance Group and Chief Clinical Officer

The HSE Notifiable Incident Guideline was formally ratified and recorded in the minutes of the Implementation Working Group on 4 June 2025.

Name: (print)	Dr Orla Healy
Title:	National Clinical Director, Quality and Patient Safety
Signature: (e-signatures accepted)	
Registration number: (if applicable)	

Name: (print)	
Title:	
Signature: (e-signatures accepted)	
Registration number: (if applicable)	

Appendix III – Notifiable Incident Guideline Audit Checklist

Audit Checklist: Notifiable Incident Guideline (2026)

Please note: This audit checklist is focused specifically on the identification and reporting of notifiable incidents, and training on this guideline.

Section 1: Identification & Classification of Incidents

Audit Criteria	Yes	No	N/A	Comments/Evidence
Are staff aware of the definition and criteria of a notifiable incident under the Patient Safety Act 2023?				
Are tools / checklists (e.g. Cooling Candidacy Assessment) used where required?				
Is there evidence that notifiable incidents are being correctly identified?				
Is decision making documented in determining if an incident is a notifiable incident or not and if not, why?				

Section 2: Notification Process

Audit Criteria	Yes	No	N/A	Comments/Evidence
Were incidents reported to the regulator via NIMS within 7 calendar days where a service was satisfied that it is a notifiable incident?				
Was the regulator correctly identified (HIQA, MHC, Chief Inspector)?				
Is there documentation of when and by whom the notification was submitted?				
Was the form submitted on NIMS?				

Section 3: Training & Awareness

Audit Criteria	Yes	No	N/A	Comments/Evidence
Have staff received training on the Notifiable Incident Guideline?				
Are there local information sessions or induction materials available?				
Are clinical staff trained on definitions and examples of notifiable incidents?				
Is there a process to verify staff understanding of responsibilities?				