Open Disclosure Policy

Communicating with Patients Following Patient Safety Incidents

Reference Number NATOD-POL-001

Building a Better Health Service | Seirbhís Sláinte Níos Fearr á Forbairt

National Quality Improvement Team

HSE Open Disclosure Policy

Communicating with Patients Following Patient Safety Incidents

Is this document a:

Policy [√] **Procedure** [ ] **Protocol** [ ] **Guideline** [ ]

Insert Service Name(s), Directorate and applicable Location(s):
All staff within the HSE and services funded by the HSE

Title of Policies, Procedures, Protocols and Guidelines (PPPG) Development Group:	This policy was revised and updated by the National Open Disclosure Lead in the HSE in consultation with HSE Services, patient representatives and informed by comment by the State Claims Agency.
Reference Number:	**NATOD-POL-001**
Version Number:	2 (*This policy replaces the HSE Open Disclosure Policy 2013 (Reference: October 2013 | QPSD-D-062-1)
Publication Date:	12/06/2019
Date for revision:	12/06/2021
Electronic Location:	www.hse.ie/opendisclosurepolicy

Version	Date Approved	List section numbers changed	Author
2	**Approved by HSE Directorate Team** **6th March 2019**	All sections have been revised and updated in line with (i) the commencement of Part 4 of the Civil Liability Amendment Act 2017 and (ii) the recommendations in the "Scoping Enquiry into the Cervical Check Screening Programme Report" 2018.	HSE National Open Disclosure Office. Ms Angela Tysall Ms Karen Reynolds Ms Kelly McDyer

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Addendum

Please note that this is an interim revision of the HSE Open Disclosure Policy. This policy replaces the HSE Open Disclosure Policy dated 8th October 2013. This policy will require further review following:

(i) the development and publication of operational guidance for clinical audit of interval cancers in screening services by the Expert Working Group of the **Clinical Audit of Interval Cancer in the Screening Programmes**. This guidance will set out the principles and processes for how audit and individual case review should be undertaken following a diagnosis of interval cancer in the screened population

and

(ii) the commencement of provisions for mandatory open disclosure in the forthcoming **Patient Safety Bill**

This policy remains valid until such further review as outlined above.

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Part A

1. Introduction

1.1 The majority of services provided by health and social care organisations are safe and result in good outcomes, both for those receiving and for those providing these services. Healthcare is complex and, sometimes despite our best efforts, things can go wrong and patients may experience harm as a result. When things go wrong it may be due to a combination of factors including the vulnerability of those receiving care, the fallibility of those providing care and the dynamic and complex nature of the health care environment.

This policy applies to patient safety incidents and reflects the primacy of the right of patients to have full knowledge about their healthcare as and when they so wish and to be informed about any failings in that care process, however and whenever they may arise.

The ethos of this policy is to ensure that the rights of all patients and staff involved in and/or affected by patient safety incidents are met and respected, that they are communicated with in an honest, open, timely, compassionate and empathic manner and that they are treated with dignity and respect.

Open disclosure is a core professional requirement which is anchored in professional ethics. Communicating effectively with persons affected in a compassionate, empathic and thoughtful manner, especially when providing information about a patient safety incident, is a crucial part of the therapeutic relationship and if done well can mitigate anxiety and enhance trust in the staff, the organisation and the health care system.

1.2 What is a Patient Safety Incident?

A patient safety incident, in relation to the provision of a health service to a patient by a health services provider, means

"an incident which occurs during the course of the provision of a health service" which:

(a) has caused an unintended or unanticipated injury, or harm, to the patient

(b) did not result in actual injury or harm to the patient but was one which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm
or
(c) unanticipated or unintended injury or harm to the patient was prevented, either by "timely intervention or by chance", but the incident was one which the health services provider has reasonable grounds for believing could have resulted in injury or harm, if not prevented. (Civil Liability Amendment Act 2017)

Therefore a patient safety incident includes harm events, no harm events and near miss events.

1.3 What is Open Disclosure?

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 and the steps being taken by the health services provider to try to prevent a recurrence of the incident. (HSE 2019)

A Relevant Person, in relation to a patient, means a person who is (a) a parent, guardian, son or daughter, a spouse, or a civil partner of the patient, (b) who is cohabiting with the patient or (c) whom the patient has nominated in writing to the health services provider as a person to whom clinical information in relation to the patient may be disclosed. (Civil Liability Amendment Act 2017)

Open disclosure of a patient safety incident involves:

(a) a process of open, honest, transparent and timely communication with patients and/or their relevant person following a patient safety incident
(b) an acknowledgement of what has happened and of the impact of the patient safety incident on the patient – impact includes physical, psychological, financial and/or social
(c) a factual explanation in relation to what has happened and how/why it happened
(d) listening to and hearing the patient's story i.e. their understanding of what has happened and their description of the impact of the patient safety incident
(e) demonstrating empathy, kindness and compassion towards all those involved in and/or affected by the patient safety incident that has occurred to include the patient, their relevant person(s) and staff

(f) an apology/expression of regret (as appropriate to the situation) – this must be sincere and personal to the patient and/or their relevant person and to the given situation
(g) shared decision making in relation to on-going care and treatment and the management of the patient safety incident that has occurred
(h) affording the patient and/or their relevant person the opportunity to ask questions and responding honestly and factually to any questions/concerns arising
(i) the provision of immediate and on-going support for the patient and/or their relevant person, as appropriate
(j) the provision of immediate and on-going support for staff involved in and/or affected by the patient safety incident, as appropriate
(k) reassuring the patient and/or their relevant person in relation to any learning that has occurred as a result of the patient safety incident and
(l) providing information on the steps being taken or planned by the health services provider to try to prevent a recurrence of the incident.

1.4 The Principles of Open Disclosure

There are ten principles that underpin the Open Disclosure Process as outlined below (*__Note: see Appendix B__ for detailed information on these principles).

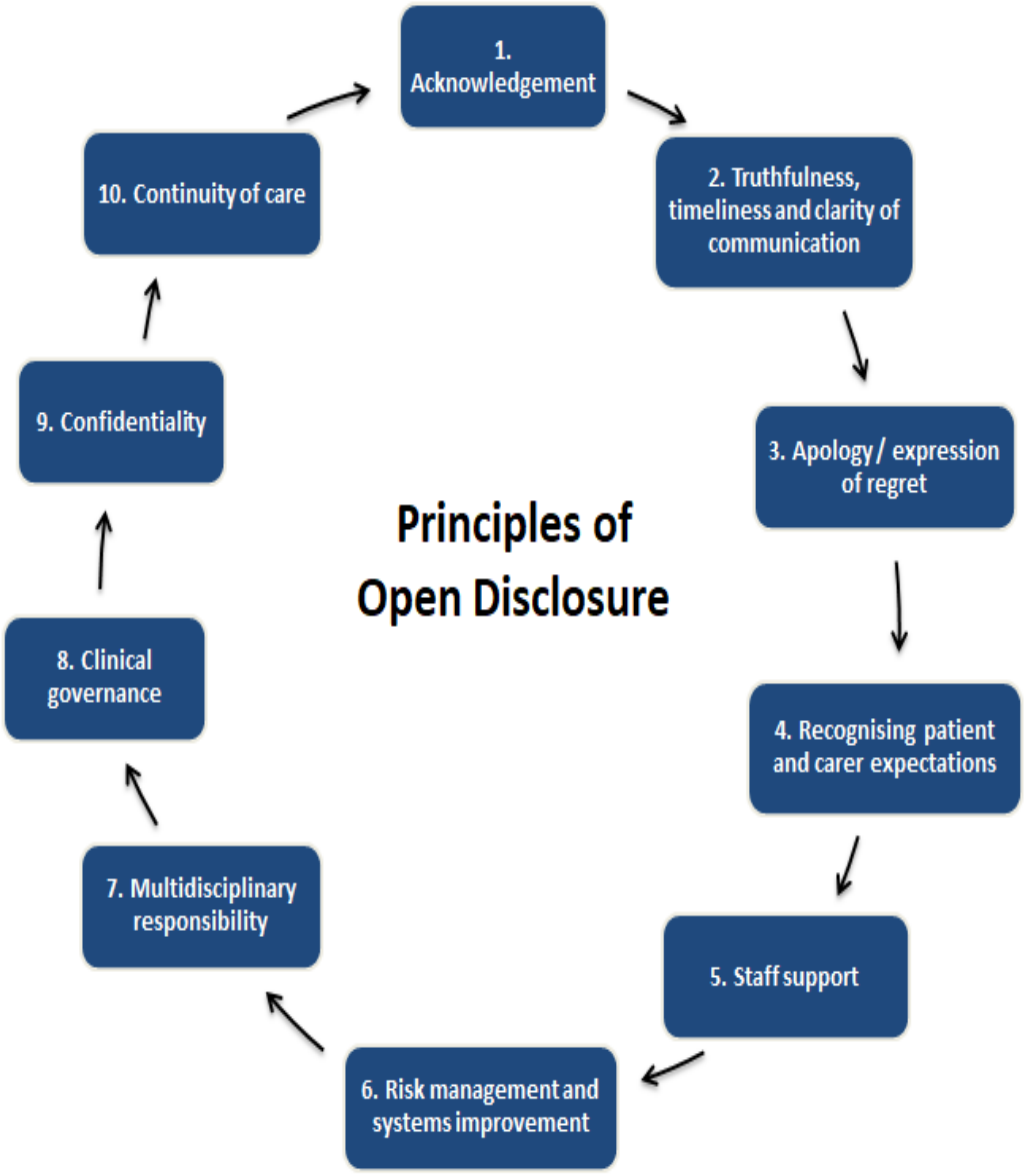


Figure 1: Ten Principles of Open Disclosure

1.5 How must Open Disclosure be managed?

Open Disclosure must be managed using the principles and process as set out in this policy document.

In addition to the principles and process set out in this document, the Civil Liability (Amendment) Act, 2017, sets out some additional steps which provide certain statutory protections to such Open Disclosure. This is referred to in this policy as "CLA Open Disclosure". It should be emphasised that there is currently no mandatory requirement to make Open Disclosure in accordance with the Civil Liability (Amendment) Act, 2017. CLA Open Disclosure set out in legislation is voluntary and provides certain protections in respect of how information and apologies provided to the patient can subsequently be used. If the health services provider wishes to avail of the statutory protections when making Open Disclosure, there are certain additional requirements that staff must comply with. The statutory protections do not apply to any disclosures made to patients (and/or relevant persons), unless they are made completely and entirely in line with the steps set out under legislation. The procedure for managing CLA Open Disclosure is available here

When open disclosure is made, it must always be managed in a manner which is compassionate, caring and empathic for all those involved in and/or affected by patient safety incidents.

1.6 Process of Open Disclosure

Where a patient safety incident occurs, the health services provider must make an open disclosure of the incident to the patient and/or, where appropriate, to their relevant person.

Before embarking on the open disclosure process, the health services provider should consider whether they wish to avail of the statutory protections set out under the Civil Liability (Amendment) Act 2017 ("CLA Open Disclosure"). If so, the detailed process to be followed is available here

If CLA Open Disclosure is not being invoked, the format of open disclosure initially may vary depending on the circumstances and may not always involve a formal open disclosure meeting. For example, if complications arose during the course of an operation, this may be disclosed to the patient when they are first reviewed by the Consultant following the procedure rather than at a formal meeting. In this example, there may of course be a formal meeting held subsequently when further information is known.

1.7 Levels of Open Disclosure

The level of response required will be defined by the degree of harm the patient has experienced, the level of additional interventions/treatments required as a result of this harm and/or the expectations of the patient or their appropriate person.

This response may vary from one open disclosure meeting to a number of meetings.

A **low level response** is usually initiated for patient safety incidents where there has been no harm to the patient or the harm to the patient is minimal – this level of response may involve just one meeting with the patient (i.e. Category 3 incidents as per the HSE Risk Impact Table - see Appendix C)**.**

A **high level response** involves the full open disclosure process and will be initiated for patient safety incidents where the patient has suffered a moderate or higher level of harm (i.e. Category 1 and Category 2 Incidents as per HSE Risk Impact Table – see Appendix C). This level of response may involve an initial open disclosure meeting with the patient and/or relevant person to acknowledge that a patient safety incident has occurred followed by a further meeting(s) to update the patient and/or relevant person as additional information becomes available.

Occasionally patients may expect or request a high level response to a low level event.

1.8 Communicating risks to patients

It is important that complications, risks and side effects associated with medical conditions, care and treatment are communicated to patients in a timely manner that is open and which they can fully understand. Such communication must also explore benefits, the views of the patient and their options and be consistent with HSE values.

Consent must be obtained from the patient before starting any treatment or investigation, providing personal or social care or involving a patient in teaching and research.

Refer to the HSE National Consent Policy available here

2. Policy Statement

It is the policy of the HSE that patients are communicated with in an open, honest, transparent and empathic manner following patient safety incidents, that they are provided with a sincere and meaningful apology when they are harmed as a result of a patient safety incident and that this communication process is initiated in a timely manner (ideally within 24 – 48 hours of the incident occurring or becoming known to the health services provider).

This policy is aligned with the HSE core values of care, compassion, trust and learning and with the principles upon which the HSE Incident Management Framework 2018 are based to ensure that this policy:

(i) is person centred care,
(ii) is fair and just,
(iii) promotes openness and transparency,
(iv) is responsive and
(v) is focused on learning and improvement.

3: Policy Requirements

3.1 Open Communication: Patients must be communicated with in an open, honest and transparent manner on an on-going basis in relation to all aspects of their care and treatment. Patients have the right to have full knowledge about their healthcare and, in particular, have a right to be informed when things go wrong, for whatever reason, during their health care journey.

3.2 Presumption of Capacity: Staff must work on the presumption that every adult patient has the capacity to make decisions about their care. A person whose decision-making capacity is in question is entitled to open disclosure on an equal basis with others and to be provided with any necessary supports to facilitate their involvement in the open disclosure process.

3.3 Provision of appropriate medical care and treatment: When something goes wrong the first response must be to the patient directly affected. It is important to focus first and foremost on the physical needs of the patient through the provision of appropriate medical treatment or other care to manage any harm that has occurred, relieve suffering and minimise the potential for further harm to occur.

Patients and/or their relevant person(s) involved in/affected by the patient safety incident must be treated with care, compassion and empathy and in a manner that is respectful and dignified.

3.4 Events that trigger open disclosure

Open disclosure must be regarded as a normal part of an episode of care and a critical element of continuous effective communication with patients.

Table 1: Events that trigger Open Disclosure

Type of Event	Disclose Yes/No
Harm event	Always disclose
Suspected harm event (harm is suspected but not confirmed)	Always disclose
No Harm event*	Generally disclose – It is important to be sure that harm has not occurred as a result of an incident and the best way to ensure this is to discuss the incident with the patient. This approach is recommended for most no-harm events.
Near Miss event*	Near Miss events generally do not require open disclosure but must be assessed on a case by case basis, depending on the potential impact the event could have had on the patient. If, after consideration of the near miss event, it is determined that (i) there is a risk of/potential for future harm i.e. there is potential for the "near miss" event to become a "harm" event in the future and/or (ii) that informing the patient would assist in the prevention of future harm this must be discussed with the patient.

***Note:** It is acknowledged that the communication of all near miss and no-harm incidents to patients is not practicable. The following questions will assist staff when determining a decision in relation to communicating "no-harm events" or "near miss" events:

- Will the distress or psychological harm of disclosing the information outweigh the benefit that could feasibly be achieved by disclosure?
- Is there potential for the "no harm" event or "near miss" event to become a "harm" event in the future?
- Will disclosure reduce the risk of future harm events?
- Will disclosure maintain the patient's/relevant person's trust in the service?

It is important that no harm events and near miss events are reported and monitored by the health services provider and that actions are taken to mitigate any risks identified.

3.5 Timing of Open Disclosure

When something goes wrong the open disclosure process must be initiated as soon as possible and as is practicable (ideally within 24 - 48 hours after the incident occurs or becomes known to the health services provider or as soon as the patient is available both physically and emotionally to take part in the discussion and, if deemed necessary, to have a support person present).

3.6 Assessing the Level of Response required to the Patient Safety Incident

The member of staff who detected the patient safety incident will assess the incident, in consultation with the principal healthcare practitioner or manager, as appropriate, and determine the level of response required. See section 1.7 above.

The member of staff, in consultation with the principal healthcare practitioner and/or health services provider, should also consider whether they wish to avail of the statutory protections which are available under CLA Open Disclosure.

3.7 Initiating a Low Level response:

The member of staff involved in the incident, with the support of a manager or colleague, will (i) meet with the patient and/or their relevant person, (ii) acknowledge what happened and the impact on the patient (if any) and (iii) provide an explanation, a meaningful apology and reassurance in relation to on-going care and treatment. This conversation may involve one meeting with the patient or, in the event that the patient has been discharged or has indicated a preference, he/she can be contacted by telephone or similar method of communication. The information provided, apology and any agreed actions must be documented in the patient's healthcare record. The need for a further meeting will be assessed based on the outcome of this first meeting.

3.8 Initiating a High Level response:

Open disclosure will be undertaken ideally in a face-to-face meeting with the patient and/or their relevant person. Open disclosure will be led by the principal health practitioner involved in the care of the patient or a health practitioner deemed appropriate by the health services provider. If it is not practicable for the patient to attend a meeting, the patient can be contacted by telephone or similar method of communication.

3.9 Preparing for an Open Disclosure Meeting

Health services providers must adequately prepare for an open disclosure meeting by giving due consideration to:

(a) the nature of the patient safety incident and the level of open disclosure required
(b) establishing the facts available to the health services provider at the time of the open disclosure meeting
(c) the need to consult with relevant stakeholders prior to the open disclosure meeting
(d) who the open disclosure should be made to (i.e. the patient and/or their appropriate person)
(e) who should make the open disclosure i.e. establishing the open disclosure team
(f) determining if an apology is required and the wording of such an apology
(g) the provision of support to the patient and/or relevant person to assist them in preparing for and attending an open disclosure meeting e.g. advocacy support, patient information leaflet, appointment of a designated person, providing information on how the meeting will be conducted
(h) whether the statutory protections available under CLA Open Disclosure are being sought.

3.10 Appointment of the Designated Person

Patients who have suffered harm will likely need emotional and psychological support and this must arrive seamlessly in the immediate aftermath of the patient safety incident and on an on-going basis thereafter for as long as is required. The early assignment of a named designated person by the health services provider is necessary to maintain personal contact between the patient/their relevant person and the health services provider and to ensure that the patient/their relevant person do not feel isolated and that their support and communication needs in respect of the plans for the management of the incident (including review) are identified, communicated and addressed. The designated person will have the necessary skills and experience required to fulfil their role. The name of the designated person must be recorded in the incident management/open disclosure record and a direct line telephone number provided to the patient/relevant person and staff members involved.

3.11 Information to be provided at Open Disclosure Meeting

The patient must be informed of all the facts available to the health services provider at the time of the open disclosure meeting in relation to the patient safety incident. It is not necessary to know all of the facts

pertaining to the patient safety incident to commence the communication process with the patient and in those circumstances, additional information can be provided to the patient when it becomes available.

Table 2 sets out the information to be provided at the Open Disclosure meeting.

Table 2: The Information to be provided at an Open Disclosure Meeting

- The names and roles of staff present at the open disclosure meeting.
- A description of the patient safety incident – an acknowledgement of what happened, when it happened and when/how the patient safety incident came to the attention of the health services provider.
- The facts available at the time of the open disclosure meeting in relation to how/why the patient safety incident occurred and any known event or factor which lead or contributed to it.
- Where all the facts are not available a description of the actions being taken and the timeframe expected by the health services provider to establish further information.
- The impact of the patient safety incident on the patient and any known or likely consequences for the patient going forward as a result.
- A sincere and meaningful apology (see section 3.12).
- Factual responses to questions/clarifications sought by the patient/their relevant person.
- The actions/measures taken or planned by the health services provider to manage the incident.
- The learning identified and the actions taken or planned by the health services provider to try to prevent a recurrence of the incident.
- Agreed next steps to include the planned communication process with the patient and/or their relevant person.
- The details of the support services available to the patient and/or their relevant person.
- The name and contact details for the designated person whom the patient/relevant person can contact directly should they require further information/clarification of any information provided (see section 3.10).

3.12 Apology

When a failure or error in the delivery of care/treatment is identified the patient and/or relevant person must be provided with a sincere and meaningful apology in a timely manner which is personal to the patient and to the given situation. When things go wrong during a patient's health care journey, for whatever reason, a genuine expression of regret delivered in a manner which is empathic is always appropriate.

3.13 Providing Additional Information

All additional relevant information obtained subsequent to the first open disclosure discussion, including the findings and recommendations of any reviews undertaken by the health services provider as a result of the patient safety incident, must also be provided to the patient and/or their relevant person, as appropriate, in a timely and supportive manner.

Open disclosure will be undertaken ideally in a face-to-face meeting and led by the principal health practitioner involved in the care of the patient or a health practitioner deemed appropriate by the health services provider. If it is not practicable for the patient to attend a meeting, the patient can be contacted by telephone or similar method of communication. A record of the details of the additional information provided must be recorded in the open disclosure record.

3.14 Clarification of Information provided

All requests received by the health services provider in relation to the clarification of information provided during or after an open disclosure meeting must be referred to the designated person and responded to factually and in a timely manner.

A record of the information provided in relation to a request for clarification must be documented in the open disclosure record.

3.15 Deferral of Open Disclosure

3.15.1 Only in **rare** and **exceptional** circumstances must open disclosure of a patient safety incident be deferred and the decision to defer must always be based on the safety and wellbeing of the patient.

3.15.2 When a decision is made to defer open disclosure of a patient safety incident to the patient for the reasons indicated in section 3.15.3 below consideration must be given at this time to

initiating open disclosure with the patient's relevant person taking into consideration matters relating to patient confidentiality and data protection as outlined in section 3.16 below.

3.15.3 Deferral of open disclosure may be a consideration in the following circumstances:

• The patient and/or their relevant person cannot be contacted. In this situation the health services provider must document in the healthcare record the reasonable steps taken to try to establish contact with the patient and/or their relevant person.

• The patient refuses open disclosure. In this situation the patient must be made aware of the benefits of open disclosure. The patient's decision must be respected and documented in the healthcare record. The patient must be advised of their right to revisit this decision at a later stage and the name and contact details of a contact person provided should they wish to do so. Open disclosure to the patient's relevant person will be offered to the patient and initiated only if the patient consents to this.

• The patient is extremely ill and is unable to participate in an open disclosure meeting. Disclosure to the patient's relevant person must be considered in these circumstances (**see section 3.16** below).

• The clinician has concerns that initiating open disclosure with the patient may put the patient at risk of causing harm to themselves or to others (**see section 3.15.4 below).** Disclosure to the patient's relevant person must be considered in these circumstances **(see section 3.16 below).**

3.15.4 When a clinician has concerns that open disclosure may put the patient at risk of causing harm to themselves or to others, and disclosure to the patient's relevant person is not possible, the decision in relation to deferring open disclosure must be:

(a) the consensus of more than one clinician
(b) agreed by the most senior clinician in the organisation/directorate e.g. Clinical Director/GP
(c) documented in the patient's healthcare record and the rationale for this decision provided and documented
(d) communicated to and agreed by the local accountable officer
(e) revisited at a later stage when the patient's condition has improved.

The planned date to revisit this decision must be documented in the patient's healthcare record - this date will be dependent on and

appropriate to the given situation and should not exceed a period of four weeks following the date on which the decision to defer disclosure was made. The service must have processes in place to ensure that follow up occurs.

3.15.5 In all circumstances where a patient has experienced serious harm (i.e. A Category 1 incident), and a decision is made not to disclose for the reasons as outlined in section 3.15.4 above, this decision must, in addition to 3.15.4 above, be discussed with and agreed by the Senior Accountable Officer and must have input and agreement from a minimum of two independent patient representatives/advocates. This decision must be revisited at a later stage when the patient's condition has improved. The planned date to revisit this decision must be documented in the patient's healthcare record - this date will be dependent on and appropriate to the given situation and should not exceed a period of four weeks following the date on which the decision to defer disclosure was made. The service must have processes in place to ensure that follow up occurs.

3.15.6 Any discussion regarding the deferral of disclosure with independent patient representatives/advocates referred to at 3.15.5 above must be carried out in accordance with GDPR and the principles of patient confidentiality. Therefore the patient must be anonymised i.e. personal data must not be provided to the patient representative/advocate that could identify the patient e.g. name, address, medical records number, race. In addition, only data relevant to the patient safety incident and disclosure may be discussed.

3.15.7 Services must have in place clearly defined reporting/escalation processes to the Senior Accountable Officer when a decision is made not to engage in open disclosure of a serious harm event.

3.16 Open Disclosure to the Relevant Person

3.16.1 Disclosure of information to an adult patient's relevant person must only be undertaken with the consent of the patient.

3.16.2 When the patient is unable, for whatever reason (e.g. the patient is too ill), to provide consent the decision to disclose information to the relevant person must be made by the most responsible person (MRP) involved in the care of the patient i.e. the principal healthcare practitioner or an appropriate delegated person when the MRP is not available.

3.16.3 The decision by a health services provider to disclose to the patient's relevant person must take into consideration:
(a) the known will and preference or instruction provided by the patient in relation to the sharing of their information e.g. advance healthcare directive or information/instruction provided by the patient in their healthcare record.
(b) who the disclosure should be made to e.g. information provided by the patient in their healthcare record or in an advance healthcare directive i.e. establish if the person has appointed a designated healthcare representative,
(c) what information is deemed appropriate and justifiable for the health services provider to share i.e. the information provided to the relevant person must include only the necessary information relating to the patient safety incident. The patient must be informed at a later stage of any open disclosure made to the relevant person and the details of what was disclosed. This must be recorded in the patient's healthcare record.

3.16.4 When a patient dies:
When a patient dies following a patient safety incident communication with their relevant person must be initiated as soon as possible and is practicable in a manner that is open, honest, empathic and sensitive **(See sections 3.16.2 and 3.16.3 above).** Open channels of communication must be maintained and a designated person assigned to maintain personal contact between the relevant person and the health services provider and to provide information, care and support, as required. This includes providing information in relation to the Coroner's process and what to expect.
Communication with the relevant person following the death of a patient must take into consideration and be led by the grieving process of the relevant person(s).

3.17 Record Keeping

3.17.1 Documentation of open disclosure: The salient points discussed with patients and/or their relevant person during open disclosure meetings, including the details of (i) who was present at the open disclosure meeting, (ii) the information provided, (iii) the apology provided (iv) agreed care/treatment plan and actions, must be documented in the patient's healthcare record.

3.17.2 Open disclosure must be recorded on the National Incident Management System (NIMS) indicating if open disclosure has occurred and the date open disclosure occurred. If open disclosure has not occurred the reason must be provided.

3.17.3 The Civil Liability Act Prescribed Statements (forms) When open disclosure is managed under the provisions of the Civil Liability Act copies of all prescribed statements produced during the course of the open disclosure process must be stored separately to the health care record (e.g. open disclosure file/incident management file). These forms must be identified using the patient's unique identifier and an inventory of such records must be maintained on record and accessible by the health services provider.

3.17.4 Other documents: The minutes of formal open disclosure meetings, pre, during and post disclosure checklists, incident report forms and records of communication i.e. copies of written communication, details of telephone communication between the health services provider and the patient must be kept on record in a file separate to the health care record e.g. open disclosure file or incident management file.

3.18 Follow Up Care

3.18.1 Following a formal open disclosure meeting the patient and/or their relevant person, if appropriate, will be provided with a letter containing the information provided at the open disclosure meeting, the name and contact details of the designated person, the details of the apology provided and of any actions agreed.

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

- Did the patient and/or relevant person feel that they were treated with dignity and respect during the open disclosure meeting?
- Did the patient and/or their relevant person feel that they were listened to and heard during the open disclosure meeting?
- Did the patient and/or their relevant person receive an appropriate and meaningful apology?
- Did the patient and/or their relevant person receive answers to their questions?

- Does the patient and/or their relevant person have any further questions/clarifications which they require a response to?

3.19 Providing a Safe, Supportive Environment for Staff

The HSE will provide a safe, supportive and caring environment for staff involved in and/or affected by patient safety incidents:

3.19.1 The HSE will ensure an environment where staff are safe and supported in the identification and reporting of patient safety incidents and also during the open disclosure and review process following a patient safety incident.

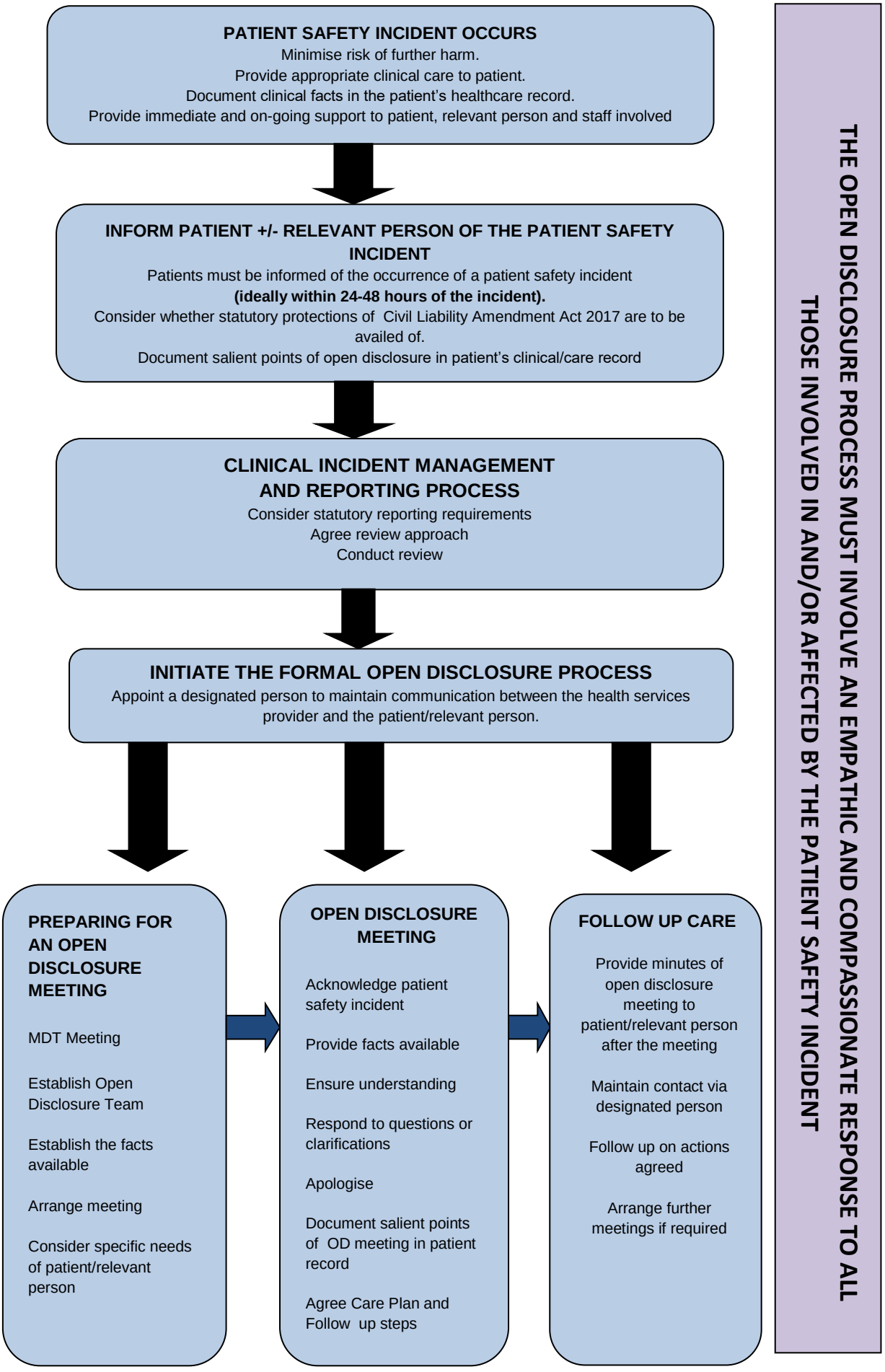
- The Act is available here
- This procedure is available here
- The prescribed statements (forms) are available here

3.19.2 The HSE will ensure that staff are informed of the legal protections available to them under the provisions of Part 4 of the Civil Liability (Amendment) Act 2017 and of the procedure that must be followed for staff to avail of these protections.
Part 4 of this Act makes provides certain protections regarding the information and apology provided during CLA Open Disclosure.
To avail of the protections available within Part 4 of the Act the open disclosure process must be undertaken in strict compliance with (i) the procedure as set out in Part Four of the Act and (ii) the Civil Liability (Open Disclosure) Prescribed Statement Regulations 2018 accompanying Part 4 of the Act.

3.19.3 Patient safety incidents may impact on the staff directly involved and other members of the team and wider organisation. It is important that the impact of patient safety incidents on staff is recognised and managed in a caring, supportive and compassionate manner. The HSE will provide services to support staff who are involved in and/or affected by patient safety incidents.

3.19.4 The HSE will provide and facilitate on-going training on open disclosure for all health and social care staff. All senior managers and clinicians must attend skills training on the management of the open disclosure process. The level of training provided to staff will be appropriate to the grade and role of the staff member. Training records must be maintained at service level and all training must be recorded on the HSE national open disclosure training database.

3.20 Summary Flowchart – Open Disclosure Process



3.21 This policy must be used in conjunction with:

- The HSE/SCA guidance "Open Disclosure National Guidelines: Communicating with patients and their families following patient safety incidents in healthcare" available here
- The HSE Incident Management Framework 2018 available here
- The Civil Liability (Amendment) Act 2017 available here
- The Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018 available here
- The HSE Procedure for Managing Open Disclosure under the provisions of Part 4 of the Civil Liability (Amendment) Act 2017 and The Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018 available here
- The Civil Liability Act Forms available here

Part B

4. Purpose

The purpose of this policy is to set out the minimum requirements for the management of open disclosure following patient safety incidents to fulfil professional, ethical, regulatory and legal obligations.

5. Scope

This policy and the related Open Disclosure Guidelines are intended to cover all publicly funded health and social care services provided in Ireland including but not limited to:

- Hospital Groups
- Community Health Organisations
- National Ambulance Services
- National Services e.g. National Screening Services, National Transport Medicine Programme, Irish Blood Transfusion Service
- HSE Funded Agencies e.g. Section 38/39 agencies.

6. Objectives

The objectives of this policy are:

6.1 To ensure that open, honest and transparent communication with patients and their relevant person occurs following patient safety incidents using a standardised approach across all health and social care services.

6.2 To ensure that this communication is undertaken in a timely (ideally within 24 – 48 hours), empathic, compassionate and informed manner.

6.3 To ensure that patients are provided with a timely, sincere and meaningful apology when they experience harm as a result of a failure in the delivery of care or when an error occurs.

6.4 To ensure that patients and their relevant person are provided with sufficient support in the immediate aftermath of a patient safety incident and thereafter, as required.

6.5 To promote a culture of openness and transparency across all health and social care services – a culture that promotes and facilitates efficient and effective reporting of patient safety incidents, learning and quality improvement.

6.6 To ensure that staff involved in and/or affected by patient safety incidents are identified, monitored and provided with adequate care and

support in the immediate aftermath of the patient safety incident and thereafter, as required, including the provision of support throughout the open disclosure and incident review process.

6.7 To support and enable staff and services to engage in effective and meaningful open disclosure.

6.8 To ensure that all health and social care services have the required governance processes in place to include accountability arrangements and to enable effective and meaningful open disclosure.

7. Outcomes

The expected outcomes of this policy are as follows:

7.1 The establishment of a culture which promotes and supports a standardised approach to open communication between patients, their relevant person, health and social care services and staff following patient safety incidents.

7.2 Communication occurs in a timely, informed, compassionate and empathic manner.

7.3 Patients, their relevant persons and health and social care staff involved in and/or affected by patient safety incidents are provided with immediate and on-going support, as required and relevant to their individual needs, following patient safety incidents.

7.4 All health and social care services within the scope of this policy have a consistent process for the management of open disclosure.

7.5 All health and social care services within the scope of this policy meet their professional, ethical, regulatory and legal requirements in relation to the management of open disclosure.

7.6 All health and social care services have clear governance arrangements in place in relation to the implementation of this policy.

8. Supporting Evidence

8.1 Legislation

- The Civil Liability (Amendment) Act 2017
- The Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018
- The Assisted Decision-Making (Capacity) Act 2015. In this regard, it is noted that many of the provisions of this Act have not yet commenced.

8.2 Regulation

- The National Standards for Safer Better Healthcare 2012: Standard 3.5 states:

  "Service providers fully and openly inform and support service users as soon as possible after an adverse event affecting them has occurred, or becomes known and continue to provide information and support as needed"

- The Medical Council Guide to The Professional Conduct and Ethics for Registered Medical Practitioners 2016 states:

  "Patients and their families, where appropriate, are entitled to honest, open and prompt communication with them about adverse events that may have caused them harm"

- The Nursing and Midwifery Board of Ireland: Code of Professional Conduct and Ethics for Registered Nurses Midwives December 2014)

  "Safe quality practice is promoted by nurses and midwives actively participating in incident reporting, adverse events reviews and open disclosure"

- CORU Codes of Practice for Allied Healthcare Professionals

- Pharmaceutical Society of Ireland Code of Conduct for Pharmacists

8.3 Related HSE PPPGs and National Standards

- The HSE and State Claims Agency National Guidelines: "*Open Disclosure: Communicating with Patients and their Families following adverse events in Healthcare".* (Document reference number QPSD-GL-063-1)

Note: This policy must be used in conjunction with these guidelines.

- The HSE Incident Management Framework 2018.
- Your Service Your Say: The Management of Patient Feedback for Comments, Compliments and Complaints. HSE Policy 2017.
- National Standards for Safer Better Healthcare, 2012.
- National Standards for Safer Better Maternity Services 2016.
- National Standards for the Conduct of Reviews of Patient Safety Incidents 2017.
- National Standards for Residential Services for Children and Adults with Disabilities 2013.
- National Standards for Residential Care Settings for Older People in Ireland 2016.
- The National Healthcare Charter 2012: "You and Your Health Service".
- The HSE Policy for the Prevention and Management of Critical Incident Stress 2012.
- The HSE National Consent Policy 2017
- HSE Standards and Recommended Practices for Healthcare Records Management 2011.

9. Governance

Open disclosure is an integral component of the incident management process. Primary responsibility and accountability for the effective management of patient safety incidents, including the open disclosure process, remains at organisational level where the patient safety incident occurs. Effective governance arrangements are required to support timely and effective open disclosure. Central to this is an explicit management commitment to safety that promotes a culture of openness, trust and learning between persons who may be affected by patient safety incidents and those delivering and managing the services within which the patient safety incident occurs.

Governance arrangements must support the effective management of open disclosure. The accountability arrangements for open disclosure must be clearly defined. Governance arrangements for open disclosure should clearly set out the roles, accountabilities and responsibilities at all levels of the service. This should include details of delegated accountability, responsibility or authority. An organisation chart must be available setting out these arrangements.

To underpin the effectiveness of these arrangements, explicit management commitment to the development of capacity and capability and the consistent use of NIMS for the management of data and information relating to open disclosure is required.

9.1 Roles and Responsibilities

9.1.1 HSE Corporate

The HSE National Open Disclosure Steering Committee has been established to strengthen corporate oversight, strategic leadership and accountability with the on-going implementation of the national open disclosure programme and policy.

The primary objective of the work of the steering committee is to build the capacity and capability of HSE staff and services to improve the implementation and practice of open disclosure for all patients, clients and service users. This will be delivered by working in collaboration with services and patient representatives.

The national open disclosure policy and programme is co-ordinated via the national open disclosure office and will reflect the strategic and policy direction established by the HSE leadership team and will be consistent with the policies and strategy of the HSE and Department of Health.

9.1.2 Managers

It is the role and duty of all health and social care managers at all levels in the organisation to:

- Comply with this policy.
- Ensure that all employees/services under their management, supervision and responsibility are aware of and comply with this policy and the related Open Disclosure Guidelines which accompany this policy.
- Ensure that their services have a clearly defined process in place for the management and recording of open disclosure.
- Ensure that all staff are clear as to their professional, ethical, regulatory and legal responsibilities and obligations in relation to open disclosure.
- Lead and oversee the implementation of the HSE Open Disclosure Policy at service level – the implementation plan must consider the specific requirements of the service and patients accessing that service and the relevant support(s) required.
- Ensure accountability and ownership for open disclosure at every level in the organisation.
- Facilitate role appropriate training for employees on this policy.
- Attend skills training on open disclosure.
- Monitor and audit compliance with this policy.
- Escalate incidences of non-compliance with this policy.
- Ensure that open disclosure is embedded in the service's governance programme/framework.

- Prepare an annual report on the implementation of open disclosure within the service.
- Provide reports on open disclosure to senior management staff in the HSE as required/requested.

9.1.3 All Staff

It is the role and duty of all staff to:

- read this policy and to understand their professional, ethical, regulatory and legal responsibilities/obligations in relation to open disclosure.
- comply with this policy.
- attend role appropriate training on this policy.
- report all patient safety incidents to facilitate timely open disclosure.
- participate in open disclosure discussions, as required.
- promote a culture of openness, honesty and transparency in the workplace.
- communicate with patients and their relevant person involved in and/or affected by patient safety incidents in a manner which is compassionate, caring, kind and empathic.
- comply with their professional codes of conduct and ethics as they relate to open disclosure.
- notify non-compliance of this policy to their line manager.

10.0 Monitoring, Audit and Evaluation

The Senior Accountable Officer is responsible for the monitoring of performance in relation to open disclosure, the monitoring of key performance indicators, verification of compliance with the policy, management of non-compliance with the policy and evaluating patient experience.

Services will be subject to compliance verification audits undertaken by the Quality Assurance and Verification Division.

The HSE will develop key performance indicators for open disclosure for inclusion in the HSE Service plan for 2020 and onwards.

The HSE will develop a compliance self-assessment tool for this policy.

The HSE has developed a patient experience questionnaire to support this policy and measuring the patient's experience of open disclosure – this will inform learning and improvement at local and national level.

Health service providers are required to record open disclosure on the National Incident Management System and can provide reports on this data from NIMS.

Suggested areas for services to monitor and audit are as follows:

- Compliance with open disclosure policy using a compliance self-assessment tool.
- Number of open disclosures occurring using NIMS or other data.
- Standard of documentation in relation to open disclosure.
- The patient experience of the open disclosure process.
- Staff experience of the open disclosure process.
- Number of staff attending open disclosure training with a breakdown of staff groups.

11.0 Revision

Revision of this document, in conjunction with the related HSE and SCA Open Disclosure Guidelines will be undertaken and co-ordinated via the National Open Disclosure Office (within the office of the Chief Clinical Officer) on a 2 yearly basis, or earlier in the event of changing best practices, changes to legislation or structures as appropriate.

Further revision of this policy will be undertaken to align it with the Patient Safety Act when commenced.

The review of the document and the guidelines will include feedback from healthcare staff and patients in relation to the effectiveness of the policy.

12.0 Implementation Plan

12.1. A communications plan has been developed in conjunction with the HSE Communications department. This plan includes the following:

- An update of the HSE open disclosure webpage content
- Upload of the revised policy and policy summary document to the HSE website
- A Managers toolkit which will be electronically available on the HSE website to include
  - Manager Briefing Note
  - Team Talks Document
  - Poster for Staff Noticeboard
  - PowerPoint Presentation Slide deck for managers to provide update on revised policy to staff
  - Summary document of the revised policy

- Broadcast email to go to system
- Intranet announcement
- Broadcasts to go out on Twitter and LinkedIn
- Letter sent from Chief Clinical Office to senior managers to notify them of the policy update and of their responsibility to ensure that this is brought to the attention of all managers and staff.

12.2 Open disclosure leads and trainers across the health and social care system will be updated on the changes to the policy and the national training programmes will be adjusted accordingly by the HSE National Open Disclosure Office.

12.3 National, regional and local QPS offices will assist in the implementation of this policy and the accompanying guideline.

12.4 The implementation plan at local/service level should provide for the following: (Refer to the HSE/SCA implementation proposal and organisational checklist to guide implementation at service level – these documents are available here

12.4.1 **Policy**: The service is operating an open disclosure policy which is in compliance with the national policy and which outlines clearly staff roles and responsibilities and internal processes for the management of open disclosure. There is an implementation plan in place. Open disclosure is integrated in other relevant policies, procedures, protocols and guidelines e.g. incident reporting, incident management, complaints management, look back reviews, assisted decision making.

12.4.2 **Leadership**: Clear expectations are set in relation to open disclosure and the assignment of responsibility for the implementation of the policy and guidelines i.e. named person(s). The implementation of the HSE Open Disclosure Policy is included in the organisation's annual service plan. The service has a designated open disclosure lead with clear reporting lines.

12.4.3 **Training**: Staff training requirements are identified and a training plan developed. Role specific training is provided and e-learning programmes accessed as available. All senior managers and medical staff must attend open disclosure skills training. Training statistics are maintained at service level and all open disclosure training is recorded on the national training database. Training will be made available for patient advocates/patient representatives and designated persons.

12.4.4 **Resources**: Identify the realistic resources required to implement the policy and guidelines. Utilise the additional open disclosure resources available for services, trainers and staff on the HSE website available here

12.4.5 **Measurement of compliance with the policy:**
Compliance with this policy is monitored and non-compliance is reviewed and managed appropriately. Reports will be generated annually on policy compliance and key performance indicators. Audit and evaluation mechanisms will be used to measure compliance.

12.4.6 **Support for patients, their relevant person and staff involved in/affected by patient safety incidents:**
The service will set out the supports which are available and make this information available to patients, their relevant person and staff. All services will have staff trained in peer support/critical incident stress management.

13. Policy Development and Consultation Process

This policy was revised and updated by the National Open Disclosure Office in consultation with HSE Services, Department of Health, patients and patient representatives (see Appendix D) and informed by comment by the State Claims Agency.

This policy has been informed by:

- Part 4 of the Civil Liability (Amendment) Act 2017.
- The Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018.
- The Assisted Decision-Making (Capacity) Act 2015.
- The HSE Incident Management Framework 2018.
- Learning and recommendations from the Scoping Inquiry into the Cervical Check Screening Programme by Dr Gabriel Scally published in September 2018.
- The learning from the 2 year open disclosure pilot programme in 2 hospitals in the Republic of Ireland (The Mater Misericordiae University Hospital, Dublin and Cork University Hospital, Cork City) which finished in October 2012.

The findings and recommendations of the independent evaluation of the 2 year pilot programme which was undertaken by Dr Jane Pillinger and which was published in 2016 available here.

- The findings and recommendations of the audits by the HSE Quality Assurance and Verification Division of compliance with the HSE Open Disclosure Policy 2013 undertaken in four early adopter acute hospital sites in Ireland in 2016.

- Learning from work undertaken already across the health care system in relation to the national implementation of the HSE Open Disclosure policy since it's launch in November 2013.

- Research of best practice in open disclosure in other countries that have had open disclosure standards in place for some time and in particular Australia, Canada, America and the UK.

- Learning from the Irish Hospice Foundation's programme on "Breaking Bad News".

- Learning from national and international reviews of patient safety incidents.

Appendix A Glossary of Terms

Term / Abbreviation	Definition
Adverse Event	An incident which resulted in harm that may or may not be the result of error. (HSE Incident Management Framework 2018)
Acknowledgement	An acceptance of the truth or existence of something.
Apology	An apology in relation to an open disclosure of a patient safety incident means an expression of sympathy or regret. (Civil Liability (Amendment) Act 2017) It is a genuine expression of being sorry for what has happened.
Category 1 Incident	**Category 1 Major/Extreme –** Clinical and non-clinical Incidents rated as major or extreme as per the HSE's Risk Impact Table.
Category 2 Incident	**Category 2 Moderate –** Clinical and non-clinical incidents rated as moderate as per the HSE's Risk Impact Table.
Category 3 Incident	**Category 3 Minor/Negligible –** Clinical and non-clinical incidents rated as Minor or Negligible as per the HSE's Risk Impact Table.
CLA Open Disclosure	Open disclosure is where a health services provider discloses, at an open disclosure meeting, to— (a) a patient that a patient safety incident has occurred in the course of the provision of a health service to him or her, (b) a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient concerned, or (c) a patient and a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient (Civil Liability Amendment Act 2017)
Designated Person	A person to liaise with the health services provider and the patient or relevant person (or both of them) in relation to the open disclosure of the patient safety incident. (Civil Liability (Amendment) Act 2017) **Note: This definition must not be conflated with the definition of the Designated Healthcare Representative in the ADM Act 2015**
Error	The failure of a planned action to be completed as intended or use of a wrong inappropriate or incorrect plan to achieve an aim. (HSE Incident Management Framework 2018)
GDPR	General Data Protection Regulation
Harm	Harm to a person: Impairment of structure or function of the body and or any detrimental effect arising from this, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological. The degree of harm relates to the severity and duration of harm and the treatment implications that result from a patient safety incident (As adapted from the World Health Organization's Conceptual Framework for the International Classification of Patient Safety, 2009.) Harm to a thing: Damage to a thing may include damage to facilities or systems, for example, environmental, financial, data protection breach etc.

	Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury. (HSE Incident Management Framework 2018)
Health Services Provider	(a) a person, other than a health practitioner, who provides one or more health services and for that purpose— (i) employs a health practitioner for the provision (whether for, or on behalf of, that person) by that practitioner, of a health service, (ii) enters into a contract for services with a health practitioner for the provision (whether for, or on behalf of, that person) by that health practitioner of a health service, (iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, that person, (iv) enters into an arrangement with a health practitioner— (I) for the provision by that health practitioner of a health service (whether for, or on behalf of, that person, or through or in connection with that person), (II) for the provision by that health practitioner of a health service on his or her own behalf (whether through or in connection with, or by or on behalf of, that person or otherwise), or (III) without prejudice to the generality of *clause (II)*, to provide that health practitioner with privileges commonly known as practising privileges (whether such privileges are to operate through or in connection with, or by or on behalf of, the person or otherwise), or (v) insofar as it relates to the carrying on of the business of providing a health service— (I) employs one or more persons, (II) enters into a contract for services with one or more persons, (III) enters into an agency contract for the assignment of an agency worker, or (IV) enters into an arrangement with one or more persons, in respect of the carrying on of that business, or (b) a health practitioner who, or a partnership which, provides a health service and does not provide that health service for, or on behalf of, or through or in connection with (whether by reason of employment or otherwise), a person referred to in paragraph (a) and includes a health practitioner who, or a partnership which— (i) employs another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner or the partnership) by that other health practitioner of a health service, (ii) enters into a contract for services with another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner or the partnership) by that other health practitioner, of a health service, (iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, the first-mentioned health practitioner or the partnership, or (iv) insofar as it relates to the carrying on of the business of providing a health service— (I) employs one or more persons, (II) enters into a contract for services with one or more persons, (III) enters into an agency contract for the assignment of an agency worker, or (IV) enters into an arrangement with one or more persons,

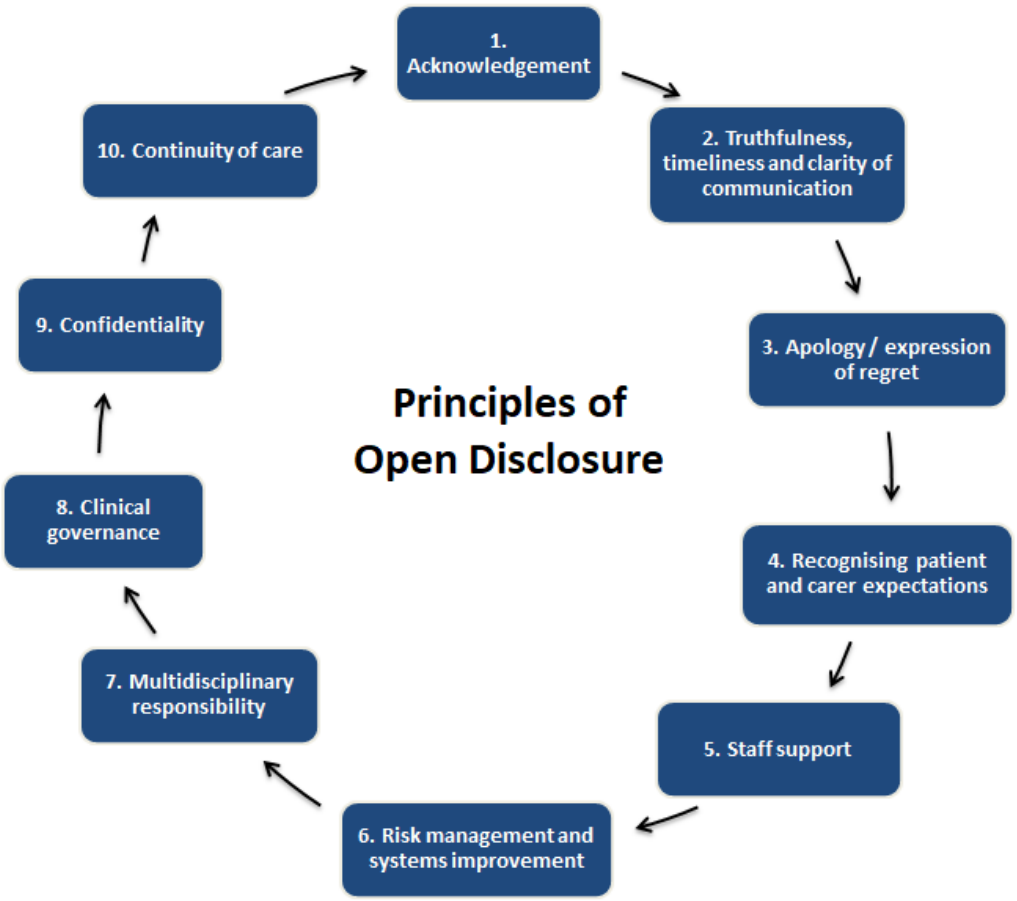
	in respect of the carrying on of that business; (Civil Liability Amendment Act 2017)
HSE	Health Service Executive
Incident	An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include patient safety incidents which result in harm; near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or patient complaints which are associated with harm. Incidents can be clinical or non-clinical and include Incidents associated with harm to: - patients, patients, staff and visitors - the attainment of HSE objectives - ICT systems - data security e.g. data protection breaches - the environment (HSE Incident Management Framework 2018)
Just Culture	An environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action. (HSE Incident Management Framework 2018)
Local Accountable Officer	Person in charge of the service/directorate in which the patient safety incident occurred e.g. Service manager, ADON, DON, Clinical Lead. This person's accountability will normally be to the Senior Accountable Officer
Moderate Harm	- Significant injury requiring medical treatment e.g. Fracture and/or counselling. - Agency reportable, e.g. HSA, Gardaí (violent and aggressive acts). - >3 Days absence - 3-8 Days extended hospital stay - Impaired psychosocial functioning greater than one month less than six months (As per HSE Risk Impact Table)
Near Miss Event	An incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a patient during the provision of a health service to that patient. (National Standards for the Conduct of Reviews of Patient Safety Incidents)
National Incident Management System (NIMS)	The National Incident Management System, hosted by the clinical indemnity scheme, is a highly secure web-based database which facilitates direct reporting of adverse events by state authorities and healthcare enterprises. It is the single designated system for reporting of all incidents in the public healthcare system i.e. for HSE and HSE funded services. (HSE Incident Management Framework 2018)
No Harm Event	An incident occurs which reaches the patient but results in no injury to the patient. Harm is avoided by chance or because of mitigating circumstances. (HSE Incident Management Framework 2018)
Open Disclosure HSE 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 and the steps being taken by the health services provider to try to prevent a recurrence of the incident. (HSE 2019)
Patient	"Patient" means, in relation to a health services provider, a person to whom a health service is, or has been, provided; (Civil Liability Amendment Act 2017) **Note:** Please note that the term "patient" used throughout this policy includes **patients, service users and clients** of the HSE and of services funded by the HSE.
Patient Safety Incident	A patient safety incident, in relation to the provision of a health service to a patient by a health services provider, means an incident which occurs during the course of the provision of a health service" which: (i)has caused an unintended or unanticipated injury, or harm, to the patient, (ii)did not result in actual injury or harm to the patient but was one which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm, or: (iii) unanticipated or unintended injury or harm to the patient was prevented, either by "timely intervention or by chance", but the incident was one which the health services provider has reasonable grounds for believing could have resulted in injury or harm, if not prevented. (Civil Liability (Amendment) Act 2017)
Principal Health Practitioner	A principal health practitioner in relation to a patient, means a health practitioner who has the principal clinical responsibility for the clinical care and treatment of the patient. (Civil Liability (Amendment) Act 2017)
Relevant Person	"Relevant person", in relation to a patient, means a person— (a) who is— (i) a parent, guardian, son or daughter, (ii) a spouse, or (iii) a civil partner of the patient, (b) who is cohabiting with the patient or (c) whom the patient has nominated in writing to the health services provider as a person to whom clinical information in relation to the patient may be disclosed (Civil Liability (Amendment) Act 2017) **Note: This definition must not be conflated with the definition of "relevant person" in the Assisted Decision-Making (Capacity) Act 2015**
Senior Accountable Officer	In the context of the management of an incident, the Senior Accountable Officer is the person who has ultimate accountability and responsibility for the services within the area where the incident occurred. (HSE Incident Management Framework 2018)
Serious Harm	Harm that result in a rating of major or extreme as per the HSE's Risk Impact Table. (HSE Incident Management Framework 2018)
SCA	State Claims Agency

Service	Please note that the term "service" as used throughout these guidelines refers to all HSE health and social care services including services funded by the HSE. (HSE Incident Management Framework 2018)
Staff	(a) a person who: (i) has entered into, or works under (or where the employment has ceased, had entered into or worked under), a contract of employment, with the health services provider, or (ii) is (or was) placed for the purpose of vocational training with the health services provider, and (b) a fixed-term employee of the health services provider, and a reference to an employee, in relation to a health services provider, shall be construed as a reference to an employee employed by that health services provider. (In line with the definition of Employee as defined in the Civil Liability (Amendment) Act 2017)
Suspected Harm Event	A suspected harm event is an incident which is an event or circumstance which could have or did lead to unintended and/or unnecessary harm (WHO)

Appendix B
The 10 Principles of Open Disclosure

There are ten principles designed to assist health and social care services to create and embed a culture of open disclosure. These have been adopted from the UK National Patient Safety Agency. The disclosure process must encompass these principles.



An Overview of the 10 Principles of Open Disclosure

1. Acknowledgement

- Acknowledge what has happened and the impact on the patient/relevant person
- Consider physical, emotional, social and financial impact.

2. Truthfulness, Timeliness and Clarity of Communication:

Truthfulness

- Stick to the facts of the patient safety incident.
- Remember that you won't always have and don't need to know all the answers initially. If you don't know the answer tell the patient that you don't know.

- Provide reassurance regarding the review of the incident and when further information may be available.
- Do not speculate.
- Agree next steps and future communications.

Timeliness

- Timing is of the essence – open disclosure must occur as soon as possible and is practicable (ideally within 24 – 48 hours of the incident occurring or becoming known to the health services provider).
- Timing may be influenced by the condition of the patient, availability of the patient, agreement of the patient, availability of the relevant person, availability of the most responsible person caring for the patient etc.

Clarity of Communication

- Avoid medical jargon.
- Use simple language which the patient can understand.
- Ensure understanding by asking the patient to feedback to you their understanding of what they have been told and by providing any clarifications sought.
- Encourage questions and provide factual answers.
- Use an interpreter, if required.

3. The Apology

- Provide an apology/expression of regret for what has happened and for how it has impacted on the patient/relevant person.
- When it is clear, following a review of the patient safety incident, that the healthcare provider is responsible for the harm to the patient (e.g. an error or failure in the delivery of care has occurred) it is imperative that there is an acknowledgment of responsibility and an apology provided as soon as possible after the patient safety incident.

Acknowledge: Acknowledge what it is that you are apologising for:

Explain: Explain why or how it happened – this explanation must be factual

Delivery:

- An apology should not be rushed.
- The language used in the apology must be supportive and empathic.
- An apology must be genuine, respectful, sincere and personal to the individual and the given situation.
- Consider the tone of voice and body language.
- Maintain confidentiality.
- Consider who should deliver the apology/who the patient expects to apologise?

Make Reparation:

- Outline the steps taken and/or planned by the health services provider to put things right
- Increased contact, if required.
- Provide reassurance regarding on-going care/treatment
- Consider waiving expenses, as appropriate

4. Recognising Patient and Carer Expectations

- Consider the perspective of the patient
- Put yourself in their shoes
- Consider what would you expect if this was you or your loved one
- In summary patients want an acknowledgement of what has happened, an explanation as to how or why it happened, a meaningful apology, reassurance in relation to their on-going care and treatment and in relation to the steps being taken by the health services provider to try to prevent a recurrence of the same incident.

5. Staff Support

- When a patient safety incident occurs the care of the patient and relevant person is paramount.
- Parallel to this it is important to identify the staff involved in and/or affected by the patient safety incident and to ensure that they are being supported in the immediate aftermath of the incident and on an on-going basis for as long as is required.
- Consider the impact of the incident on the wider organisation also.

6. Risk Management and Systems Improvement

- Open disclosure is an essential component in the incident management and quality improvement process.
- Incidents are identified, managed, reported, disclosed and reviewed and learning is derived from them. Actions are then taken to try to prevent a recurrence of the incident.
- Keep the patient and relevant person involved – their story and perspective is an important part of the review and incident management process.
- Consider the role of risk management department.

7. Multidisciplinary Responsibility

- Open disclosure involves multidisciplinary accountability and response.
- Clinical, senior professional and managerial staff must be identified to lead in and support the process.
- Open disclosure relates to all staff groups and not just medical staff.
- All staff have a role in reporting patient safety incidents.
- All staff have a role in supporting patients and colleagues involved in patient safety incidents.

8. Clinical Governance

- The open disclosure process is one of the key elements of the HSE Clinical governance system.
- Health and social care services are required to have appropriate accountability structures in place which ensure that open disclosure occurs and that it is integrated with other clinical governance systems and processes including clinical incident reporting and management procedures, systems analysis reviews, complaints management and privacy and confidentiality procedures.

9. Confidentiality

- The information collated following a patient safety incident is often of a sensitive nature and therefore patient confidentiality is paramount.
- Patient information is held under legal and ethical obligations of confidentiality.
- All health and social care policies, procedures, and guidelines in relation to privacy and confidentiality for patients and staff should be consulted with and adhered to.

10. Continuity of Care

- Steps must be taken to reassure the patient in relation to the management of their immediate care needs and also reassure them that their care will not be compromised going forward.
- Transfer of care to another facility/clinician may be requested by the patient and should be facilitated when it is possible to do so.
- A member of staff (designated person) must be identified who will act as a contact person for the patient to keep them informed of the situation and to maintain open channels of communication between the patient and the health and social care service.
- Consider waiving fees if the patient has been harmed as a result of a failure/error in the delivery of care.
- If the patient indicates that they are submitting a complaint or that they plan to pursue a legal case they must not be treated any differently.
- If there is a breakdown in the patient/clinician relationship, consider referral to another clinician if the breakdown is irreparable and the patient agrees.

Appendix C
HSE Risk Impact Table

HSE Risk Assessment Tool

2. IMPACT TABLE	Negligible	Minor	Moderate	Major	Extreme
Injury	Adverse event leading to minor injury not requiring first aid. No impaired Psychosocial functioning	Minor injury or illness, first aid treatment required <3 days absence < 3 days extended hospital stay Impaired psychosocial functioning greater than 3 days less than one month	Significant injury requiring medical treatment e.g. Fracture and/or counselling. Agency reportable, e.g. HSA, Gardaí (violent and aggressive acts). >3 Days absence 3-8 Days extended hospital Stay Impaired psychosocial functioning greater than one month less than six months	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling Impaired psychosocial functioning greater than six months	Incident leading to death or major permanent incapacity. Event which impacts on large number of patients or member of the public Permanent psychosocial functioning incapacity.
Service User Experience	Reduced quality of service user experience related to inadequate provision of information	Unsatisfactory service user experience related to less than optimal treatment and/or inadequate information, not being to talked to & treated as an equal; or not being treated with honesty, dignity & respect - readily resolvable	Unsatisfactory service user experience related to less than optimal treatment resulting in short term effects (less than 1 week)	Unsatisfactory service user experience related to poor treatment resulting in long term effects	Totally unsatisfactory service user outcome resulting in long term effects, or extremely poor experience of care provision
Compliance with Standards (Statutory, Clinical, Professional & Management)	Minor non compliance with internal standards. Small number of minor issues requiring improvement	Single failure to meet internal standards or follow protocol. Minor recommendations which can be easily addressed by local management	Repeated failure to meet internal standards or follow protocols. Important recommendations that can be addressed with an appropriate management action plan.	Repeated failure to meet external standards. Failure to meet national norms and standards / Regulations (e.g. Mental Health, Child Care Act etc). Critical report or substantial number of significant findings and/or lack of adherence to regulations.	Gross failure to meet external standards Repeated failure to meet national norms and standards / regulations. Severely critical report with possible major reputational or financial implications.
Objectives/Projects	Barely noticeable reduction in scope, quality or schedule.	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Significant project over – run.	Inability to meet project objectives. Reputation of the organisation seriously damaged.
Business Continuity	Interruption in a service which does not impact on the delivery of service user care or the ability to continue to provide service.	Short term disruption to service with minor impact on service user care.	Some disruption in service with unacceptable impact on service user care. Temporary loss of ability to provide service	Sustained loss of service which has serious impact on delivery of service user care or service resulting in major contingency plans being involved	Permanent loss of core service or facility. Disruption to facility leading to significant 'knock on' effect
Adverse publicity/ Reputation	Rumours, no media coverage. No public concerns voiced. Little effect on employees morale. No review/investigation necessary.	Local media coverage – short term. Some public concern. Minor effect on employees morale / public attitudes. Internal review necessary.	Local media – adverse publicity. Significant effect on employees morale & public perception of the organisation. Public calls (at local level) for specific remedial actions. Comprehensive review/investigation necessary.	National media/ adverse publicity, less than 3 days. News stories & features in national papers. Local media – long term adverse publicity. Public confidence in the organisation undermined. HSE use of resources questioned. Minister may make comment. Possible questions in the Dáil. Public calls (at national level) for specific remedial actions to be taken possible HSE review/investigation	National/International media/ adverse publicity, > than 3 days. Editorial follows days of news stories & features in National papers. Public confidence in the organisation undermined. HSE use of resources questioned. CEO's performance questioned. Calls for individual HSE officials to be sanctioned. Taoiseach/Minister forced to comment or intervene. Questions in the Dail. Public calls (at national level) for specific remedial actions to be taken. Court action. Public (independent) Inquiry.
Financial Loss (per local Contact)	<€1k	€1k – €10k	€10k – €100k	€100k – €1m	>€1m
Environment	Nuisance Release.	On site release contained by organisation.	On site release contained by organisation.	Release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service etc.)	Toxic release affecting off-site with detrimental effect requiring outside assistance.

1. LIKELIHOOD SCORING

Rare/Remote (1)		Unlikely (2)		Possible (3)		Likely (4)		Almost Certain (5)	
Actual Frequency	Probability	Actual Frequency	Probability	Actual Frequency	Probability	Actual Frequency	Probability	Actual Frequency	Probability
Occurs every 5 years or more	1%	Occurs every 2-5 years	10%	Occurs every 1-2 years	50%	Bimonthly	75%	At least monthly	99%

3. RISK MATRIX

	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare/Remote (1)	1	2	3	4	5

Appendix D

Consultation List: Patient Representatives

This policy was revised and updated in consultation with the following patient representatives/patient representative groups:

- Patients for Patient Safety Ireland – national patient representative group
- Patients and patient representatives from the HSE Cervical Check service.
- Four independent patient advocates

Acknowledgement: The HSE acknowledges the feedback provided by patients/patient representatives throughout the development of this policy.

Appendix E

Signature Sheet

I have read, understood and agree to adhere to the attached policy

Name (Block Capitals)	Signature	Job Title	Date

Signature Sheet

I have attended training relevant to my role on the attached policy

Name (Block Capitals)	Signature	Job Title	Date