Department of Health

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Contents

Preface

The National Open Disclosure Framework (Framework) is an initiative of the Department of Health (DOH) which aims to promote a clear and consistent approach by health and social care service providers, and other organisations where appropriate, to open communication with patients/service users and any relevant support person following a patient safety incident or an adverse event. This includes a discussion about what has happened, why it happened, and what is being done to prevent it from happening again. The Framework was prepared by the National Patient Safety Office (NPSO) of the DOH and informed by recommendations from the Independent Patient Safety Council (IPSC) which were developed based on independent research and consultation undertaken by consultants during 2020.

The Framework is designed to provide overarching principles and a national, consistent approach to open disclosure in health and social care in Ireland which can then be drawn from to suit the needs of the various organisations, i.e., across public and private health and social care service providers, service regulators, health and social care professional regulators, health and social care educators and other relevant bodies and organisations. It is designed to be used in the development, or upgrading, of an organisation's internal policies, processes, and practices regarding patient safety incidents and adverse events, and to facilitate open communication. The Framework has been developed for application in a wide range of health and social care services and health and social care agencies and as such, individual organisations will need to consider implementing the process outlined in this Framework within their existing internal policies, which may need to be changed or upgraded to facilitate the open disclosure process.

The Framework guides the operational procedures and standards which determine how patients/service users, their families, or support persons and carers are communicated when something goes wrong in the course of their care. The Framework leads relevant health and social care service providers through the substantial culture change required to improve patient/service user outcomes and experience in this area. The Framework also recognises and guides developments in the substantial education and learning changes required to enable these improvements.

Chapter 1

1.1 Introduction

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. However, health and social care are complex and, sometimes despite best efforts, things can go wrong. Patients/service users 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 and social care environment.

When something has gone wrong with patient/service user care, this is referred to as a patient safety incident or adverse event, and open disclosure is the professional, ethical, and humane response to patients/service users and their support persons involved in and affected by patient safety incidents or adverse events.

The Framework applies to patient safety incidents and adverse events and reflects the importance of the right of patients/service users and their support persons to have full knowledge about their health and social care, 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 Framework is to ensure that the rights of all patients/service users and health and social care staff involved in and affected by patient safety incidents and adverse events are met and respected and that they are communicated in an honest, open, timely, compassionate, and empathic manner and that they are treated with dignity and respect.

1.2 What is Open Disclosure?

Open disclosure is defined by the Health Service Executive (HSE) 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*'.[1]

Open disclosure is described by the Australian Commission on Safety and Quality in Healthcare as '*the open discussion of incidents that result in harm to a patient while receiving health care. The elements of open disclosure are an expression of regret, a factual explanation of what happened, the potential consequences and the steps being taken to manage the event and prevent recurrence*'.[2]

Healthcare Improvement Scotland, in its 'Being Open Framework', states '*that open and effective communication with people should begin at the start of their care and continue throughout all the care they receive. This should be no different when an adverse event happens. Being open when things go*

[1] HSE Open Disclosure Policy (2019) https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opendisclosure/hse-open-disclosure-full-policy-2019.pdf

[2] Australian Open Disclosure Framework (2013) https://www.safetyandquality.gov.au/sites/default/files/migrated/Australian-Open-Disclosure-Framework-Feb-2014.pdf

wrong is key to the partnership between patients and those who care for them. We have a professional duty to acknowledge when something has gone wrong and provide an honest explanation. Openness about what happened and discussing adverse events promptly, fully, and compassionately can help people cope better with the after-effects of adverse events. Being open involves:

- *acknowledging, apologising, and explaining when things go wrong*
- *if appropriate, conducting a thorough review into the adverse event which involves patients, families, carers, and staff, and aims to identify lessons that will support improvements and help prevent the adverse event from being repeated, and*
- *providing support for those involved to address any physical and/or psychological consequences of what happened'*[3]

1.3 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

1.1 **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.

1.4 What is an adverse event?

An adverse event is an incident which resulted in harm that may or may not be the result of an error.[4]

1.5 Principles of Open Disclosure

This Framework was developed within complex and dynamic processes. It attempts to address the issues and concerns of patients/service users, health and social care professionals, managers and organisations, and other key stakeholder groups. Several themes were consistently identified throughout the consultation and independent research which informed the recommendations of the IPSC and have become the principles on which the Framework is built.

[3] Healthcare Improvement Scotland 'Being Open Framework' (2015) http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/being_open_guidance.aspx

[4] HSE Open Disclosure Policy (2019) https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opendisclosure/hse-open-disclosure-full-policy-2019.pdf

They include the following:

- **Open, Honest, Compassionate, and Timely Communication**
- **Patient/Service User and Support Persons' Entitlements in Open Disclosure**
- **Supporting Health and Social Care Staff**
- **Promoting a Culture of Open Disclosure**
- **Open Disclosure for Improving Health and Social Care Policy and Practice**
- **The Importance of Good Clinical and Corporate Governance for Open Disclosure**

A summary of the principles is provided in **Chapter 3**.

Key Message

- The Framework aims to promote a clear and consistent approach by health and social care service providers, and other organisations, where appropriate, to open communication with patients/service users and their support persons following a patient safety incident or an adverse event.

- The Framework is designed to be used in the development, or upgrading, of an organisation's internal policies, processes, education and training, and practices regarding patient safety incidents and adverse events.

- The Framework ensures that the rights of all patients/service users and health and social care staff involved in and affected by patient safety incidents and adverse events are met and respected.

- Open disclosure is an open, consistent, compassionate, and timely approach to communicating with patients/service users and, where appropriate, their support persons following patient safety incidents or adverse events.

Chapter 2

2. Context

2.1 Development & Implementation of the Framework

The Framework is underpinned by evidence, practice in other jurisdictions, and recommendations from the Independent Patient Safety Council.

2.1.1 Role of the Independent Patient Safety Council (IPSC)

The IPSC was appointed by the then-Minister for Health, Simon Harris T.D., and met for the first time in January 2020. The IPSC was appointed to provide advice and guidance to the Minister for Health from a broad range of perspectives on the development of patient safety policy. One of the first areas of focus for the IPSC was the development of recommendations in respect of a national policy framework on open disclosure in health and social care.

Crowe Ireland, a consultancy firm, was commissioned in April 2020 by the DOH to research evidence and provide support to the IPSC in relation to the development of recommendations to the Minister for Health for a national policy framework on open disclosure in health and social care in Ireland. The IPSC engaged in a process of drafting and refining recommendations and opted to present the recommendations grouped around key principles. In making these recommendations, the IPSC recognised that considerable work had been undertaken in the HSE to improve the organisation's approach to open disclosure, and the recommendations intended to build and expand on existing practice and support further development through a national policy framework.

The full recommendations of the IPSC can be read online here (https://www.gov.ie/en/publication/6d9878-the-independent-patient-safety-council/#recommendations-to-the-minister-on-a-national-policy-framework-for-open-disclosure-in-healthcare-in-ireland) and are also provided in Appendix 1.

2.1.2 Role of Department of Health (DOH)

The Department of Health (DOH), using the recommendations of the IPSC, developed this national policy framework for open disclosure in health and social care in Ireland. The Framework aims to provide a unified and consistent approach to open disclosure across public and private health and social care service providers, service and health and social care professional regulators, health and social care educators, and other relevant bodies and organisations.

2.1.3 Role of Individual Organisations

It is the responsibility of each relevant organisation to adopt the Framework and to embed positive open disclosure cultures and behaviours into practice. Individual organisations will need to identify mechanisms and initiatives that support the consistent, coherent, and sustainable implementation of open disclosure in line with the principles of this Framework. Each relevant organisation will be required to submit an annual report to the Minister for Health regarding their implementation of open disclosure and compliance with the Framework. The monitoring and evaluation of the implementation of the Framework and the specific reporting requirements for individual organisations are explained in more detail in Chapter 7.

The Framework applies to the following organisations and individuals:

- Health Service Executive
- Voluntary Hospitals
- Private Hospitals
- Nursing Homes
- Residential Care Settings
- Outpatient Health Services
- Primary Care Health Services
- National Ambulance Service
- Health Information and Quality Authority
- Mental Health Commission
- Irish Medical Council
- CORU
- Nursing and Midwifery Board of Ireland
- Dental Council of Ireland
- Pharmaceutical Society of Ireland
- Pre-hospital Emergency Care Council
- Education and Training Bodies
- Providers of Health Service Workers
- All other providers of health and social care services, including private practitioners regulated by any of the professional and service regulators listed above.

2.2 Evidence & Practice in other Jurisdictions

Open Disclosure, in the context of Irish health and social care, is the term that has been adopted in Ireland to describe the broad processes which relate to patients/service users being informed of patient safety incidents and adverse events which arose in relation to the health and social care which they have received. Other terms are in use in other jurisdictions, for example, "open communication" or "duty of candour" or "being open".

2.2.1 Duty of Candour in Scotland

The Scottish Government's organisational Duty of Candour provisions within the Health (Tobacco, Nicotine, etc. and Care) (Scotland) Act 2016 (The Act) and The Duty of Candour Procedure (Scotland) Regulations 2018 set out the procedure that organisations providing health services, care services, and social work services in Scotland are required by law to follow when there has been an unintended or unexpected incident that results in death or harm (or additional treatment is required to prevent injury that would result in death or harm). The 'duty of candour' creates a legal requirement for health and social care organisations to inform people (or their families/carers acting on their behalf) when they have been harmed (physically or psychologically) as a result of the care or treatment they have received. **A number of criteria must be met in order for the duty of candour procedure to be activated.** It is the responsibility of the individual organisation to activate the duty of candour procedure and to assess if the specified criteria have been met. Organisations set

out in an annual report the way that the duty of candour procedure has been followed for all the cases that they have identified.

2.2.2 Duty of Candour in England

The Duty of Candour is a statutory duty to be open and honest with patients or their families, when something goes wrong that appears to have caused or could lead to significant harm in the future. It applies to all health and social care organisations registered with the regulator, the Care Quality Commission (CQC) in England. **The duty of candour specifically relates to notifiable patient safety incidents, which are defined in the regulations**. It is the responsibility of the individual organisation to investigate individual patient safety incidents, while the CQC ensures that individual providers are fulfilling their responsibilities in relation to the duty of candour.

2.2.3 Open Disclosure in Australia

The Australian Open Disclosure Framework is a national initiative of the Australian, and state and territory governments, in conjunction with private health services, through the Australian Commission on Safety and Quality in Health Care (the Commission). It is intended to contribute to improving the safety and quality of health care. Open Disclosure is mandated in the National Safety and Quality Health Service (NSQHS) Standards, and the Australian Open Disclosure Framework has been endorsed by the Australian Health Minister as a resource to support organisations in developing open disclosure processes and policies.

2.3 Current Legislative Context in Ireland

A range of policies, legislation, guidelines, and requirements in relation to open disclosure and associated issues (such as serious incident management) exist across the health and social care sector.

2.3.1 Civil Liability (Amendment) Act 2017

The current legislative foundation for open disclosure is the Civil Liability (Amendment) Act 2017. The Act sets out the general way in which open disclosure should operate. The Act is clear that undertaking open disclosure and the provision of an apology in line with the provisions of the Act does not invalidate insurance, constitute an admission of liability or fault, and is not admissible in proceedings. It also provides for the process to be followed when open disclosure takes place. By including these protections, the 2017 Act was designed to support open disclosure by providing a mechanism to allow health practitioners to engage openly and provide comprehensive information about the patient safety incident at an open disclosure meeting without concern that this communication would comprise an admission of liability or invalidation of indemnity cover in the event of legal proceedings.

The Civil Liability (Amendment) Act 2017 allows for voluntary disclosure and does not include a requirement for mandatory reporting of open disclosure incidents. The protections of the act can only be availed of if the process as set out is followed. This process is clearly detailed and involves completing documentation in advance of any open disclosure meeting taking place. If this process is not followed, health practitioners cannot avail of the protections of the Civil Liability (Amendment) Act 2017.

2.3.2 National Treasury Management Agency (Amendment) Act 2000

Under section 11 of the National Treasury Management Agency (Amendment) Act 2000 all health providers with indemnity provided by the State Claims Agency (SCA) must report any adverse incident to the Agency as soon as possible. The system used to capture this information is the National Incident Management System (NIMS). This system is used by HSE-funded hospitals to report clinical and non-clinical incidents.

2.3.3 Patient Safety (Notifiable Patient Safety Incidents) Bill 2019

The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 is designed to build on the 2017 Act. The Bill provides for mandatory open disclosure by health and social care service providers and health and social care practitioners of certain patient safety incidents and adverse events. The Bill includes a list of notifiable patient safety incidents that are externally reportable to the Health Information Quality Authority (HIQA), Chief Inspector of Social Services (CISS), and the Mental Health Commission (MHC). This external reporting is designed to contribute to learning and system-wide improvements. The 2019 Bill extends the reporting requirements for notifiable patient safety incidents to private hospitals.

The Bill sets out the procedures explaining how health and social care services providers should organise open disclosure with patients/service users in the case of a notifiable patient safety incident. The obligation to carry out open disclosure and notify the appropriate regulator will be on the health and social care service provider. Failure to comply with the legislation without reasonable excuse shall be an offence. Whilst this offence applies to health and social care service providers rather than health and social care practitioners, as defined within the Bill, it must be noted that health and social care practitioners practising as health and social care service providers may also be liable. The Bill is currently going through the legislative process in the Oireachtas and it is anticipated that it will be enacted shortly.

2.4 Current Policy Context in Ireland

Open disclosure policies are in place in some, but not all, health, and social care service providers in Ireland. The existing policies deliver an inconsistent approach to open disclosure.

2.4.1 Health Service Executive (HSE)

The HSE has a comprehensive open disclosure policy, first launched in 2013 and revised in 2019. The IPSC recognised and acknowledged the work of the HSE in developing a culture of and commitment to open disclosure in practice and this Framework is built on this foundation.

The policy sets out the procedures for open disclosure within the HSE. It is clear the provisions of the Civil Liability (Amendment) Act 2017 are separate and additional to the processes outlined in the HSE policy document and the latter explicitly advises staff to consider whether they wish to invoke the protection of the Act and the requirements that will pertain to such protection.

The policy is aligned with the HSE Incident Management Framework 2020, which considerably reformed the previous approach to responding to patient safety incidents and adverse events. The Incident Management Framework incorporates a commitment to open disclosure in Step

2 of its process. This means that open disclosure should be an immediate action after an incident has occurred and been identified. Furthermore, the Framework states that where an incident involves a patient/service user, attention and effort must also be given to initiating open disclosure, as prompt, open, and transparent communication with the person affected and their support person is required.

2.4.2 Other Healthcare Providers

Other healthcare providers outside of the HSE do not appear to have published policies on incident management or open disclosure, although it is evident that many of those in, for example, the voluntary sector, follow the HSE policies. For example, in consultation with the RCSI Hospital Group, it was evident they follow the HSE policies but deliver their own training for this area.

The National Ambulance Service (NAS) has its own policy for the Management of Adverse Clinical Events. In relation to Open Disclosure section 7.4 covers notification of the affected patients/service users and states that NAS has a policy of open disclosure to patients/service users affected by an adverse clinical event and the affected person will be kept informed of the event and its outcome.

The Dublin Fire Brigade, which provides pre-hospital emergency care services in Dublin, has an adverse clinical events policy, and supports open disclosure to patients/service users. Within the paramedic and advanced paramedic training programmes, communication of adverse events is included, and the management of an adverse event, including the communication to patients/service users and family members in respect of this, is part of the examination process for the trainees.

2.4.3 Health and Social Care Service Regulators

The Mental Health Commission (MHC) jointly developed with HIQA a set of *National Standards for the Conduct of Reviews of Patient Safety Incidents*, which refers to open disclosure in the context of reviewing and managing patient safety incidents. Both MHC and HIQA have drafted standards which require providers to have policies in place that provide for the promotion of a culture which includes open disclosure following an adverse event and suitable arrangements to support patients/service users and staff involved in adverse events.

Most regulators for health and social care professionals make reference to open disclosure in their codes of conduct and ethics, and guidance. Some regulators specifically refer to open disclosure, while others do not use that terminology but the principle behind it is included. There is also a variation in whether the code states if you “should” or you “must” openly disclose following a healthcare incident. See also appendix 2 (Open Disclosure in Regulated Professions).

Key Message

- The Independent Patient Safety Council (IPSC), informed by research and evidence, made recommendations to the Minister for Health in January 2021 regarding the development of a national policy framework on open disclosure in health and social care in Ireland.

- The Framework aims to provide a unified and consistent approach to open disclosure across public and private health and social care service providers, service and health and social care professional regulators, health and social care educators, and other relevant bodies and organisations.

- It is the responsibility of each relevant organisation to adopt the Framework and to embed positive open disclosure cultures and behaviours into practice.

- Open disclosure is the term used in Ireland. Other terms are in use in other jurisdictions, for example, “open communication”, “duty of candour” or “being open”.

- Following the introduction of legislative provisions for open disclosure in the Civil Liability (Amendment) Act 2017, the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 will, when enacted, provide further legislative context for open disclosure in Ireland.

- There is a strong policy context for open disclosure in health and social care services as most relevant health and social agencies have policies regarding open disclosure in place, but these are inconsistent. The HSE has a well-developed open disclosure policy upon which this Framework is built.

Chapter 3

3.1. Principles of Open Disclosure

In order to support the development and implementation of an open disclosure framework for health and social care services in Ireland, the Independent Patient Safety Council (IPSC) developed robust recommendations and comprehensive principles to underpin this work with the aim of improving the health and social care culture where open disclosure is integral to everyday practice. The full recommendations of the IPSC are provided in Appendix 1 and a summary of each principle is provided below.

Principle 1: Open, Honest, Compassionate, and Timely Communication

- Open Disclosure is defined as an open, consistent, timely approach to communicating with patients/service user when things go wrong and is a core component of competent health and social care service.
- Open disclosure must be considered a fluid process based on information available rather than as a once-off event. In many instances, patient safety incidents/adverse events do not require a formal open disclosure meeting, but it must be considered an integral aspect of communication between health and social care staff and patients/service users.
- Patients/service users and staff must understand what open disclosure means, what types of incidents require formal open disclosure, the information that must be provided, how the process should be managed, what is disclosed, and how it works, in order to ensure consistency and avoid confusion.
- Instigation of formal open disclosure process is in addition to timely communication with the patient/service user about what happened.

Principle 2: Patient/Service User and Support Person's Entitlement in Open Disclosure

- In the event of a patient safety incident or adverse event, patients/service users and their support person want an acknowledgment, an explanation of what happened and why, an apology, and reassurance as to their ongoing treatment and care as well as steps to prevent a recurrence of the incident. The apology must be genuine, respectful, sincere, and timely, even in the absence of the full facts being known.
- Patient safety incidents and adverse events must be acknowledged at the earliest opportunity. This should consider the physical, emotional, social, and financial impact of the patient safety incident or adverse event and the patient/service user.
- Patients/service users and their support persons are entitled to an explanation and to be fully informed of the facts surrounding the patient safety incident or adverse event and its consequences. **This may occur as a process as the full facts of the patient safety incident or adverse event emerge over time**. Patients/service users should be supported as appropriate to their individual needs and treated with empathy, respect, and compassion.

Principle 3: Supporting Health and Social Care Staff

- While patients/service user and their support person must be at the heart of the open disclosure process following a patient safety incident or adverse event, it is important that staff involved and affected by these incidents are identified and supported on an ongoing basis.
- Staff should be encouraged, empowered, and obliged to recognise and report patient safety incidents and adverse events. Staff should be supported and prepared to take part in open disclosure through easily accessible information, communication skills training and education, and supportive procedures. Staff should be fully supported through the open disclosure process.
- Open disclosure involves multi-disciplinary accountability and responses and relates to all staff groups and not just clinical staff. Staff at managerial, clinical, and non-clinical levels must be identified to lead the process and all staff have a role in supporting patients/service users, their support persons, and other staff after a patient safety incident or adverse event.
- Staff must recognise and understand their obligations in relation to open disclosure and that a failure to disclose may result in consequences. Providers must include in their policies, mechanisms to empower staff to report patient safety incidents or adverse events and communicate openly with patients/service users when patient safety incidents or adverse events occur.

Principle 4: Promoting a Culture of Open Disclosure

- A supportive culture is critical to effective open disclosure. Recognition must be given to the importance of developing and maintaining a culture in which open disclosure takes place as a matter of course, in a patient centred way by staff that are supported to do so.
- A "just culture" is based on fairness and recognises the capacity for human error and the role of the system and environment in patient safety incidents and adverse events and in which everyone seeks to learn and improve. It ensures people are accountable for their actions and responsible for learning. This approach will better meet the needs of patients/service users in relation to open disclosure, patient safety incident and adverse event management, and patient outcomes.
- Culture change requires strong leadership and a multifaceted approach including an onus on providers to demonstrate that effective processes are in place to support the development of a just culture for open disclosure. As such, providers must identify clinical and managerial champions to lead and promote open disclosure in policy, education, and practise.
- Education and training programmes must be provided for all clinical and non-clinical staff to support and promote a culture of open disclosure.

Principle 5: Open Disclosure for Improving Policy and Practise in Health and Social Care

- Open disclosure is one essential component of addressing learning from a patient safety incident or an adverse event. Incidents must be identified, managed, reported,

disclosed, reviewed and the learning derived from them. Effective, accessible, and timely open disclosure processes may help to reduce the need for escalation of concerns and reduce the impact on patients/service users and their support persons after an incident.

- It is also imperative that action takes place to prevent the recurrence of a patient safety incident or an adverse event. Patients/service users should be involved in the management and review of patient safety incidents and adverse events and be informed of the review outcome.

Principle 6: Clinical and Corporate Governance for Open Disclosure

- Providers must have governance frameworks with appropriate accountability structures in place which ensure that open disclosure occurs and is integrated with other clinical and corporate governance processes including clinical incident reporting and management procedures, systems analysis reviews, complaints management, and privacy and confidentiality procedures. The governance framework for open disclosure encompasses provider's policies, clinical governance frameworks, corporate governance frameworks, monitoring, regulation, and legislation.

3.2 The Need for Open Disclosure

Effective open disclosure can improve patient/service user, staff, and community confidence in how the health and social care system responds to patient safety incidents and adverse events and can be fundamental to maintaining or re-building the trust between health and social care staff and patients/service users and their support persons[5].

Open disclosure often forms the basis of an ethical response by the health and social care service provider to the patient/service user and their support person in relation to a patient safety incident or adverse event. It benefits the patients/service users, health and social care staff, and providers in relation to coping with a patient safety incident or adverse event and in reaching a stage of closure following their experience of the incident.

3.2.1 For *patients/service users* the open disclosure process:

- can assist the healing partnership between the patient/service user and the health and social care provider.
- help to rebuild the trust and confidence that is vital for the patient/service user in relation to the health and social care service they are attending.
- can reassure the patient/service user in relation to their ongoing care and their ability to continue an effective relationship with the health and social care service provider and between patients/service user and clinicians.
- encourages a culture of honesty and openness.

[5] Open disclosure: Clinical Excellence Commission - Open Disclosure - Clinical Excellence Commission (nsw.gov.au)

- can lead to enhanced relations with patient/service users and clinicians, health and social care professionals, and health and social care service providers.

3.2.2 For *health and social care staff* the open disclosure process:

- encourages a culture of honesty and openness.
- helps to foster an environment where staff are more willing to learn from patient safety incidents and adverse events.
- enhances management, clinician, and other staff relationships.
- leads to better relations with patient/service users and their support persons.
- can assists health and social care staff recover from the incident.
- helps to improve clinical practice by learning from errors.

3.2.3 For *health and social service care providers* the open disclosure process:

- Improves quality of care due to greater availability of data on patient safety incidents and adverse events
- Increases transparency and trust gained from the communities they serve.

3.3 The Importance of Open Communication

Effective communication with patients/service users commences from the beginning of an episode of care and continues throughout their care. It is also important that complications, risks, and side effects associated with medical conditions, care, and treatment are communicated to patients/service users in a timely manner that is open and which they can fully understand.

When care doesn't go as planned, there is an ethical responsibility for clinicians and other health and social care staff to maintain honest and open communication with patients/service users, their support persons, and carers. Ensuring that communication after a patient safety incident or adverse event is open, honest, and timely is important to improving overall patient safety. Open disclosure is already occurring in many areas of the health and social care system, and the Framework sets out a consistent and effective method of communication following patient safety incidents and adverse events which aims to strengthen current progress and build a health and social care sector wide culture of open disclosure. This includes communication between clinicians and:

• patients/service users, support person, and carers.

• their colleagues and peers.

• the non-clinical workforce.

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 or adverse event, is a crucial part of the therapeutic relationship and if done well, can mitigate anxiety and enhance trust in staff, the organisation, and the health and social care system.

3.4 Creating a Culture of Open Disclosure

A culture of openness and transparency that promotes and facilitates efficient and effective reporting of patient safety incidents and adverse events, learning, and quality improvement must be in place across all health and social care services.

3.4.1 Promoting a *"Just Culture" and avoiding a "Blame Culture"*

A supportive culture is critical to effective open disclosure. Organisations must recognise the importance of developing and maintaining a culture in which open disclosure takes place as a matter of course, in a patient and service user-centred and compassionate way, by health and social care staff who are supported to do so. The health and social care system must avoid a "blame culture", which seeks to place responsibility for patient safety incidents and adverse events on individual health and social care staff, in favour of a "just culture", which promotes psychological safety.

A just culture seeks to balance the need to learn from mistakes and the need to take disciplinary action. It is important that health and social care providers foster a positive, supportive work environment where good communication, support, and mutual respect are the norm. Where a just culture exists, staff will feel more encouraged and willing to report incidents, including their own, in the knowledge that there is the fair-minded treatment of this information and that there are structures in place within the service to promote learning from incidents and to ensure that steps are taken to prevent or reduce the likelihood of a recurrence of the incident. It is important that staff involved in patient safety incidents and adverse events can participate in the review of the incident and that they are also involved in helping to bring the incident to closure or resolution.

A just culture also offers a climate which fosters trust in which the staff are not held solely accountable for systems failings over which they have no control. There needs to be a general acknowledgment within the multidisciplinary health and social care team and the public that things can go wrong, and mistakes will occur.

A "just culture" however is not "non-accountable". Incident reviews should identify where reckless/negligent conduct and known violations of policy/procedure exist and ensure that the appropriate action is taken as per the service's internal policies, procedures, protocols, and/or guidelines.

3.4.2 Factors that will help promote a *"just culture"*

A "just culture" supports a disclosure culture and developing a safe and just culture within any health and social care service is an integral component of implementing this Framework. Health and social care service providers need to foster a culture where health and social care staff feel supported and are encouraged to identify and report patient safety incidents and adverse events so that opportunities for system improvements can be identified and acted on. This will help create an environment that minimises patient/service user harm and ensures systems learning while at the same time promoting professional accountability.

This should include the following:

a. Providing an environment where patients/service users, their support persons, and their carers:

– receive the information they need to understand what happened.

– can contribute information about the patient safety incident or adverse event and, where possible and appropriate, participate in the incident review.

b. Creating a culture where patients/service users, their support persons and carers, clinicians and other staff, and managers all feel supported.

c. Integrating open disclosure with investigative processes to identify why patient safety incidents and adverse events occur.

d. Implementing the necessary changes in systems of clinical care based on the lessons learned.

3.4.3 Development of Local Policies to Support a Culture of Open Disclosure

Local policies must recognise and address the role of a supportive culture in effective open disclosure. The Open Disclosure Framework provides a flexible framework designed to be used by organisations, health and social care professionals, and managers when developing or amending policies and procedures for open disclosure. It is essential that each organisation's policy and procedure meet its unique needs while reflecting the specific legal, regulatory, and institutional considerations as relevant.

Key Message

- The Independent Patient Safety Council developed robust recommendations and comprehensive principles to underpin the open disclosure framework.
- Open disclosure builds trust among patients/service users in how the health and social care service providers respond to patient safety incidents and adverse events.
- Open disclosure supports both patients/service users and health and social care staff affected by patient safety incidents and adverse events to reach closure after their experience.
- A supportive culture is critical to effective open disclosure. Organisations must recognise the importance of developing and maintaining a culture in which open disclosure takes place as a matter of course, in a patient-centred or service user centred and compassionate way and supported by all health and social care staff.
- Health and social care service providers must demonstrate that they have put in place effective processes by which they support the development of a positive and just culture for open disclosure.

Chapter 4

4.1 Open Disclosure in Practice (Health Service Providers)

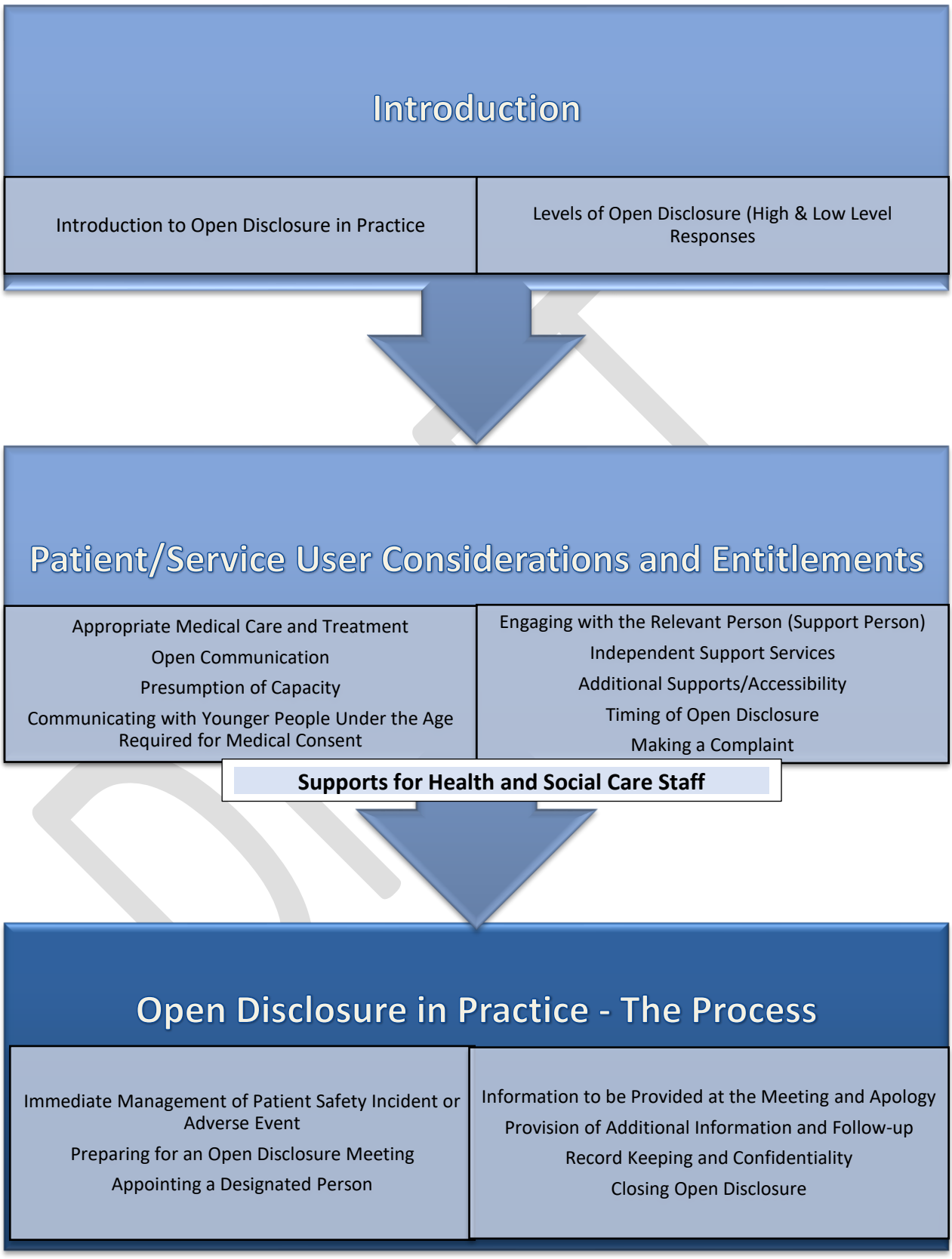
To establish a consistent approach to open disclosure across the entirety of the health and social care sector in Ireland, it is important that open disclosure is managed using the principles and processes set out in this Framework. **Health and social care service providers must have a policy on open disclosure in place that aligns with the provisions of the Framework**. Health and social care service providers must include mechanisms in their open disclosure policies empowering staff to report patient safety incidents and adverse events and to communicate with patients/service users and their support persons openly in relation to these incidents. Providers must communicate this policy clearly to all clinical and non-clinical staff including agency staff and patients/service user and their support persons.

When an open disclosure is made, it must be managed in a manner that is compassionate, caring, and empathic towards all those involved in and/or affected by patient safety incidents or adverse events. Open disclosure must be regarded as a normal part of an episode of care and a critical element of continuous effective communication with patients/service users, support persons, and health and social care staff. Open disclosure must be considered as an ongoing and fluid process as information becomes available rather than a one-off event. A genuine empathic apology or expression of regret during open disclosure is always appropriate.

Patients/service users, support persons, and all clinical and non-clinical health and social care staff including agency staff must understand each point listed below to ensure consistency and avoid confusion:

- what does open disclosure mean,
- what types of incidents require formal open disclosure,
- the information that must be provided,
- how the process should be managed,
- what is disclosed and how it works.

4.2 Chapter Overview



4.3 Introduction to Open Disclosure in Practice

When a patient safety incident or an adverse event occurs, the health and social care service provider must make an open disclosure of the incident to the patient/service user and their support person. Before embarking on the open disclosure process, the health and social care service provider should consider whether they wish to avail of the statutory protections set out in Part 4 of the Civil Liability (Amendment) Act 2017 ("CLA Open Disclosure").

A **patient safety incident**, in relation to the provision of a health service to a patient by a health service provider, means "an incident which occurs during the course of the provision of a health service" which*:*

d) has caused an unintended or unanticipated injury, or harm, to the patient.
e) did not result in actual injury or harm to the patient but was one which the health service provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm

or

f) 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).

An **adverse event** is an incident which resulted in harm that may or may not be the result of an error.[6]

Whilst patients/service users, and their support persons are entitled to open, timely, and clear communication about all aspects of their care, including if and when something goes wrong, not all "open disclosure" requires a formal process. A tiered, proportionate response to open disclosure, appropriate to what has happened and the impact on the patient/service user and their support person, is the approach that is required, in line with legislative requirements, regulatory codes of conduct, ethics, guidance and organisational policies. Whilst some degree of judgment may be required in individual cases as to the appropriate level of response and the way in which disclosure should take place, organisational open disclosure policies should provide clear guidance on determining the level of response required to a patient safety incident or adverse event. Training should be provided by all health and social care service providers to all clinical and non-clinical staff including agency staff about open disclosure as well as assessing the level of response required to a patient safety incidence or adverse event.

Levels of Open Disclosure

The level of response required will be defined by the degree of harm the patient/service user has experienced, the level of additional interventions/treatments required as a result of this

[6] HSE Open Disclosure Policy (2019) https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opendisclosure/hse-open-disclosure-full-policy-2019.pdf

harm, and the expectations of the patient/service user and their support person. This response may vary from one open disclosure meeting to a number of meetings.

Low-Level Response

A **low-level response** is usually initiated for patient safety incidents where there has been no harm to the patient/service user or the harm to the patient/service user is minimal – this level of response may involve at a minimum having one meeting with the patient/service user and their support person. It is important to remember that these factors should be considered in combination with the expectations of the patient/service user and their support person in determining if a patient safety incident requires a low-level response.

Examples of where less formal responses might be required include:

- Near misses and no-harm incidents
- No increased level of care required
- No, or minor, psychological, or emotional distress

High-Level Response

A **high-level response** involves the full open disclosure process and will be initiated for patient safety incidents or adverse events where the patient/service user has suffered a moderate or higher level of harm. This level of response should involve an **initial open disclosure meeting** with the patient/service user and their support person to acknowledge that a patient safety incident or an adverse event has occurred **followed by a further meeting(s)** to update the patient/service user and their support person as additional information becomes available.

In the following circumstances, it is evident that a more formal response to a patient safety incident or adverse event is required:

- Death or significant injury following a patient safety incident or adverse event.
- Permanent or considerable lessening of body function following a patient safety incident or adverse event.
- Where there has been a requirement for a significant escalation of care or major change in clinical management (e.g., admission to hospital, surgical intervention, a higher level of care, or transfer to intensive care unit).
- Major psychological or emotional distress.
- Where a patient/service user or their support person requests a more formalised or escalated response.

Health and social care staff should consider whether an incident requiring a high-level response is a notifiable incident listed under schedule 1 of the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019, for which mandatory open disclosure applies.

4.4 Patient/Service User Considerations & Entitlements

Open disclosure is a dynamic process, and it should be tailored to the patient/service user, their support person, and their needs. The topics in this section are helpful to consider before embarking on the process of open disclosure with a patient/service user and their support person. Organisational policies should provide clear guidance to all health and social care staff in relation to these considerations.

4.4.1 Provision of Appropriate Medical Care and Treatment

When something goes wrong the first response must be to the patient/service user directly affected. It is important to focus first and foremost on the physical needs of the patient/service user 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. Consideration should also be given to the psychological needs of the patient/service user at this time.

4.4.2 Open Communication

The patient/service user and their support person must be communicated in an open, honest, and transparent manner on an ongoing basis in relation to all aspects of their care and treatment. The patient/service user and their support person have the right to have full knowledge about their care and, in particular, have a right to be informed when things go wrong, for whatever reason, during their health and social care journey.

4.4.3 Presumption of Capacity

Staff must work on the presumption that every adult patient/service user has the capacity to make decisions about their care. A person/service user 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 support to facilitate their involvement in the open disclosure process.

4.4.4 Communicating with Younger People Under the Age Required for Medical Consent

Where an adverse event involves children, the clinical team will, together with the parents/carers need to make informed but complex assessments of what the child should be told. The involvement of young people in the open disclosure process will have to be assessed by the clinical team on a case-by-case basis, taking into account whether the child is mature enough to receive the information and having regard to the wishes of the young person and the parents where appropriate.

4.4.5 Engaging with the Relevant Person (Support Person)

Disclosure of information to an adult patient's/service user's support person must only be undertaken with the consent of the patient/service user.

"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 service provider as a person to whom clinical information in relation to the patient may be disclosed.

(Civil Liability (Amendment) Act 2017)

When the patient/service user is unable, for whatever reason (e.g., the patient/service user is too ill), to provide consent, the decision to disclose information to the support person must be made by the Most Responsible Person (MRP) involved in the care of the patient/service user i.e., the principal healthcare practitioner or an appropriate delegated person when the MRP is not available. The principles of confidentiality and data protection must be upheld.

The decision by a health and social care service provider to disclose to the patient's/service user's support person must take into consideration:

- the known will and preference or instruction provided by the patient/service user in relation to the sharing of their information e.g., advance healthcare directive or information/instruction provided by the patient/service user in their healthcare record.
- who the disclosure should be made to e.g., the information provided by the patient/service user in their healthcare record or in an advance healthcare directive i.e., establish if the person has appointed a designated healthcare representative.
- what information is deemed appropriate and justifiable for the health and social care service provider to share i.e.; the information provided to the support person must include only the necessary information relating to the patient safety incident or adverse event. The patient/service user must be informed at a later stage of any open disclosure made to the support person and the details of what was disclosed. This must be recorded in the patient's/service user's healthcare record.

When a patient/service user dies following a patient safety incident or adverse event, communication with their support person must be initiated as soon as possible and is practicable in a manner that is open, honest, empathic, and sensitive. Open channels of communication must be maintained, and a designated person assigned to maintain personal contact between the support person and the health and social care service 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 support person following the death of a patient/service user must take into consideration and be led by the grieving process of the support person.

4.4.6 Independent Support Services

The Patient Advocacy Service (PAS) is available to support patients/service users and their support persons who have been affected by patient safety incidents and adverse events in acute public hospital settings and public nursing homes. The services of PAS will be expanded in time to support patients/service users of other publicly funded health and social care services.

Health and social care service providers falling outside the scope of PAS must arrange for similar independent support services to support patients/service users and their support persons who have been affected by patient safety incidents and adverse events. Such independent support services must be appropriately qualified and have sufficient experience to support patients/service users and their support persons. The support service must be independent of the health and social care service provider.

Health and social care service providers must give patients/service users and their support person information about independent support services available to support patients/service users. This information should be provided as soon as possible following the patient safety incident or adverse event to facilitate early contact and support for patients/service users and their support persons.

4.4.7 Additional Support

Support for patients/service users and their support persons must be accessible where special circumstances may make them more vulnerable. For example, this would include those with disabilities, mental health difficulties, linguistic difficulties, and others. Health and social care staff should have regard for their own policies and procedures in supporting vulnerable people and consideration should be given to the provision of trained advocates to support vulnerable people through the open disclosure process.

Patients/service users and their support persons involved in/affected by the patient safety incident or adverse event must be treated with care, compassion, and empathy and in a manner that is respectful and dignified.

Importantly, the ongoing care of a patient/service user must not be affected by open disclosure of a patient safety incident or an adverse event. At a patient's/service user's request or when it is in their best interest, the patient's/service user's care should be transferred to another clinician or service provider.

4.4.8 Timing of Open Disclosure

When something goes wrong i.e., a patient safety incident or adverse event occurs, 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 and social care service provider or as soon as the patient/service user is available both physically and emotionally to take part in the discussion and if deemed necessary, to have a support person present). Instigation of a formal open disclosure process should be in addition to timely communication with the patient/service user and their support person about what happened.

Only in rare and exceptional circumstances might an open disclosure of a patient safety incident or adverse event be deferred and the decision to defer must always be based on the safety and wellbeing of the patient/service user. When a decision is made to defer open disclosure of a patient safety incident or adverse event to the patient/service user, consideration must be given to initiating open disclosure with the patient's/service user's

support person. The decision to defer open disclosure should not affect or impact ongoing communication with the patient/service user and their support person about their care.

Open disclosure must be considered as an ongoing and fluid process as information becomes available rather than a one-off event.

4.4.9 Making a Complaint

Patients/service users and their support persons have the right to escalate complaints or concerns about the disclosure process or the patient safety incident or adverse event itself – and be supported to do so – through any and all mechanisms available, including the right to seek legal or other forms of redress. This information should be made readily available to patients/service users and their support persons at the start of the open disclosure process or upon request. The right to make a complaint should be also advertised clearly in all health and social care settings through accessible and user-friendly means such as posters, leaflets, etc.

4.5 Supports for Health and Social Care Staff

All open disclosure in relation to patient safety incidents and adverse events must be patient and service user-centered and place the needs of the patient/service user and their support persons at the heart of the process. In addition, it is important to identify the health and social care staff involved and affected by the patient safety incident or adverse event and to ensure that they are being supported in the immediate aftermath of the incident and on an ongoing basis for as long as is required, in recognition of the impact of such incidents on health and social care staff.

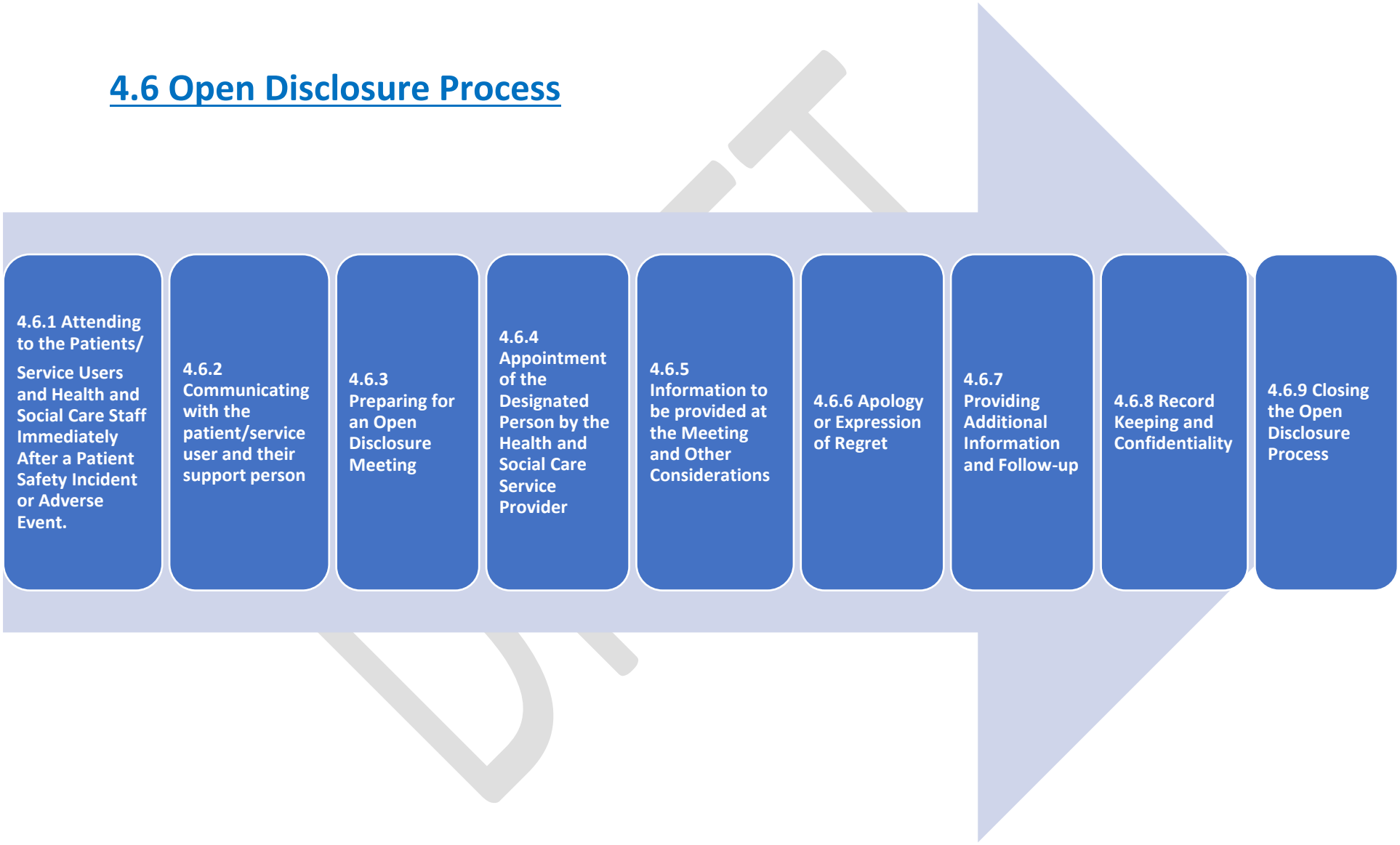
All staff delivering health and social care must be:

- encouraged, facilitated, empowered, and obliged to recognise and report patient safety incidents and adverse events.
- provided with training and education in open disclosure and communication skills (with emphasis on face-to-face skills training).
- provided with debriefing, and critical incident stress management.
- prepared to participate in open disclosure.
- supported through the open disclosure process by the health and social care provider.
- Supported in engaging in any audit of open disclosure practice.

4.6 Open Disclosure Process

The open disclosure process may provide for different approaches in the cases of low and high-level responses. It is likely that low-level responses will not require all the steps described. The following process outlines all possible considerations when designing an open disclosure process and individual organisations will update or design their own internal policies with this process in mind.

4.6 Open Disclosure Process



4.6.1 Attending to the Patients/Service Users and Health and Social Care Staff Immediately After a Patient Safety Incident or Adverse Event.

Before preparing for an open disclosure meeting, it is important to appropriately manage the situation in the immediate aftermath of the patient safety incident or adverse event to avoid any possible or further potential harm. Firstly, it is imperative to ensure the appropriate clinical management of the patient/service user to avoid further harm occurring. The patient/service user should be informed of what has happened at the earliest possible opportunity and depending on the level of response required, the clinician should signal to the patient/service user the need for a formal open disclosure meeting. Clinicians and other health and social care staff involved in the patient safety incident or adverse event should be monitored and supported as appropriate to their needs. Effective internal communication between health and social care staff involved at this point is crucial to avoid mixed messaging which could cause confusion and further distress to the patient/service user. In cases where there is delayed detection of harm, communication with the patient/service user and their support person must be made as soon as is practicable to ensure that open disclosure is commenced.

4.6.2 Communicating with the patient/service user and their support person

Communication with patients/service users and their support persons must be compassionate, truthful, timely, and clear. If things go wrong, the patients/service users and their support persons must be provided with information about what happened in a timely, open, compassionate, and honest manner. This applies to all patient safety incidents or adverse events. **The instigation of formal open disclosure should be in addition to timely communication to patients/service users and their support persons to advise them of what has happened.**

4.6.3 Preparing for an Open Disclosure Meeting

Health and social care service providers must prepare appropriately for the open disclosure meeting, and the level of preparation will be proportionate to the seriousness of the incident. When indicated, a preliminary multi-disciplinary team meeting should be held to prepare for the formal open disclosure meeting to discuss and agree on the following:

1. The nature of the patient safety incident or adverse event and the level of open disclosure required.
2. The facts of the patient safety incident or adverse event which are available at the time of the meeting.
3. The consultation with relevant stakeholders that is required, including all health and social care staff involved in the incident.
4. Whether open disclosure will be made to the patient/service user, their support person, or both.
5. Establishment of the open disclosure team and deciding who should lead the open disclosure meeting.
6. Whether an expression of regret or an apology is most appropriate.

7. Appropriate support for the patient/service user and their support person prior to the meeting including, patient/service user information leaflets, information on how the meeting will be conducted, the appointment of the designated person, and provision of advocacy support or independent supports services depending on the needs of the patient/service user and their support person.
8. Appropriate support for affected health and social care staff including emotional support as well as professional support including, debriefing, training, and preparation for the formal meeting.
9. Whether the open disclosure team wishes to conduct the process as set out in the Civil Liability (Amendment) Act 2017.
10. Appropriate reimbursement of out-of-pocket expenses incurred by the patient/service user and their support person such as travel, parking, or other fees where the patient/service user was harmed as a result of a failure/error in the delivery of care.
11. Appropriate records should be kept throughout the open disclosure process.

In the case where a patient/service user and their support person refuse open disclosure; they should be reminded of the benefits of open disclosure and their right to full open disclosure should they change their mind. It is appropriate at this stage and throughout the process to involve the patient/service user and their support person and consider their preferences such as the timing, location, and lead person to deliver the open disclosure.

4.6.4 Appointment of the Designated Person by the Health and Social Care Service Provider
It is essential that patients/service users and their support person are supported in the immediate aftermath of a patient safety incident or adverse event. The designated person assigned by the health and social care service provider is the appointed lead for dealing with clarification requests received from patients/service users and their support person about information received during or after an open disclosure meeting. Preparing the patient/service user and their support person for the open disclosure meeting is the main purpose of appointing the designated person and they should have the necessary skills to carry out the functions of the role.

The designated person must liaise with the relevant health and social care staff in preparing and agreeing on a response to the clarification request. Clarification should be provided to patients/service user and their support person in a timely and supportive manner.

The appointment of a designated person by the health and social care service provider must take place immediately to maintain a seamless line of communication between the patient/service user, the support person, and the health and social care service provider. It is important that the patient/service user and their support person do not feel isolated and that their support and communication needs are addressed in relation to the ongoing management of the patient safety incident or adverse event including the open disclosure process.

4.6.5 Information to be provided at the Meeting and Other Considerations

Patients/service users and their support persons must be informed of all the facts surrounding the patient safety incident or adverse event available to the health and social care service provider at the time the open disclosure meeting takes place. It is not necessary to know all facts at this point and additional information can be provided to the patient/service user and their support person when it becomes available.

When a patient safety incident or adverse event occurs, patients/service user and their support person want:

- ***an acknowledgment of what happened,***
- ***an explanation of what happened and why,***
- ***an apology and reassurance as to their ongoing treatment and care and,***
- ***the steps being taken to prevent a recurrence of the incident.***

At the outset, the names and roles of health and social care staff present at the open disclosure meeting should be provided so that the patient/service user and their support person feel more at ease.

Patient safety incidents and adverse events must be **acknowledged** at the earliest opportunity. This should include a description of the incident, when it happened, and how it came to the attention of the service provider. The acknowledgment should consider the physical, emotional, social, and financial impact of the patient safety incident or adverse event on the patient/service user and their support person.

Patients/service users and their support persons are entitled to an **explanation** and to be fully informed of the facts surrounding the incident and its consequences. This should include the facts as to why and how the incident happened and any known causal factors. The impact of the patient safety incident or the adverse event must be fully disclosed as well as any future consequences on the patient/service user that are anticipated as a result of the incident. Where the full facts pertaining to the incident are not available, a description of the steps being taken and the expected timeframe to establish further information should be provided. This process requires effective and timely communication with the patient/service user and their support person as the full facts of the incident emerge over time.

Patients/service users and their support persons should be **provided with reassurance as to their ongoing care** and where appropriate or at the patient's/service user's and support person's request, they should be transferred to another clinician or service provider if necessary. Patients/service users and their support persons are entitled to factual responses to questions or clarifications sought at the meeting and if required for this to be provided at an additional information meeting or in writing.

At this point, it is appropriate for health and social care staff to encourage the patient/service user and their support person to tell their story of the events of the patient safety incident or adverse event including the effects that the incident had on them personally. Patients/service

users and their support persons should be supported as appropriate to their individual needs and treated with empathy, respect, and compassion.

The patient/service user and their support person are entitled to a description of the **measures being taken** by the health and social care service provider to manage the incident as well as the learning identified and how this is being incorporated into the service's processes to reduce the risk of the incident recurring.

Before concluding the meeting, the patient/service user and their support person must be **provided with an agreed communication plan** between the health and social care service provider and the patient/service user and their support person. This will also include the name and contact details of the designated person and details of support services available to the patient/service user and their support person.

Patients/service users and their support persons should be **supported to escalate complaints or concerns** regarding open disclosure and patient safety incidents or adverse events, including their right to seek legal or other redress and this choice should not affect how they are treated. Service providers must provide all relevant information to support patients/service users and their support persons who chose to activate various escalation processes in relation to the patient safety incident, adverse event, or the open disclosure process.

4.6.6 Apology or Expression of Regret

When something goes wrong in the delivery of health and social care, the patient/service user and their support person must receive an apology or expression of regret for what happened. The apology must be genuine, respectful, sincere, and timely, even if all the information is not yet available. It must also be personal to the individual and situation. The apology must include:

- An acknowledgment of what is being apologised for and that the patient/service user and their support person are unhappy with the outcome.
- An explanation of why/how the incident happened.
- The words “I am sorry for what has happened” and for how the situation impacted the patient/service user and their support person.
- Outline the steps taken to prevent a recurrence.
- The apology should highlight the support available to patient/service user and their support person in relation to the incident and open disclosure including all avenues for escalating disclosure processes and concerns.

4.6.7 Providing Additional Information and Follow-up

Additional information obtained by a health and social care service provider subsequent to the initial open disclosure meeting must also be communicated to the patient/service user and their support person in a timely and supportive manner. For example, such information might include the findings and recommendations of a review of a patient safety incident or adverse event that has occurred as well as the changes in policy that have taken place as a

result of the recommendations and measures to ensure these changes are implemented effectively.

Patients/service users and their support persons must be kept informed, even in the absence of any material update, regularly and at a minimum every 3 months until such time as the open disclosure process has been completely closed off.

Following a formal open disclosure meeting, the patient/service user and their support person should be provided with a letter containing the details provided at the open disclosure meeting. Organisations must have a system in place to learn from each open disclosure which is communicated clearly to the patient/service user and their support person and explains how patient/service user and their support person feedback is used in improving the open disclosure and patient safety incident and adverse event management processes. Each patient/service user and support person must be invited to provide feedback on their experience of the open disclosure process. The invitation to participate in the feedback and learning session should be issued at a mutually agreed date to allow the patient/service user and their support person some time to reflect on their experience.

4.6.8 Record Keeping and Confidentiality

Documentation of the open disclosure should commence once staff becomes aware that a patient safety incident or adverse event has occurred, and this should continue throughout and until the completion of the process. Good documentation is an integral component of effective communication and contributes to the success of open disclosure. A record of the information provided should be documented in the open disclosure record or patient/service user record. The level of information required as part of the record will be dependent on the seriousness of the incident. Organisational policies must outline the specific record keeping requirements of the Civil Liabilities (Amendment) Act and the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019.

The patient's/service user and their support person's right to confidentiality and privacy must be supported throughout all aspects of the open disclosure process.

4.6.9 Closing the Open Disclosure Process

It is important that the open disclosure process is closed appropriately so that patients/service users and their support persons can experience psychological closure after a potentially traumatic incident. Patients/service users and their support persons are likely to experience psychological closure when they have received an acknowledgment of what has happened, an apology, an explanation of the situation, open and informative answers to their questions, and reassurance as to their care and actions are taken to prevent a recurrence of the incident and have a regular and open communication throughout. The health and social care service provider should consider providing a summary of the process to the patient/service user and their support person at this point and ask if the patient/service user

and their support person have any outstanding concerns or complaints about the process and consider any further action required arising from this.

Closing the process should be mutually agreed upon between the patient/service user, their support person, and the service provider. All information requested by the patient/service user and their support person and any other relevant information from reviews of patient safety incidents or adverse events should be made available to the patient/service and their support person user in an accessible report format. The patient/service user and their support person should be kept up to date on further developments on actions taken to reduce the risk of such incidents recurring and consideration should be given to involving patients/service users and their support persons in service improvement processes.

The health and social care service provider must ensure that the patient/service user and their support person are reassured as to the continuity of their care with the appropriate health and social care service provider and clinician. Effective communication between the open disclosure team and the GP or other treating clinicians should take place to hand over care if appropriate.

Health and social care service providers must have a system in place to obtain feedback from the patient/service user and their support person on the open disclosure process to inform future policy and quality improvement. Relevant personnel should be identified for monitoring the effectiveness of policy changes that occurred as a result of the open disclosure. These changes should be communicated to all clinical and non-clinical staff across the organisation and throughout the wider health and social care sector, if possible, to demonstrate the value of the open disclosure process.

Key Message

- Health and social care service providers must have a policy on open disclosure in place that includes mechanisms to empower health and social care staff to report patient safety incidents and adverse events and to communicate openly with patients/service users and their support persons in relation to these incidents.

- Open disclosure policies must be communicated clearly to all clinical and non-clinical staff including agency staff and patients/service users and their support persons.

- When an open disclosure is made, it must always be managed in a manner which is compassionate, caring, and empathic towards all those involved and affected by patient safety incidents or adverse events. Open disclosure must be regarded as a normal part of an episode of care and a critical element of continuous effective communication with patients/service users and their support persons and health and social care staff.

- The level of response required will be defined by the degree of harm the patient/service user has experienced, the level of additional

interventions/treatments required as a result of this harm, and the expectations of the patient/service user and their support person.

- Open disclosure is a dynamic process, and it should be tailored to the patient/service user, their support person, and their needs. Organisational policies should provide guidance to health and social care staff in relation to patient/service user considerations and entitlements including but not limited to; presumption of capacity, engaging with the support person, additional support, provision of appropriate medical care and treatment, and timing of open disclosure.

- A clear open disclosure process must be in place which outlines the immediate management of a patient safety incident or adverse event, the appointment of a designated person, the information to be provided at open disclosure meetings, and record-keeping and confidentiality.

- When a patient safety incident or adverse event occurs, patients/service user and their support person want:
    - an acknowledgment of what happened,
    - an explanation of what happened and why,
    - an apology and reassurance as to their ongoing treatment and care and,
    - the steps being taken to prevent a recurrence of the incident**.**

- Supports must be in place for both health and social care staff and patients/service users and their support persons involved in patient safety incidents and adverse events.

Chapter 5

5.1 Open Disclosure in Practice (Non-Health Service Providers)

It is acknowledged that there has been significant movement in the last several years towards an increased awareness of open and frank communication, accessible information, and a culture of open disclosure. However, further cultural change is needed within health and social care services in Ireland to fully embed this into practice.

Undergraduate and postgraduate education, workplace induction, education and training, ongoing professional development, policy, standards, and guidelines related to open disclosure are all essential in promoting change in workplace culture and health and social care professional practice. The professional regulators, education bodies, and health and social care service regulators play an important role in initiating and sustaining these changes.

All professional regulators, educational bodies, and health and social care service regulators involved in the education and training of health and social care professionals and regulation of their profession and workplace must embed open disclosure into their operations as outlined by the Framework and should seek to include open disclosure in all aspects of their business, where appropriate.

5.2 Professional Regulators

Policies & Codes of Conduct

Professional regulatory bodies must include clear and unequivocal obligations for open disclosure in codes of conduct, ethics, and guidance for regulated professional practitioners, aligned to the definitions and terminology set out by the Framework. Where appropriate, professional regulators should develop a policy in relation to open disclosure to support registered professional practitioners to embed open disclosure into their individual practice.

Open Disclosure Framework Policy in all Education Bodies and Clinical Training Sites

Professional regulators must ensure that all educational bodies involved in the delivery of undergraduate and postgraduate academic programmes with clinical components have a policy in relation to open disclosure in place, which aligns with the principles of the Framework. This also includes clinical training sites involved in the delivery and supervision of student clinical and practice placements.

Undergraduate and postgraduate education and training

In the approval, accreditation, and monitoring of undergraduate education and training programmes with clinical components and, where relevant, postgraduate education and training programmes with clinical components for clinical professions, the professional regulators must ensure that the educational body has embedded communication skills, patient safety incident and adverse event management, and open disclosure into all programmes. The professional regulator must ensure that the provisions outlined above are also evident in the design and delivery of the programmes.

Professional Development

Professional regulators must ensure that any guidance or requirements related to professional development, lifelong learning, and maintenance of professional competence require registrants to engage in learning related to open disclosure and to keep up to date with legislative and policy changes related to open disclosure. Professional regulators should be as specific as possible regarding the embedding of open disclosure into informal and formal learning including engaging in peer discussions, peer review, focus meetings, supervision, and seeking feedback on their communication skills and participation in open disclosure.

Professional regulators will approve and accredit Continuing Professional Development (CPD) training programmes on open disclosure submitted by education bodies, private and public education and training providers, and health and social care service providers. All approved CPD training programmes on open disclosure should be published by the professional regulators on their websites for easy access for their registrants.

5.3 Education Bodies

Undergraduate and Postgraduate Education & Training

Education bodies involved in the delivery of undergraduate and postgraduate academic programmes with clinical/practical components to the health and social care professions must include communication skills with a specific focus on open disclosure in their programmes and ensure that the programmes adequately prepares graduates to understand and participate in open disclosure as part of their professional practice. Health and social care graduates should have undertaken training in relation to patient safety incidents and adverse events management as part of their education and training. Health and social care graduates should also understand the legislative and policy frameworks underpinning open disclosure, the associated legal protections afforded to them, and the legal responsibilities related to open disclosure. Health and social care graduates should be able to discuss the role of open disclosure in the provision of safe, patient and service user-centred, and effective health and social care services.

This applies to **all formal education and training programmes with clinical/practical components**, not just programmes that are subject to accreditation or approval and monitoring by a professional regulator.

Clinical and Practice Placements

Educational bodies must ensure that all training sites involved in the delivery and supervision of student clinical and practice placements have a policy in relation to open disclosure in place, which aligns with the principles of the Framework. All academic and clinical staff responsible for the clinical and practice education of health and social care staff and students, both in the educational body and clinical training sites, must have undertaken formal training in relation to open disclosure and should ensure that all students on placement have an opportunity to learn more about open disclosure in practice. Additional support must be

provided to any students and/or trainees involved in open disclosure and patient safety incidents and adverse events during placement or internship.

5.4 Health and Social Care Service Regulators

Standards, Guidance & Inspections

Health and social care service regulators such as the Health Information and Quality Authority (HIQA) and Mental Health Commission (MHC) must embed the principle of open disclosure, as outlined in the Framework, into their standards and guidelines for health and social care services. Inspections of services must assess compliance with the Framework including, but not limited to:

- The existence and communication of an open disclosure policy to patients/service users, support persons, and clinical and non-clinical staff including agency staff.
- Education and training and support system are available to all clinical and non-clinical staff including agency staff.
- Identification and appointment of clinical and management champions for open disclosure.
- Culture that supports patient safety incident and adverse event reporting and open communication with patients/service users, support persons, and clinical and non-clinical staff including agency staff.
- Evidence of learning from patient safety incidents and adverse events.
- Systems in place to seek feedback from patients/service users, support persons, and clinical and non-clinical staff including agency staff regarding their experience of open disclosure and patient safety incident and adverse event management and evidence of incorporating this learning into practice.
- Systems of clinical and corporate governance which support the practice of open disclosure and reporting of patient safety incidents and adverse events throughout the service.

Care Experience Survey

HIQA should include questions about open disclosure and open communication into the National Care Experience Surveys and should use the learning from this activity to inform future standard and guidance development and inspections. The MHC should include questions about open disclosure and open communication in any surveys directed at patients/service users, support persons, and clinical and non-clinical staff including agency staff.

Key Message

- All professional regulators, educational bodies, and health and social care service regulators involved in the training and education of health and social care professionals and regulations of their profession and workplace must embed open disclosure into their operations as outlined in the Framework and should seek to include open disclosure in all aspects of their business, where appropriate.

- Professional regulatory bodies must include clear and unequivocal obligations for open disclosure in codes of conduct, ethics, and guidance for regulated practitioners aligned to the definitions and terminology as outlined in the Framework.

- In the approval, accreditation, and monitoring of undergraduate education and training programmes with clinical components and postgraduate training programmes with clinical components, the professional regulators must ensure that educational bodies have embedded communication skills, patient safety incident and adverse event management, and open disclosure into all programmes.

- Professional regulators must ensure that any guidance or requirements related to professional development, lifelong learning, and maintenance of professional competence require registrants to engage in learning related to open disclosure and to keep up to date with legislative and policy changes related to open disclosure.

- Education bodies involved in the delivery of undergraduate and postgraduate education and training to health and social care professions must include communication skills with a specific focus on open disclosure in their programmes and ensure that the programmes adequately prepare graduates to understand and participate in open disclosure as part of their professional practice.

- Health and social care service regulators must embed the principle of open disclosure, as outlined in the Framework, into their standards and guidelines for health and social care service providers and assess compliance as part of the inspection of services.

Chapter 6

6.1 Drivers for Change

Open disclosure is an issue of concern for many patients/service users, support persons, and clinical and non-clinical health and social care staff. While much has been done to advance this change in our health and social care system in Ireland, barriers to, and potential for improvements in open disclosure policy and activity remain.

The successful embedding of open disclosure into practice in a consistent way across the health and social care sector in Ireland is heavily dependent on cultural change as discussed in Chapter 2. This change will also require a multi-faceted approach and strong leadership and governance.

The introduction and implementation of this national policy framework is a significant step towards this cultural change, but health and social care service providers and other health and social care agencies will be integral to initiating, growing, and sustaining a culture of open disclosure in practice.

6.1.1 Learning & Continuous Improvement

Patient safety incidents and adverse events must be identified, managed, reported, disclosed, and reviewed, and learning derived from them. Health and social care service providers must demonstrate that mechanisms are in place for learning and improvement in respect of adverse events and patient safety incidents and the open disclosure process associated with these. It must be clear how learning from patient safety incidents and adverse events has informed policy and practice change.

Health and social care service providers and other health and social agencies must review their open disclosure policies, guidelines, and any other associated documentation such as codes of conduct, ethics or guidance, standards of practice, and template documents regularly, or when legislative changes occur and at least once every three years. The review and updating of relevant documentation should be informed by any relevant learning from the application and implementation of policies in practice.

Health and social care service providers must identify and regularly monitor the patient/service user, support persons, and clinical and non-clinical staff experience of open disclosure. This information will then be used to:

- Inform policy;
- Support capacity building;
- Empower patients/service users, and their support persons to speak up and ask questions;
- Assess how success is measured and encourage leadership;
- Shift to proactive rather than reactive approaches to safety and disclosure;
- Continuously improve education and training content and delivery.

6.1.2 Communication, Engagement & Feedback

In the first instance, open disclosure policies and other relevant documentation must be clearly communicated to all patients/service users, support persons, and clinical and non-clinical staff including agency staff. Open disclosure policies, standards and guidelines, professional codes, ethics and guidance, and education and training that make provision for open disclosure should be developed, updated, and reviewed in collaboration with all key stakeholders including patients/service users, support persons, and clinical and non-clinical staff including agency staff.

Those involved in open disclosures, patients/service users, support persons, and clinical and non-clinical staff including agency staff, should be provided an opportunity to give feedback on their experience and there must be a system in place to learn from the feedback provided. Patients/service users, support persons, and clinical and non-clinical staff including agency staff must be kept informed of how the feedback they have provided has been used by the health and social care service provider to improve policy and practice.

Questions regarding the experience of open disclosure and the management of patient safety incidents and adverse events should be included in surveys and questionnaires that are circulated to patients/service users, support persons, and clinical and non-clinical staff including agency staff. Health and social care service providers and other health and social agencies must embed feedback mechanisms regarding open disclosure and patient safety incident/adverse event management into their existing systems, where possible.

Mechanisms to assess the culture and practice of open disclosure must be put in place by health and social care service providers, to provide regular data on how it is working for patients/service users, support persons, and all clinical and non-clinical staff including agency staff and what progress is being made towards a “just culture” rather than a “blame culture”.

6.1.3 Leadership

Health and social care service providers must demonstrate that they have put in place effective processes by which they support the development of a positive and “just culture” for open disclosure. Health and social care service providers must be able to demonstrate that all clinical and non-clinical staff including agency staff are encouraged to report and disclose patient safety incidents, adverse events, or any concerns to patients/service users, support persons, colleagues, and managers. Health and social care service providers must be able to demonstrate that they have an **“open disclosure by default”** approach and that patients/service users and their support persons are provided with relevant information in a timely manner. Health and social care service providers and all clinical and non-clinical staff including agency staff must not adopt a defensive approach seeking to minimise or delay the provision of information by any means.

Leaders and managers within organisations should ensure that the implementation of the principles of open disclosure forms a key part of the learning systems within their organisations and that the necessary integration and alignment with organisational processes

and procedures is in place. The central emphasis on communication, support, learning-focused reviews, and transparency in clinical and corporate governance should be reflected throughout the organisation. International evidence demonstrates that open disclosure creates larger benefits for the health and social care system and patients/service users by fostering cultures of openness and trust (Australian Framework 2013).

6.1.4 Training & Development

Formal Induction and Training

Health and social care service providers must ensure that all clinical and non-clinical staff, existing and new entrants, and agency staff, participate in induction, initial, and refresher training that prepares them to effectively participate in open disclosure as part of their role. Induction, initial, and refresher training should deliver the knowledge, skills, and competency needed by all clinical and non-clinical staff including agency staff to effectively participate in open disclosure and comply with any relevant organisational policies and procedures.

Induction, initial, and refresher training should keep all clinical and non-clinical staff including agency staff up to date with any relevant changes or updates to the legislative and policy frameworks underpinning open disclosure, and the associated legal protections afforded to all staff, and their legal responsibilities related to open disclosure. All clinical and non-clinical including agency staff should understand the role and value of open disclosure in the provision of safe, patient/service user-centred, and effective health and social care services.

All health and social care service providers must ensure that all clinical and non-clinical staff including agency staff attend a **refresher training at least once every three years** and retain a record of the training completed. Each health and social care service provider will designate specific personnel to lead the development and delivery of training and the establishment of a support system in relation to open disclosure.

When providing eLearning training, service providers should ensure that it is a combination of eLearning and face-face training with an emphasis on communication skills development through practice and role play. eLearning alone is not sufficient for clinical staff who will be expected to engage in the open disclosure process.

Informal Learning

Employers should ensure that all clinical and non-clinical staff including agency staff have access to informal learning opportunities and supports to discuss the implementation and engagement with open disclosure in practice. Communication skills, with a specific focus on open disclosure, should be routinely featured in informal learning practices such as in-services, case discussions, supervision, mentoring, focus meetings, and others. All clinical and non-clinical staff including agency staff should be able to safely discuss their experiences of

open disclosure with peers and line managers to build a culture of open disclosure in practice and to continuously learn from and improve their communication skills, with a specific focus on open disclosure.

Ongoing Professional Development

All clinical and non-clinical staff, including agency staff, should periodically include learning about open disclosure in their professional development. This can be formal or informal. If the legislative and policy framework underpinning open disclosure has been updated, formal learning should be undertaken. Professional regulatory bodies will approve and provide a list of accredited continuing education programmes on open disclosure on their websites. The education providers of continuing education programmes on open disclosure will also publish their approved programmes on their websites.

Educational bodies involved in the delivery of undergraduate and postgraduate academic programmes with clinical/practical components should ensure that training in relation to communication skills, patient safety incident and adverse events management, and open disclosure is included. Students in such programmes should understand the role of leaders and senior health and social care staff in building a culture of openness and open disclosure and should have the skills to support colleagues in embedding this into practice.

6.1.5 Open Disclosure Champions

Clinical and managerial champions must be identified and appointed by health and social care service providers to lead and promote open disclosure policy, education, and training, and monitor practice.

Strong clinical leadership is necessary to build a just culture of open disclosure and reporting within health and social care organisations. Health and Social Care providers should appoint clinical leaders tasked with ensuring open disclosure practice is embedded across the organisation. Clinical leaders should have protected time outside of their clinical duties to undertake this work.

Championing of open disclosure is equally important in non-clinical settings and champions must be identified and appointed to lead and promote open disclosure policy. The importance of such champions was highlighted both in the report by the IPSC on underpinning principles and by a number of stakeholders in the focussed engagement process around this work.

Key Message

- Health and social care service providers must demonstrate that mechanisms are in place for learning and improvement in respect of patient safety incidents and adverse events and the disclosure process associated with these. It must be clear how learning from patient safety incidents and adverse events has informed policy and practice change.

- Open disclosure policies and other relevant documentation must be clearly communicated to all patients/service users, support persons, and clinical and non-clinical staff including agency staff. Open disclosure policies, guidelines, and any other associated documentation should be developed, updated, and reviewed in collaboration with all key stakeholders including patients/service users, support persons, and clinical and non-clinical staff including agency staff.

- Those involved in open disclosure and patient safety incidents and adverse events should be provided an opportunity to give feedback about their experience.

- Leaders and managers in health and social care services need to ensure that open disclosure is a key part of the internal learning systems of the organisation and aligns with other organisational policies and processes.

- Health and social care service providers must ensure that all clinical and non-clinical staff, existing and new entrants, and agency staff, participate in induction, initial, and refresher training that prepares them to effectively participate in open disclosure as part of their role.

- Health and social care service providers must appoint open disclosure champions to lead and promote open disclosure policy, education, and training, and monitor practice.

Chapter 7

7.1 Monitoring and Evaluation of Open Disclosure

Ongoing monitoring and evaluation of open disclosure is essential for the successful implementation of the Framework and to embed a culture of open disclosure across the Irish health and social care sector. Monitoring involves activities such as reporting, recording, measurement of open disclosure in practice, training, education, and policy implementation. Evaluation involves the collection and analysis of open disclosure data to inform future policy. The effective monitoring and evaluation of open disclosure in policy and practice will demonstrate how health and social care organisations comply with the principles set out in this Framework and how they are contributing to its implementation.

It is important to recognise that open disclosure is only one component of addressing patient safety incidents and adverse events in health and social care services. Patient safety incidents and adverse events must be identified, managed, reported, disclosed, and reviewed to derive learning that can help to improve quality and safety across the services and health and social care system.

Measurement is a key component of clinical governance, risk management, and quality improvement. Internal measurement and evaluation foster and contribute to accountability and performance culture. Health and social care organisations should develop open disclosure key performance indicators, evaluate open disclosure performance, and integrate outcomes into quality improvement, clinical governance, and performance monitoring.

The mechanisms and indicators for monitoring and evaluation of open disclosure will depend on the type of organisation and its functions. Health and social care service providers, health and social care service regulators, professional regulators, and education bodies all have a role to play by collecting and analysing data on open disclosure, patient safety incidents and adverse events and establishing any associated learning to improve quality and safety in health and social care services in Ireland.

Organisations must consider how to measure the successful implementation of the Framework, and this will depend on their role or functions. The subsections below outline the monitoring and evaluation mechanisms that organisations must consider for the implementation of the Framework.

7.2 Monitoring and Evaluating Implementation of this Framework: Department of Health

The Department of Health will monitor the implementation of this Framework in keeping with the principles below. Health and social care service providers, health and social care service regulators, and professional regulators will be **required to submit an annual report by the first week of April each year to the Minister for Health outlining how they are complying**

with each relevant section of the Framework, with the option to offer an explanation for any circumstances in which they are not complying.

The Minister/Department of Health will publish an annual national report on open disclosure to share the nationwide progress of the development and implementation of policies and procedures, development and delivery of training programmes, the establishment of support structures for staff and the number of trained staff and the appointment and training of champions in open disclosure. The number of open disclosure events initiated and closed by health and social care service providers should also be reported.

7.3 Health and Social Care Service Provider Considerations

Health and social care service providers are responsible for promoting open communication, ensuring that procedures exist for open disclosure and the management of patient safety incidents and adverse events. This should be reflected in their relevant policies and procedures, education, training, and relevant operational workings. The continuous monitoring and evaluation of open disclosure, patient safety incidents and adverse events in practice will reduce risk, inform future policy, and ensure the shift from a 'blame' culture to a 'just culture' where open communication is valued and accepted as the norm.

Health and social care service providers need to ensure appropriate direction and internal control through a system of clinical and corporate governance. By continuously monitoring performance and evaluating healthcare systems and processes for learning and improvement, health and social care service providers can ensure good governance, risk management, and quality improvement. Monitoring and evaluation of data on patient safety incidents, adverse events and open disclosure is a vital part of this process.

An annual report on open disclosure must be submitted by health and social care service providers to the Minister/Department of Health to demonstrate how they are meeting the requirements of the Framework.

The health and social care service providers' annual report will include information regarding:

a. Development and implementation of open disclosure policy.
b. Development and implementation of open disclosure training for all clinical and non-clinical staff including agency staff.
c. Evidence of the availability of support structure for all staff clinical and non-clinical including agency staff.
d. The number of trained clinical and non-clinical staff including agency staff.
e. The number of appointed and trained clinical and managerial open disclosure champions.
f. The number of open disclosure events initiated and closed.

Health and social care service providers must also comply with the requirements for mandatory open disclosure as set out in the Patient Safety (Notifiable Patients Safety Incidents) Bill 2019 (once enacted).

7.4 Health and Social Care Service Regulator Considerations

Health and social care service regulators are responsible for setting standards for the delivery of safe, effective health and social care and inspecting service providers against these standards. Health and social care service regulators, therefore, play a vital role in monitoring standards in relation to open disclosure and the management of adverse events/patient safety incidents.

The health and social care service regulators such as the Health Information and Quality Authority (HIQA) and the Mental Health Commission (MHC) should include in their monitoring standards the implementation of the open disclosure framework policy in designated centres and other relevant services and registered mental health services. In particular, the development and implementation of the open disclosure policy, availability of training and support structure for all clinical and non-clinical staff including agency staff, and the appointment of open disclosure champions.

It is recognised that Open disclosure is currently inspected by HIQA under the Standards for Safer Better Healthcare 2012 (Standard 3.5). This should be extended to private hospitals once the relevant provisions of the Patient Safety (Notifiable Patients Safety Incidents) Bill 2019 are enacted.

Opportunities for promoting the importance of open communication and open disclosure after patient safety incidents and adverse events should be examined as well as ensuring that the principles of the Framework are ingrained in the development of future standards and inspections.

An annual report on open disclosure must be submitted by HIQA and MHC to the Minister/Department for Health to assess their compliance with the Framework.

The health and social care service regulators' annual report will focus on the implementation of the requirements of the Framework in the designated centres and other relevant services and registered mental health services and will include information regarding the:

a. Development and implementation of open disclosure policy.
b. Development and implementation of open disclosure training for all clinical and non-clinical staff including agency staff.
c. Availability of support structure for all clinical and non-clinical staff including agency staff.
d. Appointment and training of open disclosure champions.

7.5 Professional Regulator Considerations

Professional regulators investigate complaints received about healthcare professionals specified under their legal mandate, evaluate whether health and social care professionals meet the requirements to practice in Ireland, and ensure that their registrants carry out and maintain records of continuing professional development. They maintain the register of the health and social care practitioners that they regulate and also evaluate and approve academic health and social care programmes with clinical components delivered by education bodies. Professional regulators therefore play a key role in monitoring health and social care professionals' compliance with open disclosure practise as well as ensuring that open disclosure is a key component of approved academic health and social care programmes with clinical components.

Professional regulators should report on changes to their relevant regulatory framework which aim to embed open disclosure into health and social care professional practises (e.g., codes of conduct, ethics, guidance, or standards where relevant). Professional regulators should also report on the number of undergraduate and postgraduate academic programmes with clinical/practical components that they have evaluated and approved which prepare the graduates in open communication, management of patient safety incidents and adverse events and open disclosure. These courses should prepare graduates in the associated policy and legal framework, including the relevant protections afforded to healthcare professionals under the Civil Liability Amendment Act 2017 and the Patient Safety (Notifiable Patients Safety Incidents) Bill 2019 once enacted.

Professional regulators should also report on the number of approved CPD training programmes on open disclosure available for their registrants and publish a list of these CPD training programmes on their websites.

An annual report on open disclosure must be made available by all professional regulators to the Minister/Department of Health to assess their compliance with the Framework.

The professional regulators' annual report will include information regarding the:

a. Details of Open disclosure embedded in the code of conduct/ethics.
b. Number of approved academic health and social care programmes with clinical /practical components incorporating open disclosure training.
c. Number of approved CPD courses on open disclosure.

7.6 Education Body Considerations

Education bodies providing academic programmes with clinical components deliver undergraduate (e.g., Trinity School of Medicine) and postgraduate (e.g., Irish College of General Practitioners) courses in health and social care education, providing graduates with the essential training needed to work effectively in the Irish Health and Social Care Sector. In recognition of the changing culture within health and social care, these providers are extremely well placed to educate prospective graduates in open communication,

management of patient safety incidents and adverse events and open disclosure when things go wrong in health and social care. By promoting the importance of these concepts through education and training, education bodies can equip graduates for a career in the modern health and social care service, reinforcing a culture of openness between clinicians, staff, and patients/service users and their support persons.
Education bodies must report on how open communication, management of patient safety incidents/adverse events and open disclosure are incorporated into health and social care programmes with clinical components to the relevant professional regulators. The report should include the development and implementation of policy, and the development and delivery of training in open disclosure.

Education bodies should also report on the CPD courses that they offer in open communication, patient safety incident/adverse event management, and open disclosure and indicate whether these courses have been accredited by their relevant regulatory body. These CPD courses should also be published on the websites of the education bodies.

7.7 Annual Report to the Minister for Health

An aggregated report based on the annual reports submitted by health and social care providers, health and social care regulators, and professional regulators and their stakeholders will be produced annually by the National Patient Safety Office to brief the Minister for Health. The Minister will be briefed on the compliance of stakeholders, the progress of the development and implementation of open disclosure policies, the development, approval, and delivery of education and training programmes, and the inclusion of open disclosure in all approved health and social care programmes with clinical/practical components and the number of staff and students trained. The Minister will be also briefed on the appointment of open disclosure champions, and the number of open disclosure events initiated and closed by health and social care service providers.
The aggregated report should also include the details of stakeholders who are not meeting the requirements of the Framework. These organisations should identify what sections of the Framework they consider challenging to implement and provide an explanation as to why. The annual aggregated report on the implementation of the Framework will be published on the Department of Health website to inform the public and it will be circulated to relevant stakeholders.

7.8 Review of the Policy

The regulation of the initial implementation of the Framework is a light-touch approach and the Department of Health will formally review the implementation of the Framework after 3 years. In the event that the implementation of the Framework is not deemed to be successful, the Department of Health will review the implementation model and initiate a more regulated approach to ensure that all the requirements of the Framework are fully implemented and adopted by all concerned stakeholders.

Key Messages

- Health and social care service providers, health and social care service regulators, and professional regulators must develop key performance indicators, appropriate to their organisational functions for measuring the implementation of the Framework.

- Health and social care service providers, health and social care service regulators, and professional regulators must submit an annual report to the Department of Health/Minister for Health outlining how they are complying with the implementation of this framework. Education bodies must submit their annual report to their respective professional regulators.

- Organisations who are not meeting the requirements of the Framework must identify what sections of the Framework they consider challenging to implement and provide an explanation as to why.

Appendix 1: IPSC Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland.

Independent Patient Safety Council

Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland

January 2021

Contents

Foreword from the Chairperson

Dear Minister

On behalf of the Independent Patient Safety Council, I am pleased to present you with our recommendations for a national policy framework for open disclosure in healthcare in Ireland.

The ministerially appointed Council provides advice and guidance to inform policy direction in relation to patient safety policy and works in support of the promotion of a culture of patient safety throughout the health services. In January 2020, the Council was asked by the then Minister for Health to undertake an examination of open disclosure policy in healthcare at the national level and make recommendations to him in relation to the development of a national policy framework regarding open disclosure in healthcare in Ireland.

Open disclosure is an issue of concern for many patients and service users. While much has been done to advance it in our healthcare system in Ireland, barriers to, and potential for improvement in open disclosure remain. Our recommendations present high-level principles and approaches to implementation to support the development and embedding of a national policy framework for open disclosure in healthcare in Ireland.

We trust that you will find that these high-level principles and recommendations will support a coherent approach from which you and your department can develop the framework and its implementation, leading to an improved culture where open disclosure is integral to everyday practice within our health system.

While the recommendations now furnished are those of the Council alone, and come from the many perspectives of our expert members, our discussions benefitted substantially from the evidence and analysis gathered by Crowe and published in the report "Evidence to Support independent Patient Safety Council for the Development of Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland", and we thank them for their assistance.

I would like to take this opportunity to thank my fellow members of the Independent Patient Safety Council for their hard work and commitment to this project in a time of enormous pressure for all those working in our health system. I would also like to thank the National Patient Safety Office in the Department of Health for their excellent and consistent support. My thanks also to all those who contributed to discussions and requests for information.

Noeline Blackwell
Chair, Independent Patient Safety Council

January 2021

Introduction

Open disclosure is an open, consistent, compassionate, and timely approach to communicating with patients/service users and/or their support persons following adverse events and patient safety incidents. Open disclosure is the professional, ethical and humane response to patients/services users and their support persons involved in/affected by patient safety incidents/adverse events. When something has gone wrong with patient or service user care, this is referred to as an adverse event or patient safety incident.

It is important that health and social care staff and providers have clarity on what is meant by open disclosure in terms of what is to be disclosed and in what way. Whilst patients/service users and support persons are entitled to open, timely, and clear communication about all aspects of their care, including if and when something goes wrong, not all "open disclosure" requires a formal process. A tiered, proportionate response to open disclosure, appropriate to what has happened and the impact on the patient/service user or support persons, is the approach that is required, in line with legislative requirements, regulatory codes of conduct or ethics, and organisational policies. Whilst some degree of judgement may be required in individual cases as to the appropriate level of response and the way in which disclosure should take place, guidance on this should be key in open disclosure policies and training across all health and social care providers.

Examples of where less formal responses would be required include:

- Near misses and no-harm incidents
- No increased level of care required (e.g. a surgical procedure necessitated by the event or transfer to an operating theatre or intensive care unit)
- No, or minor, psychological or emotional distress

However, in the following circumstances, it is evident that a more formal response to a patient safety incident or adverse event is required:

- Death or significant injury following a patient safety incident or adverse event
- Permanent or considerable lessening of body function following a patient safety incident or adverse event
- Where there has been a requirement for a significant escalation of care or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care, or transfer to intensive care unit)
- Major psychological or emotional distress
- Where a patient/service user or support person requests a more formalised or escalated response.

The development of these draft recommendations has been based on the evidence provided in the Crowe report to the Independent Patient Safety Council and the Council's subsequent deliberations on its findings. The Council engaged in a process of drafting and refining recommendations, and has opted to present the recommendations grouped around key principles.

A set of recommendations is set out for each principle, to indicate how the Council believes these principles should inform the national policy framework and health and social care policy and practice, and how they should be implemented and monitored.

There is some degree of overlap with the principles on which the current HSE open disclosure policy is based and many of these recommendations reflect existing practice. This is not to suggest that such policies and practice are not in place or effective: quite the reverse, in that it is intended to support what is positive about the current policy and practice and to build on this and expand beyond the HSE. Considerable work has been undertaken in the HSE to improve the organisation's approach to open disclosure and these recommendations are intended to support this through the national policy framework.

The recommendations set out in this document, based on a set of key principles, are intended to apply across the entire health and social care sector and to all adverse events and patient safety incidents, including those requiring lower- and higher-level responses.

The recommended key principles underpinning the policy framework are as follows:

- **Open, Honest, Compassionate, and Timely Communication**
- **Patient/Service User and Support Persons' Entitlements in Open Disclosure**
- **Supporting Health and Social Care Staff**
- **Promoting a Culture of Open Disclosure**
- **Open Disclosure for Improving Health and Social Care Policy and Practice**
- **Clinical and Corporate Governance for Open Disclosure**

Principle 1: Open, Honest, Compassionate, and Timely Communication

1.1 Open disclosure[1] is defined as an open, consistent, compassionate, and timely approach to communicating with patients/service users and/or their support persons following adverse events and patient safety incidents. When something has gone wrong with patient or service user care, this is referred to as an adverse event or patient safety incident[2].

Open disclosure is a core component of excellent care within a compassionate and competent health and social care system, across all health and social care settings including those in the public and private sectors.

Communication with patients/service users and/or their support persons must be compassionate, truthful, timely, and clear. If things go wrong, the patients/service users and/or their support persons must be provided with information about what happened in a timely, open, compassionate, and honest manner. This applies to all patient safety incidents or adverse events.

1.2 Open disclosure must be considered an integral aspect of communication between health and social care staff and patients/service users and/or their support persons. Whilst there must be formal open disclosure processes in place for serious incidents resulting in patient harm, most patient safety incidents or adverse events do not require a formal process to be initiated and the disclosure of these incidents must be part of open and truthful communication to patients/service users and/or their support persons. Incidents resulting in more significant impact on patients/service users and/or their support persons will require a more formalised approach.

1.3 Open disclosure must be considered as an ongoing and fluid process as information becomes available rather than a one-off event.

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1. Whilst there are valid misgivings about the terminology, in the absence of a universally acceptable alternative and mindful of the wording in existing and forthcoming legislation and in many existing policies such as those in the HSE, for the purposes of the national policy framework, the Council recommends the use of the term "open disclosure" to refer to the communication between health and social care staff and health and social care service providers to patients and/or support persons in respect of patient safety incidents.

2. The term "patient safety incident" is used in HSE policies and in the Patient Safety Bill 2019. However, the application of the national policy framework to all health and social care means that broader terms are needed rather than solely referring to "patients", hence the use in this document of "adverse events and patient safety incidents".

1.4 It is important that health and social care staff (clinical and non-clinical) and patients/service users and their support persons have clarity and understanding of what open disclosure means, what type of incidents require open disclosure, the information that must be provided, how the process should be managed, what is disclosed, and how it works. If there is ambiguity, confusion, or doubt on any of these, open disclosure is less likely to happen in a consistent, effective, and appropriate manner.

1.5 There must be clarity in respect of the appropriate level of response to adverse events and patient safety incidents: health and social care staff must be clear on the types of incidents that require the initiation of a formal open disclosure process, which must include a timely initial discussion with the patient/their support person to advise them about what has happened and the facts that are available at that time. This will be followed at a later stage by a formal open disclosure meeting when more information relating to the incident becomes available.

1.6 The instigation of formal open disclosure should be in addition to timely communication to patients/service users and/or their support persons to advise them of what has happened.

Implementation of this principle

1.7 Building on the significant work already undertaken across the health and social care sector in developing open disclosure policies, there must be consistent policies on open disclosure across all health and social care service providers, clinical education providers, and health and social care regulatory bodies, aligning with the national framework principles, definitions, and provisions.

1.8 Health and social care providers must communicate their open disclosure policies and procedures to patients/service users and/or their support persons clearly and in a way that ensures they are understood.

1.9 Policies on open disclosure are intrinsically linked to patient/service user safety policies and incident management policies. They must be clear and consistent with these policies in respect of identifying when incidents occur, the requirements for disclosure to patients/service users and/or their support persons, the requirements for disclosure to the health and social care service providers as relevant, and the requirements for compliance with relevant legislation such as the provisions of the Patient Safety Bill 2019.

1.10 Health and social care providers must integrate and align open disclosure policy and practice with the contractual roles and responsibilities of health and social care staff and all relevant policies and procedures pertaining to the fulfilment of their contractual obligations.

Principle 2. Patient/Service User and Support Persons' Entitlement in Open Disclosure

2.1 In the event of an adverse event or patient safety incident, patients/service users and/or their support persons want an acknowledgement of what has happened, an explanation as to how or why it happened, a meaningful apology, and reassurance in relation to their on-going care and treatment and in relation to the steps being taken to try to prevent a recurrence of the same incident.

2.2 All adverse events and patient safety incidents must be **acknowledged** to the patients/service users and/or their support persons at the earliest opportunity that is practicable. This acknowledgement must consider the physical, emotional, social, and financial impact of the incident on the patients/service users and/or their support persons.

2.3 The patient/service user and/or support persons are entitled to **an explanation**, to be fully informed of the facts surrounding an adverse event or patient safety incident and its consequences (which may involve a process as the full facts in respect of an incident emerge); to be treated with empathy, respect, compassion, and consideration; and to be supported in a manner appropriate to their particular needs.

2.4 The patients/service users and/or their support persons must receive an **apology** or expression of regret for what has happened in respect of an adverse event or patient safety incident. An apology must be genuine, respectful, sincere, and personal to the individual and the given situation. An apology must be given at the earliest opportunity that is practicable, even if all the information relating to the adverse event or patient safety incidence is not yet available.

The apology must include:

(i) an acknowledgement of what it is that the service is apologising for;
(ii) an explanation of why or how the situation occurred;
(iii) the words *I am sorry for what has happened* and for how the situation has impacted the patient and/or their support person;
(iv) an outline of the steps taken or planned by the service to put things right.

It should include reference to the supports available to patients/service users and/or their support persons in relation to the incident and open disclosure, and all avenues for escalating disclosure processes and/or concerns.

2.5 Patient or service user **ongoing care and treatment** must not be compromised or delayed in respect of the disclosure of an adverse event or patient safety incident. If requested by patients/service users and/or their support persons, or in the patient/service user's best interests where appropriate, transfer of care to another clinician or to another health or social care provider must be facilitated when it is possible to do so. Patients/service users and/or their support persons exercising their right to seek recourse or redress must not be treated differently.

2.6 Patients/service users and/or their support persons have the right to escalate complaints or concerns about the disclosure process or the adverse event or patient safety incident itself – and be supported to do so – through any and all mechanisms available, including the right to seek legal or other redress.

2.7 The patient/service user right to confidentiality must be maintained throughout any open disclosure process.

Implementation of this principle

2.8 Consideration should be given to the provision of independent support services to all affected patients/service users and/or their support persons, should they need it. This support should be free and independent of the health or social care provider (separate and distinct from legal or policy obligations for health and social care providers to appoint a designated liaison person) and provided by suitably trained and competent personnel to support the patients/service users and/or their support persons for as long as is required. All patients/service users and/or their support persons involved in the aftermath of an adverse event or patient safety incident should:

- be enabled to participate in the open disclosure;
- be supported through the open disclosure process;
- have access, where needed, to independent support to help in the immediate aftermath of the incident and on an on-going basis for as long as is required;
- be informed by health and social care staff and/or health and social care providers of the independent support that is available to them and empowered to avail of it.

2.9 Support for patients/service users and/or their support persons must be accessible where special circumstances may make them more vulnerable (such as those with disabilities, mental health difficulties, etc.), including:

- policy guidance for open disclosure procedures for these categories of patients/service users;
- training for health and social care service providers and staff tailored to open disclosure for vulnerable patients/service users and support persons;
- the provision of patient/service user advocates with particular training in advocating for and communicating with people in these situations.

2.10 Open disclosure policies in health and social care providers must encompass procedures for the provision of information and apologies, and must include procedures for providing updated information to patients/service users and/or their support persons following internal reviews or investigations into adverse events or patient safety incidents.

2.11 There should be legal, indemnity, and employment protections for the provision of information and apologies by health and social care workers and/or health and social care providers in respect of open disclosure communications.

2.12 In the event that patients/service users and/or their support persons later wish to pursue formal, legal or other redress following an adverse event or patient safety incident, health and social care providers must also provide at this stage all the relevant information to facilitate patients/service users and/or their support persons to exercise this right.

Principle 3. Supporting Health and Social Care Staff

3.1 All open disclosure in relation to adverse events and patient safety incidents must be patient- or service-user-centred and place the needs of the patient/service user and/or support persons at the heart of the process. In addition, it is important to identify the staff involved in and/or affected by the adverse event or 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, in recognition of the impact of such incidents on staff. All staff in health and social care delivery must be:

- encouraged, facilitated, empowered, and obliged to recognise and report adverse events and patient safety incidents;
- prepared to participate in open disclosure through easy access to information, communication skills, training and education, and supportive procedures;
- supported through the open disclosure process.

3.2 Open disclosure involves multidisciplinary accountability and response. Clinical, non-clinical, and managerial staff must be identified within health and social care providers to lead and support the process. Open disclosure relates to all staff groups and not just clinical staff. All staff have a role in reporting adverse events and patient safety incidents. All staff have a role in supporting patients/service users, support persons, and colleagues involved in adverse events and patient safety incidents.

3.3 It must be recognised that failure to disclose openly to patients/service users and/or their support persons in relation to an adverse event or patient safety incident may be subject to consequences and that all health and social care staff must clearly understand their obligations in relation to open disclosure.

Implementation of this principle

3.4 Health and social care providers must include mechanisms in open disclosure policies to empower staff to report adverse events and patient safety incidents and to communicate with patients/service users and/or their support persons openly in relation to these incidents.

3.5 Health and social care staff must have access to and participate in appropriate training, guidance, and support in relation to open disclosure to patients/service users and/or their support persons. Each health and social care provider should designate specific personnel to lead on this.

3.6 Mechanisms to facilitate this type of training, guidance, and support to health and social care staff working outside organisational settings or in very small organisations must be put in place.

3.7 Health and social care professional regulatory bodies must include clear and unequivocal obligations for open disclosure in codes of conduct and ethics for regulated practitioners, aligned to the definitions and terminology set out in the policy framework.

3.8 Education and training bodies for all clinical professions must include modules in relation to communication skills, adverse event and patient safety incident management, and open disclosure in undergraduate, postgraduate, specialist training, and continuing education and development programmes.

Principle 4. Promoting a Culture of Open Disclosure

4.1. A supportive culture is critical to effective open disclosure. Recognition must be given to the importance of developing and maintaining a culture in which open disclosure takes place as a matter of course, in a patient- and service user-centred and compassionate way, by health and social care staff who are supported to do so. The health and social care system must avoid a "blame culture", which seeks to place responsibility for adverse events and patient safety incidents on individual health and social care staff, in favour of a "just culture", which promotes psychological safety.

4.2. A just culture is one based on fairness, which recognises the capacity for human error and the role of system and environmental factors in adverse events and patient safety incidents, and in which everyone seeks to learn and improve. It includes ensuring people are accountable for their actions and responsible for learning. This approach will better meet the needs of patients/service users and/or their support persons in relation to open disclosure and the management of adverse events and patient safety incidents. as well as patient outcomes.

Implementation of this principle

4.3. Culture change requires a multi-faceted approach and strong leadership. Health and social care providers must demonstrate that they have put in place effective processes by which they support the development of a positive and just culture for open disclosure.

4.4. Clinical and managerial champions must be identified by health and social care service providers to lead and promote open disclosure policy and practice.

4.5. Education and training programmes must be provided for all health and social care staff to support and promote a culture of open disclosure.

4.6. Health and social care providers must be able to demonstrate that staff are encouraged to disclose adverse events, patient safety incidents, or any concerns to patients/service users, support persons, and colleagues or managers.

4.7. Health and social care providers must be able to demonstrate that they have an "open disclosure by default" approach and that patients/service users and/or their support persons are provided with relevant information in a timely manner. Health and social care

providers and staff must not adopt a defensive approach seeking to minimise or delay the provision of information by any means.

4.8. Mechanisms to assess the culture and practice of open disclosure must be put in place by health and social care providers, to provide regular data on how it is working for patients/service users and for health and social care staff and what progress is being made towards a just culture rather than a blame culture.

4.9. Health and social care providers must identify and regularly monitor the patient/service user and health and social care staff experience of open disclosure. This information will then be used to:

- Inform policy;
- Support capacity building;
- Empower patients/service users and/or their support persons to speak up and ask questions;
- Assess how success is measured and encourage leadership;
- Shift to a proactive rather than reactive approach to safety and disclosure.

Principle 5. Open Disclosure for Improving Policy and Practice in Health and Social Care

5.1 Open disclosure is one essential component of the process of addressing an adverse event or patient safety incident and learning from this to improve services in the health and social care system.

5.2 Adverse events and patient safety incidents must be identified, managed, reported, disclosed, and reviewed, and learning derived from them.

5.3 An effective, accessible and timely open disclosure process may help to reduce the need for further escalation and minimise the impact involved following an adverse event or patient safety incident.

5.4 Actions must be taken to try to prevent a recurrence of such incidents. Patients/service users and/or their support persons must be involved in the process of management and review of adverse events and patient safety incidents and must be informed of the outcome of such reviews.

Implementing this principle

Continuing to build on the work of the health and social care providers and regulators:

5.5 The health and social care service providers and regulators must provide clarity and guidance, including clear guidance materials such as checklists, for health and social care staff in respect of the requirements to disclose and report on adverse events and patient safety incidents.

5.6 There must be provider-level and national mechanisms for recording, reporting on, and monitoring adverse events and patient safety incidents, the response to these, and the open disclosure associated with them, as happens within the National Incident Management System. Consideration should be given to the use of the National Incident Management System by other health and social care providers to record and report such incidents and disclosure.

5.7 Open disclosure processes should be as simple and as accessible as possible for patients and staff.

5.8 Health and social care providers must demonstrate that mechanisms are in place for learning and improvement in respect of adverse events and patient safety incidents and the disclosure process associated with these.

5.9 Open disclosure reports from health and social care providers must include examples of the types of incidents that led to policy changes thereafter as a section in the report and should be available for review by the appropriate regulatory bodies.

Principle 6. Clinical & Corporate Governance for Open Disclosure

6.1. Health and social care services must have governance frameworks with appropriate accountability structures in place which ensure that open disclosure occurs and that it is integrated with other clinical and corporate governance systems and processes, including clinical incident reporting and management procedures, systems analysis reviews, complaints management, and privacy and confidentiality procedures.

6.2. The governance framework for open disclosure encompasses health and social care provider policies, clinical governance frameworks, corporate governance frameworks, monitoring, regulation, and legislation.

Implementing this principle

6.3. It is important that the governance of open disclosure be based on a "comply or explain" concept, whereby compliance with obligations to disclose adverse events and patient safety incidents is expected and staff and/or health and social care service providers who have not complied must be accountable for providing explanations as to why this is the case.

6.4. Annual reporting by health and social care providers on open disclosure must be put in place. Reporting should be integrated with other related reporting, such as incident management, to ensure that it is not fragmented and that data can be captured and reported on in simpler, more useful ways. Examples of "good" annual reports, and/or templates for these, should be shared to promote excellence.

6.5. The inclusion of open disclosure as part of HIQA and Mental Health Commission guidance and monitoring should be considered, particularly in light of the proposed extension of this role to private hospitals.

6.6. The Patient Safety Bill 2019, on passing into law, must, before commencement of its provisions, be accompanied by a clear set of guidance materials for all health and social care service providers and practitioners to support the correct interpretation and application of the legislation.

6.7. The legislation must be considered as one part of an overall national policy approach to, and governance of, open disclosure and not as a single lever or tool for change.

Appendix 2: Open Disclosure in Regulated Professions in Ireland.

Professional Regulator	**Open Disclosure/Duty of Candour/Open Communication is in place in the Code of Conduct, Ethics, or Guidance** (Including Reporting Adverse events/Patient Safety Incidents)	**Title of the Document**
Medical Council	Yes	• Guide to Professional Conduct and Ethics for Registered Medical Practitioners (Amended) 8th Edition 2019
Nursing and Midwifery Board	Yes	• Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives
Pharmaceutical Society Ireland	Yes	• CODE OF CONDUCT - Professional Principles, Standards and Ethics for Pharmacists
Dental Council	Yes	• Code of Practice relating to: Professional Behaviour and Ethical Conduct Promoting transparency and enhancing public confidence in the dental profession
CORU	Yes	• Dietitians Registration Board Code of Professional Conduct and Ethics • Medical Scientists Registration Board Code of Professional Conduct and Ethics • Optical Registration Board Code of Professional Conduct and Ethics for Dispensing Opticians • Optical Registration Board Code of Professional Conduct and Ethics for Optometrists • Occupational Therapists Registration Board Code of Professional Conduct and Ethics • Physiotherapists Registration Board Code of Professional Conduct and Ethics

		• Radiographers Registration Board Code of Professional Conduct and Ethics • Social Care Workers Registration Board Code of Professional Conduct and Ethics • Speech and Language Therapists Registration Board Code of Professional Conduct and Ethics • Social Workers Registration Board Code of Professional Conduct and Ethics • Podiatrists Registration Board Code of Professional Conduct and Ethics
PHECC	No	No

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