Draft Regional Being Open Framework for the HSC

December 2024

Contents

1.0 Introduction - Background and Purpose

This Framework was developed through a Co-Production process involving service users, carers, leadership, and staff from HSC organisations, as well as the Department of Health, community and voluntary sector, the Coroner's Service and independent health sector organisations.

The aim was to respond to the 2018 report from the Inquiry into Hyponatraemia Related Deaths (IHRD) by Justice O'Hara KC. The report into the deaths made 96 recommendations and 120 actions for the Department of Health and the Health and Social Care sector.

The findings of the Inquiry are available at Report of the Inquiry into Hyponatraemia related Deaths (ihrdni.org)

Key recommendations of the report relate to a Duty of Candour and emphasised that:

- Every healthcare organisation and everyone working for them must be open and honest in all their dealings with patients and the public.
- Where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or duly authorised representative) should be informed of the incident and given a full and honest explanation of the circumstances.
- Full and honest answers must be given to any question reasonably asked about treatment by a patient (or duly authorised representative).
- Any statement made to a regulator or other individual acting pursuant to statutory duty must be truthful and not misleading by omission.
- Any public statement made by a healthcare organisation about its performance must be truthful and not misleading by omission.
- Healthcare organisations who believe or suspect that treatment or care provided by it, has caused death or serious injury to a patient, must inform that patient (or duly authorised representative) as soon as is practicable and provide a full and honest explanation of the circumstances.
- Registered clinicians and other registered healthcare professionals, who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare organisation by which they are employed has caused death or serious injury to the patient, must report their belief or suspicion to their employer as soon as is reasonably practicable.

A complete account of the recommendations of the report can be found here.

Patient safety incidents can have devastating emotional and physical consequences. Being Open about what happened and discussing incidents promptly, fully and compassionately can help patients and professionals to cope better with the after-effects.[1]

The **Framework** includes:

a) a **definition of what 'Being Open'** means.
b) the **principles of 'Being Open'**.
c) the **process of implementing 'Being Open'**.
d) how to **assess and measure the cultural change** towards 'Being Open'.

1.1 Background

The Inquiry into Hyponatraemia-Related Deaths (IHRD) was published following an extensive investigation into the deaths of 5 children in hospitals in Northern Ireland.

It concluded that the deaths had been avoidable and that the culture of the health service at the time, arrangements in place to ensure the quality of services and the behaviour of individuals had contributed to those unnecessary deaths.

The Inquiry Report made 96 recommendations across a number of themes and there are many linkages between this policy and others developed as part of the overall implementation programme. Primarily, this policy should be considered in the context of other recommendations and guidance particularly those focusing on candour and openness.

The IHRD recommendations on Duty of Candour and Openness are set out in Appendix 1, with links given to related recommendations.

1.2 Purpose of this Framework

The purpose of this Framework is:

- To improve patient safety and the quality of services by developing an open, just and learning culture.[2]
- To ensure that all people in contact with our organisations (employees, patients, relatives and the public) can expected to be treated in an open, fair and compassionate way.
- That patients and those supporting them will be listened to, understood and treated with respect.
- That HSC staff are entitled to visible, engaged and inclusive leadership.

[1] The World Health Organisation (WHO) has defined patient safety as 'the absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with health care to an acceptable minimum'. envisaging a world in which no one is harmed in health care, and every patient receives safe and respectful care every time, everywhere'.

[2] Restorative Just and Learning Culture :: Mersey Care NHS Foundation Trust

- That senior leaders will listen to concerns and create safe spaces for learning.
- That learning will be promptly disseminated across the system.

This framework provides a consistent regional approach to the practical arrangements and principles to be followed by HSC Arms Length Bodies in order to create a culture of openness where trust can flourish between service users, staff and the organisations that make up the HSC system.

The key principles have been developed in line with the recommendations from the Inquiry into Hyponatraemia Related Deaths and the Independent Neurology Inquiry.

1.3 Scope of the Framework

This framework applies to all sixteen HSC Arms-Length Bodies, as set out in Appendix 2. These include:

a) all HSC Trusts (Belfast Trust, Southern Trust, South Eastern Trust, Northern Trust and Western Trust) including the Northern Ireland Ambulance Service, and each member of staff employed within these organisations;

b) The HSC regulators, including RQIA and NI Social Care Council;

c) All HSC partner organisations including the Public Health Agency, the Patient Client Council, the Northern Ireland Medical & Dental Training Agency, NI Guardian Ad Litem Agency and the Northern Ireland Practice and Education Council; and

d) The NI Blood Transfusion Service, Adult Safeguarding Board and Business Service Organisation.

2. Development of a Regional Being Open Framework for the HSC

"Being Open" is a core value of the Health and Social Care system in Northern Ireland.[3] This value is described as a commitment to "being open and honest with each other and acting with integrity and candour". A core purpose of being open is to encourage learning from mistakes and develop better systems that help improve patient safety and quality of care.

Understanding what this means in practice has been an evolving challenge, with multiple public inquiries raising questions about how concerns are raised and acted upon. Specifically, the Inquiry into Hyponatraemia Related Deaths (IHRD) made a number of recommendations for the introduction of a Statutory Duty of Candour in

[3] https://jobs.hscni.net/Information/23/health-social-care-values

Northern Ireland for organisations and individuals and the introduction of criminal sanctions for breach of this duty.[4]

Alongside the possibility of the introduction of statutory instruments to require candour within HSC, there is the recognition that staff and organisations need support and direction to develop an open, just and learning culture. The purpose of this "Being Open Framework" is to provide this guidance.

2.1 The Wider Context - Patient Safety and an Open, Just and Learning Culture

There is clear evidence to support the relationship between Patient Safety and an Open, Just and Learning Culture.[5]

The HSCNI has "Openness and Honesty" as one of its core values.[6]

All HSCNI Trusts are all involved in the development of policy to support an Open, Just and Learning culture within the health service. While openness is one of the key components of this, it is also a principle that underpins each of the other elements.

An **Open Culture** is one in which staff, at all levels, feel empowered and supported to speak openly about their work and the work of others in the context of patient safety, staff safety and the quality of care they provide:

- as a matter of routine during normal business;
- to help improve services; and
- when the provision of care has gone wrong, and harm has been caused.

A **Just Culture** is about creating a culture of fairness, transparency and learning. It recognises that success or mistakes happen and are the product of many factors and focuses on changing systems and processes to make it easier for people to do their job safely.

A Just Culture is about ensuring everyone is confident that they will be treated fairly when something goes wrong. It is not about an absence of responsibility and accountability. Staff remain professionally accountable for their practice within the scope of their contracts of employment, accrediting bodies and the law.[7]

A **Learning Culture** is one in which there is support and freedom for staff and service users to speak openly about and reflect on what has worked well, and what could be improved in the provision of care, and that the health system is inquisitive and

[4] https://www.health-ni.gov.uk/ihrd
[5] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05303
[6] https://jobs.hscni.net/Information/23/health-social-care-values#
[7] NHS England » Improving patient safety culture – a practical guide

responsive to this information; proactive and eager to improve systems and services in response – both routinely and when the provision of care has gone wrong.

2.2 Existing Legislative Duties and Guidance

There are existing legislative duties including for example HSC policies, HSC circulars, professional codes of practice, external regulatory and professional reviews, public inquiries and internal HSC organisational governance and assurance arrangements that relate to each of the components of an Open, Just and Learning Culture, and to a professional Duty of Candour (including but not limited to the following):

2.2.1 Open Culture:

- Duty of Quality.[8]
- Personal Public Involvement (PPI) Statutory Duty.[9] [10]
- Staff Contracts and terms of employment.
- Professional Duty of Candour and Standards of Conduct and Practice.[11] [12]
- DoH Early Alert System.
- Memorandum of Understanding (MOU) investigation patient or client safety incidents.
- DoH Raising a Concern in the Public Interest (Whistleblowing) HSC Framework and Model Policy for HSC organisations.
- HSC Trust Adverse Incident Reporting Policy, including near misses and the management of Serious Adverse Incidents.
- HSC Trust Being Open Policies.
- HSC Complaints Procedures.
- HSC Cooperating with Coroner's investigations and Preparing for Inquests Regional Policy.

[8] The statutory duty of quality (found in The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003).

[9] The Health and Social Care Reform Act (NI) 2009 placed a statutory legislative requirement on certain HSC organisations to involve and consult patients, carers and the PCC on the planning, delivery and evaluation of services.

[10] Guidance for HSC organisations on arrangements for implementing effective PPI in the HSC (HSC (SQSD) 03/2012.

[11] The professional duty of candour (applying to healthcare professionals) extends to all occasions when something goes wrong with treatment or care and the patient suffers harm or distress as a result. It also applies in situations where it is anticipated that the patient will suffer harm or distress as a result of something going wrong with their care. Additionally, it requires that risks are discussed before beginning treatment or providing care, and it requires that healthcare professionals follow the organisational policy for reporting incidents and near misses, and for senior clinicians that they actively foster and contribute to a culture of learning and improvement. GMC and NMC - Guidance on the professional duty of candour (March 2022) - General Medical Council (GMC) - Patient Safety Learning - the hub (pslhub.org)

[12] Northern Ireland Social Care Council Standards of Conduct and Practice at Standards of Conduct and Practice - NISCC

- HSC Trust Management of Health and Safety Policies.
- Morbidity and Mortality Review Guidance and HSC Policies; and
- HSC Trust Reporting of Injuries, Diseases and Dangerous Occurrences Regulations Policies.

2.2.2 Just Culture:

- Contract and terms of employment.
- Complaints, Serious Adverse Incidents and learning systems.
- Regulatory bodies oversight, training and sanctions.
- HR Policies including for example Grievance, Disciplinary, Bullying and Harassment, Performance Management and Capability Processes.
- HSC Lookback Reviews.
- Public Inquiries.
- Independent Inquiries.

2.2.3 Learning Culture:

Self-correcting mechanisms in organisations refer to processes, systems, or behaviours that enable an organisation to promptly identify learning and actions to address its own mistakes, inefficiencies, or deviations from goals without requiring external intervention. These mechanisms are typically embedded in the organisation's structure, culture, or feedback systems and allow for continuous improvement and learning. Self-correcting mechanisms are essential for developing an Open, Just and Learning culture in healthcare. The following are some potential examples of components that can help in the delivery of these goals.

- HSC Regional Shared Learning from Serious Adverse Incident Reviews, Never Events and Complaints and Claims Reviews.
- HSC Trust Board Committees including the Patient Safety and Quality Committee and Board Sub Committees.
- HSC Trust Mortality and Morbidity committees.
- Safeguarding policies.
- Safeguarding Boards Safety reporting and analyses.
- Actions from organisational self-correcting mechanisms
- RQIA reviews and reports.
- RQIA inspections and reports.
- Patient and Client Council Reports.

Each of the main **professional bodies** that represent the professional interests of staff have **policies relating to openness and a duty of candour, and it is accepted that openness and candour** are core components of professional standards.

It is recognised the guidance and many of the policies listed above are **based on cross cutting themes** and will support elements of each of the components of open, just and learning cultures.

3 Understanding Openness and Culture

This section will outline the principles of openness at three levels, culture with three interlinked and interdependent components and the enabler for openness and the enablers for openness within the HSC.

3.1 Levels of Openness

The HSC Being Open Framework is intentionally expansive and inclusive. This derives from the assumption that if the **general and routine culture** of the organisation is **open, then when things go wrong,** staff will find it easier automatically to be open as a matter of normal practice. The Framework describes Openness at three levels as shown in Table 1 below.

Table1 Being Open Framework Levels of Openness

	Organisational Infrastructure	Organisational Behaviours	Organisational Beliefs and Narratives
Routine Cultural Openness	e.g. What systems are in place to support routine openness?	e.g. What staff or managerial behaviours are exhibited to encourage routine openness?	e.g. What do people believe will be the consequences of routinely being open?
Openness focused on constant Learning	e.g. What systems are in place to facilitate ongoing learning and improvement?	e.g. How do staff or managers respond to learning opportunities?	e.g. What do people believe about the sincerity of the organisation's desire to learn and improve?
Openness when things go wrong	e.g. What systems are in place to ensure openness when things go wrong?	e.g. How do staff or managers behave when things go wrong?	e.g. What do people believe will be the consequences when things go wrong?

3.1.1 Routine Openness

Routine Openness, as the name suggests, is where openness is an intrinsic and routine component of day-to-day activity.

Routine Openness is experienced by patients and service users through the proactive routine sharing and accurate recording of information by staff about their treatment and care. In addition, routine openness is experienced by patients and service users when staff proactively explain treatment and care options and obtain agreement or consent when necessary.

Routine Openness is facilitated for staff through the routine provision of regular and frequent opportunities to reflect on patient safety, staff health, safety and wellbeing and the quality of care they provide, to share experiences and to provide support to each other in the challenges they face as teams.

Organisations can facilitate routine openness through the provision of opportunities and time for staff to reflect on their work experiences, in teams and individually.

3.1.2 Openness with a Focus on Learning

Openness with a focus on learning, is an intrinsic component of any organisation's learning culture.

Openness with a focus on learning is experienced by patients and service users through being actively listened to by staff when concerns are raised by families or individuals. Those concerns acknowledged, recorded and meaningfully addressed by the organisation.

Openness with a focus on learning when services change, or are withdrawn, is based on the statutory duty of involvement. Staff and Organisations should learn from patients, service users and carers feedback and use any learning to improve patient safety and the quality of care.

Openness with a focus on learning is experienced by staff as support from their organisation to speak openly about and learn from their experiences, both good and bad, and the proactive sharing and implementation of the consequent service improvements and changes.

Openness with a focus on learning requires the presence of psychological safety, where staff, patients and service users feel able to talk about sub-optimal experiences without fear of disproportionate or unfairly punitive responses. When individuals feel psychologically safe, they feel included, valued and respected. They believe they can speak up, ask questions or make mistakes without being embarrassed, marginalized or punished. This will enhance opportunities for improvements in patient safety, staff safety and the quality of care they provide

Openness with a focus on learning requires an organisation to "de-stigmatise" errors and mistakes and shift the focus away from blame to learning, while maintaining appropriate service governance and accountability.

3.1.3 Openness when Things go Wrong

Openness when things go wrong can be understood as a Duty of Candour.

Openness when things go wrong is experienced by patients, service users, and families, as the timely and proactive provision of accurate information, proactive listening and providing meaningful support whenever the provision of care has gone wrong, patient safety has been compromised or quality of care has been compromised and harm or death has been caused.

Organisations have a responsibility to support staff involved in incidents where harm or death has been caused to be open and to participate in whatever processes may arise.

Openness when things go wrong may often include the provision of an apology to those affected, this should not impact any subsequent formal investigation to determine cause or liability.

Openness when things go wrong includes openness about a person's own actions, as well as their observations of others.

Openness when things go wrong involves participation in whatever formal processes of inquiry that may arise as a consequence of the incident.

Organisational openness should look beyond the individuals involved to see if system weaknesses or the provision of resources contributed to an incident.

Organisations should be open to the recognition and acceptance of resource allocation having an impact on care provision and its potential to contribute to patient safety.

3.2 A Culture of Openness in the HSCNI

This approach is intentionally focused on developing and supporting a culture of openness in the HSCNI system. This is a recognition that neither legislation nor policy alone will necessarily inspire the behaviours that are intrinsic to an open organisation.

This approach is intentionally focused on describing the support that it is necessary to provide to staff and the public, in order for them to feel both empowered and secure enough to be open in the way this framework expects.

The primary responsibility for this support lies with the main employers, who as part of their duty of care, should ensure that their staff and the public are provided with the tools and encouragement necessary to operated openly as this framework describes.

For the purposes of the HSCNI Openness Framework, culture is understood to have three interlinked and interdependent components:

1. **Formal Structures.** These are the policies, procedures and expected practices that an organisation has explicitly articulated to describe the

parameters within which it expects its staff to behave and how it involves and engages its patients and service users.

2. **Accepted Behaviours**. These are the behaviours, both positive and negative, that characterise how the policies, procedures and expected practices are realised. Accepted behaviours are treated as "the norm" in organisations.

3. **Agreed Beliefs and Narratives.** These are the beliefs and assumptions staff and the public have about the culture of the organisation, and the degree to which the organisation's behaviours are consistent with its values.

3.3 Enablers for Openness

The following are the enablers for the three levels of openness in respect of the three levels of openness interlinked and interdependent components outlined above:

3.3.1 Routine Openness:

(i) Formal Structures

Supporting the provision of routine regular individual supervision/ support of staff, and training for those with supervisory responsibilities on facilitating openness.

Employing organisations should incorporate a "Duty of Candour" into their contracts of employment for all staff.

Supporting the provision of regular formal staff group reflection meetings, and training for those with responsibility to facilitate these.

The incorporation of opportunities for sharing experiences in other regular staff engagements such as safety huddles or shift/ team handover meetings.

Providing openness awareness training through corporate and local induction and ongoing training programmes which should be considered as mandatory training.

Building a clear understanding with the public about the standards of openness they can expect from HSC organisations.

Providing training, resources and support for staff to effectively use involvement mechanisms (PPI), when service change takes place or is proposed within their area.

(II) Accepted Behaviours

Managerial leaders supported and trained to role model reflection and openness in their own behaviours and in their facilitation and management of others.

Senior leaders (clinical and managerial) supported and trained to role model reflection and openness in their own behaviours and in their facilitation and management of others.

Examples of appropriate behavioural responses identified and discussed as positive case studies in staff meetings and staff engagement events.

Leaders should actively promote the need for patient, service user and carer involvement and to seek assurance that all change affecting the provision and delivery of care has been informed by a meaningful involvement process.

The inclusion in meetings of feedback from patients and service users to highlight where improvement is needed and where things are working well.

(iii) Agreed Beliefs and Narratives

The development of case studies highlighting appropriate routine openness.

The promotion through publication and social media dissemination of successful examples of routine openness and its beneficial consequences.

The inclusion in celebration and award events of excellent examples of routine openness or the creation of innovative mechanisms to support routine openness.

3.3.2 Openness with a Focus on Learning

(I) Formal Structures

All processes organisations have that are focused on capturing learning from incidents, near misses or improvement initiatives should be underpinned by the principles of openness.

All processes that organisations have that are designed to investigate patient safety incidents or near misses or other possible staff safety or quality of care errors should

be constructed in such a way as to incentivise and applaud openness. Care should be taken that these systems are not unnecessarily punitive and do not create a disincentive for openness. The involvement of patients, service users and their carers, in such processes, should reflect the principles of openness.

Systems should be designed that support staff to be open in circumstances where there has been a patient safety incident, near miss or quality improvement opportunity.

Systems should be designed that actively inform the public of service of improvements that have occurred as a consequence of staff openness.[13]

(II) Accepted Behaviours

The acceptance and normalisation of speaking about mistakes or near misses is critical to the development of an open culture. The behaviours and reactions of managers and senior leaders to mistakes gives a clear signal to staff concerning whether it is safe for them to speak up, and consequently whether they feel psychological safe enough to do so.

Managers and senior leaders should be supported to respond to the open discussion of patient safety incidents, near misses or improvement opportunities by staff with compassion, understanding, acceptance and support. Without compromising appropriate and proportionate accountability requirements, managers and senior leaders should be supportive and understanding of mistakes, making a distinction between routine mistakes and fundamental service failures. To a large extent, speaking openly about routine mistakes helps prevent these escalating to service failures. All incidents should be initially viewed from the perspective of any wider potential system failings having a contribution, rather than through the narrow lens of the individual or team.

Where the opportunity for learning and service improvement is identified, it should be communicated widely alongside the celebration / recognition of the staff involved and the positive impact of their openness – a “good save” approach.

[13] This aligns with the expectations of Section 19 of the Reform Act. Section 19 (1) Each body to which this section applies must take such steps as it considers appropriate— (a)to promulgate information about the health and social care for which it is responsible; (b)to obtain information about— (i)the needs of persons to whom that care is being or may be provided; and (ii)the efficacy of that care; (c)to encourage and assist persons to whom that care is being or may be provided— (i)to avail of that care in an appropriate manner, having regard to the need to use resources in the most economic, efficient and effective way; and (ii)to maintain and improve their own health and social well-being.

(iii) Agreed Beliefs and Narratives

The aim is to create narratives in the organisation that support the development of confidence within staff teams that they will be supported and dealt with positively and fairly if they are open when faced with an incident, near miss or service improvement opportunity.

Organisations should actively seek out and then publicise patient safety and quality improvement initiatives as a result of staff, through their courage to be open when faced with patient safety incidents, near misses or service improvement opportunities.

Organisations should use proactive staff engagement mechanisms with their staff teams to celebrate examples of good practice in openness and to explicitly celebrate and promote to staff the support provided to encourage openness.

3.3.3 Openness when things go wrong.

(I) Formal Structures

The formal processes in place such as the Serious Adverse Incident (SAI) response should be underpinned by the principles of openness. A programme to redesign the current SAI Procedure is progressing, led by the Department and working with a wide range of stakeholders to develop proposals.

The aim of the proposed new Framework is to deliver a more streamlined and simplified process for reviewing Patient Safety Incidents. Rebalancing the current system is key to help ensure that learning reviews are of a high quality, are concluded in a timelier manner, with a focus on understanding how the Patient Safety Incident has occurred, and that there is system wide learning leading to demonstrable and sustainable improvements in care. This will better serve all those involved in the process including patients, families and staff.

Similarly, how organisations deal with complaints, raising concerns / whistleblowing or any other forms of feedback should be supported by the principles of openness.

Patients and service users who have been directly affected by an incident or their nominated family member or representatives, should have access to all information about the incident as soon as it is available, in a way that is accessible to them.

Engagement with patients, service users or nominated family members or representatives who have been directly affected by an incident should be led by a

senior competent person and should be a priority action, at the earliest opportunity. This engagement should be both to provide information and to actively listen to the concerns of those involved.

An apology and expressions of compassion and empathy should be freely offered at the earliest opportunity. It is accepted that these do not constitute an acceptance of responsibility or liability.[14]

Depending on the seriousness of the incident, formal support for those directly impacted by it should be provided including access to therapeutic support where appropriate.

A liaison person should be appointed from the organisation whose responsibility it is to keep the patient, service user or nominated family members or representatives apprised of the progress of whatever formal processes are involved. (IHRD recommendation 37iii and iv).

Predicted timescales should be described early in the process to patients, service users or nominated family members or representatives who have been impacted. Regular contact should be maintained, and where there is undue delay, this should be explained. Managing reasonable expectations and maintaining regular contact is extremely important at this stage.

Where other organisations are involved such as the Coroner, Ombudsman, PSNI and HSENI, the original care provider should provide access to independent support and advice to patients, service users or nominated family members or representatives to help them navigate the various processes.[15]

Staff involved, either directly or indirectly, should have access to the information about the incident as soon as possible. Clarity should be sought and provided if there is the possibility of a legal or coronial process, and the impact of this explained as soon as possible.

Staff involved either directly or indirectly should be immediately provided with support including directly line management support, and access to therapeutic support if that is appropriate.

[14] Read saying sorry (duty of candour) - NHS Resolution

[15] Memorandum of understanding Memorandum of Understanding (MOU) Investigating patient or client safety incidents2013

In the case of teams, the possibility of a supportive team de-briefing should be considered.

Staff involved either directly or indirectly should be advised as quickly as possible of the possible process. Where other agencies are involved, staff should be supported to understand the process.

If there is an extended process, a senior manager should be appointed who can independently support staff, alongside the provision of other staff support opportunities.

If the process involves temporary suspension of staff, mechanisms should be devised whereby appropriate support and contact can be provided to staff without compromising any other formal process.

(II) Accepted Behaviours

The behaviours of all involved in all aspects of a situation such as this should be imbued with compassion, professionalism and care for all those directly affected.

As far as is possible, all parties involved should be provided with as much accurate information and meaningful support as possible as quickly as possible, irrespective of any views about responsibility or liability, and without compromising any other formal processes.

Formal support should be offered to patients, service users and nominated family members or representatives.

Managers involved in dealing with patients, service users or nominated family members or representatives should be supported and trained in compassionate care and effective communication in times of crisis.

Managers involved in dealing with and supporting staff should be supported and trained in compassionate care and effective communication in times of crisis.

A distinction should be made between the formal processes that may need to operate, and the provision of compassionate support for all of the those involved and impacted.

A preferred method of contact and communication for the patients or service user and a clear informed consent to share information nominated family members or representatives should be sought at the earliest opportunity. [16]

The development of the process, the predicted timescales, and any outcomes should be communicated in a timely and compassionate way to patients, service users, and staff who have been involved. Family members should be included if appropriate consent exists or has been obtained.

Actively inform the public by means of publication of the lessons learned and subsequent service improvements.

Any consequent disciplinary or legal process that arises should be managed in a similar way with appropriate communication and support for patients, service users, nominated family members or representatives and staff.

(III) Agreed Beliefs and Narratives

Organisations should seek to foster a culture of compassionate support and understanding for all involved, where a mistake has been made and harm has been caused.

Organisations should seek to foster a culture in which the processes to understand root causes, or responsibility are not punitive, but restorative.

Organisations should seek to foster a culture in which the process to determine appropriate compensation where harm has been caused, and where liability is clear is not unnecessarily combative.

Organisations should seek to create confidence within their staff groups that they will be appropriately and fairly understood and supported when mistakes happen.

4 HSC Leadership and Oversight to Promote Openness

[16] Data Protection Act 2018 and the General Data Protection Regulation, the Privacy and Electronic Communications (EC Directive) Regulations 2003 across the UK; and the Freedom of Information Act 2000

4.1 Governance and Accountability Arrangements

The following points outline the key elements of governance required for the implementation of the Framework:

- Accountability for facilitating an open culture in an organisation must be understood to be the responsibility of the most senior leaders.

- At Board level, the metrics that indicate levels of openness in an organisation should be regularly and routinely monitored by the whole board.

- A Non-Executive Director should be appointed to take specific responsibility for overseeing the Being Open Framework implementation and monitoring its effectiveness within the organisation.

- Reporting and monitoring arrangements to the Board of the HSC Trust should be through the Patient Safety and Quality Committee of the Board of Directors (see Sections 4.2 and 4.4 to 4.6).

- The Chief Executive of the organisation as Accounting Officer, has overall accountability for ensuring the implementation, development and effectiveness of the Being Open Framework.

- The Chief Executive is responsible for ensuring the development and provision of training and support for staff (see Section 7).

- In the circumstances where more than one HSC Organisation is involved when 'things go wrong,' the accountability and assurance arrangements for openness should be clearly defined within the HSC organisation's Being Open Policy .

4.2 HSC Board Committee Oversight

Oversight and monitoring will be fulfilled by the Patient Safety and Quality Committee of the HSC Trust Board.[17] Regular reports and updates should be submitted to the Board Patient Safety and Quality Committee where Non-Executive Directors can seek assurance that the organisation is compliant with the Being Open Framework, learning is taken forward and concerns are being escalated to the Board if appropriate (see Monitoring and Reporting at Sections 4.4 to 4.6.

[17] INI Recommendation 20: The NI Department of Health should ensure that Trust Boards have a Safety and Quality Sub-Committee, which has a similar status to the Audit Committee

HSC organisations should audit the approach to the implementation of the Being Open Framework within a defined period from the date of dissemination to ensure adherence to the principles and procedures outlined. To provide a second level of assurance to the HSC Board of Directors, the approach to the implementation of the Framework should be subject to independent audit within the organisation's Internal Audit plan.

4.3 Metrics of Openness

A matrix for considering the development of **metrics of openness** should be agreed, for example:

Table 2 Metrics[18] of Openness Grid

[18] Metrics, in this context, is defined as the measurable quantitative assessment commonly used for assessing, comparing, and tracking performance

METRICS	Policies and Procedures	Accepted Behaviours	Narratives and Beliefs
Routine Openness	• Practice of regular supervision/ support • Opportunity for reflection in regular routine group meetings • Formal opportunities for reflection in schwarz rounds • Feedback from staff surveys • access to training for all staff on openness	• senior leaders visible in supporting openness • examples reported of open discussion and reflection • evidence through messaging to staff of a focus on openness	• feedback from discussion with staff of the acceptability of openness • stories of the positive outcomes of staff being open
Openness focused on learning	• metrics on numbers of Datix raised reported at board • evidence and metrics of actions taken • metrics on near misses reported at board – and evidence of action taken and lessons learned • examples provided to board of mechanisms that exist to capture and implement learning.	• Board and senior leaders are seen to affirm the learning from errors – and to affirm when staff have been open • Board and senior leaders' model restorative models when mistakes happen • Openness is included in recognition and awards processes • Learning is reported and celebrated	• Staff report that the organisation is genuinely open to learning • Staff report that there is not a punitive approach to mistakes, and that they see how learning and change happens – through staff survey results • Staff express belief that they are supported to learn
Openness when things go wrong	• Metrics on SAIs and other mechanisms that capture mistakes – routinely reported to the board • Reports on the learning outcomes – routinely reported to the board • Audits of the application of learning – routinely reported to the board • Narrative welfare reports on support provided to all involved in serious incidents – reported routinely to the board • Mechanisms to monitor the progress of investigations and the degree to which they diverge from predicted reasonable timelines – reported routinely to the board	• Senior leaders in the organisation report routinely on the degree to which the processes that are underway are operating openly • Senior leaders in the organisation report routinely on the effectiveness of the support that is being provided to patients, service users and staff who have been affected by an incident • Senior leaders are seen to behave with compassion in the face of challenging and difficult incidents	• Staff report that the organisations supports them through the difficult processes of investigation after a critical incident – through staff surveys or direct engagement • Patients and service users report that they are treated fairly, compassionately, and professionally through the difficult processes associated with critical incidents. • The legal processes and formal disciplinary processes often associated with critical events do not get in the way of communication support and respectful engagement with patients, service users and staff.

The matrix should be completed for an individual team or area when work to adopt a more open culture begins. The matrix can then be completed on a bi-yearly basis in order to demonstrate progress.

4.4 Data Collection and Reporting Metrics

Datix forms a significant element of data collection across the other UK countries. Adverse incidents, complaints and claims and within NI some HSC Trusts have already been utilising the Datix system across the adverse incident and complaints modules.

Data will also be required to be analysed from a range of other sources including; service user and staff feedback and surveys, leadership walkrounds and engagement events, induction and ongoing training, shared learning committees and forum, quality improvement projects and quality metrics and professional reporting.

The following table is a sample of reporting metrics:

Table 3 Reporting Metrics

Metric	Measure	Oversight
1 Routine Openness		
Policies and Procedures	Analysis of access and uptake on staff induction and training programmes.	Patient Safety & Quality Committee
Accepted Behaviours	Analysis of leadership walkrounds. Corporate briefings by senior management.	
Narratives and Beliefs	Reports on being open from: ➢ Service User/ PPI Feedback including complaints management ➢ Staff Surveys.	
2 Openness focused on learning		
Policies and Procedures	Audit of compliance with policy through data collected via Datix	Patient Safety & Quality Committee
Accepted Behaviours	Analysis and Reports on Staff Surveys	
Narratives and Beliefs	➢ Quarterly lessons learned report to Board through the Patient Safety and Quality Committee. ➢ Quarterly reports to Patient Safety and Quality Committee on quality improvement projects linked to learning from being open incidents.	

Metric	Measure	Oversight
	➢ Bi annual summary of Trust PPI engagement the Patient Safety and Quality Committee	
3 Openness when things go wrong		
Policies and Procedures	Monthly/Quarterly status reports to Patient Safety and Quality Committee using Datix ➢ % of initial being open discussions which took place ➢ % of written record that the discussion took place within the patient record, Datix and within the investigation report. Annual audit of compliance with policy through Datix. Audit of a small sample of completed SAI reviews to include patient engagement responses within that process. Audit of a small sample of closed complaints. Summary report on the review of learning from adverse incidents and complaints to Board. Summary report on relevant quality improvement projects arising from being open process to Board.	Patient Safety & Quality Committee
Accepted Behaviours	Annual Professional reports to Board to include data on compliance with Being Open Framework	
Narratives and Beliefs	Service User Feedback Staff Surveys	
Composite annual report by Patient Safety and Quality Committee to Trust Board to include the three components.		

4.5 Organisational Monitoring Arrangements

Monitoring of the Being Open Framework will be through the HSC Trust's Integrated Governance and Board Assurance Framework arrangements through the Patient Safety and Quality Committee to Trust Board (see Section 4.2).[19] Assurance must be sought to ensure all relevant aspects of the Being Open guidance and the organisation's self-correcting mechanisms are effectively implemented and utilised.

[19] Add reference for the IG and BAF Guidance when

This will enhance patient safety, staff wellbeing, and the quality of care, while driving continuous improvement in how the HSC organisation meets its legal obligations, including the Duty of Quality.

HSC organisations should audit compliance with the Being Open Framework within a defined period from the date of dissemination to ensure adherence to the principles and procedures as outlined utilising the metrics included in Sections 4.3 and 4.4. To provide a third level of assurance to the HSC Board of Directors, the framework should be subject to independent audit within the organisation's Internal Audit plan.

The DoH will seek additional assurance on HSC organisations' compliance with this Regional Policy (see Section 5).

4.6 Organisational Reporting arrangements

HSC organisations will be required to report annually on compliance with the Being Open Framework and publish their reports. Reporting within HSC organisations will be based on the parameters set out within the Being Open Metrics at Section 4.3 and the Data Collection Metrics at Section 4.4 Table 2.

As above in Section 4.2 HSC organisations should provide regular reports to the Board of Directors through the Trust Board Patient Safety and Quality Committee.

Reports on Being Open should be included in the annual and mid-year Governance Reports made by the HSC organisation to the DoH.

Confidentiality

It is important to ensure that the requirements of the General Data Protection regulation (GDPR) are adhered to when accessing, processing and disclosing service user information. Reports and publications must not identify any person to whom health care is being provided by or on behalf of the HSC organisation, or any person acting on behalf of a service user.

Care must also be taken not to unwittingly enable a person to be identified from the information provided within a report.

5 DoH Monitoring Arrangements

5.1 Department of Health

The expectation is that there will be local ownership and accountability in accordance with the integrated governance and assurance arrangements of the HSC organisation. However, the DoH will seek additional assurance on HSC organisations' compliance with this Regional Framework.

SPPG will also provide a further assurance by holding provider organisations to account on the delivery of safe services which are of sufficient quality and facilitate the HSC system to embed a culture of learning.

5.2 The Regulation and Quality Improvement Authority (RQIA)

The **Regulation and Quality Improvement Authority (RQIA)** is an independent non-departmental public body charged with overall responsibility for regulating, inspecting and monitoring the standard and quality of health and social care services provided by independent and statutory bodies in Northern Ireland. The HSC Quality Standards 2006 set the framework within which RQIA have the authority to assess statutory services provided by the HSC Trusts. The RQIA may carry out reviews, investigations and inspections of these services, report on their findings and require improvements to be made.

RQIA has a duty to assess and report on HSC Services and Registered Services sector to the DoH keeping the DoH informed about the provision of services and in particular about their availability and quality, and encouraging improvement in the quality of services through the exercise of their duties. Where HSC organisations are required to implement Quality Standards set out by the DoH, the RQIA will assess the effectiveness of local implementation of those standards, policies and procedures, and will use their findings and associated information to identify areas for improvement within organisations and identify system wide issues for the purposes of raising standards across services.

Once approved, the standards on Openness form part of that regulatory process. RQIA can also be commissioned to review the application of the Being Open standards and organisational process of assurance across the health and social care system.

6 Other External Monitoring Options

Other options to support an open, just and learning culture and to support systems of external monitoring and independent scrutiny of the Being Open Framework will be explored and may include the following:

6.1 The Introduction of an Independent Speaking Up Guardian Model

In 2015, Sir Robert Francis was commissioned to conduct an independent review into the freedom to speak up and the creation of an open and honest reporting culture in the NHS.[20] The Francis Review related to NHS England however, the principles and proposals for a freedom to speak-up model was believed to have applicability to health

[20] Sir Robert Francis. Freedom to Speak Up Review. 11 February 2015 accessed via Sir Robert Francis' Freedom to Speak Up review - GOV.UK (www.gov.uk)

and social care across the four countries of the United Kingdom. There was growing evidence and acknowledgement of the contribution staff can make to patient care through speaking up.

Different approaches to implementing the principles of the Francis Review were adopted by each of the devolved administrations including the revision of guidance and in England the National Guardian's Office (NGO) was established in April 2016 as an independent non-statutory body. The NGO is an Arm's Length Body tasked with normalising speaking up and leading effective cultural change. The NGO leads, trains and supports a network of FTSU Guardians in England and provides support and challenge to the healthcare system in England on speaking up.

The extant guidance for raising concerns / whistleblowing within health and social care in Northern Ireland was revised and issued in March 2023.[21] The Raising Concerns Framework was developed in response to the recommendations arising from the Regulation and Quality Improvement Authority's (RQIA) Review of the Operation of Health and Social Care Whistleblowing Arrangements.[22]

The Framework describes the role of Public Interest Advocates within each organisation and the appointment of a Non-Executive Director (NED) to have specific responsibility for oversight of the culture of raising concerns in the public interest within their organisation. The adoption of a similar model to the NGO i.e. independent scrutiny and the creative of a supportive network for the PIAs and the Designated NEDs could further support the Being Open Framework and patient safety initiatives.

6.2 The Introduction of an Independent Patient Safety Commissioner

In England, the Patient Safety Commissioner (PSC) has published a set of Patient Safety Principles. The Principles provide a framework for decision making, planning and collaborative working with patients as partners in a just and learning culture and are for everyone working in the healthcare system. They include a commitment to listening to patients and staff, make it easy for everyone to learn from mistakes and for being transparent and accountable.[23]

The role of the first PSC in England was created by the government after a recommendation from the Independent Medicines and Medical Devices Safety Review

[21] 'Your right to Raise a Concern (Whistleblowing) HSC Framework and Model Policy' March 2023. The Framework sets out the legal framework and guidance on the implementation of local policy within HSC organisations and includes a link to a comprehensive guide to the legal framework at public-interest-disclosure-guidance.pdf.

[22] RQIA review is accessed at Review of the Operation of Health and Social Care Whistleblowing Arrangements (RQIA, 2016)

[23] Patient Safety Principles - Patient Safety Commissioner

in 2020, *First Do No Harm*, conducted by Baroness Cumberlege (Cumberlege Review).[24]

The Cumberlege Review called for a PSC to be appointed 'to be the patients' port of call, the listener, the advocate, that holds the system to account, monitors trends, and demands action where necessary'. The role is to promote **patient safety in relation to medicines and medical devices** and to promote patients' voices.

The PSC is independent of government and the healthcare system the Commissioner's funding is provided by the Department of Health and Social Care (DHSC). The PSC remains accountable to Parliament including through the Health and Social Care Committee.

6.3 HSC Regional Patient Safety and Quality Committee

The role of the HSC Regional Patient Safety and Quality Committee (the Regional Committee) is to facilitate the consolidation of learning, evidence-based initiatives, and best practices in patient safety and quality across all HSC Trusts. The Regional Committee aims to promote continuous improvement in patient safety and quality across HSC organisations and key stakeholders, fostering a harmonised approach to learning, monitoring, care efficacy, and reporting.

As outlined in Section 4, each HSC Trust Board will be required to establish a Patient Safety and Quality Committee, which will have a status comparable to that of the Audit Committee. The Regional Committee will include representatives from each Trust's Patient Safety and Quality Board Committee and will be chaired by an independent individual appointed by the Department of Health. The Committee will also have representation from relevant regulatory bodies and key stakeholders.

The primary purpose of the Regional Committee is to oversee the implementation of a system-wide patient safety and quality improvement programme, proactively strengthening self-correcting mechanisms across the system. Additionally, it will provide the Department of Health with evidence-based recommendations and assurances that patient safety and quality are integral to everyday care delivery.

The Regional Committee will issue recommendations related to patient safety and quality to individual Trusts as necessary and will report directly to the Department of Health at regular, pre-agreed intervals.

[24] Cumberlege Review. Loc. Cit.

7 Training and Education to support openness

HSC organisations have a responsibility to train and support staff to properly understand and exercise their responsibilities to be open routinely, focused on learning and when things go wrong. (See also Section 8 - Other Resources to Support Being Open). The following training and education options should be applied:

- Being Open, and the various contexts in which it applies will be a mandatory component part of induction and ongoing training for all staff.

- The various ways in which different professions are required to show openness should be reflected in bespoke training for various professional groups, this is especially true for medical specialists.

- Ongoing refresher training should be available for all staff. Minimum 3 years or upon the publication of new legislation or guidance. Timescales for refresher training should be specified with the organisation's statutory/mandatory training matrix.

- While in person training may be required for some specialist staff, online training modules can be an efficient way to distribute mandatory openness training packages.

- The provision of support for staff should be through mentorship, coaching and supervision.

- Specific specialist openness training should be provided for senior managers responsible for overseeing investigations and providing support to staff involved. Similarly, for those who are required to support patients, service users, family members or their representative through these processes.

- Specific specialist training should be provided to Non-Executive Board members on their responsibilities to oversee the development of an open culture.

8 Other resources available to support Being Open

Regulators and professional bodies should develop mechanisms to support and guide organisations in the development of openness.

A range of options in respect of the resources required to support the HSC Being Open Framework should be considered and should include the following elements:

a. Guidance for Staff on Being Open

i. Development of a Charter for Staff[25]

ii. Development of guidance identifying responsibilities at each level of openness

iii. To be developed and co-produced based on this framework

b. Guidance for Organisations on Being Open

i. Development of a Charter for Organisations

ii. Identifies and articulates the means through which they will support their staff to be open at the three levels of openness

iii. To be developed and co-produced based on this framework

c. Guidance for the public – what to expect from an open, just and learning healthcare organisation

i. A statement of expectations for the public in their dealings with an open healthcare organisation

ii. To be developed and co-produced based on this framework

9 Implementation Plan

Following consideration of responses to this consultation, a finalised Being Open Framework will be co-designed with the HSC Trusts. A full implementation plan will be developed with the expectation of the implementation commencing in September 2025.

10 Evaluation of the HSC Being Open Framework

The DoH will undertake a formal review of the implementation and efficacy of the Being Open Framework. The evaluation of the Framework will also be undertaken in the spirit of co-production.

[25] A sample Staff Charter can be accessed at NHS Resolution Charter (April 2023) at Just and learning culture charter - NHS Resolution

It is envisaged that this evaluation will take place within two years from the date of dissemination of the Framework to the HSC system.

APPENDICES

Appendix 1 IHRD Recommendations on Duty of Candour and Openness

	Ref	RECOMMENDATION	Report Reference	Workstream
CANDOUR	1	A statutory duty of candour should now be enacted in Northern Ireland so that:	Vol 3, Chapter 8: Section 8.47 Page 55 Section 8.103-106 Page 73-74	**1-Duty of Candour**
		(i) Every healthcare organisation **and** everyone working for them must be open and honest in all their dealings with patients and the public	Vol 3, Chapter 8: Section 8.101 page 72 Section 8.103 page 74	**1-Duty of Candour** *Linked to:* *6 - Training* *8 - Workforce and professional regulation*

	Ref	RECOMMENDATION	Report Reference	Workstream
		(ii) Where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or duly authorised representative) should be informed of the incident and given a full and honest explanation of the circumstances.	Vol 2, Chapter 4: Section 4.150 –152 Pages 47 – 48 Section 4.157 Page 49	**1-Duty of Candour** *Linked to:* *5-SAI* *6-Training* *7-User experience* *8-Workforce and professional regulation*
		(iii) Full and honest answers must be given to any question reasonably asked about treatment by a patient (or duly authorised representative).	Vol 1, Chapter 3: Section 3.178 Page 181 Section 3.242-244 Page 203-204 Section 3.245-248 Page 204 – 206	**1-Duty of Candour** *Linked to:* *6-Training* *7-User experience*

	Ref	RECOMMENDATION	Report Reference	Workstream
			Vol 2, Chapter 4: Section 4.86 -88 Page 29 Section 4.310 (ii) Page 92 Section 4.330 Page 98 Vol 2: Chapter 5 Section 5.253-5.254 Page 181	*8-Workforce and professional regulation*
		(iv) Any statement made to a regulator or other individual acting pursuant to statutory duty must be truthful and not misleading by omission.	Vol 1, Chapter 3: Section 3.179 -180 Pages 181-182 Section 3.195-196 Page 186	**1-Duty of Candour** *Linked to:* *6-Training* *8-Workforce and professional regulation*

	Ref	RECOMMENDATION	Report Reference	Workstream
		(v) Any public statement made by a healthcare organisation about its performance must be truthful and not misleading by omission.	Vol 1, Chapter 3: Section 3.200 Page 188 Section 3.202 Page 188	**1-Duty of Candour** *Linked to:* *6-Training*
		(vi) Healthcare organisations who believe or suspect that treatment or care provided by it, has caused death or serious injury to a patient, must inform that patient (or duly authorised representative) as soon as is practicable and provide a full and honest explanation of the circumstances.	Vol 1, Chapter 3: Section 3.178 Page Vol 2: Chapter 5: Section 5.253 Page 81	**1-Duty of Candour** *Linked to:* *5-SAI*
		(vii) Registered clinicians and other registered healthcare professionals, who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare organisation by which they are employed has caused death or serious injury to the patient, must report their belief or suspicion to their employer as soon as is reasonably practicable.	Vol 2, Chapter 4: Section 4.47-53 page 17-19 Section 4.54-55 Page 19-20 Section 4.130 Page 41 Section 4.145 Page 46	**1-Duty of Candour** *Linked to:* *5-SAI*

	Ref	RECOMMENDATION	Report Reference	Workstream
			Section 4.217 Page 66 Section 4.241 Page 72-73 Section 4.301 Page 89 Section 4.306 Page 98	*8-Workforce and professional regulation*
	2	Criminal liability should attach to breach of this duty and criminal liability should attach to obstruction of another in the performance of this duty.	<u>Vol 3, Chapter 8:</u> Section 8.103 Page 73 Section 8.106 Page 74	**1-Duty of Candour** <u>*Linked to:*</u> *8-Workforce and professional regulation*
	3	Unequivocal guidance should be issued by the Department to all Trusts and their legal advisors detailing what is expected of Trusts in order to meet the statutory duty	<u>Vol 3, Chapter 8</u>: Section 8.104-page 74	**1-Duty of Candour** <u>*Linked to:*</u> *6-Training*

	Ref	RECOMMENDATION	Report Reference	Workstream
	4	Trusts should ensure that all healthcare professionals are made fully aware of the importance, meaning and implications of the duty of candour and its critical role in the provision of healthcare.		**1-Duty of Candour** *Linked to:* *6-Training*

APPENDIX 2 HSC Arm's Length Bodies 'in scope' for the Policy of Openness

Bodies within Scope of Independent Inquiries Recommendations (IHRD and INI)

A public body is a formally established organisation that is (at least in part) publicly funded to deliver a public or government service. The term refers to a wide range of entities that are covered within the public sector though not those public entities that do not require staff to operate, such as public funds or trusts.

Arm's length bodies (ALBs) are a specific category of public body that can include executive agencies ('EA'), non-departmental public bodies ('NDPBs') and non-ministerial departments ('NMDs').

A review of all such public bodies identified 16 organisations that were within the scope of the IHRD recommendation, as set out below.

1.1 Arm's length bodies:

- Belfast Health and Social Care Trust
- Business Services Organisation (BSO)
- Health and Social Care Board (HSCB)
- Northern Health and Social Care Trust
- Northern Ireland Ambulance Service
- Northern Ireland Blood Transfusion Service
- Northern Ireland Guardian Ad Litem Agency
- Northern Ireland Medical and Dental Training Agency
- Northern Ireland Practice and Education Council (NIPEC)
- Northern Ireland Social Care Council (NISCC)
- Patient and Client Council
- Regional Agency for Public Health and Social Well Being (PHA)

- Regulation and Quality Improvement Authority (RQIA)
- South Eastern Health and Social Care Trust
- Southern Health and Social Care Trust
- Western Health and Social Care Trust

Independent Inquiries Programmes (IHRD and INI)

Set out below is the definitive list of healthcare organisations within the scope of the IHRD and INI Recommendations. Not all recommendations apply to every organisation.

- The 16 Arm's Length Bodies, as set out above
- All organisations registered with and inspected by RQIA to provide health and social care services
- All registrants with professional health care regulators