Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Serious Adverse Incident Redesign Programme

Framework for Learning and Improvement from Patient Safety Incidents

Consultation Document

March 2025

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FOREWARD FROM THE MINISTER OF HEALTH

Every day there are thousands of contacts and care interventions across our healthcare system, the majority of which deliver high quality and in many circumstances life-saving care and treatment. People reasonably expect health and social care (HSC) to be safe and if that care fails to meet an acceptable standard, they are entitled to openness and to feel able and supported to find out the reasons why.

There are undoubtedly examples of good practice being implemented across the HSC system as part of the current approach to undertaking Serious Adverse Incident reviews, however there is also a clear evidence base from Inquiries, reviews and reports locally, nationally and internationally which highlight the need for change and improvement.

Many of the recent Inquiries and reviews have recommended a fundamental redesign of the current Serious Adverse Incident Procedure to move away from a rigid, process driven process which takes too long and often doesn't involve meaningful engagement with patients, families and staff towards a more flexible approach which places All those Affected at the heart of the review process.

The draft Framework for Learning and Improvement from Patient Safety Incidents and supporting documentation, which you will have the opportunity to express your views on in this consultation, have been developed by building on the evidence base and incorporating the views of a wide range of stakeholders.

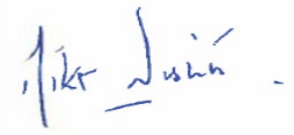
Some of the key aims of the redesigned process are to deliver a more streamlined and simplified process for reviewing Patient Safety Incidents to enable the completion of reviews in a timelier manner, with a focus on the prompt identification of the factors

causing or contributing to the incident, therefore delivering an early understanding of what happened and why.

The draft Framework also focuses on providing meaningful and compassionate engagement and support for All those Affected and Staff Affected. I believe it is essential that All those Affected must be at the heart of the Patient Safety Incident review process and their experiences must be sought out and valued, as trusted sources of information on patient safety, and as partners in service delivery. Equally, our Staff must be able to voice their views, ideas and concerns without fear. Supporting an environment that welcomes, encourages and seeks out patient and staff experience is not only the right thing to do, but the essential thing to do in delivering continuous improvement to the delivery of care.

Simply introducing a new process is not enough and significant cultural change is required to move away from a blame culture towards an open, honest, learning culture. We do not underestimate the magnitude of this task and recognise that cultural change takes time and is a continuous process.

Part of this process is to attempt, once again, to build confidence in the integrity and openness of the HSC system and we encourage you to engage as fully as you can in this consultation process and help progress the redesign of the Serious Adverse Incident Procedure in a way that is really going to have a positive impact.



Mike Nesbitt, MLA

Minister of Health

GLOSSARY

All those Affected	One of the earliest steps in the Patient Safety Incident Learning Review process is to consider and identify in a structured way who 'All those Affected' include. Organisations should consider service users, patients, families, carers, victims, victim's families and visitors that may be affected by a Patient Safety Incident, when determining who All those Affected are. *(Adapted from the Conceptual Framework for the International Classification for Patient Safety definition of Person Affected)*
Patient	A person who is receiving, or has received, care provided by, or on behalf of, a HSC body. *(The Health and Social Care Complaints Directions NI 2009)*
Patient safety	The term used nationally and internationally to describe the freedom from unnecessary harm or potential harm associated with healthcare services and the reduction of risk of unnecessary harm to an acceptable minimum. *(World Health Organisation, 2009)*
Patient Safety Incident	A Patient Safety Incident is an incident or circumstance (including omissions) which could have resulted or did result in harm to a patient or group of patients, and which provides an opportunity for system learning. *(Adapted from the WHO patient safety curriculum guide 2011)*
Staff Affected	Staff Affected are those staff who have been directly involved in or impacted by a Patient Safety Incident. HSC organisations should at an early stage consider and identify in a structured way who all Staff Affected include. *(Framework for Learning and Improvement from Patient Safety Incidents)*
Systems-based approach	The focus of a system-based approach is examining the components of a system (e.g. person(s), tasks, tools and technology, the environment, the wider

	organisation) and understanding their interdependencies (i.e. how they influence each other) and how those interdependencies may contribute to patient safety. (*PSIRF NHS England*)
System wide learning	In order to improve patient safety, system wide learning involves everyone learning together and improving together.
Victim	A victim must be a close relative or someone acting lawfully on behalf of the "patient" and who witnessed the Patient Safety Incident or its immediate aftermath.

PATIENT SAFETY OVERVIEW

The challenges facing our Health and Social Care (HSC) system in Northern Ireland are complex and systematic in nature and delivering safe, effective and quality care is of paramount importance across all disciplines and roles. Recommendations from various review reports and public inquiries have highlighted serious failings within the health service of Northern Ireland and have been clear that effective patient safety systems and culture are key for HSC moving forward.

The Department is committed to delivering the recommendations from relevant reports and inquiries to build a safer, more patient centred health system with public safety, confidence in HSC services and quality improvement at the heart. This must be considered in the wider context of developments to continually improve the quality of care in HSC services.

Healthcare staff operate within complex systems with many factors influencing the likelihood of error. Evidence and best practice in other nations suggests that patient safety is not about individual effort, it requires a safety culture in every HSC organisation based on trust, openness and strong collective leadership. Too often this open and learning culture is prevented by fear and blame.

Many staff feel that they work in a dangerous and toxic environment with a blame culture that jeopardises patient safety and discourages learning and reflection. In order to improve patient safety outcomes, there must be a move away from this negative blame culture towards a just culture which creates a psychologically safe space for staff to report any potential patient safety issues and engage openly in the learning processes. Part of this cultural change will include supporting an environment that welcomes, encourages and seeks out patient, family and staff experience to deliver continuous improvement to the delivery of care.

It is the wider local clinical and organisational governance systems, and the culture within HSC organisations, which can best assure the implementation of best practice and identify potential patient safety issues.

The effectiveness of any Patient Safety System depends on robust mechanisms for organisations to receive qualitative and quantitative information from various sources. Patient Safety systems are comprised of a number of legislative duties, policies and professional codes of practice that relate to each of the components of an open, just and learning culture. This can include Incident Reporting and Review Procedures, Being Open Policies, Raising Concern mechanisms, Complaints processes, Conduct and Performance processes and Fitness to Practice procedures.

All procedures and processes with a relevance to patient safety must interface with and influence each other appropriately in order to deliver effective Patient Safety Systems in HSC organisations and it is important to consider this wider context when providing your input to this consultation.

THIS CONSULTATION AND HOW TO RESPOND

TOPIC OF THIS CONSULTATION

This consultation seeks views on the development of a new process for the review of Serious Adverse Incidents (SAI) for the purposes of learning and improvement. The consultation will focus on the following four draft documents:

- The Framework for Learning and Improvement from Patient Safety Incidents
- Regional Standards for the Conduct of Patient Safety Incident Learning Reviews
- Principles for Engaging, Involving and Supporting All those Affected by a Patient Safety Incident
- Principles for Engaging, Involving and Supporting Staff Affected by a Patient Safety Incident

SCOPE OF THIS CONSULTATION

We are keen to hear the views of all those who are interested in patient safety issues and the improvement of Health and Social Care (HSC) services in Northern Ireland, including:

- members of the public;
- service users, family members, carers, victims and victims' families with lived or living experience of the extant Serious Adverse Incident Procedure;
- community and voluntary sector organisations;
- HSC staff
- healthcare regulators;
- health professionals;
- local councils;
- trade unions;
- academics; and
- other government Departments and agencies.

GEOGRAPHICAL SCOPE

The redesigned process falls within the scope of the Devolved Administration of Northern Ireland. However, we have and will continue to work closely with the UK government, Scotland, Wales, the Republic of Ireland and other Countries on these draft proposals.

BODY RESPONSIBLE FOR THE CONSULTATION

This consultation is being undertaken by the Serious Adverse Incident and HSC Complaints Policy Branch in the Department of Health.

DURATION

The consultation will run for 12 weeks from 10 March 2025 to 6 June 2025.

ENQUIRIES

For any enquiries about the consultation, please email the Department of Health at PSIConsultation@health-ni.gov.uk or write to:

Serious Adverse Incident Redesign Programme

Serious Adverse Incident and HSC Complaints Policy Branch

Department of Health

Castle Buildings, Stormont Estate

Belfast, BT4 3SQ

HOW TO RESPOND

Online

You can respond online by accessing the consultation documents on the Northern Ireland Government Citizen Space website and completing the online survey. The online version can be accessed at:

https://consultations2.nidirect.gov.uk/doh-1/patient-safety-incidents

Via email or in writing

We would prefer responses using Citizen Space, however, if you wish to send an email or hard copy, please download, complete and return the Consultation Response Form provided at consultation response form and send it to the email or postal address provided above.

When responding please confirm whether you are replying as an individual in a professional or private capacity or submitting an official response on behalf of an organisation. If you are replaying on behalf of an organisation, please include:

- your name;
- your position (if applicable);
- the name of your organisation;
- an address (including a postcode); and
- an email address.

CONSULTATION RESPONSE

We will consider the responses received and publish a report summarising the consultation findings on the Department's website.

ACCESSIBILITY

Alternative formats of this consultation document and the questionnaire (such as other languages, large type, Braille, easy read and audio cassette) may be made available on request. Please email the Department of Health at PSIConsultation@health-ni.gov.uk to discuss your requirements.

IMPACT ASSESSMENTS

In accordance with the relevant statutory requirements, the following impact assessment screening documents have been prepared and are available on the Department's website for consideration during this consultation:

• Equality Screening, Disability Duties and Human Rights Assessment

• Rural Needs Impact Assessment

• Data Protection Impact Assessment screening

These screenings have indicated that there is no significant negative impact from the new process in terms of Equality of Opportunity, Good Relations or Rural Needs and thus no need for further Equality or Rural Impact Assessments. As part of this consultation, we welcome comments on these screening documents or inputs on areas where those responding may feel we should take further information into consideration in any future screening.

Consultation Questions **Screening**
1. Have you any comments on either the Equality/Good Relations, Rural or data protection screening documents? 2. Are there any areas or issues you feel we should be considering in future screenings?

PRIVACY, CONFIDENTIALITY AND ACCESS TO CONSULTATION RESPONSES

For this consultation, we may publish all responses except for those where the respondent indicates that they are an individual acting in a private capacity (e.g., a member of the public). All responses from organisations and individuals responding in a professional capacity will be published. We will remove email addresses and telephone numbers from these responses; but apart from this, we will publish them in full. For more information about what we do with personal data please see our consultation privacy notice at Annex A.

response, and all other responses to this consultation, may also be disclosed on request in accordance with the Freedom of Information Act 2000 (FOIA) and the Environmental Information Regulations 2004 (EIR); however, all disclosures will be in line with the requirements of the Data Protection Act 2018 (DPA) and the UK General Data Protection Regulation (UK GDPR).

If you want the information that you provide to be treated as confidential it would be helpful if you could explain to us why you regard the information you have provided as confidential, so that this may be considered if the Department should receive a request for the information under the FOIA or EIR.

BACKGROUND AND THE CASE FOR CHANGE

BACKGROUND TO THE CURRENT SERIOUS ADVERSE INCIDENT (SAI) PROCESS/PROCEDURE

In 2004, the Department of Health introduced Regional Guidance on 'The Reporting and Follow-up on Serious Adverse Incidents'. In May 2010, the operational management of SAIs transferred from the Department of Health to the former Health and Social Care (HSC) Board, and *The Procedure for the Reporting and Follow-up of SAIs* guidance document was published by the HSC Board working in partnership with the Public Health Agency (PHA) and collaboratively with the Regulation and Quality Improvement Authority (RQIA) for those SAIs involving Mental Health and Learning Disability, as well as those commissioned services within the independent sector.

The procedure was most recently updated in 2016 and provides guidance to all Arms Length Bodies (ALBs) and Special Agencies on the management of SAIs which may arise during the course of their business or commissioned service.

The procedure provides the definition of an adverse incident and separate criteria which determines whether an adverse incident is a SAI and the need for the Department of Health (via the Strategic Planning and Performance Group (SPPG)) to be notified. It also describes the necessary form of review to be taken in order to ensure both local and regional learning is shared to ensure improved care and safety of patients.

The Procedure was amended in 2013 to include an additional SAI criterion which called for any death of a child in receipt of HSC Services to be reported; this was in recognition of the on-going Inquiry into Hyponatraemia-related Deaths (IHRD). The procedure also replaced the single investigation process for all SAIs to three levels to reflect the complexity of some incidents and to ensure the timely identification of learning.

The HSC Board issued a revised SAI procedure in 2016, which amended the SAI criteria, removing the mandatory requirement to report the death of a child as an SAI following a recommendation contained within the Donaldson Report, 'The Right Time, The Right Place'. The 2016 version of the guidance remains the current operational procedure.

OVERVIEW OF THE EXTANT SERIOUS ADVERSE INCIDENT PROCEDURE

An Adverse Incident (AI) is defined as any event or circumstance that led or could have led to serious unintended or unexpected harm, loss or damage to people, property, environment or reputation. On identification of an AI, the reporting organisation is responsible for determining if the incident meets one or more of the SAI criteria. The SAI will be reported to SPPG who will also be advised on the level of review to be

undertaken based on the complexities of the review of the incident. All HSC Trusts record adverse incidents on a localised DATIX Risk Management system which is commissioned through a regional contract.

SAI reviews should be conducted at a level appropriate and proportionate to the complexity of the incident under review, to assess what happened; why it happened; what went wrong and what went well; what has changed or what needs to change; and to identify any local or regional learning. The three levels of review outlined in the current procedure are:

- Level 1 Review – Significant Event Audit (SEA)

This level of review should be performed by a team which includes all relevant professionals yet be appropriate and proportionate to the type of incident and professional groups involved.

- Level 2 Review – Root Cause Analysis (RCA)

A core review panel should be comprised of a minimum of three people of appropriate seniority and should be multi-disciplinary. The team should have no conflicts of interest to the incident concerned and should have an Independent Chair (independent of the incident but may be from within the same organisation).

- Level 3 – Independent Review

Level 3 reviews will be considered for SAI's that:

- are particularly complex involving multiple organisations;
- have a degree of technical complexity that requires independent expert advice; and
- are very high profile and attracting a high level of both public and media attention.

Team membership for Level 3 reviews must be agreed between the reporting organisation and the SPPG/PHA Designated Review Officer prior to the Level 3 review commencing. In some instances, the whole team may be independent to the organisation(s) where the incident(s) occurred.

Level 1 SEAs must be completed and returned to SPPG/PHA within 8 weeks of the SAI being notified. On completion of a Level 2 review, final reports must be submitted to

SPPG within 12 weeks from the date the incident was notified. Level 3 reports are to be submitted within a realistic timescale agreed by SPPG/PHA and the Reporting Organisation.

On receipt of completed SAI reports, a professional group from across SPPG and the PHA is convened to review the reports to ensure:

- the Service User and Family Engagement Checklist has been completed satisfactorily;
- themes and learning are identified and disseminated for implementation; and
- a robust review has been undertaken; (for level 2 and 3 SAI reviews only).

Based on the information provided to SPPG, if the professional group is not satisfied with the content of the report, they will continue to liaise with relevant organisation and will not close the SAI until satisfied the information demonstrates required action and learning.

When the SAI is closed any recommendations and further actions required will be monitored through the reporting organisation's internal governance arrangements, however occasionally and when dealing with particularly complex SAIs, where there are regional recommendations, a request may be made to organisations involved in the SAI review to provide an additional assurance mechanism to advise that action following a SAI has been implemented.

THE CASE FOR CHANGE

Recommendations arising from a number of Inquiries and Reviews have contributed to a clear and strong evidence base underpinning the need to redesign the current approach to learning following Adverse Incidents and SAIs. These include the Regulation and Quality Improvement Authority (RQIA) review of Systems and Processes for Learning from Serious Adverse Incidents (SAIs), and relevant recommendations from the Inquiry into Hyponatraemia-related Deaths report (IHRD) and the Independent Neurology Inquiry (INI).

It is clear from the findings of these Inquiries and Reviews that our current approach to investigating SAI's has become too process driven and the engagement and support of All those Affected by SAIs is not always optimal. Also, the time taken to complete investigations is too long, it lacks flexibility, is resource intensive and there is sometimes limited evidence of improvement in care.

Inquiry into Hyponatraemia-related Deaths Report Summary

On 31 January 2018 the Inquiry into Hyponatremia Related Deaths (IHRD) was published following an extensive investigation into the deaths of five children in hospitals in Northern Ireland. After hearing evidence from a wide range of individuals and organisations it concluded that the five deaths had been avoidable and that the culture of the health service at the time, arrangements in place to ensure the quality of the services and behaviour of individuals has contributed to those unnecessary deaths.

The inquiry found that the SAI Procedure presents a number of critical decision-making points that are open to 'subjective interpretation' and the exercise of 'discretion', such as whether to report an incident, who should investigate and the appropriate level of investigation.

Another key finding of the Inquiry was that the internal investigations into the deaths of the five children and their surrounding circumstances were inadequate and that they failed to appropriately identify the underlying causes.

As a result, the IHRD report made 96 recommendations[1] of which 10 recommendations (18 actions) related to strengthening and improving the SAI procedure.

In developing the recommendations, the IHRD report had been guided by five key principles[2]:

1. That healthcare services exist to serve the patient
2. That the quality of healthcare is dependent upon both clinical and non-clinical services
3. That the particular needs of children must be addressed
4. That leadership and candour must be accorded the utmost priority if the fullest learning is to be gained from error
5. That progress should be subject to regular external review

Independent Neurology Inquiry Report summary

The Independent Neurology Inquiry was established by the Permanent Secretary of the Department of Health in May 2018. This was as part of a series of actions taken in response to the recall of neurology patients by the Belfast Health and Social Care (HSC) Trust. The decision to hold a public inquiry of this type was driven by the fact that the Northern Ireland Assembly was at that time suspended and there was no Health Minister in place. The Inquiry was subsequently converted to a statutory public inquiry by the Minister of Health, Robin Swann MLA, on 11th of December 2020.

[1] IHRD Report Vol 3 Chapter 9 Pages 84-97
[2] IHRD Report January 2018: Vol 3 Chapter 9 Section 9.1

The Independent Neurology Inquiry, published their report in June 2022, recommendation 23 of the report calls for the Department of Health to '*review (and if necessary, change) the early warning alert process and the serious adverse incident process to assure itself that these processes are clear, well understood and operate in the interests of patients*.

Regulation and Quality Improvement Authority (RQIA) Review of the Systems and Processes for Learning from SAIs in NI Report Summary

In April 2018, the Department of Health commissioned the RQIA to examine the application and effectiveness of the *Procedure for the Reporting and Follow-up of Serious Adverse Incidents in Northern Ireland (November 2016)*. The review was to focus on the extent to which the existing process delivers learning and the extent to which stakeholders, particularly patients and families are adequately involved.

An independent Expert Review Team (ERT) was commissioned by the RQIA and consisted of a number of clinical members with experience in corporate governance and serious incident investigation in NHS England. The ERT undertook a mixed methodology approach with evidence gathered using focus groups, interviews, semi-structured questionnaires and assessment of SAI review reports completed by HSC Trusts between November 2016 and March 2018.

The review team also examined the extent to which patients and their families were engaged and involved in the SAI process and the level of professional support provided to staff who were delivering the care at the time of the SAIs as well as those conducting the review.

The ERT found that neither the SAI review process nor its implementation is sufficiently robust to consistently enable an understanding of what factors, both systems and people, led to a patient or service user coming to harm. In addition, the review team stated that the process does not deliver well-formulated SAI review reports, evidence-based recommendations or action plans that will enhance the safety and quality of healthcare provision across the region both in the short and longer term.

The RQIA Report was published on 7 July 2022 and found that the current Regional procedure focuses too heavily on process and non-attainable timescales, instead of focusing on consistently delivering the practice of investigating well and identifying key causes and their contributory factors to construct meaningful recommendations and learning. Improving this situation will require both the procedure and the system in which it operates to be redesigned.

Five recommendations were made to support the Redesign Programme.

Ongoing Public Inquiries

Where appropriate, acknowledgment will also be given to other public inquiries; this includes consideration of the Infected Blood Inquiry findings and ongoing public inquiries including the Urology Services Inquiry and the Muckamore Abbey Hospital Inquiry. Consideration will be given to the applicability of recommendations from these Inquiries in relation to the Redesign Programme.

STATISTICS

To date in the 2024/2025 reporting period from 1 April 2024 to 31 December 2024 ***455*** SAIs were reported to the SPPG/PHA. Of these 455 SAIs, 410 were classified as Level 1, Significant Event Audits, 41 were classified as Level 2, Root Cause Analyses and 4 were classified as Level 3 Independent Reviews.

SAIs were reported from across a range of Programmes of Care with the majority of SAIs originating from acute services, mental health and maternity and child health.

PROPOSALS – VISION, HIGH-LEVEL THEMES, OUTCOMES

In developing this consultation and draft proposals, the Department of Health has collaborated and extensively engaged with a number of key stakeholders (see Annex B); this includes those with lived experience of the extant SAI procedure, relevant professional officers, HSC Trusts, other nations and, other relevant bodies from across the HSC sector in Northern Ireland. Through positive engagement, the Department of Health has listened to, recorded and considered the views of stakeholders and has set out the proposals below.

The Department of Health recognises that some stakeholders have specific views and concerns around the proposed redesigned approach. All views and feedback received from stakeholders on the draft proposals have been documented and considered. It is important, however, to acknowledge that consensus on all aspects of the proposed approach may not be achievable as the Department of Health must ensure a balanced approach in considering the views of all stakeholders including service users, patients, families and staff.

The draft Framework for Learning and Improvement from Patient Safety Incidents describes the high-level strategic approach to learning from Patient Safety Incidents and does not describe operational detail. The draft Framework will, however, be supplemented by more detailed guidance documents which include the other three documents included in this consultation as well as additional operational guidance to

be developed during the implementation phase of the Redesign Programme, such as a methodology and toolkit, roles and responsibilities and governance, oversight and accountability guidance.

The approach in other Nations and Best Practice

As part of the Redesign programme of work and to inform the development of the draft proposals, the Department of Health examined the approach to the conduct of Patient Safety Incident reviews in other jurisdictions. These include the Republic of Ireland, England, Scotland, Wales, Canada, New Zealand, Denmark, South Africa and Australia. These jurisdictions were chosen following a review which identified relevant developments in the review of Patient Safety Incidents in terms of recent policies, procedures and guidelines being developed.

The Department of Health also reviewed relevant Patient Safety Incident literature and reports from, for example, the World Health Organisation, the Institute for Healthcare Improvement, and the Health Services Safety Investigations Body. Based on this evidence, a draft Framework and accompanying guidance was developed using best practices in Patient Safety Incident investigation.

VISION

The overall vision is to introduce a new overarching Regional Framework with supporting guidance to deliver a more flexible, streamlined and simpler review process, with a focus on learning and improvement, framed within a culture of safety, openness and compassion. This will help ensure that Patient Safety Incident Learning Reviews are:

- of a high quality;
- focused on meaningful engagement with All those Affected;
- concluded in a timelier manner;
- focused on understanding how and why the incident occurred; and
- identifying system wide learning leading to demonstrable and sustainable improvements in care.

The new Framework will form part of a wider policy agenda to support an Open, Just and Learning Culture. There will be less focus on blame and culpability which can be counter-productive to learning, however the appropriate accountability for an action or omission where that is necessary will continue through the appropriate mechanisms. Compassionate and meaningful engagement with All those Affected by an incident and Staff Affected will be core to the refreshed review process.

Consultation Questions **Vision**
3. Do you agree with the described vision?

HIGH-LEVEL THEMES

Focus on Learning

The redesigned process has been renamed ***'The Framework for Learning and Improvement from Patient Safety Incidents'*** to define what the system will deliver - learning following Patient Safety Incidents.

Learning and Improvement is one of the draft Framework's five key themes and describes how there should be a clear culture of learning from Patient Safety Incidents within and between HSC organisations where learning is supported and encouraged by leadership.

The draft Framework is clear that the purpose of the redesigned process is not solely to identify learning but also to effectively implement and embed it in practice, making the necessary improvements to ensure an improvement in patient safety across the organisation and ultimately the HSC system.

Terminology

The terminology 'Patient Safety Incident' was considered extensively by the Redesign Programme Team. The Department of Health acknowledges that the HSC system utilises a range of terminology for individuals using their services, for example the social care sector use the terms 'service recipient' or 'client', rather than patient. However, after reviewing the approach taken in other nations, as well as best practice in literature, it was agreed that the term patient would be used, with a clear definition provided.

The draft Framework introduces the new terminology 'All those Affected' by a Patient Safety Incident with organisations expected to consider service users, patients,

families, carers, victims, victim's families and visitors that may be affected by a Patient Safety Incident, when determining who All those Affected are.

Following discussion and debate, the term 'victim' has been included in the definition of 'All those affected', despite the fact that it is not usually associated with Patient Safety Incidents.

In doing so, it is important to clarify that the definition of a victim in a healthcare sense differs from the legal definition of a victim of crime.[3] This term also needs to be differentiated from the term 'secondary victim' which in recent years has been referred to as the healthcare professional who experiences emotional distress following an adverse event.[4]

The Department of Health has referred to what the courts have recently decided in regard to medical negligence when considering the term victim in the context of a Patient Safety Incident.[5]

In law, the patient is considered the first victim of medical negligence, but the definition of a secondary victim needed to be clarified.

The supreme court in its ruling affirmed that in order to fulfil the definition of a secondary victim in medical negligence the following three criteria must be met:

1. There is, or was, a sufficiently close tie of love and affection between the claimant and the person(s) suffering physical injury (i.e. 'proximity' further discussed below). This means no bystanders will be able to claim.

2. They were present at an accident of immediate aftermath, with 'accident' meaning an external event negligently caused.

3. The psychiatric injury suffered was caused by the direct perception of the accident or immediate aftermath.

Therefore, for the purpose of Patient Safety incidents, the term victim is defined in the following terms:

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[3] Section 28 of the Justice Act (Northern Ireland) 2015 (www.legislation.gov.uk/nia/2015/9/contents/enacted) sets out what is meant by a 'victim' for the purpose of the Victims Charter.

[4] Wu AW, 'Medical error: the second victim. The doctor who makes a mistake needs help too' BMJ 2000;320:726–27

[5] Paul and another (Appellants) v Royal Wolverhampton NHS Trust (Respondent), Polmear and another (Appellants) v Royal Cornwall Hospitals NHS Trust (Respondent) and Purchase (Appellant) v Ahmed (Respondent) {2024} UKSC 1

'A victim must be a close relative or someone acting lawfully on behalf of the "patient" and who witnessed the Patient Safety Incident or its immediate aftermath.'

Engagement, Involvement and Support of All those Affected

All those Affected by a Patient Safety Incident are entitled to openness, to understand when harm has or may have occurred in the context of their care and to understand how the health care system has learned from events which have occurred and has made changes and improvements to prevent and minimize similar events happening again.

One of the focuses of the draft Framework is to understand how and why an incident occurred as well as delivering learning which leads to evidenced sustainable improvement in patient safety. This is best achieved by placing All those Affected by an incident at the heart of the learning review process and allowing their unique perspective and lived experience to be a central component of the review.

Engagement, Involvement and Support of All those Affected is another of the draft Framework's five key themes and describes how HSC organisations should engage with All those Affected by a Patient Safety Incident in a collaborative, person-centred way and listen to and involve them, as active partners in the process throughout, in line with their wishes.

The draft Framework is supported by the draft Principles for Engaging, Involving and Supporting All those Affected by a Patient Safety Incident.[6] The draft Principles set out what All those Affected should expect from the Patient Safety Incident Learning Review Process, aiming to ensure that everyone involved regardless of their background or medical knowledge, can understand and actively participate in the process.

Engagement, Involvement and Support of Staff Affected

Engagement, Involvement and Support of Staff Affected is a key theme under the Framework and describes how HSC organisations will apply **'just culture'** principles where Staff Affected by a Patient Safety Incident are treated fairly and openly and are supported through a constructive and learning focused system.

Similar to the approach for All those Affected by a Patient Safety Incident, a set of draft Principles for staff have also been produced to set out set out the expectations for how Staff Affected by a Patient Safety Incident should be engaged with, involved and supported as part of the Patient Safety Incident Learning Review Process, regardless of

[6] Hereinafter referred to as 'The Principles'

the type of review undertaken. Also ensuring that where staff are involved in a Patient Safety Incident they are treated fairly and openly.

HSC organisations will use both sets of Principles in conjunction with the Framework and the Regional Standards for the Conduct of the Review of Patient Safety Incidents[7]. The Standards are designed to guide HSC organisations and those who provide care on behalf of the HSC on how they are expected to comply with the Framework and provide an agreed expectation to give confidence to All those Affected by a Patient Safety Incident as well as ensuring the appropriate level of accountability.

Methodology

As defined in the draft Framework, the purpose of a Patient Safety Incident Learning Review is to

- examine the events leading up to the incident;
- analyse what happened and why;
- specifically identify factors in the system, using systems-based methodologies, that contributed to the incident and what needs to change to prevent it from occurring again; and
- indicate how learning will be disseminated and embedded in future practice and systems, and how resulting enhanced practice and learning will be evidenced and verified.

Operational Methodology guidance will be provided to HSC organisations to assist them in the conduct of Patient Safety Incident Learning Reviews and will describe how Patient Safety Incidents should be reviewed, outlining the different types of review, and methodologies, all of which are underpinned by a system-based approach which recognise the important role of contributory factors.

Patient Safety Incidents can be identified in several way which may include:

- Team discussion;
- Staff observation;
- The input of All those Affected; (for example, questions, concerns, information)
- Coroner's reports;
- Clinical review meetings;
- Mortality and Morbidity processes;

[7] [7] Hereinafter known as the Standards

- Complaints;
- Litigation;
- Audits;
- Chart reviews; and
- Patient experience surveys e.g. Care Opinion.

The draft Framework is firmly anchored to the HSC core values of openness and honestly and will fully align with and support the Department's Being Open Framework[8]. The draft Framework therefore supports a culture of openness and proportionate accountability where individuals are encouraged to report Patient Safety Incidents and feel confident enough to speak up with things go wrong without a fear of blame.

It is the responsibility of all healthcare staff to identify and report Patient Safety Incidents in accordance with their HSC organisation's policies and practices and to ensure the immediate escalation of incidents meeting Patient Safety Incident criteria (as described in an organisations Patient Safety Incident Learning and Improvement Plan) to the relevant line manager and the Patient Safety Incident team. These responsibilities will be further defined in a supporting roles and responsibilities guidance document.

Before deciding whether to undertake a Patient Safety Incident Learning Review and which methodology to use, each HSC body must develop a Patient Safety Incident Learning and Improvement Plan using a Regional template and by analysing its unique patient safety data from a wide range of relevant sources. These sources might include but are not limited to:

- Coroners;
- Litigation;
- Risk assessments;
- Audits;
- Case mix;
- Performance data;
- Care Opinion;
- RQIA;
- Any ongoing safety actions; and (for example, in response to recommendations from other reviews internally or externally)
- Any ongoing Quality Improvement work.

[8] The Department's Being Open Framework is currently in draft pending the outcome of public consultation.

It is ultimately the responsibility of each HSC organisation to determine the appropriate response to a Patient Safety Incident, based on their plan, however all plans will be reviewed and agreed in collaboration with the SPPG thereby providing Regional oversight and challenge of the organisations' patient safety priorities and response types.

The draft Framework recognises three types of review:

- Concise
    - Structured Judgement Review
    - After Action Review
    - Specific Review Tool
- Thematic
- Comprehensive

All the review methodologies are underpinned by the five overarching themes described in the draft Framework and a system-based approach. Although the type of review or methodology may vary across the region for particular incidents, the quality of reviews and the engagement, involvement and support provided to All those Affected and Staff Affected will remain a consistent requirement across all learning reviews.

Concise Review

Typically, a concise approach can be completed in a timely manner and is considered a more targeted and streamlined approach to a Patient Safety Incident Learning Review. It is typically led by one person (facilitator) with the necessary knowledge, skills and training.

Comprehensive Review

A comprehensive approach is usually undertaken when the Patient Safety Incident is complicated or complex and/or the context is such that the contributory factors leading to the Patient Safety Incident are not clearly understood.

It may also be necessary to conduct a comprehensive review subsequent to any other review method.

Thematic Review

A Thematic approach can be used by HSC organisations to review Patient Safety Incidents that are identified by a particular theme. For example:

- A group of individual Patient safety incidents, similar in composition and/or origin.
- A group of Patient Safety Incidents that are impacted by a similar contributing factor(s), and who experience the same harmful incident (to greater or lesser degrees).
- A group of completed comprehensive and/or concise incident analyses.

If following the completion of a Patient Safety Incident Learning Review, those involved believe that another review method is necessary to identify all the learning or that the Patient Safety incident is more complex than initially thought, then a further review using an alternative methodology can be undertaken.

Independence

It is usually preferable that a Patient Safety Incident is reviewed as closely to the area in which it occurred/emerged as practicable, this is because those directly involved in the incident will be best placed to understand the circumstances and identify learning and improvement opportunities. Removing the review of an incident from the area in which it occurred entirely would lead to the loss of the cultural and contributory factors of those who were directly involved.

There will however be occasions when a greater level of independence is required. The decision on the requirement for independence either internal or external to the HSC organisation should be decided at the outset of the review process and the rationale clearly documented and explained to All those Affected and Staff Affected.

The requirement for and the decision on the level of independence will have no set criteria, however, to assist HSC organisations there will be a set of guiding principles to inform their discussions and decisions in this regard.

HSC organisations will be expected to decide on the level of independence required based on the circumstances of the individual Patient Safety Incident. Determinations in this regard are likely to be influenced by factors such as the level of harm, complexity, requirement for specific subject matter expertise, and the public interest.

The Department of Health is currently considering the requirement to establish a team of Regional trained independent facilitators which organisations can utilise for those Patient Safety Incidents that will require the highest level of independence.

Timeframes

Whilst there are no specific timeframes mandated in the draft Framework, indicative time frames are set out for the differing review types and it is expected that timeframes will be agreed with All those Affected from the outset.

It is accepted that some reviews may take longer to complete, particularly where they involve several organisations or are particularly complex. However, it is important to balance the time taken to complete a review against the impact that prolonged reviews can have on All those Affected and the potential risk to patient safety if the appropriate actions to prevent reoccurrence are not identified and resolved.

Flexibility

Feedback on the current SAI process is that it is too rigid, prescript and process driven. The criteria-based approach is not intelligence led, or data driven and can lead to ineffective use of resource.

The new draft Framework expects HSC organisations to take a proportionate approach to Patient Safety Incident Learning Reviews. HSC organisations are expected to consider a number of factors when deciding if a review is required and if required, then on the appropriate type of review.

Factors to be considered which would determine if a review is required could include the circumstances, level of harm arising and whether any new learning would potentially arise from a review of the incident.

Factors to be considered when a review is not required could be when these types of Patient Safety Incidents have been recognised regionally and have been subject to regional improvement plans and work and are considered therefore not likely to yield further new learning.

An example of when a review may not be required could be where there are challenges with system wide pressures, which can result in delayed response times to patients waiting in the community for an ambulance, which has arisen as a result of ambulance handover delays.

Factors to be considered in relation to the appropriate type of review could include the complexity of the incident and/or review, requirement for specialist input separate to the organisation where the incident occurred, incidents that span multiple organisations and the scope of learning arising e.g. local to a service vs regional/national level.

The decision regarding whether a review should be undertaken and the type of review, must be fully documented, evidenced and subject to robust governance and oversight processes for example audit/checking by both local and Regional oversight systems.

The approach taken must not be based solely on the presence or absence of harm but must also consider other factors such as near misses, the severity of the incident, the probability of reoccurrence, the complexity and the impact on the organisation and those involved and must involve compassionate discussion and explanation with All those Affected.

This less rigid and re-balanced approach should allow HSC organisations to complete reviews much more proportionately and quickly. By allowing organisations to take a response and proportionate response they will have the ability to generate insights into the present and future as well as past events giving a more holistic approach to patient safety which allows them to respond to incidents that maximise learning and drive system improvement.

Where there is an existing robust and rigorous review process for the purpose of identifying learning in the context of certain incidents, for example a Domestic Homicide Review (DHR), then the principle of 'Do once and do well' will apply. The new draft Framework will make clear this principle which should avoid unnecessary duplication which can happen currently leading to delay, inefficient use resource and confusion and re-traumatization for All those Affected and Staff Affected. There will be some Patient Safety Incidents that where a comprehensive review will be mandated, and a list of these Patient Safety Incidents can be found at **Annex C.**

Consistency

The intent of the draft Framework is to allow HSC organisations the flexibility to identify and address the risks that are most relevant to them, to deliver the most improvement to their services. There will be differences in organisations' patient safety data and ongoing quality or system improvement initiatives which will influence their Patient Safety Incident Learning and Improvement Plan, and therefore their decision on the type of review to undertake and the methodology to utilise. Although the type of review or methodology may vary across the Region for particular Patient Safety Incidents, the

quality of reviews and the engagement, involvement and support provided to All those Affected and Staff Affected will remain a consistent requirement across all Patient Safety Incident Learning Reviews.

The draft Framework will be Regional and will be supported by Regional Standards, guidance and training. All organisations will be required to demonstrate how the Standards are met by establishing robust and rigorous governance structures, policies and procedures. Overall responsibility for oversight and governance of this process will rest with organisational Boards, supported by collective leadership through the organisation.

There will also be external oversight, governance and accountability – for example from SPPG/ PHA who will ensure consistency across the Region when appropriate.

RQIA may also use the Standards as part of their regulatory and inspection function. RQIA's role in the redesigned process will be further explored in the next phase of the Redesign Programme.

Learning

The draft Framework describes the different approaches to reviewing Patient Safety Incidents through a range of methodologies that are underpinned by an understanding and consideration of system based contributory factors. This is in keeping with national and international best practice.

The draft Framework and supporting guidance recognise that healthcare delivery is a complex environment and there can be many contributing factors when something goes wrong.

The system-based approach to learning lessons is a structured process that aims to identify what happened, how and why it happened, what can be done to reduce the risk of reoccurrence and make services safer. The process considers how all parts of the healthcare system may have interacted and contributed to the outcome. In considering an incident in this manner it is more likely that the findings identified will lead to actions required to address any system issues which may have existed.

Using this approach will best help reduce reoccurrence and improve care and also supports an open, just & learning culture with less focus on individual blame.

When learning has been identified the draft Framework and Standards will expect robust monitoring and evaluation of the learning to ensure it has been effectively implemented, embedded in practice and that there is evidence of improvement as a result.

Co-ordination and communication of the learning to ensure it is appropriately shared system wide will be carried out by a Regional body.

Systems Supporting Learning

The draft Framework encourages and supports a significant cultural shift towards systematic patient safety management by embedding Patient Safety Incident Learning Reviews within a wider organisational system of learning and improvement.

One of the five key themes of the draft Framework is Learning and Improvement and describes how HSC organisations will ensure and demonstrate the timely identification, dissemination and/implementation of learning within and across organisations to sustainably improve patient safety.

Learning systems must be effectively utilised by HSC organisations to integrate internal and external learning from Patient Safety Incidents and technology should be leveraged to improve patient safety through system learning at a local and Regional level.

Information on learning from Patient Safety Incidents must be shared across the system and with partners in other sectors where appropriate. Learning must be timely and relevant and demonstrate a clear understanding of what can be done to prevent the Patient Safety Incidents reoccurring which should help to assure and give confidence to All those Affected.

Oversight and Assurance

The primary responsibility for implementing the Framework and Standards will rest with HSC organisations who will be expected to put in place oversight and governance processes to assure their effective implementation and to monitor and evaluate these processes. This could include for example sample checking and/ or peer review of decisions, alongside the commissioning of Internal Audit reviews to assess compliance and external review by an appropriate body when indicated.

HSC organisations must be able to evidence the effectiveness of their governance and oversight to SPPG/PHA in their Regional oversight capacity as follows:

- the Patient Safety Incident has been appropriately identified and documented;
- the appropriate type and methodology of review has been undertaken;
- the required quality and standard for a Patient Safety Incident Learning Review is achieved;

- relevant learning has been identified and appropriately shared;
- learning has been implemented and has led/is leading to demonstrable improvement; and
- the required standard for engagement, involvement and support of All those Affected by a Patient Safety Incident and Staff Affected has been met.

The role of Regional oversight will be redefined and rebalanced '*in a way that allows organisations to demonstrate [improvement], rather than compliance with prescriptive, centrally mandated measures'*[9], and to compliment and support organisational roles.

Oversight Arrangements will be developed for HSC organisations, including those in a Regional oversight role. The purpose of these Oversight Arrangements for Learning and Improvement from Patient Safety Incidents are to:

- Ensure that there is clear multi-level accountability[10] and responsibility for the management of Patient Safety Incidents across the HSC sector;
- Enable the proactive identification, reporting, monitoring, and escalation of patient safety issues;
- Ensure alignment of the response to and learning from Patient Safety Incidents across the HSC and wider system;
- Verify the implementation of recommendations and review the evidence demonstrating their effectiveness in leading to improvements;
- Ensure a coordinated approach to learning from Patient Safety Incidents;
- Identify when HSC organisations may benefit from or require support; and
- Provide assurance on all aspects of the Framework to those who use our services, staff and the public more generally.

The approach to oversight will be underpinned by the following key principles:

[9] A framework for measuring and monitoring safety – The health Foundation https://www.health.org.uk/publications/a-framework-for-measuring-and-monitoring-safety

[10] Multi-level accountability is best described as both vertical as in up through the organisations and out with the organisations to SPPG (DoH)/PHA etc and horizontal across organisations. Traditionally accountability has been seen as being confined to organisational boundaries but given that patient safety often transcends these boundaries it also needs to have a degree of flexibility in the role sharing between organisational boundaries.

1. **Open and Transparent**

    - Oversight arrangements are clearly articulated ensuring they are easily understood by all involved, including staff and All those Affected and that all involved know how they will be measured and assessed.
    - Oversight metrics are standardised and based on best practice.
    - Oversight arrangements clearly describe the approach to be taken when an HSC organisation fails to appropriately adhere to the Framework and Standards.
    - There must be a mechanism for all those involved in a Patient Safety Incident to challenge the oversight arrangements if necessary.

2. **Objective and independent**

    - Regional oversight must follow the principles set out in this document and integrate with existing departmental governance, accountability and performance management arrangements.
    - Organisational Boards must have a means of challenging and critiquing assurances/ information presented to them on Patient Safety Incident Learning Reviews using robust, rigorous and effective governance systems.

3. **Proportionate and Effective**

    - Oversight Arrangements should not be one size fits all, they should focus on areas of risk, be proportionate to the performance of the Trust and have criteria for intervention with HSC organisations feeling empowered to make their own improvements. However, there will be expected minimum oversight arrangements for every HSC organisation.
    - There must be flexibility in how oversight is carried out within these described principles which may mean adjusting the specifics of the approach.
    - Oversight should place minimal additional burden on HSC organisations to avoid duplication, by using existing processes.

4. **Collaborative and supportive**

    - Oversight arrangements should be collaborative and strike a balance between challenge and support.
    - There may be a requirement for targeted support and enhanced oversight arrangements where the need is identified.

5. **Clear accountability**

    - Accountabilities should be clearly defined, with HSC organisations demonstrating how they are following these levels of accountability.
    - Roles and responsibilities should be clearly described and followed.
    - There must be a comprehensive delegation Framework and robust quality assurance arrangements.

Regional Surveillance

It is intended that as part of the redesigned process a Regional surveillance programme for Patient Safety Incidents will be implemented. This will allow the ongoing collection, analysis, interpretation and dissemination of patient safety incident data across the system.

This Regional surveillance system will form another layer of oversight and monitoring for identifying trends and themes in Patient Safety Incidents.

By monitoring the position across the region in relation to Patient Safety Incidents, we can also better understand the nature and magnitude of the Patient Safety Incidents and the potential causations allowing for a proactive approach to identifying certain incidents before they cause patient harm.

Education and Training

Education and Training will be a key component of the implementation phase of the Framework and will be vital to ensure consistency across the region.

The Department of Health is developing a regionally standardised Training Programme with the HSC Leadership Centre which will consist of several tiers. These tiers will include:

- general training for all staff setting out the key themes of the Framework and the core objectives of the Standards;
- training for staff who undertake Patient Safety Incident Learning reviews which incorporates, technical knowledge, input from experts, leadership attributes, systems-based responses and the importance of report writing;
- training for staff who will undertake the single point of contact role to engage with All those Affected by a Patient Safety Incident in an open, compassionate and person-centred way; and
- training for those in governance and leadership positions on effective oversight of the Framework and Standards.

Interfaces and Influencers

There may be specific instances where the Framework is not the most appropriate governance tool for managing and responding to an issue initially raised for consideration as a Patient Safety Incident. Examples include where the matter relates to conduct or performance, or where it is necessary to consider whether anyone has been harmed by a specific hazard (for example, where a Lookback Review may be appropriate).

In such cases, the extant appropriate governance processes must be followed. Any such decision to follow a separate process must be transparent, documented by the HSC organisation and explained fully to All those Affected by the incident, including staff.

Managing Transition

The Department of Health recognises that the proposed new approach to learning from Patient Safey Incidents will represent a significant change for HSC organisations and will therefore require an appropriate period of implementation, supported by a detailed implementation plan. A managed transition from the current SAI procedure to the new Framework is key and has been identified as a priority as part of forward planning.

Appropriate consideration will be given to the management of SAI cases which have been identified and are being progressed under the current SAI Procedure, and HSC organisations will need to ensure that they have robust plans in place to address any backlog in reviewing current SAI cases.

Consultation Questions **Principles**
4. Do you agree with the described High-Level Themes? 5. Do you feel any High-Level Themes are missing?

OUTCOMES

The Department of Health has engaged with relevant stakeholders to inform and shape the development of the following four draft documents:

- The Framework for Learning and Improvement from Patient Safety Incidents
- Regional Standards for the Conduct of Patient Safety Incident Learning Reviews
- Principles for Engaging, Involving and Supporting All those Affected by a Patient Safety Incident
- Principles for Engaging, Involving and Supporting Staff Affected by a Patient Safety Incident

The Framework for Learning and Improvement from Patient Safety Incidents is the overarching Regional framework to deliver learning and improvements from Patient Safety Incidents across the HSC system and is based on best practice nationally and internationally. The Framework supports and encourages compassionate engagement with All those Affected by Patient Safety Incident, including staff and is a more streamlined and simpler process.

Consultation Questions **Framework for Learning and Improvement from Patient Safety Incidents**
6. Do you support the over-arching approach described in the Framework for Learning and Improvement from Patient Safety Incidents?

The Regional Standards for the Conduct of Patient Safety Incident Learning Reviews are based on best practice and the recommendations from relevant public inquiries and reports and provide an agreed expectation of how HSC organisations must comply with the Framework.

The Standards will be used to inform the governance and oversight of the Patient Safety Incident Learning Review process both at an organisational and Regional level and will also be referred to by other bodies who have a legal or statutory function in relation to inspections and the registration of HSC services for example the Regulation and Quality Improvement Authority (RQIA).

Consultation Questions **Regional Standards for the Conduct of Patient Safety Incident Learning Reviews**
7. Do you agree that a set of Standards are essential for organisations to meet the expectations and outcomes of the Framework and supporting documentation?

The Principles for Engaging, Involving and Supporting All those Affected by a Patient Safety Incident set out the expectations for All those Affected by a Patient Safety Incident in the review process and will be used by HSC organisations to develop formal governance structures to assure and demonstrate the effective implementation of the Framework and Standards.

The Principles are intended to be high-level and will be supplemented by a FAQs document which gives additional detail and can be used by HSC organisations to develop information leaflets to further advise and support All those Affected.

Consultation Questions **Principles for Engaging, Involving and Supporting All those Affected by a Patient Safety Incident**
8. Do you support the Principles for Engaging, Involving and Supporting All those Affected by a Patient Safety Incident and do you feel any principles are missing?

The Principles for Engaging, Involving and Supporting Staff Affected by a Patient Safety Incident set out the expectations for Staff Affected by a Patient Safety Incident in the review process and will be used by HSC organisations to develop formal governance structures to assure and demonstrate the effective implementation of the Framework and Standards.

The staff Principles are also intended to be high-level and will be supplemented by a FAQs document which gives additional detail and can be used by HSC organisations to develop information leaflets to further advise and support All those Affected.

Consultation Questions **Principles for Engaging, Involving and Supporting Staff Affected by a Patient Safety Incident**
9. Do you support the Principles for Engaging, Involving and Supporting Staff Affected by a Patient Safety Incident and do you feel any principles are missing?

Consultation Questions
10. Is there anything else you would like to add to your consultation response?

NEXT STEPS

This consultation will play a key role in the development of a new Framework for Learning and Improvement from Patient Safety Incidents and its supporting guidance. The Department of Health is keen to hear from you so that we can take account of any comments, inputs and views that will help to further refine and develop the proposals.

Following closure of the consultation, all responses will be considered by the Department and a Consultation Response report will be published in due course.

The Department will continue to engage with stakeholders following the public consultation, and as the Redesign Programme progresses.

If you have any questions or queries relating to this consultation exercise, please contact the Department via email at: PSIConsultation@health-ni.gov.uk.

Please note the consultation will close at 5pm on 6 June 2025. If you submit your response after this date, the Department of Health cannot guarantee that it will be considered.

ANNEX A - CONSULTATION PRIVACY NOTICE

Data Controller Name: Department of Health (DoH)

Address: Castle Buildings, Stormont, BELFAST, BT4 3SG

Email: PSIConsultation@health-ni.gov.uk

Telephone: 02890 522 027

Data Protection Officer Name: Charlene Maher

Telephone: 02890522353

Email: DPO@health-ni.gov.uk

Being transparent and providing accessible information to individuals about how we may use personal data is a key element of the Data Protection Act (DPA) and the UK General Data Protection Regulation (UK GDPR). The Department of Health (DoH) is committed to building trust and confidence in our ability to process your personal information and protect your privacy.

Purpose for processing

We will process personal data provided in response to consultations for the purpose of informing the development of our policy, guidance, or other regulatory work in the subject area of the request for views. We will publish a summary of the consultation responses and, in some cases, the responses themselves but these will not contain any personal data. We will not publish the names or contact details of respondents but will include the names of organisations responding.

If you have indicated that you would be interested in contributing to further Departmental work on the subject matter covered by the consultation, then we might process your contact details to get in touch with you.

Lawful basis for processing

The lawful basis we are relying on to process your personal data is Article 6(1)(e) of the UK GDPR, which allows us to process personal data when this is necessary for the performance of our public tasks in our capacity as a Government Department.

We will only process any special category personal data you provide, which reveals racial or ethnic origin, political opinions, religious belief, health or sexual life/orientation when it is necessary for reasons of substantial public interest under Article 9(2)(g) of the UK GDPR, in the exercise of the function of the department, and to monitor equality.

How will your information be used and shared

We process the information internally for the above stated purpose. We don't intend to share your personal data with any third party. Any specific requests from a third party for us to share your personal data with them will be dealt with in accordance with the provisions of the data protection laws.

How long will we keep your information

We will retain consultation response information until our work on the subject matter of the consultation is complete, and in line with the Department's approved Retention and Disposal Schedule Good Management, Good Records (GMGR).

What are your rights?

- You have the right to obtain confirmation that your data is being processed, and access to your personal data
- You are entitled to have personal data rectified if it is inaccurate or incomplete
- You have a right to have personal data erased and to prevent processing, in specific circumstances
- You have the right to 'block' or suppress processing of personal data, in specific circumstances
- You have the right to data portability, in specific circumstances
- **You have the right to** object to the processing**,** in specific circumstances
- **You have rights in relation to** automated decision making and profiling.

How to complain if you are not happy with how we process your personal information

If you wish to request access, object or raise a complaint about how we have handled your data, you can contact our Data Protection Officer using the details above.

If you are not satisfied with our response or believe we are not processing your personal data in accordance with the law, you can complain to the Information Commissioner at:

Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire SK9 5AF

ICO Complaints Form

ANNEX B – STAKEHOLDERS ENGAGED DURING THE CONSULTATION DEVELOPMENT

Department of Health: • Chief Medical Officer Group • Chief Nursing Officer Group • Office of Social Services • Strategic Planning and Performance Group • Medical Leaders Forum	**Health and Social Care (HSC) Trusts:** • Belfast Trust • Northern Trust • Northern Ireland Ambulance Service • South Eastern Trust • Southern Trust • Western Trust
Those with lived experience: • Family member representatives on the Redesign Programme structures • Workshop with interested individuals identified from the open recruitment opportunity • PCC SAI Engagement Platform	**Other Nations/Countries:** • NHS England, Health Service Safety Investigations Body (HSSIB), and Integrated Care Boards (ICBs) • Scotland • Wales • Republic of Ireland • Australia
All Party Health Spokespeople	Northern Ireland Committee for Health
Public Health Agency (PHA)	Patient and Client Council (PCC)
Coroners Service for Northern Ireland	Regulation and Quality Improvement Authority (RQIA)
Royal College of General Practitioners (RCGP)	Mental Health Champion
Police Service for Northern Ireland (PSNI)	HSC Leadership Centre
Department of Justice (DoJ)	Health and Social Care Quality Improvement (HSCQI)
Public Protection Arrangement Northern Ireland (PPANI)	Northern Ireland Public Service Ombudsman (NIPSO) Patient Safety Conference
Commissioner Designate for Victims of Crime	

ANNEX C – MANDATED COMPREHENSIVE REVIEW LIST

- Never Events[11];
- Deaths of patients in police custody which have involved nurse led healthcare;
- Suspected Mental Health Related Homicides[12];
- Suspected Suicide in any HSC Facility; a suspected suicide during authorised/agreed leave or following unplanned leave from any HSC facility; a suspected suicide occurring within 3 months of a planned discharge from an HSC facility; and
- Unexpected/Unexplained deaths in any care setting where following review, an issue has been identified which requires further review to determine if it has been caused by the systems in place or care provided.

[11] doh-letter-to-chief-exec-never-events.pdf (health-ni.gov.uk)

[12] When a homicide has been committed by a person who is or has been under the care, i.e. subject to a regular or enhanced care programme approach, of specialist mental health services in the six months prior to the event. (*Independent investigation of adverse events in mental health services – NHS England)*