



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

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Serious Adverse Incident Redesign Programme

Framework for Learning and Improvement from
Patient Safety Incidents

Consultation Analysis Report

February 2026

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MINISTERIAL FOREWORD

I am pleased to publish this analysis report outlining the findings of the public consultation to consider a strategic redesign of the current Serious Adverse Incident (SAI) procedure. This work represents a significant step in our ongoing efforts to build a more open, transparent, and learning-focused Health and Social Care (HSC) system.

Whilst there are undoubtedly examples of good practice being implemented across the HSC system as part of the current approach to undertaking SAI reviews, the need for change has been clearly articulated through the recommendations of the Inquiry into Hyponatraemia-Related Deaths (IHRD) and other public inquiries. These inquiries have highlighted systemic failings at times in how SAIs were handled - particularly in relation to openness, accountability, and communication with patients and families. These findings underscore the importance of creating a culture where all those affected by incidents are treated with compassion and respect, where learning is prioritised over blame, and is also identified and implemented promptly.

In response, my Department has worked with stakeholders across the HSC system to co-design a new strategic approach to learning and improvement from SAIs. This includes a proposed vision, high-level themes, and a suite of draft strategic documents that aim to support a consistent, person-centred, and system-wide response to Patient Safety Incidents. The consultation process has been extremely beneficial in shaping and reaffirming this work and I am grateful to all those who contributed their views.

The consultation responses demonstrate strong support for the direction of travel, particularly the emphasis on openness, system-wide learning, supporting cultural change and compassionate and meaningful engagement with patients, families and staff. This aligns closely with the principles and objectives set out in the Being Open Framework.

Changing the terminology from Serious Adverse Incident to Patient Safety Incident aligns with modern, system based patient safety frameworks, and will support wider cultural transformation across the HSC system designed to strengthen patient safety.

My officials will now take time to consider the consultation responses in greater detail to inform changes to the draft *Framework for Learning and Improvement from Patient Safety Incidents* and supporting documentation. Once finalised, these documents will establish the agreed strategic governing framework for learning and improvement, providing a clear articulation of the refreshed approach. A managed transition and implementation phase will follow.

As we move into that implementation phase, our collective focus working closely with the HSC will be on embedding the strategic Framework and supporting principles in practice - ensuring that learning is not only captured but acted upon, and that all those affected are supported to speak up and engage openly. This is about more than policy or procedure: it is about enhancing a culture of openness and transparency, where continuous learning and improvement is further supported and embedded as part of our everyday practice.

Ensuring that our HSC system learns from Patient Safety Incidents in a compassionate, transparent, timely and effective way is a key priority for my Department and the HSC system. This is essential not only for improving patient safety and outcomes, but also for building trust and confidence in the HSC system.

I would like to thank all those who contributed to the consultation and to the wider co-design process. Your insights and experiences have been invaluable in shaping this work. Together, we can build a safer, more compassionate HSC system for everyone in Northern Ireland.



Mike Nesbitt, MLA

Minister of Health

BACKGROUND AND INTRODUCTION

The Procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAIs) 2016 is the current guidance on the management of SAIs in the HSC Sector in Northern Ireland.

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 SAIs. These include the Regulation and Quality Improvement Authority (RQIA) review of Systems and Processes for Learning from Serious Adverse Incidents, 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, the procedure lacks flexibility, is resource intensive and there can be limited evidence of improvement in care.

In this context, a programme of work began to redesign the system for learning to articulate the high-level strategic approach to ensuring that there is learning from, and improvement following, a SAI. To take this work forward the Department of Health (DoH) established a number of project structures, with inclusive and wide ranging membership that includes representatives from across a number of areas in the DoH (including the Strategic Planning and Performance Group (SPPG)), the Public Health Agency (PHA), HSC Trusts, family members with lived experience of the current SAI procedure or a general interest in patient safety, the RQIA and the Patient and Client Council (PCC).

The Project structures developed the draft proposals including the high-level overarching Framework for Learning and Improvement from Patient Safety Incidents, a set of regionally agreed Standards for the Conduct of Patient Safety Incident Learning Reviews, Principles for Engaging, Involving and Supporting All those Affected by a

Patient Safety Incident and Principles for Engaging, Involving and Supporting Staff Affected by a Patient Safety Incident. The development of the proposals was informed by the DoH's extensive engagement and collaboration with a number of key stakeholders including 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 and beyond in Northern Ireland. The draft proposals are not intended to cover all operational details or to refresh all local systems for identification, assessment and learning following Patient Safety Incidents. Rather, they set out the overarching strategic direction for how healthcare organisations, providers and staff respond to and learn from Patient Safety Incidents.

The Framework for Learning and Improvement from Patient Safety Incidents consultation was the culmination of this work and aimed to allow an even wider range of interested individuals and organisations to comment on the proposed approach to build on the draft proposals.

This report provides an analysis and summary of the comments made in response to each consultation question. It also covers comments and views shared during consultation events and those in formal consultation response submissions to the DoH. All the views, comments and suggestions made during the consultation period have been considered by the DoH.

PUBLIC CONSULTATION PROCESS

The consultation launched on 10 March 2025 and was initially intended to run until 6 June 2025. The DoH received a number of requests to further extend the public consultation period and as a result the closing date was extended until 20 June 2025, meaning the consultation ran for 15 weeks.

The key purpose of the consultation was to seek views on the development of a new strategic approach for the review of SAIs for the purposes of learning and improvement and on a draft Equality Screening and a draft Rural Needs Impact Assessment.

The consultation focused on the proposed vision, high-level themes and the following four draft documents:

- The Framework for Learning and Improvement from Patient Safety Incidents¹
- 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

All documentation was published on the DoH's website, and the consultation was promoted on social media. ([Framework for Learning and Improvement from Patient Safety Incidents Consultation | Department of Health](#)).

Views were sought on 15 questions covering, personal information, screening documents, vision, high-level themes and draft proposals. The questions are set out alongside an analysis of the responses in the next chapter.

Respondents could respond to the consultation via a number of routes:

- By completing the online questionnaire provided on the Northern Ireland Government Citizen Space website;

¹ Herein after referred to as 'The Framework.'

- By completing the MS Word response questionnaire and either posting or emailing to the DoH;
- By submitting views and comments in an alternative format, e.g. an email, letter or free submission.

Alternative formats of the consultation document and questionnaire such as other languages, large type, Braille, easy read and audio were available from the DoH on request.

Information was collected in a mixed method design, generating both quantitative and qualitative data.

A breakdown of the number of responses and the route used to respond is provided in table 1 below.

CONSULTATION ENGAGEMENT EVENTS

As part of the public consultation targeted engagement events were held to broaden participation and capture the views and perspectives of a diverse range of stakeholders including service users and their families/carers; HSC staff and system leaders.

At the request of the DoH, the PCC facilitated an online engagement event to hear directly from the public and HSC staff. This event, held on 15 May 2025, was open to individuals with experience of the current SAI review process as well as those with a general interest. A total of 63 people registered, representing a wide spectrum of backgrounds—members of the public with lived experience, those with a general interest, voluntary and community sector representatives, HSC staff and leaders, healthcare regulators, and PCC Council members. Of these, 26 individuals attended the event and were provided with a briefing paper outlining the main proposals and supporting documents in advance.

To help ensure meaningful and proportionate involvement of those with lived experience in the SAI Redesign Programme, in November 2023, the DoH undertook a publicly advertised, open recruitment exercise to identify representatives to join the

programme structures. There was significant interest in this opportunity with 29 applications received, and 3 family representatives were selected to join the Redesign Programme structures. The remaining applicants were given the choice to engage with the Redesign Programme of work at a later date should they wish to do so.

Subsequently, they were invited to a virtual consultation workshop held on 12 May 2025, which was attended by 4 of the invited individuals.

QUANTITATIVE OVERVIEW

In total 67 formal consultation responses were received within the consultation period. A further 2 responses were received just outside of the consultation deadline; the DoH has taken the decision to also consider these late responses making the total number of responses **69**. Of the 69 responses, 43 were received on behalf of organisations and 26 were received from individuals. Of the 69 respondents, 52 provided responses via either the online questionnaire on the Citizen Space website or by completing the MS word response questionnaire via email. The remaining 17 responses provided general comments and narrative only but did not specifically respond to the consultation questions. The quantitative analysis will therefore only cover the 52 questionnaire responses, however the qualitative data from **all** 69 responses, as well as additional comments and feedback from consultation events, has been considered and reflected in this report.

A further breakdown is provided below:

Table 1: Breakdown of consultation responses received

Email	Number	Percentage
Organisations	30	83%
Individuals	6	17%
Total	36	100%

Citizen space	Number	Percentage
Organisations	13	39%
Individuals	20	61%
Total	33	100%

INDIVIDUAL RESPONSES

Of the **26 individuals** who responded to the consultation, 2 provided general narrative only and 24 completed the consultation questionnaire. A majority of 16 of the 24 individual respondents who completed the questionnaire (67%) confirmed that they have had lived or close hand experience of the current Procedure for the Reporting and Follow up of SAIs 2016.

Figures 1 and 2 below show the breakdown of individual responses:

Figure 1: Number of individual respondents with lived or close hand experience of the current SAI procedure.

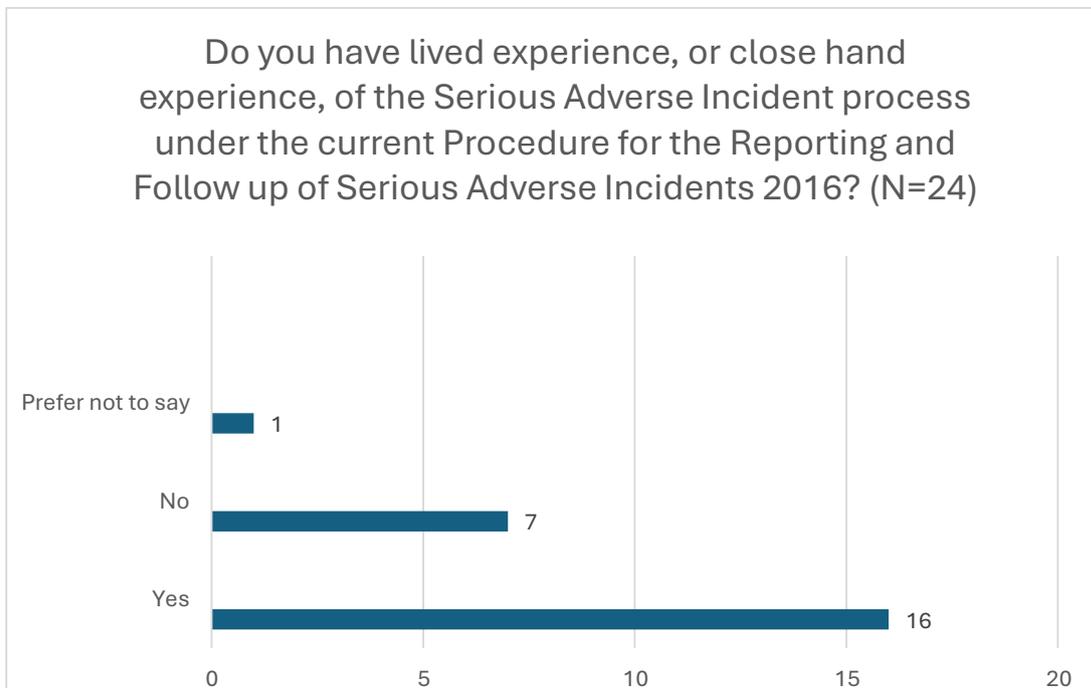
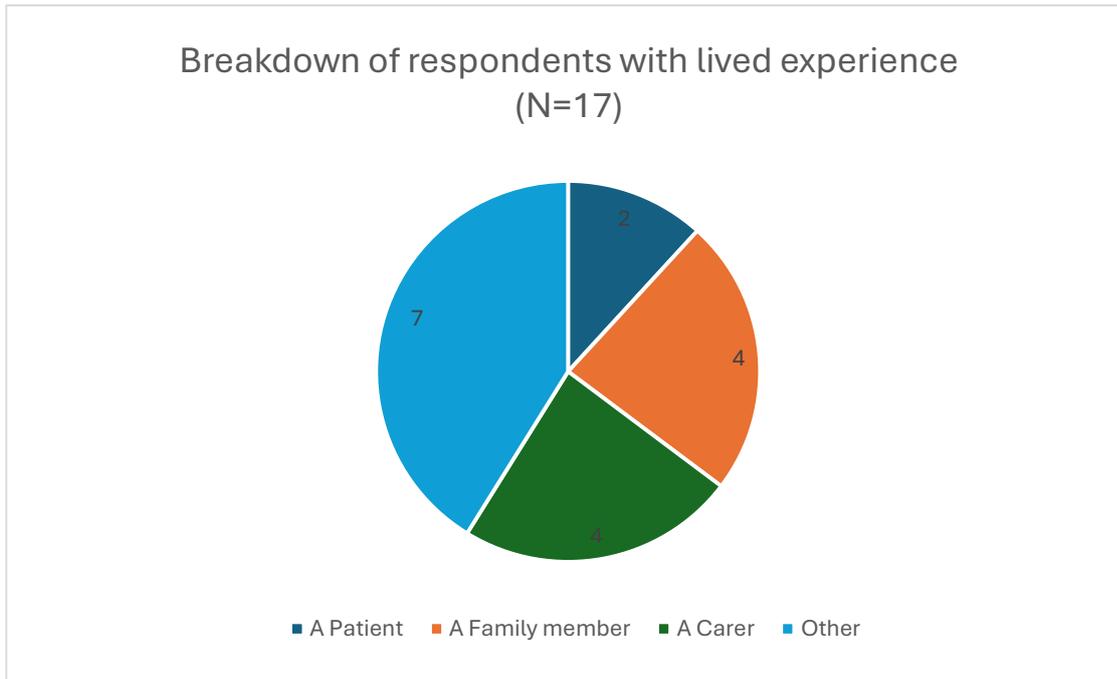


Figure 2: Breakdown of how the respondents with lived or close hand experience have experienced the current SAI procedure.



Of the 16 respondents with lived experience, 1 experienced the current procedure as both a family member and a carer.² Of the 7 individuals who selected the 'other' option, 5 did not specify how they had experienced the current procedure, 1 had experience as a victim who was not a patient and 1 had experience as a governance lead for healthcare in prison.

² This made the total number of responses 17 from 16 respondents.

ORGANISATIONAL RESPONSES

Of the 43 organisations who responded to the consultation, 15 provided general narrative only and 28 completed the consultation questionnaire.

Table 2 below lists, in alphabetical order, **the organisations** who submitted a consultation response.³

Table 2: List of organisations who submitted a consultation response.

Belfast Health and Social Care Trust	British Dental Association (BDA)	The British Medical Association	CAUSE
The Cedar Foundation	Commissioner for Older People for Northern Ireland (COPNI)	Commissioner for Victims of Crime Office (CVOCO)	Community Pharmacy NI
Division Clinical Psychology Northern Ireland, British Psychological Society	General Medical Council (GMC)	Information Commissioner's Office	The Medical and Dental Defence Union of Scotland (MDDUS)
Medication Safety Northern Ireland	Med-Led	Northern Health and Social Care Trust	Northern Ireland Commissioner for Children and Young People
Northern Ireland Hospice	Northern Ireland Practice & Education Council for Nursing and Midwifery	Northern Ireland Public Services Ombudsman (NIPSO)	Northern Ireland Social Care Council (NISCC)
Nursing and Midwifery Council (NMC)	Office of the Mental Health Champion	The Patient and Client Council (PCC)	Patient Safety Learning
Pharmacy and Medicines Management Team SPPG	Pharmacy Forum NI	Police Service of Northern Ireland (PSNI)	Royal College of General Practitioners Northern Ireland (RCGP)
The Royal National Institute of Blind People (RNIB)	The Royal College of Midwives	Royal College of Nursing, Northern Ireland (RCN)	Royal College of Psychiatrists (RCPsych)
Royal College of Surgeons of Edinburgh	Safeguarding Board NI	Safe Anaesthesia Liaison Group (SALG)	Sinn Féin
South Eastern HSC Trust	Southern Health and Social Care Trust	Ulster University	Wellbeing Psychology Service - BHSC
Western Health & Social Care Trust			

³ Two organisations submitted more than one response, making the total number of responses 43 from 41 different organisations.

OVERVIEW OF CONSULTATION RESPONSES

Consultation responses welcomed much of the core intent of the Framework and supporting documentation highlighting widespread support for a learning-driven, inclusive, compassionate, and systems-based approach to managing Patient Safety Incidents.

Respondents strongly supported the move towards an open and just culture that prioritises learning over blame, supports psychological safety, and promotes equity. Endorsement was given to principles that place All those Affected at the centre of the process through transparency, timely communication, and wellbeing support. Regional standards, strong leadership and robust oversight and assurance were seen as essential for consistency and effective implementation.

The consultation also highlighted several important themes and considerations that will shape future refinement and implementation of the Framework. These are presented as a high-level summary below, with more detailed analysis provided in the next section of this report.

- **Openness, Transparency and Appropriate Accountability:** Respondents strongly supported embedding openness, honesty, and transparency as core principles, alongside a shift from blame culture to appropriate accountability. It was emphasised that cultural change must be demonstrated through leadership behaviours and practical measures, and there must be clear separation between learning and accountability processes with stronger oversight and safeguards to prevent under-reporting or avoidance of responsibility.
- **Timely and inclusive communication:** Respondents emphasised the importance of timely, inclusive communication and realistic, standardised timelines to minimise trauma and maintain trust, supported by adequate resourcing and transparent processes to balance timeliness with quality and engagement.

- **Regional Consistency:** Respondents stressed the need for regional consistency in review processes, while expressing mixed views on flexibility. Some supported a proportionate approach, but others cautioned that excessive flexibility could lead to inconsistent practices, fewer reviews, and inequity—particularly for vulnerable groups. Clear criteria, structured processes, and robust monitoring were seen as essential.
- **Independence:** Respondents highlighted the need for clear criteria and robust mechanisms to ensure the appropriate level of independence in the review process, with some viewing independent oversight and regional consistency as essential for transparency, public trust, and unbiased decision-making.
- **The review process:** While there was support for the aim of simplifying and streamlining the process, there were concerns regarding the complexity of the proposals and calls for greater clarity in the review process.
- **Learning and Improvement:** The Framework’s focus on learning and improvement was welcomed with particular support for embedding evidence-based learning into practice, verifying implementation, and ensuring system-wide dissemination to drive meaningful and sustained patient safety improvements.
- **Language and Terminology:** Respondents largely welcomed the shift to learning-focused terminology and stressed the need for clear, consistent and inclusive terminology, definitions and language.
- **Oversight and Assurance:** Respondents called for robust, transparent, and enforceable governance and oversight mechanisms—underpinned by clear accountability and independent challenge, —to ensure Patient safety incidents are managed consistently, learning is embedded, and trust is maintained.
- **Implementation and Training:** Respondents welcomed the commitment to a managed transition but stressed that successful implementation requires a

detailed, phased plan with clear timelines, leadership, and resources— supported by robust, regionally developed training. It was noted that training should be mandatory, trauma-informed, and systems-based.

The consultation was focused on the strategic approach rather than the detailed operational delivery of the new process. The DoH acknowledges and agrees with many responses highlighting the importance of effective implementation to ensure the intent of the Framework is fully realised. Operational aspects will be considered and developed in partnership with HSC organisations during the subsequent implementation phase.

In summary, the consultation demonstrated strong support for the strategic principles underpinning the Framework, while highlighting critical areas requiring further clarity and operational detail. The DoH remains committed to working collaboratively with HSC organisations and stakeholders to address these concerns, refine the proposals, and ensure that implementation delivers a transparent, consistent, and learning-focused system that improves patient safety and maintains public trust.

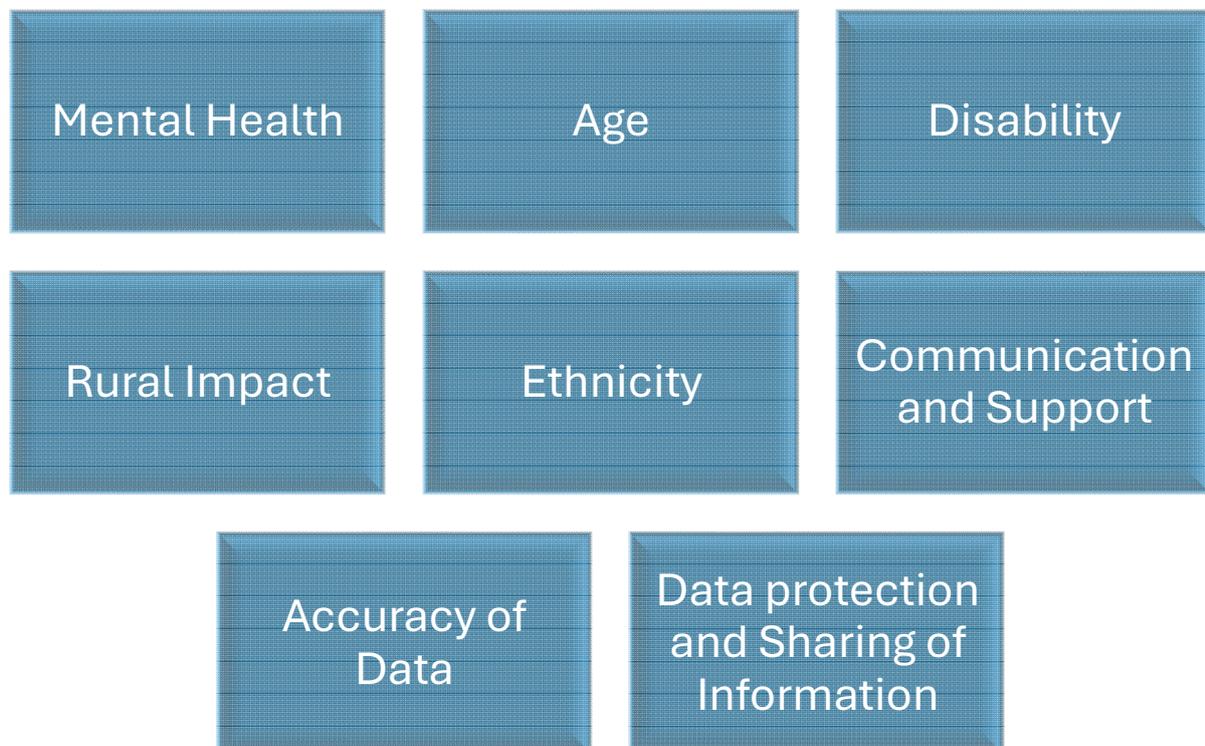
ANALYSIS OF CONSULTATION RESPONSES

SCREENING

Consultation Question 6 - Have you any comments on either the Equality/Good Relations, Rural or data protection screening documents?

Of the 52 questionnaire responses received, 7 included comments regarding the Equality/Good Relations, Rural or data protection screening documents. Figure 3 below lists a summary of the issues raised in responses.

Figure 3 – Summary of Issues raised in relation to the Equality/Good Relations, Rural or data protection screening documents.



Summary of Issues raised:

Mental Health

- Comments suggested that mental health inequalities must be thoroughly understood to lead to improvement. It was suggested that consideration should be given to any additional needs in terms of communication and engagement

with the families of a patient who has been subject to a mental health related Patient Safety Incident.

Age

- One respondent felt that the current SAI procedure is detrimental to older people and other vulnerable groups such as those with a disability and raised concern that the redesigned process would create further detriment. This response suggested that the continued use of the Post-Falls Review Procedure and the introduction of thematic reviews will further disproportionately impact older and vulnerable people as a result of grouping incidents and learning.
- It was felt that it is difficult to understand how the characteristic of age is not disproportionately affected given the age profile of HSC users in Northern Ireland. With older people more likely to live with one or more long-term health conditions, increasing the complexity of care required, the pressure on services and the risk of complications.
- It was suggested that the DoH must consult with the Commissioner for Older People Northern Ireland (COPNI) and the Human Rights Commissioner on the new proposals.
- One respondent expressed disappointment that a Child Rights Impact Assessment (CRIA) was not carried out.

Disability

- One respondent raised that there is no Accessible Health Information (AHI) standard in Northern Ireland which distinctly disadvantages those living with a sensory impairment. This respondent noted that research shows an increased risk of medication errors for those living with sight loss and underscores the greater likelihood of those with disabilities to experience Patient Safety Incidents, given their greater healthcare needs and/or hospitalisation rates.

Rural Impact

- There was agreement with the need to ensure rural dwellers do not experience the process differently and the importance of understanding rural dwellers differing needs.

Communication and Support

- The importance of effective communication from HSC organisations in the Patient Safety Incident process, to mitigate against the issues identified in the screening documents was raised. This would include providing the necessary training and ensuring those in single point of contact roles have the necessary skills to communicate with the section 75 groups.
- It was suggested that independent advocacy support is essential, particularly for those in the section 75 categories.
- Concern was raised over the accessibility of the consultation, with some groups feeling more time was required to respond meaningfully.

Accuracy of Data

- Some respondents noted concerns regarding the accuracy of the data used to complete the screening documents. It was noted that screening may have been constrained by a lack of data concerning individuals with multiple and intersecting section 75 characteristics.
- Some noted that consideration should be given to groups facing digital exclusion or other barriers to participation in the safety processes and service engagement.

Ethnicity

- One respondent noted a concern over the lack of data on race and ethnicity in Patient Safety Incidents, with this omission hindering the ability to address potential disparities in patient safety outcomes among different ethnic groups.

This response noted that it is important to collect and analyse ethnicity data to identify and mitigate risks effectively.

- The importance of mechanisms to ensure fairness and consistency for all HSC staff, including equality, diversity and inclusion training for those involved in the Patient Safety Incident process was also raised.

Data protection and Sharing of Information

- One respondent noted that the Data Protection Impact Assessment (DPIA) relates to the consultation exercise, rather than the personal data implications of the proposals. This respondent recommended conducting a DPIA on the new process, outlining how any risks in the processing of personal data as part of learning reviews will be mitigated in practice. They also felt that clarity should be provided on how individuals involved in the process will access information, i.e. whether it will be provided proactively or only upon request.

Consultation Question 7 - Any there any areas or issues you feel we should be considering in future screenings?

Of the 52 questionnaire responses received, 9 included comments on areas or issues they felt should be considered in future screenings.

Responses suggested future screenings should consider the following:

- The specific needs of autistic and neurodivergent people.
- Unpaid carers, particularly those supporting individuals with serious mental illness, who often carry the emotional and logistical burden of navigating a complex and at times, unresponsive system.
- Any potential barriers to participation for example disparities in resources, digital access and confidence navigating the system.
- The impact of the redesigned process on human rights for All those Affected and Staff.

- Data protection and GDPR issues, including considering how data will be openly and appropriately shared.
- Equivalent support for All those Affected and Staff to include for example, access to independent advocates and the long-term requirements for this support.
- The involvement and engagement of General Practitioners (GPs).
- Co-production of proposals with all stakeholders, including victim representatives.
- Commitment to truth, transparency and co-production through a model that actively seeks the truth, engages early and includes All those Affected.
- The resource implications of implementation, including detailing the additional resource and regional training that will be made available.
- Related processes for example, the complaints process, Adverse Incidents and the Post-Falls Review Process.

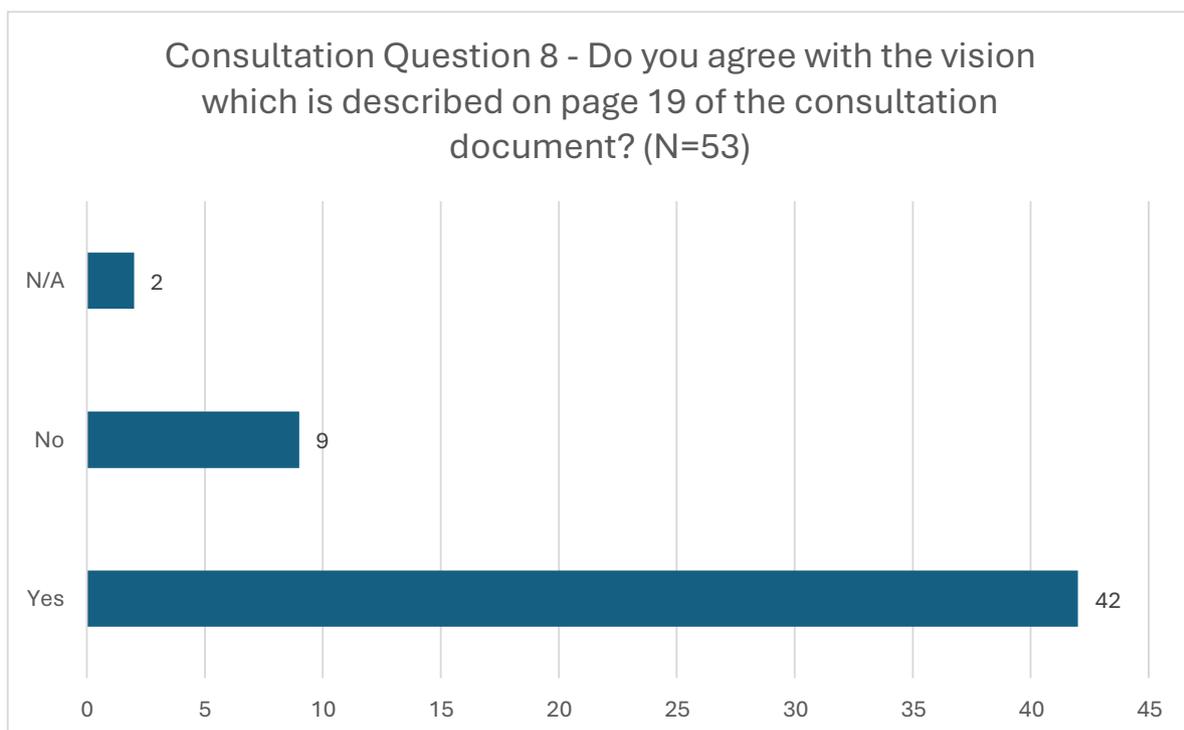
VISION

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.

Consultation Question 8 - Do you agree with the vision which is described on page 19 of the consultation document?

A majority of 42 of the 52⁴ respondents (81%) who completed the consultation questionnaire **agreed** with the vision proposed for the Framework.

Figure 4 – Breakdown of responses to consultation question 8.



Most respondents broadly agreed with the described vision and in particular welcomed the focus on the following:

⁴ One respondent answered both yes and no to this question, making the total number of responses 53 from 52 respondents. Percentages have been calculated from the overall 52 respondents.

- The move towards a learning-driven approach and in particular the focus on identifying and embedding learning which leads to sustainable system improvement.
- A more compassionate and inclusive culture with a greater focus on meaningful engagement with All those Affected and Staff Affected.
- A more flexible, simpler and timelier process which aims to ensure reviews are high quality.
- A move towards appropriate accountability with less focus on blame and culpability.
- The link to an open, just and learning culture which aligns with the wider policy agenda.
- The move towards a focus on system improvements and on identifying the factors causing or contributing to the incident to identify what happened and why.

‘We welcome the proposed Framework for Learning and improvement from patient safety incidents. It presents a positive step toward a compassionate, inclusive, and effective approach to understanding and learning from patient safety incidents across the health and social care system.’

Northern Ireland Hospice

‘I completely agree with the vision outlined, in particular the need to move toward system improvements as a predominant area of change that will have the greatest impact upon patient safety.’

Individual

While there was support for the vision overall, there were also a range of other comments provided for consideration as summarised below:

Blame Culture/Appropriate Accountability

Respondents welcomed the shift from a culture of blame to one of appropriate accountability, believing this would reduce fear around openness and transparency in Patient Safety Incidents over time. However, they stressed that openness must be balanced with clear accountability, especially in cases of negligence, and cautioned that moving away from blame must not result in avoiding responsibility.

Summary of issues raised:

- The need for clearer language to show that the Patient Safety Incident Learning Review Process is for learning and improvement, while accountability processes remain separate.
- Concerns that HSC organisations may under report Patient Safety Incidents to avoid reputational damage.
- Doubts about the current procedure's effectiveness in applying appropriate accountability, feeling that the move away from blame culture can currently be used to avoid the investigation of individual actions and therefore may fail to identify misconduct, neglect or carelessness.
- The importance of holding individuals accountable for failing to report Patient Safety Incidents.

Timeliness

Respondents strongly supported a timelier review process, noting its importance for older people and for the wellbeing of All those Affected—helping to prevent further trauma and support those dealing with grief and emotional challenges. However, they emphasised that timeframes must be realistic to allow for thorough investigation, meaningful engagement, clinical insight, and comprehensive reporting. Concerns were raised that without additional resources, the redesigned process may not improve timeliness, as staff would still be expected to complete reviews under significant time pressure while managing clinical or managerial workloads, limiting opportunities for reflective practice and meaningful learning.

Openness and honesty

Respondents supported framing the draft Framework within a culture of openness, honesty, and transparency, viewing this as essential to the redesigned process. They emphasised that this must be demonstrated through actions and outcomes, with a broader cultural shift across the HSC sector.

Summary of issues raised:

- The need to make the new process mandatory to ensure change.
- Recognition that doctors already have a professional duty to be open under GMC's *Good Medical Practice*. These standards dictate that doctors must respond 'promptly, fully and honestly to complaints and apologise when appropriate'.
- A desire for clearer commitment to transparency.
- The importance of promoting openness at all levels, including senior management, to encourage staff to feel safe to recognise and share issues which may impact patient safety.

Implementation and Resource

While a significant majority of respondents agreed with the vision outlined, many felt it lacked practical detail on how it would be translated into actionable steps and measurable outcomes. They emphasised that adequate resources are essential to support meaningful engagement, timely reviews, and effective learning. Concerns were raised about the HSC system's readiness to deliver the process and achieve meaningful change.

Summary of issues raised:

- The need for significant training and resource to operationalise the proposals.
- Doubts about HSC organisations' insight and capacity to implement the vision.
- Risk of misapplication due to the lack of clarity of intent of the language used.

- Calls for the procedure to be underpinned by legislation or Departmental direction rather than guidance.
- Challenges in shifting the language and mindset from investigation and convincing staff of the change in culture.
- The need for an independent regulatory body not funded or aligned with the DoH or HSCNI.

Engagement and Support

There was strong support for the focus of the proposals on meaningful engagement with All those Affected, with respondents stressing the importance of placing them at the heart of the review process as active partners whose insights help to shape how safety is defined, addressed and continuously reviewed. It was felt that the success of the vision will depend on these principles being embedded in day-to-day operational practice

Some responses felt that the vision is too focussed on HSC staff, arguing that the process cannot be 'equal to All those Affected' as staff have more resources for support and to protect their interests, for example the organisation, trade unions and the professional regulator. Other responses however, highlighted that the vision did not include any reference to effectively engaging with and supporting staff and that engagement must take both All those Affected and Staff Affected into account.

Summary of issues raised:

- A greater focus is required on how to support All those Affected.
- Clarity is required on how to quantify or further define 'meaningful engagement'.
- A balance is required between engagement, answering questions and concerns and quickly identifying and disseminating learning to ensure the embedding of learning is not delayed.
- Reviews should not solely be about learning but also about providing the truth to All those Affected, appropriately involving them in the review process and providing the support they require.

Learning and Improvement

The Framework's focus on learning and improvement was strongly supported with respondents welcoming the emphasis on promoting a learning culture. Success was seen as dependent on embedding learning into practice and improving patient safety.

Summary of issues raised:

- Learning should be widely disseminated across the HSC system to prevent recurrence of harm.
- Local and regional learning should be valued equally.
- Improvement should be driven by evidence-based learning.
- Learning review recommendations should move away from being focussed on staff and training, towards learning that recognises the systems in which we work need to be continually improved and adjusted to make it easier for the people working in them to consistently do the right thing.
- Recommendations should be tested with QI methodology to test, tweak, refine and embed those recommendations into everyday practice.
- Awareness should be raised of how high-level stress impacts on the learning process, as well as factors that mitigate this for example the trauma informed approaches by the Safeguarding Board for Northern Ireland (SBNI).
- The proposals should be clear on how they will link with National processes to ensure learning is shared throughout the UK and beyond.
- The vision should be strengthened with regards to improvement and how reviews should prevent similar incidents happening again.

Definitions and Terminology

Some respondents welcomed the shift in terminology from "investigation" to a focus on learning and supported the inclusive definition of All those Affected.

Significant concerns were raised by some respondents about the use of the term "victim," these respondents felt for example that the term implied blame and could set expectations of an investigative approach. Others supported the use of the term but

noted that the definition was too narrow, potentially excluding key stakeholders—such as members of the public harmed by patients under HSC care, or victims of crime involving individuals from within the HSC system. It was suggested that these individuals could be included under All those Affected or in a separate category to ensure their insights are not overlooked.

Suggestions included replacing “meaningful engagement” with “caring and supportive engagement”, and further clarity of definition was requested for the following terminology:

- High quality
- Meaningful engagement
- Timelier – do we have KPIs to benchmark against?
- What does a measure for improvement look like?
- Open, Just and Learning culture
- Appropriate accountability

Methodology

While the aim to simplify and streamline the process received strong support, some respondents questioned whether the draft proposals would achieve this. Concerns were noted that a high-level approach and multiple guidance documents could lead to confusion, inconsistency, and unclear accountability – with some potential to undermine public trust and the system’s ability to learn effectively from Patient Safety Incidents across HSC in Northern Ireland.

Summary of issues raised:

- Separate post suicide and substance overdose learning reviews from the main system using a methodology that incorporates psychological theories, patient experiences and learning from prior behaviour to inform learning and prevention strategies.

- Enable early-stage review escalation or de-escalation, to apply investigator time proportionately as themes, information, or concerns emerge.
- Strengthen the vision by incorporating a stronger emphasis on the application of a system-based approach to reviews, focusing on human and system factors to understand the ‘how and why’ rather than the ‘who.’
- Ensure predictability and consistency across the region in process and outcomes, including review types and quality, independence, engagement and support, and implementation and verification of learning and improvement.
- The Framework should link more clearly to governance structures to implement long term change.

Independence

Respondents called for greater clarity on how independence will be ensured in the redesigned process in Northern Ireland. Some felt that all reviews should include a degree of independence and should be conducted consistently across the region to build public trust. Concerns were raised about the ability of HSC organisations to deliver honest assessments of their own potential failings.

HIGH-LEVEL THEMES

Consultation Question 9 - Do you agree with the High-Level Themes which are described on pages 20-33 of the consultation document?

The consultation document proposed a range of high-level themes for the development and implementation of the new Framework and supporting documentation, which are outlined in figure 6 below.

A majority of 40 of the 52 respondents (77%) who completed the consultation questionnaire agreed with the High-Level Themes proposed for the Framework.

Figure 6 – High-Level Themes



A summary of issues raised under each High-Level Theme is provided below:

Focus on Learning

There was widespread agreement and support for the Framework's focus on learning and improvement. Respondents particularly welcomed the commitment not only to identifying learning but also to ensuring it is effectively implemented and embedded in practice to drive meaningful improvements across the system.

Summary of issues raised:

- The new process should begin with the identification of the Patient Safety Incident and conclude with the verification of the implementation of recommendations and learning across the region. Change as a result of the review process must be verified.
- Patient Safety Incident reports should be published in the spirit of openness, honesty and willingness to learn.
- When developing guidance for organisations creating Patient Safety Incident Learning and Improvement Plans, a clear focus/requirement should be placed on learning and improvement activities being embedded within these documents.

Terminology

Feedback from consultation responses focused on the following terminology:

Patient Safety Incident

A small number of respondents expressed concerns that the move away from the term 'Serious Adverse Incident' could dilute the perceived seriousness of incidents and, as a result, impact how they are managed and responded to.

A small number suggested the use of the term 'incident' suggests an automatic assumption that something has gone wrong and suggested 'Patient Safety Event' as an alternative.

Patient

It was highlighted that not all incidents involve a 'patient', and the use of this term could be challenging for the following reasons:

- Some service users may not identify with or understand the term which could reduce awareness and learning from incidents that fall outside traditional clinical settings.
- The term can be seen as reflective of a medical model of care delivery and may unintentionally suggest that Patient Safety Incidents only occur in clinical settings.
- Individuals such as foster carers and service users of social care may not see themselves represented in the proposals.

All those Affected

The introduction of the term 'All those Affected' was welcomed by some respondents, who appreciated the broader recognition of individuals beyond patients and felt it could positively impact the review process. Others found the term useful but emphasised that Staff Affected by incidents should be included within the same term, rather than being separated.

However, some respondents felt that the term is too vague and called for greater clarity to ensure it accurately reflects the experiences of all impacted groups.

Victim

Several respondents expressed strong disagreement with the use of the term 'victim' citing the following concerns:

- **Cultural misalignment:** the term is inconsistent with the principles of an open, just and learning culture.

- **Implied blame:** the term suggests the presence of a culprit and blame which contradicts the learning-focused intent of the Framework.
- **Misleading expectations:** the use of the term may create expectations of justice or legal action, rather than learning and improvement.
- **Emotional Impact:** the use of this term could cause confusion and distress for patients, families and staff involved in Patient Safety Incidents.

Other respondents accepted the inclusion of the term but found the definition problematic:

- **Lack of clarity:** the definition is unclear, confusing and open to interpretation.
- **Too narrow:** the definition risks excluding individuals harmed by Patient Safety Incidents who are not patients or patients' families such as members of the public or staff, which could undermine openness and transparency.
- **Need for co-design:** It was suggested that the definition should be revised through consultation with victims and those with lived experience.
- **Distinction needed:** Greater clarity is required in the definition between 'primary victims' and 'secondary victims.'
- **Legal framing:** the use of legal situations and definitions is counterproductive to the learning and improvement focus of the process.

The following alternatives to the 'victim' term and definition were provided:

- 'Patients and those close to them'
- 'Impacted person'
- Anyone harmed, physically or psychologically in, or as a result of, a patient safety incident and who is not a patient; or the victim's family if the victim is dead or incapacitated.'
- 'Patients who experience harm'

Patient Safety Incident Learning Reviews

There were mixed views on the proposed shift from the term “investigation” to “*review*.” Some respondents welcomed the change, seeing it as a positive move towards a learning-focused approach.

Others felt that the term “*review*” lacks robustness, impartiality, and transparency.

Engagement, Involvement and Support of All those Affected

There was strong support for the inclusion of Engagement, Involvement and Support of All those Affected as one of the Framework’s five key themes. Respondents recognised that the insights and experiences of All those Affected are a vital source of information and learning and that compassionate engagement can significantly improve their experience of the review process. It was also highlighted that engagement with the current process can be deeply painful for those affected.

Summary of Issues raised:

Clear and Practical Guidance

- More detailed guidance is required on how the needs of All those Affected will be managed in practice, particularly if they are not ready to be involved in the process.
- A mechanism should be developed to allow individuals to share important information without participating in the full review.
- Guidance should clarify the expectations for engagement under each type of review explaining the process clearly to All those Affected.

Enhanced support services

- Some respondents called for enhanced support services such as bereavement, counselling and independent advocacy. One respondent suggested what an independent advocacy support model should include, for example, it should:
 - Be independent of the service provider organisation.

- Be regionally commissioned to an agreed standard.
- Not be dependent on a referral by the service provider organisation.
- Align and deliver recommendation 37(iv) of the IHRD report.

Support for vulnerable groups

- Greater protections were recommended for certain groups such as carers, older people, children and young people and those with mental illness or disabilities.

Trauma-Informed approaches

- A compassionate, trauma-informed approach was strongly encouraged to acknowledge the emotional toll of the process.
- Respondents suggested recognising the long-term impact of Patient Safety Incidents and ensuring a duty of care to support healing and recovery.

Transparency, Openness and Truth

- One respondent proposed the creation of a Patient Safety Portal to allow individuals to share their experiences, ensuring their voices are heard and recorded. This was seen as a way to enhance transparency, accountability and recognition of the human impact of Patient Safety Incidents.
- One respondent noted that patient confidentiality should not override the rights of others to know the truth, especially in cases where harm has occurred. This respondent suggested that legal services should be used to ensure full transparency for those affected, rather than to protect organisational reputations.
- Respondents emphasised the right of individuals to understand how and why they were harmed and raised that provisions should be made for the future implementation of Duty of Candour.

Communication and Timelines

- Clear timelines and adherence to them were identified as essential, with respondents acknowledging that while families understand that delays may occur, these must be communicated proactively.
- A lack of regular updates can lead to feelings of anxiety, fear, and suspicion. This could be mitigated by realistic timelines, clear updates, and accountability for meeting deadlines.
- Communication was consistently identified as essential to be incorporated into the redesigned process.
- Engagement must go beyond one-way communication or post-decision updates. All those Affected should be actively included in the review process.
- Delivering a timely review while fully adhering to the principles of engaging All those Affected may be challenging and will require careful balancing of priorities.

Engagement, Involvement and Support of Staff Affected

There was broad support for the inclusion of staff engagement and support as a key theme within the Framework. Respondents strongly supported the emphasis on creating a constructive, fair, and learning-focused system that supports staff throughout the review process and highlighted the need for this theme to be meaningfully translated into practice.

Summary of Issues raised:

Openness and Honesty

- Staff should be given the opportunity and should be supported to engage directly and truthfully with All those Affected, in a manner aligned with restorative justice principles.
- Respondents stressed that staff should not face negative consequences for being open and honest, except in cases involving criminal activity or repeated breaches of professional standards.

- The Framework was seen as a step toward creating the conditions for openness, but respondents emphasised the need for organisations to actively foster a culture of openness rather than blame.

Support Services

- It was highlighted that staff can also be harmed by Patient Safety Incidents and should be recognised as part of *All those Affected*.
- Staff should have access to the same levels of support, engagement, and inclusion as patients, families, and members of the public.
- One respondent noted the absence of reference to occupational health or confidential support services such as those available in England and Scotland (the NHS Practitioner Health service) and the Republic of Ireland (Practitioner Health Matters).
- It was suggested that the DoH should review Patient Safety Learnings' 'Staff Support Guide: a good practice resource following serious patient harm'.

Communication and Psychological Safety

- The importance of keeping staff informed and updated throughout the process was emphasised.
- Respondents noted that the review process can have a significant impact on the psychological safety of staff and hoped the new approach would improve this.

Methodology

There was strong support for a systems-based approach to learning to improve patient safety, with emphasis on regional consistency, external oversight, and the use of standards. The proposal to establish a regional pool of trained independent facilitators was widely welcomed and it was suggested that this pool could contribute to training development and form part of a broader expert hub to provide independent analysis on safety trends and concerns.

Summary of issues raised:

Identification

Respondents called for a more inclusive and proactive approach to identifying Patient Safety Incidents, with some emphasising that anyone involved—not just healthcare professionals—should be able to raise concerns and that all voices, including patients, families, and external agencies, should be valued.

One respondent highlighted a number of concerns around the identification of mental health incidents, for example noting that unlike physical health contexts—where incidents are often sudden and clearly identifiable—in the mental health context, reviews often occur only after severe outcomes such as suicide or harm, despite long periods where preventative care could have mitigated risk. This indicates missed opportunities for learning.

Independence

Some respondents endorsed the need for independence throughout the Patient Safety Incident Learning Review process, from initial identification to closure, to help ensure transparency, public trust, and unbiased decision-making. It was suggested that a concise review should be the starting point, with clear criteria guiding whether a more comprehensive or thematic review is required and if so the level of independence of this review. The establishment of a regional pool of trained independent facilitators was widely supported, with calls for regional consistency, transparency in methodology, and robust oversight. An appropriate level of independence—whether full or partial—was viewed as essential to securing public confidence and ensuring rigorous, trustworthy reviews.

Timeliness

There was support for using concise reviews to aid timeliness and a focus on the more timely completion of reviews was welcomed. Some respondents noted the absence of specific guidance on timeframes which was seen by some as a risk to consistency and transparency, with calls for realistic, standardised timelines for each stage of the review process. It was highlighted that timely investigations are essential to minimise

trauma and that HSC organisations should be appropriately resourced to ensure that reviews are completed within reasonable timeframes.

Review Types

Respondents expressed mixed views on the proposed review types, with some seeing little change from the current procedure and calling for clearer definitions, criteria, and guidance. Thematic and concise reviews were welcomed as a valuable addition, but concerns were noted about their practical application, especially in mental health and suicide-related cases.

There was strong support for a systems-based approach to learning reviews, noting that a comprehensive training programme was deemed essential. Respondents stressed the need for robust regional oversight, consistent categorisation of Patient Safety Incidents, and safeguards against individual blame. Concerns were also raised about capacity, transparency, and the need for public input in developing methodology guidance. Calls were made for improved clarity around escalation processes and inter-agency collaboration, particularly with police and coroners, and the management of parallel investigations.

Reporting and Recommendations

Respondents stressed the importance of ensuring that final reports are complete, accurate, and inclusive of all factual information raised by those affected.

Recommendations should be developed collaboratively with commissioning organisations to ensure they are practical and SMART⁵. Some concerns were raised about privileging clinicians' accounts over those of families, with respondents highlighting the importance of balanced and inclusive reporting to support future learning and care standards.

⁵ Specific, Measurable, Achievable, Realistic, Time-Bound.

Implementation and Oversight

While the intent of the Framework was strongly supported, respondents highlighted the need for further implementation detail. There were concerns about organisational capacity, particularly among independent contractors and commissioned services. Respondents urged greater specificity in methodology guidance, clearer thresholds for timeliness and independence, and stronger engagement with patients, families, and the public. One suggestion included introducing an independent Patient Safety Commissioner to oversee learning reviews, monitor engagement, and ensure accountability.

Flexibility

There was some support for the Framework's expectation that organisations will take a proportionate and flexible approach to Patient Safety Incident Learning Reviews, particularly around the principle of 'Do once, do well.' One respondent noted that this less rigid approach would enable HSC organisations to complete reviews more efficiently and proportionately, which lends itself to maximising learning and driving system-wide improvement. Another noted that organisations should retain the professional discretion to determine whether an incident occurred and what type of review is appropriate, even when under pressure from affected individuals.

Some respondents raised concerns around flexibility for example cautioning that excessive flexibility could lead to inconsistencies, allow organisations to misuse the process, and could risk minor incidents not being reviewed—which may escalate into systemic issues. It was also noted that a structured, prescriptive process supports legal and regulatory proceedings.

Consistency

Consultation responses identified a strong emphasis on the need for regional consistency in review methodology and quality, engagement, involvement and support

of All those Affected and, in the implementation, and verification of learning.

Respondents supported the development of regional standards, guidance and training to support regional consistency, noting that variation in review types or methodologies could lead to inequity and undermine public trust.

A mandatory, regionally developed approach with clear criteria and oversight was recommended by some to prevent discretionary practices that may reduce the number or quality of reviews. The use of a regional template and oversight by SPPG and PHA was welcomed, though some noted further clarity in roles and decision-making authority was required. Consistency and transparency were noted as essential to ensuring fairness and restoring confidence in the system.

Summary of issues raised:

- Review findings on the Patient Safety Incident Response Framework (PSIRF) process in England revealed significant variation in the approach and level of detail across organisations, complicating cross-organisational comparisons and potentially hindering the identification of best practices and shared learning. It was suggested that a national standardised framework for evaluating Patient Safety Incident Response Plans is required, alongside consideration of independent external reviews of Plans to strengthen oversight.
- The DoH must address potential variation caused by the flexibility in the Framework and deliver robust monitoring via the SPPG and PHA.
- Discretion for HSC Trusts may exacerbate inconsistencies in decision-making and reporting. It was suggested that a detailed decision-making tool be provided to guide consistent decisions, incorporating risk assessment.
- Incidents occurring within Independent Sector Providers must also follow a consistent approach across all HSC Trusts.
- Without a shared approach to how reviews are conducted, recorded and reported, data cannot be meaningful compared. A more detailed, standardised approach and structured reporting formats were encouraged to support regional data monitoring and system-wide learning.

Learning

Respondents strongly supported a more robust, demonstrable approach to learning from Patient Safety Incidents, emphasising that learning must go beyond action plans and result in sustained system change. There were calls for learning to be actively implemented, verified on the ground, and continuously monitored to ensure improvement. Many highlighted the need for regional oversight, with suggestions for public reporting, thematic reviews, and feedback loops to track progress across organisations.

Concerns were raised about the effectiveness of current tools such as learning letters, with proposals for online platforms to record learning, engagement and understanding, potentially linking this to appraisal and revalidation. Respondents stressed that learning must be accessible to all sectors, including GPs, social care staff, and independent providers.

Transparency and accountability were recurring themes, with calls for anonymised public reports to show the impact of reviews and restore trust. Respondents also emphasised the importance of involving All those Affected throughout the process, including post-review, and ensuring they are informed of outcomes and changes made.

There were concerns about the potential diversion of resources from frontline services and the need for practical, cost-effective mechanisms to support learning. Suggestions included appointing a regional “speak up” champion and strengthening the role of regulators in overseeing implementation. Clarity was requested on how learning will be shared, who is responsible, and how trends and early warnings will be identified and acted upon.

Overall, respondents welcomed the Framework’s focus on learning but stressed that its success depends on clear processes, regional consistency, meaningful engagement, robust oversight and a shift from passive documentation to active, verified improvement.

Systems Supporting Learning

Respondents strongly welcomed and acknowledged the importance of systems-based approaches in the Framework. These approaches were noted as essential for understanding the broader context and contributing factors surrounding Patient Safety Incidents. Some noted that further clarity is needed in the definition of a systems-based approach to ensure consistent understanding and application across organisations.

Oversight and Assurance and Regional Surveillance

The responses received in relation to oversight, assurance and regional surveillance clearly articulated the need for stronger governance, transparency, and accountability in those areas with regard to Patient Safety Incidents.

Summary of issues raised:

Clarity on reporting and monitoring

Request for clarity on:

- who will have ownership for incident data
- if there will be a central repository to collect, store and analyse the data.
- the reports that will be shared with staff and the public to evidence learning and improvement
- how outcomes will be reviewed and used to inform service planning

Regional Response and Accountability

- Every Patient Safety Incident should be regional, and the response determined by SPPG.
- Organisations and individuals must be held to account for malpractice and concealment, with particular emphasis on leadership accountability.

Challenge mechanisms

- There must be clear pathways for external audit and a mechanism for families or staff to raise concerns about non-compliance with the Framework.
- An independent challenge function should be built into the new process when organisations refuse to initiate a review.

Values and Culture

- The language around openness, compassion and transparency is welcomed, however many of these values are not upheld in practice and stronger monitoring and external accountability mechanisms are required to ensure learning is implemented and reviews are acted upon.

Governance

- The Framework's governance model should be linked with broader accountability reforms including relevant recommendations from reports and inquiries and related workforce strategies.
- Any review of how the Framework is operating must maintain a clear qualitative focus and draw on the experience of All those Affected.
- Ensuring disseminated learning has been embedded in practice must be a clear focus of the oversight role.
- Further clarity and public engagement is required on the oversight and governance elements of the new process. Robust, transparent and consistent oversight and assurance is critical for delivering effective learning and building and maintaining trust in the new process.

Education and Training

The importance of training in successfully embedding the new approach was strongly emphasised and the commitment to train not only staff undertaking reviews but also those in governance and leadership positions was welcomed.

Summary of issues raised:

- New approaches to training should be considered, such as appreciative inquiry-based training, to foster meaningful engagement and reflection.
- There was support for the need for mandatory, role specific training.
- Training must be delivered regularly, for continuous professional development, in partnership with trade unions and professional bodies and designed for cross-disciplinary learning.
- Resources for training must be ringfenced and evaluated annually for effectiveness.
- The focus of the importance of the role of leaders was welcomed.
- One respondent felt any education programme should include training on age-related issues to ensure staff are equipped to deal with the unique, diverse challenge older people experience.
- It was raised that staff in General Practice (GP) do not have equitable access to training compared to secondary care and as small organisations, GP practices face significant resource implications in enabling training and education.
- Clarity was requested on the Regional pool of trained facilitators and who will train this group to ensure independence.

Interfaces and Influencers

Responses emphasised the need for greater clarity within the Framework regarding incidents that span multiple HSC Trusts or cross the boundary between primary and secondary care. Respondents felt that these types of interface incidents are common and often complex, yet the Framework does not currently provide sufficient detail on how they will be managed.

Responses highlighted the need to understand how governance and assurance mechanisms will work under such circumstances and whether the Patient Safety Incident Learning and Improvement Plans allow for co-operation and interoperability for cross-trust incidents. Concerns were raised about how oversight and assurance of

interface incidents will be managed and how learning from these incidents will be effectively shared across interfaces to improve safety and care.

Managing Transition

The commitment to support the proposals with a detailed implementation plan was welcomed, particularly the recognition that a managed transition is necessary.

Respondents agreed in principle with the need for a managed transition but noted the absence of detailed timelines, costings, and leadership structures.

Summary of issues raised:

- Implementation should include a phased role out with pilot sites, published milestones and the creation of a named implementation lead or commissioner
- An integrated implementation plan that connects all current reform strands should be developed and published.
- Embedding trauma informed practices, flexible engagement routes and co-designed tools will be critical.
- The Key themes outlined in the Framework must be consistently and visibly implemented and embedded in everyday practice.
- Overlapping patient safety policy and legislative proposals should be developed in an ordered and sequential manner (e.g. Being Open Framework, Duty of Candour and the Model Complaints Handling Procedure).
- Transition must not undermine effective elements of the current SAI process or add any regulatory burden; implementation must be streamlined and learning focused.
- Implementation and transition must be tailored to consider the differing nature, scale and operational capacity of independent HSC contractors, compared to the larger HSC organisations, recognising their limited resources compared to larger organisations.

- Other sectors need to be provided with the same degree of support, protected time and training on the new framework and process, as those working in secondary care.

The high-level themes emphasise a commitment to a systems-based response, just culture, openness and meaningful engagement with those affected, with a welcomed enhanced recognition of the emotional and psychological sequelae that patient safety incidents can have on all individuals affected by such challenges.

Psychological Services BHSCT

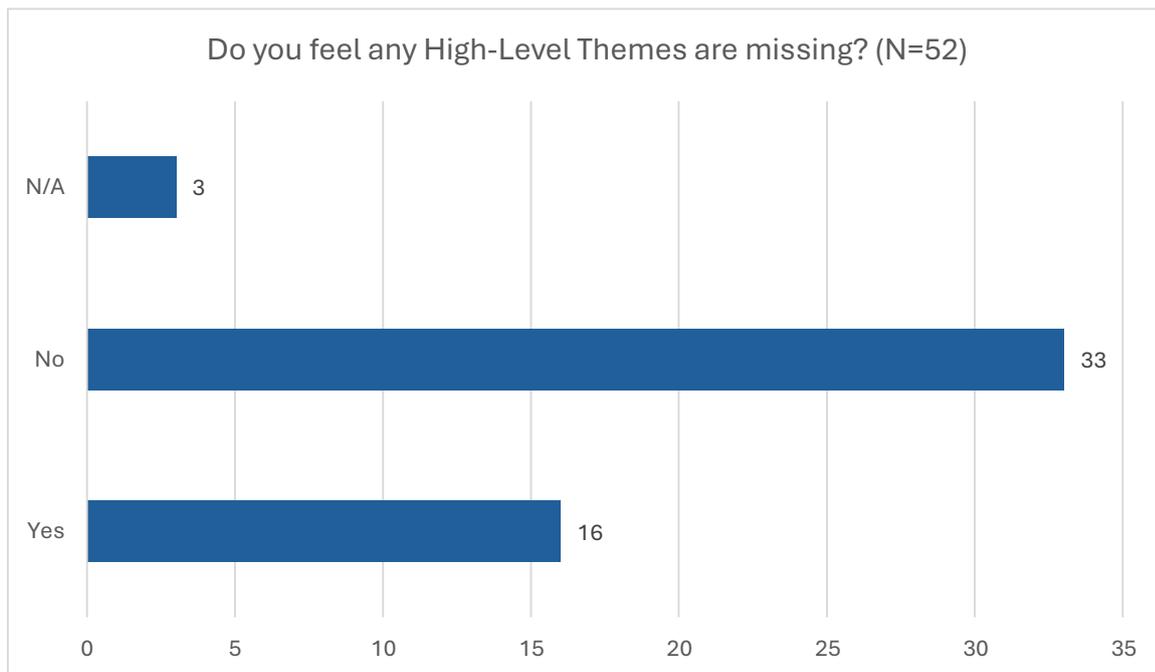
The purpose of an SAI/PSI is to learn what went wrong and make change to prevent death and harm. This **MUST** be an active process involving the design of new procedures etc. 'Teach and Test to implement them, and physical verification that the change has been made.

Individual

Consultation Question 10 – Do you feel any High-Level Themes are missing?

33 of the 52 respondents (63%) who completed the consultation questionnaire did not feel any High-Level Themes were missing, figure 7 below shows a breakdown of responses to this question.

Figure 7 - Breakdown of responses to consultation question 10



Responses that indicated High-Level Themes were missing suggested the inclusion of the following:

Mental Health

- Referral pathways for counselling for those affected.
- A dedicated theme for incidents involving homicide, serious assault, or sexual assault by individuals under mental health care.
- Equal review standards for mental health-related incidents as those applied in Domestic Homicide Reviews.
- Proposal for a joint procedure with PSNI for reviewing such incidents.
- Recognition and engagement with the Regional Mental Health Service Project.

Trauma-Informed Approach

- Embedding and operationalising trauma-informed practice and principles throughout the review process.
- Independent advocacy services.

Evidence

- Requirement for written evidence to support decisions on whether and how reviews are conducted.
- Honest, written responses to questions raised by those affected, supported by evidence.

Safety and Leadership Culture

- Addressing the psychological impact of incidents involving senior professionals.
- Emphasis on leadership's role in fostering a culture of safety, curiosity, and open communication.
- Recognition of inequality in patient safety and the need for system-wide accountability.
- Inclusion of responsibility across all levels—from frontline staff to regulators and funders.

Communication

- Embedding inclusive and accessible communication practices.
- Clear, jargon-free communication with patients, including who communicates, when, and in what format.
- Strengthening openness, honesty, and transparency.

- Suggestion for a named individual or strengthened DoH lead for quality and safety.
- Proposal for a Freedom to Speak Up Guardian.

Systems-Based Approach

- Greater emphasis on the shift to systems-based learning from Patient Safety Incidents.

Resource

- Acknowledgement of the resource requirements for governance teams and staff involved in the review process.

Interface Incidents / Transition of Care

- Oversight and assurance for cross-trust, cross-agency, and cross-sector incidents.
- Explicit inclusion of third sector and community providers.

OUTCOMES

Framework

Consultation Question 11 - Do you support the over-arching approach described in the Framework for Learning and Improvement from Patient Safety Incidents?

A majority of 45 of the 52 respondents⁶ (87%) who completed the consultation questionnaire supported the over-arching approach described in the Framework. Figure 8 and Table 3 below show a breakdown of the responses to this question.

Figure 8 - Breakdown of responses to consultation question 11.

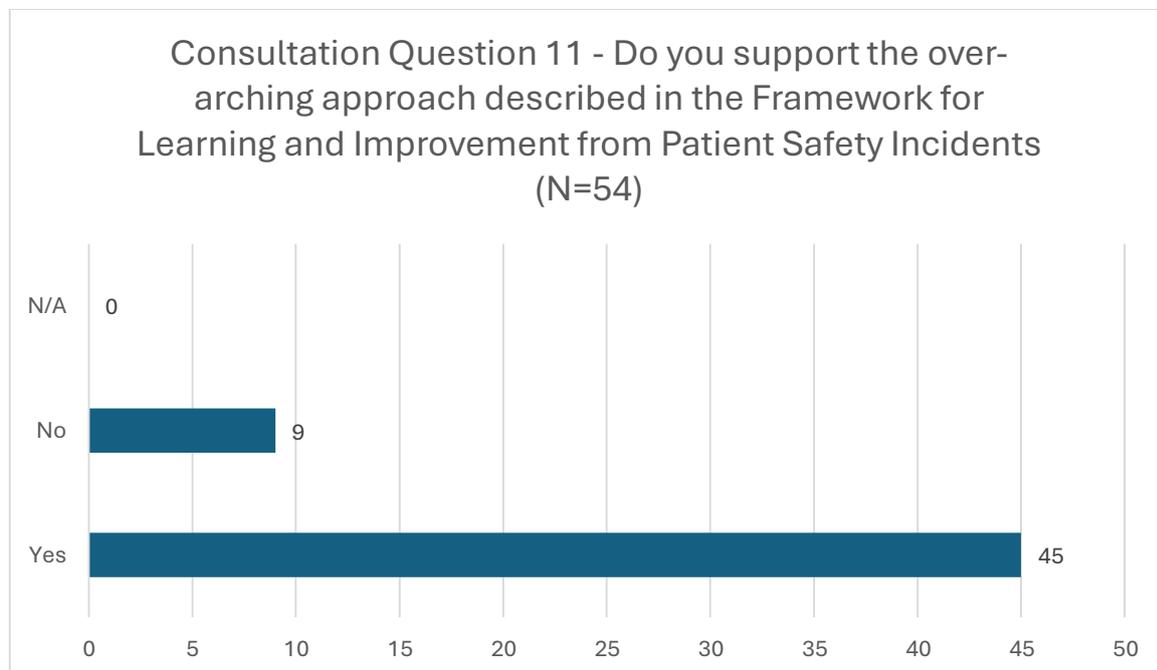


Table 3 – Breakdown of consultation responses received to question 11.

Q12	Total	Percent
Yes	45	87%
No	9	17%
N/A	0	0%

⁶ Two respondents answered both yes and no to this question, making the total number of responses 54 from 52 respondents. Percentages have been calculated from the overall 52 respondents.

The Framework was widely welcomed for its focus on learning and improvement and the systems-based approach to identifying learning. Respondents also valued the Framework's emphasis on:

- A compassionate, meaningful and person-centred approach to engagement, involvement and support of All those Affected and Staff Affected.
- Support with a strong focus on wellbeing and psychological safety.
- Timeliness and simplicity without compromising quality.
- A learning and improvement culture that moves away from blame and towards openness, empathy, and appropriate accountability.
- Learning from when things go right and not just when things go wrong.
- A commitment to equity, recognising and addressing inequalities in HSC.
- Avoiding unnecessary duplication by using the 'Do once, Do well' principle.
- The importance of regional education and training.
- The requirement for each organisation to develop and maintain a Patient Safety Incident Learning and Improvement Plan, based on a data driven approach.

Although the majority of respondents agreed with the outlined approach, many emphasised that its success would depend on the presence of strong, practical mechanisms to ensure it is effectively realised in practice. There were calls for greater clarity around the operational detail of the Framework, particularly how it will be implemented in a cost-neutral manner given the current lack of available resources. Respondents also highlighted the importance of aligning the Framework with other relevant policies in development, such as Duty of Candour, Being Open, and complaints handling, to ensure coherence and consistency across the system.

We support the overarching approach and its potential to drive cultural change towards openness, empathy and systems improvement. Success will depend on strong implementation and monitoring.

The Cedar Foundation

Summary of issues raised:

Autonomy and Accountability

Some respondents expressed concern about granting greater autonomy to HSC Trusts, citing a lack of confidence that the Framework would be consistently followed or that meaningful learning would occur. They feared this could lead to avoidable Patient Safety Incidents and a reduction in accountability. There were calls for stronger oversight and direct accountability to the DoH, as current mechanisms were seen as ineffective. Respondents also stressed the need for the process to provide clarity, accountability, and healing.

Consistency and Flexibility

Some respondents raised concerns that a flexible and proportionate approach could lead to inconsistency across the region, undermining public trust and the quality of reviews. They stressed that the public expect Patient Safety Incidents to be investigated using a consistent, regional methodology, rather than relying on localised decisions by individual organisations. The proposal to utilise a regional pool of trained investigators was widely supported with the feeling that this would allow for regional consistency and independence in learning reviews.

Some respondents also recommended a single, region-wide Patient Safety Incident Learning and Improvement Plan, rather than individual plans, with the option for organisations to opt out of specific elements, if they can provide clear justification and rationale.

Some respondents also expressed concern that the flexibility built into the Framework could lead to the dismissal of so-called 'minor' incidents, which may in fact contribute to more serious events if not addressed and suggested that all Patient Safety Incidents, regardless of perceived severity, should be investigated by trained professionals to ensure learning and prevent escalation.

Openness and Transparency

Respondents emphasised the importance of openness, transparency, and trust in the Framework and stressed that the system must be built on truth, learning, and action—not defensiveness or legal avoidance. Concerns were raised about the use of the term "victim," which was seen as counterproductive to moving away from a blame culture. Additionally, the definition of an apology was noted to be specific to England and Wales, with a suggestion to adopt more appropriate wording. While the proposals were seen as a step toward building public and staff confidence, respondents felt there were still gaps that need to be addressed to fully achieve this goal.

Engagement and Support

Respondents raised concerns about an imbalance in the support provided to staff compared to that available to others affected by Patient Safety Incidents. They noted that staff often have access to legal services, medical records, and clinical expertise, while patients, families, and carers may lack similar resources. There was a call for All those Affected to have not just signposting but a right to independent advocacy, legal and medical advice, and representation on review panels. Concerns were also expressed about the Framework's ability to ensure openness and honesty, particularly for vulnerable groups such as older people and those with mental health or learning disabilities, who may face barriers in challenging Patient Safety Incidents.

To operationalise the principles of engagement and support, it was suggested that a designated single point of contact—such as trained advocates—could guide families through the process. Some respondents highlighted the need for timely access to relevant records for staff involved in reviews to ensure accurate input. While the definition of "All those Affected" was welcomed for its inclusivity, it was noted that organisations should retain discretion to determine appropriate involvement in specific cases to protect sensitive personal data.

Methodology

There was support for the Framework's emphasis on data-driven learning and proportionate responses. Some respondents however suggested that its intention is to reduce the number of in-depth reviews completed which could compromise the identification of root causes. The lack of a regional data system and inconsistent data collection were seen as barriers to effective learning. Respondents called for greater emphasis on system-level learning, clearer articulation of how a 'just culture' will support staff engagement, and mandated protected time for staff to participate in reviews.

There were calls for greater structure and clarity in the draft proposals, particularly around:

- what constitutes a Patient Safety Incident
- timeframes
- resource requirements
- how to manage interface incidents
- the decision-making process
- the linkages between HSC organisations and other government and statutory bodies for example the Coroner
- education and training
- implementation in primary care
- how the proposals address the recommendations from inquiries and reports
- the challenge function for All those Affected

Concerns were raised about how incidents affecting staff—such as violence or abuse—would be managed, and there were calls for incidents involving serious self-harm or serious assault (including homicide and sexual assaults) to be included in the mandated comprehensive review list.

Learning

Respondents highlighted the need for clear, consistent, and evidence-based mechanisms to identify, share, and evaluate learning from Patient Safety Incidents across the region. They stressed that learning must be disseminated both within and beyond HSC, with arrangements in place to measure whether improvements are being achieved. There were repeated calls for greater clarity on how system-wide learning will be captured, themed, and shared, including the roles of the SPPG and PHA.

Respondents also recommended the use of a regional set of learning tools and highlighted the importance of linking to established resources such as the Health Foundation's framework for measuring and monitoring safety. While the Framework's cultural focus was welcomed, it was felt that more emphasis is needed on how learning will lead to the prevention of future incidents and a reduction in Patient Safety Incidents.

Governance and Oversight

Respondents emphasised the need for robust and consistent governance at both organisational and regional levels to ensure the effectiveness of the Framework. They expressed concern that without clear detail on what should be reviewed and when, the Framework may fail to deliver the necessary oversight and control—issues that have contributed to the shortcomings of the current system.

Primary Care

Some respondents expressed concern that the Framework, in its current form, is not suitable for implementation in GP or community pharmacy settings. They noted that the proposals are primarily designed around large organisations such as HSC Trusts and fail to account for the limited capacity, resources, and infrastructure of smaller providers. There was a call for meaningful engagement with primary care sectors to ensure the Framework is practical, equitable, and appropriately tailored. Respondents also highlighted the need for operational guidance that reflects the realities of these settings and mechanisms to address the imbalance of power and resources when

incidents cross the interface between primary and secondary care. Without this, the Framework risks being unworkable and inequitable across the wider HSC system.

Standards

Consultation Question 12 - Do you agree that a set of Standards are essential for organisations to meet the expectations and outcomes of the Framework and supporting documentation?

A majority of 49 of the 52 respondents (94%) who completed the consultation questionnaire agreed that a set of Standards are essential for organisations to meet the expectations and outcomes of the Framework and supporting documentation. Figure 9 and Table 4 below show a breakdown of responses to this question.

Figure 9 - Breakdown of consultation responses to question 12

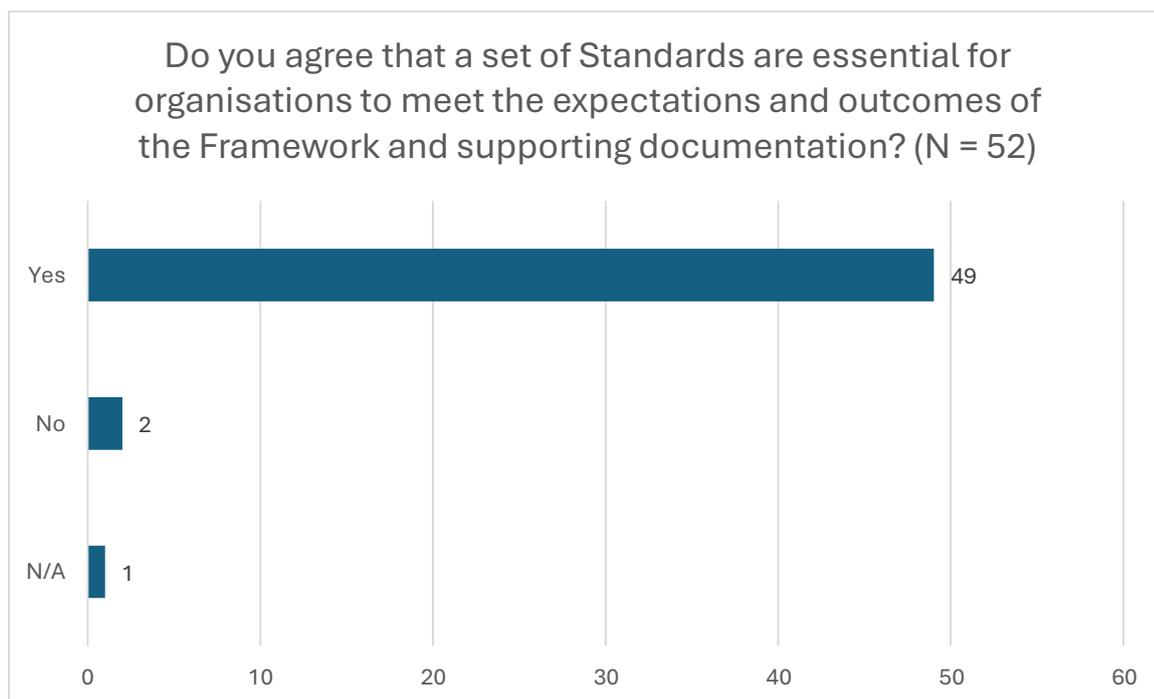


Table 4 – Breakdown of consultation responses received to question 12.

Q12	Total	Percent
Yes	49	94%
No	2	4%
N/A	1	2%

Respondents expressed strong support and agreement for the development of regional standards, highlighting several key reasons:

Consistency, Transparency and Accountability

- Standards ensure a regionally consistent and transparent approach to managing Patient Safety Incidents.
- They support accountability by providing a clear framework for monitoring, reviewing, and benchmarking performance.
- Standards can reduce variation and promote fairness, helping organisations meet their legal and moral obligations for safe care.

Clarity, Guidance, and Effective Implementation

- Clear standards offer practical guidance for staff, helping them understand expectations and carry out processes with quality and confidence.
- They enable effective implementation of the new approach, reducing the risk of uneven or subjective practices across the HSC system.
- Standards also facilitate benchmarking against a baseline, helping identify areas for improvement and ensuring compliance with best practices.

Support for Psychological Safety and Compassionate Engagement

- Respondents welcomed the emphasis on psychological safety for staff, patients, and families.
- The standard on engagement and support was praised for placing affected individuals at the centre of the process.
- The requirement for a compassionate and empathetic approach to staff was supported, including the provision of a single point of contact, timely updates, access to support services, and involvement in learning and action planning.

Outcome-Focused Assurance and System-Wide Improvement

- Standards were seen as a foundation for developing an outcome-based assurance framework, focusing on the quality and impact of Patient Safety Incident Learning Reviews rather than just process driven data collection.
- Respondents noted that without a common framework, assessing performance and driving improvement across the health and care system is extremely difficult.
- The standards offer a practical way to align regional and national efforts in patient safety improvement.

Standards offer clarity and guidance for staff involved and ensure the quality of the process.

Ulster University

We consider that 'The Regional Standards' offer an opportunity to develop an outcome-based regional assurance and oversight framework, which is focused on the quality and impact of patient safety reviews as opposed to a process-and data-driven assurance model.

The Patient and Client Council

Respondents also highlighted that the standards must be concise, measurable, robust and outcome-driven and aligned with the principles and outcomes of the Framework. They should promote equity, consistency, and compassion, be trauma-informed, adaptable across settings, and include transparent accountability. Standards should also be grounded in lived experience—especially of carers, affected families and staff—and should go beyond procedural checklists. One respondent suggested that rather than aligning with each theme, standards should focus on areas like policy, competence, training, and oversight, and be mapped to principles without adding bureaucratic burden.

Summary of issues raised:

Oversight and Accountability

Respondents emphasised that the effectiveness of the Standards will depend on them being upheld in practice, with clear consequences for organisations who fail to do so. Some respondents suggested that the Standards should be mandatory, and the entire review process underpinned by legislation, or at a minimum Departmental direction. The requirement to reference Duty of Candour in the proposals was also raised, with one respondent feeling that criminal sanctions are required when Duty of Candour is breached.

Effective monitoring and oversight—both regionally and within organisational governance—were seen as essential, including robust data interrogation by executive teams and feedback from families and staff. Flexibility in the Standards was also raised, ensuring they support learning and engagement rather than acting as rigid benchmarks.

Consistency

Respondents emphasised that standards must be applied consistently across the region to ensure fairness for All those Affected by Patient Safety Incidents, regardless of the organisation involved. Concerns were raised about the use of “proportionate response,” which lacks a clear definition and risks enabling organisations to selectively review incidents without accountability or a mechanism for those affected to challenge decisions. This flexibility could lead to regional discrepancies and unfair variation, particularly in interface incidents, and greater emphasis should be placed on regional consistency rather than proportionality.

Identification and Decision Making

Respondents highlighted the need for the Standards to clearly define how Patient Safety Incidents are identified, noting that effective use of data could help prevent incidents. One respondent stressed that any safety concern raised—regardless of who raises it—

should be treated equally, and if unresolved, must trigger a Patient Safety Incident Learning Review. They emphasised that the wishes of All those Affected should be considered when determining the type and level of independence of the review, with consistent review types applied across the region. It was also recommended that all Patient Safety Incidents undergo an initial investigation using a standardised regional methodology conducted by trained investigators, after which the appropriate review type can be determined to support meaningful learning and improvement.

Language and Terminology

Responses highlighted inconsistencies across the proposal documents, particularly in the stated purpose of the Patient Safety Incident Learning Review and the interchangeable use of terms such as principles, themes, and standards, which caused confusion. Respondents stressed that the use of “should” renders the standards unenforceable and called for consistent use of “must” to ensure clarity and accountability. Concerns were raised about the term “minimum standards,” as it may encourage organisations to meet only the lowest threshold, potentially missing opportunities for deeper learning and improvement. To truly enhance patient safety, a culture of continuous improvement beyond minimum requirements is essential. The standards must be clear, consistent, unambiguous, and achievable, using language understood across the HSC system. A schedule of definitions was recommended to support implementation, and respondents emphasised the public’s desire for honesty, simplicity, and transparency to ensure genuine learning and service improvement.

Evidence

Consultation responses noted some concerns that some of the examples of evidence provided in the learning standard are passive and ineffective under the current system. Respondents emphasised that the standard should focus not only on sharing but also on implementing and verifying learning, including assessing staff understanding. The

volume of evidence required was seen as burdensome without additional resources, and suggestions were made to simplify and standardise it.

Information sharing

Consultation responses raised concerns about the wording used around information sharing, emphasising that All those Affected by a Patient Safety Incident should be proactively provided with all relevant information to which they are entitled, with legal services ensuring full transparency. While the standards make provision for affected individuals to access relevant information, there is no equivalent assurance for staff, which was noted as a gap. One respondent also questioned the inclusion of anonymised appraisals in evidence presented to Trust Boards, warning that this could compromise the openness of the appraisal process and risk identification. A suggested alternative was for practitioners to submit standalone reflections, preserving the integrity of appraisals. Additionally, it was noted that standards must account for factors outside an organisation's control—such as delays in Coroner's reports—which may impact timelines and review processes.

Implementation

Respondents called for frontline involvement in developing the Standards and stressed that operational challenges—such as coordination with other state agencies—must be considered. Concerns were raised about the resource demands of the standards and their potential to distract from cultural change. Standards must support the overall vision, avoid tokenism, and include mechanisms to make them achievable. Pharmacy professionals noted existing robust regulatory processes and suggested that the standards should complement, not duplicate, these. Greater clarity was called for to operationalise the Standards, with emphasis on governance structures, realistic expectations, and feedback mechanisms involving All those Affected, including staff. Specific reference to managing incidents at care transitions and in primary care was also recommended.

Principles

Consultation Question 13 - 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?

A majority of 49 of the 52⁷ respondents (94%) who completed the consultation questionnaire supported the Principles for Engaging, Involving and Supporting All those Affected by a Patient Safety Incident. Figure 10 and Table 5 below show a breakdown of responses to this question.

Figure 10 – Breakdown of consultation responses to question 13.

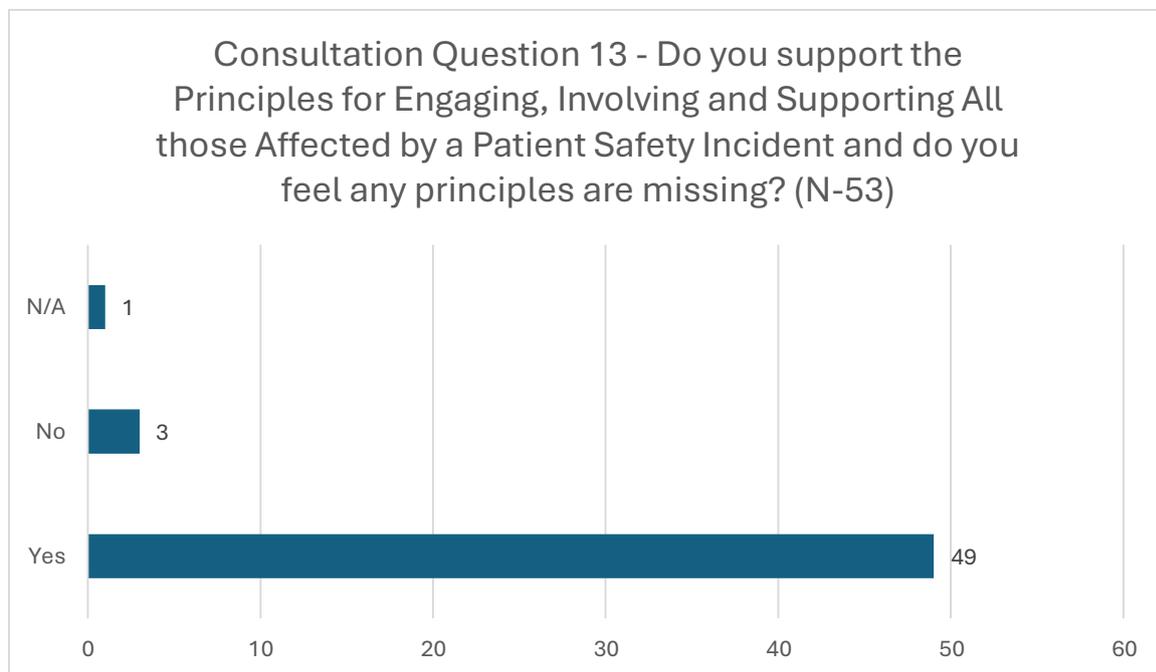


Table 5 – Breakdown of consultation responses received to question 13.

Q13	Total	Percent
Yes	49	94%
No	3	6%
N/A	1	2%

⁷ One respondent answered both yes and no to this question, making the total number of responses 53 from 52 respondents. Percentages have been calculated from the overall 52 respondents.

The Principles for Engagement, Involvement and Support of All those Affected were widely welcomed and supported. Respondents particularly valued the Principles' emphasis on:

- Learning from families' experiences to improve processes.
- Placing All those Affected and Staff Affected at the heart of the process.
- The importance of a single point of contact role.
- Completing reviews within a culture of openness, learning and fairness,
- Providing the right support at the right time.
- The values of transparency, inclusion and timely communication.
- A flexible, collaborative approach that adapts to the changing needs of those affected.
- The insights from All those Affected and Staff Affected being welcomed as essential to improve care and prevent future harm.

COPNI also welcomes the aim of the Principles '*to ensure that everyone involved regardless of their background or medical knowledge, can understand and actively participate in the process*'. Each perspective, whether that be from the patient, their family or staff, offers valuable insight into the incident, helping to improve care practices, prevent future harm, as well as enhance the overall health and wellbeing of older patients.

Commissioner for Older People Northern Ireland (COPNI)

While the principles were broadly supported and seen to align with the Framework's values, there was concern that they closely resemble the current procedure which has previously not been appropriately followed or enforced. Key challenges raised included ensuring operational clarity, translating principles into practice, and maintaining timely reviews while meeting the diverse needs of All those Affected. Practical mechanisms, clear guidelines, and adequate resourcing were seen as essential for effective implementation. It was noted that engaging with all affected individuals, especially in complex settings such as prisons, may be impractical and could detract from the core

aim of preventing repeat harm. Monitoring and evaluating the effectiveness of this approach over time was also recommended.

Patient Safety Learning supports these principles. We believe that the main challenge in this area will be translating these into practice. From the experience of implementation of the Patient Safety Incident Response Framework (PSRIF) in England, we have seen evidence of the challenges to this in practice.

Patient Safety Learning

Responses indicated strong support for meaningful, consistent, trauma-informed and timely engagement from the outset, with transparency, dignity, and respect at its core.

Summary of issues raised:

Engagement and Involvement

Emotional safety and trauma awareness were seen as essential, with calls for consistent support, early involvement, and recognition of grief and vulnerability. Respondents also highlighted the need for helping ensure clarity about the nature and intended outcomes of the review process from the outset with those affected, with greater awareness of the process required across the HSC system.

Respondents felt that families should have the right to contribute to and verify the accuracy of final reports, as omissions or inaccuracies can deepen distress and undermine learning. They believed family accounts should be given equal weight to those of clinicians, and that the process should continue beyond the final report, with families kept informed about whether meaningful change has occurred.

One respondent suggested embedding a statutory right to engagement and support to prevent exclusion due to narrow legal definitions or inconsistent practices. It was also suggested that a clear, jargon-free information leaflet should be co-produced with service users to explain the Framework's purpose and outcomes.

Concerns were raised about the needs of specific groups, including young people in social care, mental health patients, and older people, with calls for tailored engagement approaches.

There were concerns that the full involvement of All those Affected “in line with their wishes” may not always be appropriate or best practice at every level of the review.

Support

Respondents emphasised the importance of signposting All those Affected by Patient Safety Incidents to accessible and effective support services. Some noted that that advocacy support should be prioritised from the outset, with advocates actively involved in the review process. There was a call for regionally consistent support pathways offering varying levels of expertise and intensity, particularly for vulnerable groups such as older people and those with mental health needs. Respondents raised an inclusive approach with accessible communication formats is essential. Crucially, the long-term impact of both the incident and the review process must be recognised and addressed to reduce lasting harm.

Terminology

Respondents raised concerns around the terminology and clarity of definitions – particularly the definition of a ‘victim’. It was suggested that terminology should be simplified and greater clarity and consistency provided in the use of terms such as ‘should’ and ‘must’ to avoid ambiguity. It was also suggested that the term “All those Affected” should include staff to prevent confusion and a single, unified set of principles applicable to both staff and patients should be used for clarity and coherence.

Timeliness

Respondents expressed concern that achieving timeliness in the review process may be challenging, particularly when external state agencies are involved. In high-pressure environments, staff may struggle to find time to engage meaningfully with patients and families. Many noted that clear timelines—and crucially, adherence to them—are essential. While families understand that delays can occur, respondents felt delays must be communicated transparently to avoid anxiety and suspicion. Realistic timelines, regular updates, and clear accountability were seen as key to maintaining trust and ensuring effective engagement.

Training and Resource

Respondents highlighted the importance of ensuring that staff assigned to the single point of contact role receive appropriate and specialised training. This includes advanced communication skills, trauma-informed approaches, and access to supervision and support to manage the emotional demands of working in complex and distressing situations. While the principles reference staff training, concerns were raised about how staff will be given the time to participate in reviews and engage meaningfully.

Information Sharing

Respondents shared the view that transparency and timely access to information are vital for All those Affected. Some expressed concern that use of the term ‘there is an expectation that...’ could be used to limit disclosure and felt a clear commitment to proactive truth-telling is needed. It was suggested that relevant information should be volunteered proactively, not only upon request, and greater clarity was sought on whether information will proactively be provided or if data requests will be required. It was suggested that legal services should prioritise supporting truth-telling rather than protecting reputations.

Some noted that patients and families should be given the opportunity to have incidents properly recorded and to receive evidence of this. Greater emphasis was called for on listening to and documenting family input before incidents occur, especially for vulnerable patients, with records shared at the time.

Culture

Respondents agreed with the inclusion of health inequalities but felt the approach could go further by identifying and addressing the root causes of these inequalities as part of the learning process. There was scepticism about the assumption that cultural change can be directed by the DoH, with the view that meaningful change requires time, consistent leadership, and role modelling. While there was support for a culture that encourages staff to raise concerns, respondents cited evidence of staff being ignored, coerced, or even victimised for doing so, with few senior managers acting on those concerns. There was also concern about the potential for staff to be ignored, scapegoated or not prioritised in processes involving All those Affected, which could undermine trust and transparency.

Principles

Consultation Question 14 - 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?

A majority of 43 of the 52 respondents (83%) who completed the consultation questionnaire supported the Principles for Engaging, Involving and Supporting Staff Affected by a Patient Safety Incident. Figure 11 and Table 6 below show a breakdown of responses to this question.

Figure 11 – Breakdown of consultation responses to question 14.

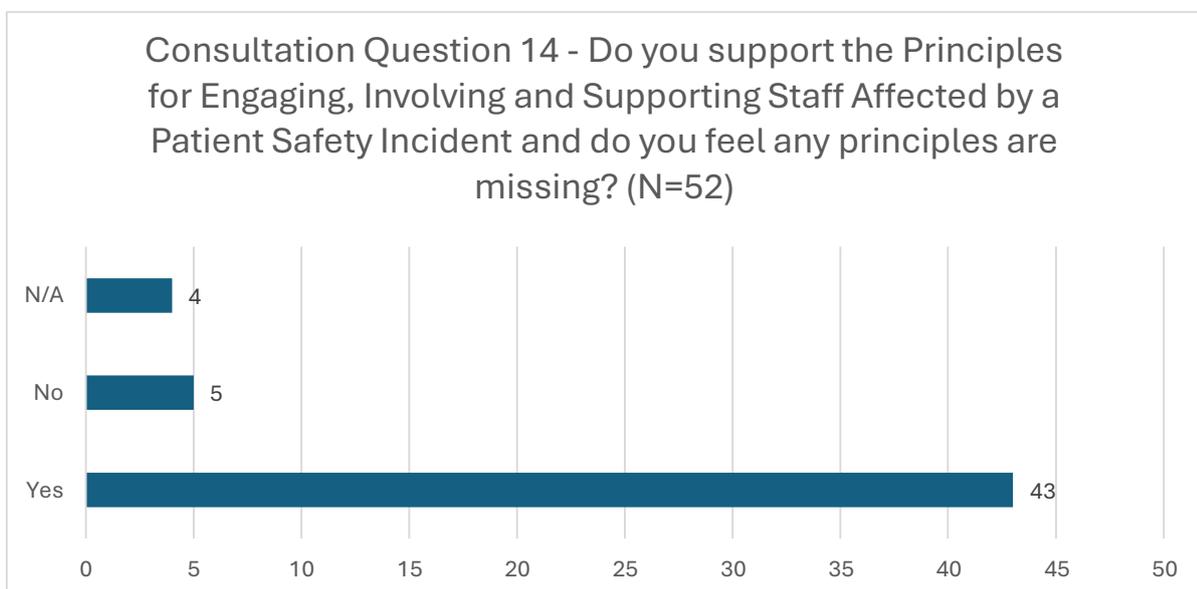


Table 6 – Breakdown of consultation responses received to question 14.

Q14	Total	Percent
Yes	43	83%
No	5	10%
N/A	4	7%

The Principles for Engaging, Involving and Supporting Staff Affected by a Patient Safety Incident were strongly supported because they promote an open and just culture and encourage transparency, fairness, and the consistent reporting of Patient Safety Incidents. Respondents valued the emphasis on creating psychologically safe environments where staff and patients feel supported in raising concerns, and where

incidents are addressed with empathy, respect, and a commitment to learning and improvement. The framework is seen as a positive step toward fostering openness rather than blame, with strong endorsement for its focus on trust, collective leadership, and the emotional wellbeing of staff. Senior leaders are expected to actively role model the behaviours that underpin this culture, reinforcing its credibility. The inclusion of respectful processes—such as sharing draft reports with affected staff and offering opportunities for dialogue—was also welcomed. Overall, the principles were viewed as compassionate and reflective, laying the groundwork for meaningful cultural change across the HSC sector.

Essential to involve staff affected by a patient safety incident, this helps to create a culture of learning and improvement, creates a safer environment for patients and staff and helps to move away from a name, blame and shame culture.

Northern Ireland Practice and Education Council for Nursing and Midwifery

The whole workplace ethos and understanding of PSI's will need to change – staff are not likely to report themselves or others if they think there is a culture of blame or fear of dismissal.

Individual

Although the principles were widely supported respondents felt separating All those Affected and Staff Affected could be confusing and that Staff Affected should be included as a sub-group of the All those Affected Principles.

Summary of issues raised:

Education and Training

Respondents highlighted the importance of robust and regionally standardised training to support staff involved in Patient Safety Incidents, with a clear preference for development of a structured programme led regionally by the DoH. Respondents

emphasised the need for enhanced leadership training and specialised development for the single point of contact role. Embedding trauma-informed practices throughout the process was seen as essential for effective engagement and learning, with reference to frameworks such as the SBNI Trauma Informed Toolkit. Education and training were viewed as critical to ensuring consistency, clarity, and confidence in applying the Framework, and fostering a culture of openness, accountability, and learning. Additionally, it was felt that those conducting reviews must be adequately trained and resourced, with ongoing professional development. It was requested that the Framework consider and address system-based learning including human factor elements, staffing levels, and resource constraints that contribute to patient safety.

Support

Respondents emphasised the need for stronger, more structured support for staff affected by Patient Safety Incidents, particularly those who had a longstanding relationship with the affected patient. There was a clear call for psychological support to be prioritised, with services such as counselling, consideration of time off, and trauma-informed care embedded throughout the process. While many welcomed the three-tiered support model, concerns were raised about its consistency, capacity, and clarity—especially regarding regional implementation and training. A small number felt the consultation was overly focused on staff, questioning the DoH’s role in supporting HSC Trust employees and highlighting the need to balance staff support with attention to victims of poor care.

There was broad agreement that staff must be treated fairly, respectfully, and without bias, with access to trade union representation and legal protection. Suggestions included embedding peer support structures, promoting restorative approaches, and ensuring staff in Northern Ireland have access to equivalent services available in other UK nations. Overall, respondents stressed that meaningful culture change requires visible, well-resourced support systems that recognise the emotional toll of Patient Safety Incidents and foster psychological safety for all involved.

Open and Just Culture

Respondents strongly emphasised the importance of fostering a culture of openness, honesty, and psychological safety, where staff feel confident to speak up about patient safety concerns without fear of career repercussions. While many welcomed the move toward a more open culture, there were concerns that the current environment—marked by workload pressures, lack of feedback, and fear of individual blame—remains a barrier to meaningful change. Several responses advocated for restorative approaches, including opportunities for staff to meet with affected families in a respectful, truth-focused setting, which could benefit both parties. There was also a call for clearer guidance on staff involvement in the review process including ethical considerations and support during media scrutiny. The need for updated terminology—such as replacing “Just Culture” with “Restorative Just Culture”—was highlighted, along with the need for clarity on what an open, just and learning approach is and that it does not mean an absence of accountability for reckless behaviour. Crucially, openness must be modelled at a leadership level, with senior leaders demonstrating transparency, fairness, and a commitment to learning from incidents. Leadership behaviours set the tone for organisational culture, and visible, honest engagement from those at the top is essential to build trust and encourage staff to speak up. One respondent questioned the balance of the Framework, suggesting it prioritises staff interests over those of patients and families. Some respondents felt the Framework should make provisions for the future implementation of Duty of Candour and consider the potential impact of a criminal Duty of Candour on openness.

Overall, the responses reflected support for a more transparent, learning-focused system that supports both staff and patients, while ensuring fairness, accountability, and genuine cultural transformation.

Implementation

Although the Principles were welcomed, respondents expressed a need for greater clarity and practical detail to allow for effective implementation, with accessible guidance and tangible processes that staff can easily understand and apply. Concerns

were raised about how success would be measured, what metrics would be used, and whether the Framework risked being perceived as a symbolic gesture rather than a meaningful tool for change.

Suggestions included developing a concise, user-friendly information leaflet to communicate the Framework's purpose and standards and appointing designated patient safety experts within each Trust to guide staff.

The importance of regional consistency in support services—particularly Occupational Health and Staff Wellbeing—was highlighted, with calls for adequate resourcing to ensure equitable access. Overall, the feedback underscored the need for a structured, well-resourced, and operationally clear approach to implementation to ensure the Framework delivers meaningful impact across the system.

Learning

Respondents stressed the importance of ensuring that learning from Patient Safety Incidents is not only captured but actively shared and embedded in practice. While there was support for a system-focused approach to learning, concerns were raised about the lack of detail on how learning would be disseminated and how staff would be meaningfully involved in that process to support effective sharing and embedding of learning. The need for protected time and space for post-event reflection was highlighted as essential for genuine engagement. Respondents welcomed the recognition that learning cannot always be immediate, and that staff need time to process events. They also called for clearer mechanisms to ensure feedback of a concern actually reaches staff after it has been raised, to avoid missed opportunities for improvement. Additional recommendations included the importance of promoting cross-disciplinary collaboration and improved communication and ensuring that learning is not reduced to an administrative exercise but becomes a driver of quality and safety.

ADDITIONAL COMMENTS, CONSIDERATIONS AND SUGGESTIONS

Consultation Question 15 - Is there anything else you would like to add to your consultation response?

Of the 52 respondents who completed the consultation questionnaire, 33 (63%) provided additional narrative to supplement their responses. This feedback, along with any further general comments not captured under the structured questions, has been summarised below to reflect the issues raised.

Implementation and Resource

Respondents strongly support the proposed Framework's principles. Many noted that successful implementation hinges on substantial additional resources, clear operational guidance, and committed leadership. Concerns were raised about how the Framework will be operationalised across diverse professional settings, particularly in areas like dentistry and primary care. Some concerns were noted about limited references in the Framework's to social services and potential that this may be viewed as a bias toward medical and clinical settings, possibly creating doubt about its applicability to the social care context. Feedback suggested that the proposals appeared to focus on large organisations with supporting infrastructure, leaving some uncertainty around how smaller, independent primary care providers—such as GPs and community pharmacies—can implement the proposals within existing structures. Additionally, the role of the HSC Leadership Centre and private companies commissioned to conduct reviews was questioned, with some respondents suggesting that outsourcing reviews is an inefficient use of public funds.

Strong governance, senior leadership and executive-level oversight, and transparent reporting by HSC Trusts were deemed essential. Other suggestions included the development of a centralised dashboard to monitor themes, actions and improvements, annual public reporting on the implementation and impact of the Framework, multi-agency oversight mechanisms and involving front line patient safety specialists and investigators. The need for staff training, protected time, and support infrastructure was repeatedly highlighted, with calls for a detailed implementation plan covering workforce capacity, and data and learning systems. Respondents also

stressed the importance of embedding psychological safety, using recognised improvement methodologies, and applying implementation science. A pilot phase, ongoing evaluation, and stakeholder engagement—including with those with lived experience—were recommended to ensure the Framework evolves effectively and delivers measurable improvements in patient safety.

Operationalisation and Supporting Guidance

Respondents identified as a gap the need for detail to be provided on how the Framework will be applied in practice. It was felt that the absence from the consultation exercise of key supporting documents—such as the methodology and toolkit, Oversight guidance and templates—limited the ability to assess how the Framework’s principles will be operationalised. There was a call for these materials to be consulted upon and tested with the HSC system and for further guidance to be provided on review types, decision-making processes, multi-agency collaboration, and information sharing, including reference to existing, linked protocols like Memorandums of Understanding. Respondents stressed the need to translate high-level principles into tangible tools and processes, particularly for smaller organisations, and to provide clear governance arrangements and concise templates.

Language, Terminology and Complexity of Proposals

Respondents highlighted the importance of consistent and inclusive language across all documentation. A single, unified glossary annexed to all materials was recommended to ensure clarity and coherence. Concerns were raised about the use of term ‘patient’ which may unintentionally exclude certain service users. Some noted the use of the term ‘victim’ as problematic, with concerns that this would challenge the principles of an open, just culture where reviews should be focused on systems and human factors rather than blame. Others noted that the definition of a ‘victim’ was confusing with calls for a revised, inclusive definition co-produced with individuals who have lived experience.

Respondents stressed that terminology should support a just culture and avoid legalistic or accusatory language that could undermine learning and openness. Suggestions included replacing “incident” with “Patient Safety Event” and avoiding separation between “All those Affected” and “Staff Affected.” Additionally, the proposals were described as unnecessarily complex, with respondents questioning the repeated claim that the Framework offers a more streamlined process—citing a lack of supporting evidence and noting that it appears at least as complex as the current system. Some noted that an aspirational tone and lack of detail were seen as barriers to understanding, and a clearer structure—such as a step-by-step flowchart—was recommended to help staff navigate the process. Overall, clarity of language and purpose was viewed as essential to fostering understanding, compliance, and inclusivity.

Culture Change and Openness

Respondents strongly emphasised that the proposed Framework will not deliver meaningful change without a fundamental shift in organisational culture—towards honesty, openness, and candour. There was widespread support for moving away from a blame-focused culture to one that prioritises learning, psychological safety, and systems thinking. This cultural transformation must be led and resourced as a strategic change initiative, with clear roadmaps, staff education, and involvement. The Framework’s recognition of just culture and proactive learning was welcomed with the feeling that this approach aligns with international best practice and is key to preventing harm before it occurs. Respondents highlighted the importance of embedding openness through regular training, sharing real-life examples, and celebrating good practice. They also called for spaces that facilitate compassionate dialogue between staff and patients and stressed the need for transparency in how culture change is implemented and evaluated. The inclusion of the Being Open Framework and Duty of Candour was recommended to reinforce these principles. Ultimately, fostering a culture where staff can speak openly about mistakes without fear is seen as essential to improving safety, trust, and care outcomes.

Communication and Support

Respondents welcomed the Framework’s commitment to involving individuals affected by Patient Safety Incidents, but stressed that this must be meaningful, empathetic, and inclusive. They called for trauma-informed communication practices, accessible engagement, and standardised guidance for staff. Specific professional support for affected staff—including confidential mental health services—was recommended, alongside advocacy and independent liaison roles for service users. One respondent identified the PCC as a key body to support service users, monitor experiences, and contribute to co-designed improvements, and suggested the RQIA should assess the consistency of learning implementation. Respondents emphasised that support for staff and service users should be equitable, and that engagement must consider grief, readiness to be involved in a learning review, and emotional impact. Timely access to information, regular updates, and emotional support were seen as essential. However, some cautioned that excessive support could compromise the rigour of investigations/reviews. Some noted concern about current defensive behaviours from staff and a lack of detail on how engagement will be improved. Early, transparent communication and therapeutic support were viewed as critical to building trust and driving meaningful change.

Methodology

Mandated Comprehensive Review List

Respondents raised concerns about the clarity, appropriateness, and operational implications of several of the incidents mandated by the comprehensive review list. The concept of “Never Events” was criticised as unhelpful to improving patient safety, and there were calls to expand the scope of the list of mandated reviews to include deaths in prison as well as those in police custody involving nurse-led healthcare.

For suspected mental health-related homicides, some respondents noted a need for consideration of language specific to Northern Ireland. These respondents also noted that a clear definition of “specialist mental health services” is needed to ensure

consistency across HSC Trusts and clarification is required as to whether patients with a mental health referral who have not yet been seen by services are included.

Regarding suspected suicides, some respondents highlighted the need for contextual clarity including for example the definition of an HSC facility, and the timeframe for reviews during planned or unplanned leave.

The category of unexpected or unexplained deaths was seen as highly subjective, with concerns about who determines the need for further review and the potential for ambiguity to undermine consistency.

Mental Health

Some respondents expressed concern about the scrutiny and handling of mental health-related incidents, noting that this area of healthcare presents unique risks, including the potential for serious harm to members of the public. Some noted a need for greater attention to be given to incidents involving mental health patients and called for 'consideration of a differentiated approach to learning from mental health-related incidents to ensure both patient and public safety. The distinction between acute mental health patients and those post-discharge was highlighted as important, especially in the context of suicide-related reviews. Respondents urged that mental health incidents be treated as a special category within the Framework.

Interface Incidents

Respondents emphasised the need for the Framework to explicitly include third sector and community providers, ensuring they have access to relevant training and guidance. A clear protocol for multi-agency incident reviews was identified as a gap, with calls for mechanisms that support joint reviews, shared learning, and coordinated action planning across organisations. Clarity was also requested on how HSC organisations will interact with other bodies such as RQIA, DoH, DoJ, and primary care in the context of certain incidents.

Dispute or Escalation Mechanism

Some noted a concern over a lack of clear criteria within the Framework for a dispute or escalation mechanism, warning that this could leave HSC Trusts vulnerable to challenge and undermine public confidence, with the fear that the new process may lead to an increase in complaints from those affected who feel a comprehensive review was warranted but not undertaken. Others noted an absence of safeguards against HSC Trusts potentially refusing to conduct SAI Reviews in order to protect staff or reputational interests, and an inequity in the ability of individuals to engage with and challenge Patient Safety Incidents. There were calls for simple, consistent public messaging led by the DoH to explain the changes.

An Appropriate Level of Independence

Some respondents felt that every incident should involve independent participants to ensure objectivity and prioritisation of those harmed. Concerns were raised about the potential for HSC Trusts to act in self-interest, underscoring the need for either fully independent investigations or external oversight to hold organisations accountable. Greater clarity was requested on the criteria for independence and the structure of the regional pool of trained facilitators. Respondents also highlighted the need for internal funding to ensure timely completion of reviews, noting that competing demands on clinical staff can hinder timeliness and effectiveness. While active clinical involvement is valued, the Framework must balance this with service pressures across many service areas.

Training

Respondents emphasised the need for a robust, regionally coordinated training programme to support the effective implementation and oversight of the Framework. This should include clear guidance on delivery, funding, and sourcing expertise in safety science and human factors. Training on systems-based methodologies, such as SEIPS, and trauma-informed practice was strongly recommended to ensure reviews are

conducted sensitively and effectively. Respondents highlighted the importance of tailoring support to different staff groups, including student nurses and doctors in training, and ensuring that training avoids re-traumatisation. It was commented that time for reflective practice, psychological support, and restorative approaches should be built into team operations to foster a psychologically safe environment. Respondents stressed that quality improvement depends not only on technical training but also on having well-supported, rested staff working in respectful and safe environments.

Data and Learning Systems

Respondents called for greater clarity on how data will be shared, trends identified, and learning applied to prevent recurrence of Patient Safety Incidents. Suggestions included establishing a new regional body for patient safety governance and ensuring clear agreements on data management responsibilities, including identification of data controllers. Concerns were raised about inconsistencies across HSC Trusts in incident reporting systems and processes, particularly with varied use of platforms like Datix. These differences could hinder standardisation and effective implementation of the Framework. Respondents also recommended that Patient Safety Incident Learning and Improvement Plans be published openly, with the DoH maintaining a central repository for public access. Further guidance was requested on how digital systems—such as encompass—will interface with existing infrastructure, and how system-wide learning will be achieved if learning is no longer submitted to SPPG.

Oversight and Accountability

Some responses highlight concerns about a lack of accountability and enforcement within the HSC system, noting that without sanctions, there is risk that HSC Trusts will not change current practices. Some noted a need for clearer processes to address performance or fitness-to-practice issues identified during learning reviews, separate from the review itself, using unbiased tools like the NHS England Being Fair guide.

Respondents stressed the need for independent oversight, challenging SPPG and PHA's perceived lack of impartiality, and advocated for a regulator not funded by DoH or HSCNI to provide external oversight of the Framework. Some respondents called for legislative backing criminal sanctions under a Duty of Candour, a redress scheme for serious failures, and clearer governance structures. Concerns were raised about the effectiveness of Trust Boards, the risks of false assurance in regional oversight, and the need to clarify the role of the Designated Review Officer. The system is seen as overly layered and slow to respond to emerging issues.

Co-production and Engagement in the Redesign Programme

A small number of respondents expressed concern that the Framework was developed around existing HSC structures rather than starting from the public and patient perspective, highlighting a lack of involvement from those with lived experience and genuine co-production. They called for a radical rethink, especially in mental health incident handling, to ensure consistency, equality, and independence. There was a suggestion that the Framework should be aligned with with Accessible Information Standards and there was support for co-producing communication tools with service users and disability advocates. It was felt that the implementation phase should involve carers and families in developing practical resources and not only involve professionals.

Some respondents felt that the consultation process was inaccessible, particularly for carers, due to timing and complexity. Respondents urged the DoH to expand public participation throughout policy development and implementation, with ongoing involvement from those with lived experience.

CONCLUSION AND NEXT STEPS

The Department wishes to thank all those who took the time to attend the public consultation events and to respond to the consultation process. The consultation captured detailed narrative feedback, which required careful and thorough analysis. This feedback is highly valuable, and all views shared have been comprehensively analysed in the production of this report. The points raised will be an important source of evidence and information moving forward.

The consultation sought to gather views on proposals for an overarching strategic approach to learning and improvement following Patient Safety Incidents. These proposals included a high-level overarching Framework, a set of regional standards, and supporting principles for Engaging, Involving and Supporting All those Affected by a Patient Safety Incident.

The consultation responses reflect strong and thoughtful engagement with the proposed Framework and supporting documentation. Overall, there was strong support for the strategic direction set out in the consultation, with respondents endorsing the proposals as a significant step towards fostering a culture that prioritises openness and learning to improve patient safety and the delivery and quality of care.

The Department will now take time to consider the responses in further detail and will work with partners to consider additions, amendments and refinements that are required to the strategic proposals. This will include ensuring alignment with the implementation of other ongoing policy development in this area including, for example, the Being Open Framework.

Once considered and approved by the Minister, publication of the Framework, Standards, and Principles will establish the agreed strategic governing framework for learning and improvement from Patient Safety Incidents. A managed transition and implementation phase is anticipated to begin in early 2026. The Department will keep interested parties informed about future developments relating to the new strategic approach and its implementation.