



The **Regulation** and
Quality Improvement
Authority

RQIA Review of the Systems and Processes for Learning from Serious Adverse Incidents in Northern Ireland

June 2022

The Regulation and Quality Improvement Authority

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Acknowledgements

RQIA wishes to thank all those who facilitated this review by participating in discussions, meetings, surveys and by providing relevant information.

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Glossary of Terms

Belfast Trust	Belfast Health and Social Care Trust
CAMHS	Children and Adolescent Mental Health Services
CQC	Care Quality Commission
DoH	Department of Health
DRO	Designated Review Officer
HSC	Health and Social Care
HSCB	Health and Social Care Board
IHRD	Inquiry into Hyponatraemia-related Deaths
Multidisciplinary	Involving professionals from different disciplines who have different professional skills, expertise and experience.
NIAS	Northern Ireland Ambulance Service
Northern Trust	Northern Health and Social Care Trust
PCC	Patient Client Council
PHA	Public Health Agency
PPI	Personal and Public Involvement
RCA	Root Cause Analysis
RQIA	Regulation and Quality Improvement Authority
SAI	Serious Adverse Incident
South Eastern Trust	South Eastern Health and Social Care Trust
Southern Trust	Southern Health and Social Care Trust
SPPG	Strategic Performance and Planning Group (formerly Health and Social Care Board)
Western Trust	Western Health and Social Care Trust

Foreword

This Review of the Systems and Processes for Learning from Serious Adverse Incidents in Northern Ireland resulted from the independent Public Inquiry led by Justice O'Hara which investigated the deaths of five children in hospitals in Northern Ireland. After hearing evidence from a wide range of individuals and organisations, it concluded that deaths had been avoidable and that the culture of the health service at the time, arrangements in place to ensure the quality of services and behaviour of individuals had contributed to those unnecessary deaths.

A key finding of the Public Inquiry was that the internal investigations into the deaths and their surrounding circumstances were inadequate. They had failed to identify the underlying causes. It also found that, as guidance on fluid management on children became available, it was not disseminated and actioned effectively across the Health and Social Care (HSC) system.

The reality is that similar situations, where events leading to harm have been inadequately investigated and examples of recognised good practice have not been followed, have been, and are likely to be repeated in current practice.

Such inadequacies bring distress and suffering to the individuals affected and their loved ones; and the staff whose efforts to provide good and safe care are undermined.

Serious Adverse Incident (SAI) reviews are a fundamental part of how the whole system should learn from harm, and make improvements to Health and Social Care services in Northern Ireland.

This Review, commissioned by the Department of Health (DoH), in its response to the recommendations of the Inquiry, and undertaken by the RQIA, has assessed the effectiveness of the current SAI process.



Christine Collins MBE
Chair

It has been one of our most significant Reviews, which has benefited from engagement with a wide range of individuals, organisations and groups across the Health and Social Care system.

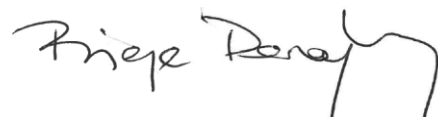
We would especially like to thank all families who contributed to the Review, as their experience of the reality from a patient and family perspective has been a key feature in shaping the Review's findings.

The Expert Review Team found that neither the SAI review process nor its implementation is sufficiently robust to consistently enable an understanding of what factors, both systems and people, have led to a patient or service user coming to harm.

HSC leaders and managers must work to make sure that if something goes wrong, all staff are confident to speak up, through a competent and independent review process, knowing that doing so will help them keep their patients and service users safe and improve the quality of care they are able to deliver.

Patients and service users, and their loved ones and advocates, must be able to take part freely and fully in the process, so they find out what happened and can help make sure it won't happen again.

On behalf of RQIA, we hope that the recommendations in this Review, which have been produced with the assistance of a wide range of patients, service users, families, clinicians and managers from across HSC, will be accepted, implemented fully, and drive improvement in safety and quality throughout the system.



Briege Donaghy
Chief Executive

Executive Summary

Background and Context

Serious Adverse Incident (SAI) reviews are a fundamental component of how we learn from harm and subsequently make improvements to the systems for the delivery of safe patient care. Regional guidance for the reporting and follow-up of SAIs in Northern Ireland has been in place since 2004. However, over the last decade, the SAI process and its implementation has come under scrutiny both regionally and nationally. Concerns have been raised around the current procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAIs) in Northern Ireland (November 2016)¹ (here-after the SAI procedure). It has also been highlighted that there is a clear need for improvement in terms of how patients, their families and staff are engaged in reviews and how subsequent learning is derived and implemented. These issues are not unique to Northern Ireland or indeed the United Kingdom. Ensuring the effective implementation of SAI reviews and subsequent learning is a considerable undertaking. Not only does the procedure itself need to be robust, but its effective application necessitates an open and supportive learning culture with SAI reviewers who are trained in the necessary skill set to undertake effective SAI reviews.

In April 2018, the Regulation and Quality Improvement Authority (RQIA) was commissioned by the Department of Health (DoH) to examine the application and effectiveness of the SAI procedure. Terms of Reference for this review were approved by the Department of Health in October 2019 and fieldwork on this review concluded in January 2021. The time taken to complete and publish this review has been significantly impacted by the system response to Covid-19 Pandemic.

Terms of Reference

The terms of reference for this review, as agreed with the DoH, were as follows:

- 1) To review the systems/ processes in place for reporting and follow-up of Serious Adverse Incidents (SAIs) across the six Health and Social Care (HSC) Trusts, the HSCB and Public Health Agency in Northern Ireland, between 30 November 2016 and 31 March 2018.
- 2) To engage with families affected by SAIs reported between 30 November 2016 and 31 March 2018, to determine their level of involvement in the Serious Adverse Incident process.
- 3) To assess the process for the classification of the severity of SAIs and to determine whether incidents are appropriately classified through this process.
- 4) To assess the level of independence of the SAI reviews progressed and assess whether a multi-disciplinary systems-wide approach to reviews has been undertaken.
- 5) To assess the development and effectiveness of action plans and recommendations arising from SAIs reviews.

- 6) To assess whether appropriate learning has been identified from the SAIs and disseminated regionally, and whether the learning can deliver measurable and sustainable improvements in the quality and safety of care.
- 7) To determine current understanding of the role of respective organisations, including the Coroner, in the process for SAI reviews, and how this understanding compares to the published roles and responsibilities as outlined in the procedure for the Reporting and Follow up of Serious Adverse Incidents.
- 8) To assess the level of professional support provided to (i) staff who were delivering care at the time of the SAIs, as well as (ii) staff conducting the review of the SAIs.
- 9) To provide a report of the findings to the Department of Health, making recommendations for improvement as relevant to the overall response to SAIs, their assessment and review, and the learning arising through these processes.

Methodology

The Expert Review Team developed a methodology specific to this review incorporating extensive engagement with a range of key individuals and organisations and patients their relatives and representative groups. Focus Groups and individual interviews were undertaken. The engagement was supported by the development of a number of semi-structured questionnaires. An important aspect of this review was the undertaking of a rigorous assessment of 66 serious adverse incident reports from all HSC Trusts in Northern Ireland.

Findings

The Expert Review Team determined that the current SAI procedure and its implementation in Northern Ireland **does not** support:

- Fulfilment of the statutory duty of Personal Public Involvement as set out in the Health and Social Care (Reform) Act (Northern Ireland) 2009.
- Reasonable application of the principles of effective SAI review practice.
- Confidence in the independence of chairs of SAI reviews at Level 2, or Level 3. Particularly in the case of Level 3 reviews, where the appointed chair is a former employee of an HSC Trust.
- Accountability of Health and Social Care organisations for:
 - decisions made regarding the level of review conducted
 - involvement and engagement with a patient and/or relatives
 - the quality of the review conducted and the acceptance of its findings and approval processes
 - evidencing that HSC Trust services have improved and are safer because of the reviews conducted
 - ensuring that issues requiring regional action to improve safety are appropriately identified and then escalated to the right people in the right organisations

- The formulation of evidence-based recommendations.
- The design of action plans that will enhance the safety and quality of healthcare provision across the region both in the short and longer term.
- The production of SAI review reports that are well-formulated, evidence-based and readable.

The Expert Review Team identified a number of reasons for this:

- The implementation of the SAI procedure focuses too heavily on process and non-attainable timescales instead of focusing on consistently conducting these reviews to a high standard.
- There was an absence of clear regional guidance on how to execute Personal Public Involvement duties and in relation to patient rights as part of an SAI review.
- There was no regional patient safety training strategy and curriculum.
- There were not clearly defined competencies required of lead investigating officers and SAI review panel chairs.
- There were not sufficient numbers of trained independent advocates for families and patients.
- There was a lack of effective training in how to execute an effective and meaningful SAI review.
- Furthermore, even where training had been delivered, the appointed chair or review leads, they did not always have sufficient authority to independently devise a review plan that fully delivers the required quality of review.
- There were also a large number of reviews identified as requiring an in-depth review but which did not require this, which was creating an unsustainable work pressure within the system.

The conclusion of the Expert Review Team is that current practice for reviewing and learning from SAIs in Northern Ireland is not achieving the intended purpose of the SAI procedure. Improving this situation will require both the SAI procedure and the system in which it operates to be re-designed.

Summary of Recommendations

The following recommendations are made to support the delivery of a new regional policy/procedure for reporting, investigating and learning from adverse events.

Number	Recommendation	Priority
1	The Department of Health should work collaboratively with patient and carer representatives, senior representatives of Trusts, the Strategic Performance and Planning Group, Public Health Agency and Regulation and Quality Improvement Authority to co-design a new regional procedure based on the concept of critical success factors. Central to this must be a focus on the involvement of patients and families in the review process.	2

2	Health and Social Care organisations should be required to evidence they are achieving these critical success factors to the Department of Health.	3
3	The Department of Health should implement an evidence-based approach for determining which adverse events require a structured, in-depth review. This should clearly outline that the level of SAI review is determined by significance of the incident and the level of potential deficit in care.	3
4	The Department of Health should ensure the new Regional procedure and its system of implementation is underpinned by 'just culture' principles and a clear evidence-based framework that delivers measurable and sustainable improvements.	3
5	The Department of Health should develop and implement a regional training curriculum and certification process for those participating in and leading SAI reviews.	3

Key Benefits

The Expert Review Team concluded that, should these recommendations be fully implemented and embraced by the Health and Social Care system in Northern Ireland, they would deliver the following key benefits:

- A clear regional framework which provides for learning from unexpected harm.
- Greater flexibility in the SAI review process, which is aligned to international best practice and allows a better opportunity for learning and safety improvement.
- A single, new report template and regional style guide that supports consistency across the region but is flexible enough to allow reviewers to add and remove sections as required.
- A lower number of in-depth Root Cause Analysis (RCA) reviews, where early case assessment shows that this level of review is not required or proportionate.
- Increased capacity within HSC to deliver structured, in-depth reviews, where early assessment indicates this is necessary.
- An appropriate amount of time to conduct a review well and involve patients and families in a way that is meaningful.
- A review process that does not cause further harm to patients, their families or staff.
- A culture of safety, openness and compassion.

1.0 Background and Context

1.1 Introduction

Health and Social Care services are used extensively across Northern Ireland daily, and most patients and their families are satisfied with their care. However, it is inevitable that some will not have a satisfactory experience while others may even experience harm. When harm occurs, there is a moral, ethical and professional duty on those involved in the delivery of care to review what happened.

When such an incident is identified, the process of reviewing an event in an effort to learn is known as an Adverse Incident (AI) review, and some will warrant a Serious Adverse Incident (SAI) review. The SAI review aims to:

- Determine if any element of the care delivery or treatment plan contributed to the harm and any underlying systemic reasons for this.
- Ensure that the necessary improvements are made to the standard of care delivered and to the underlying systems and processes that support patient safety.
- Facilitate the recovery of the patient and their family from the harming experience, so that reconciliation can occur, including continuing trust in the Health and Social Care services.

Fundamental to achieving these aims is a clear, regionally agreed approach to identifying, reporting, reviewing and learning from incidents of harm, including serious near-miss events or apparent near-miss events. Furthermore, this approach must be clearly articulated within policies and procedures.

Throughout this report, the term 'patient and family' is used to represent those that would fall under the category of patient, service user, carer, family, or family member. The Expert Review Team recognises that users of mental health and learning disability services are normally referred to as service users rather than patients.

1.2 Context

Regional guidance for the reporting and follow-up of SAIs has been in place in Northern Ireland since 2004. Over the last decade, the SAI process has come under scrutiny both regionally and nationally. Following the Public Inquiry into Mid-Staffordshire NHS Foundation Trust in 2014² the Chief Medical Officer in Northern Ireland wrote to HSC Trusts to remind them of their statutory duty in relation to the review and reporting of SAIs. This correspondence outlined a need for candour alongside meaningful engagement with patients and their families when incidents of harm have occurred.

The Donaldson Report in 2014³ highlighted concerns around the reporting of adverse incidents, ineffective processes for review, lack of expertise amongst reviewers (particularly in relation to human factors) and a failure for learning to translate into improvements in systems and patient safety. Donaldson also outlined

a need for a 'just culture' for healthcare staff participating in SAI reviews, in addition to a need for candour and openness with patients and families.

In 2018, Justice O'Hara published his long-awaited inquiry report; Hyponatraemia-related Deaths (IHRD) in Northern Ireland⁴. It called for a statutory duty of candour and made a number of recommendations in relation to reporting, investigating and sharing of learning from SAIs, including a need to increase the involvement of families in these processes. This served to further highlight a need for a review of the regional procedure for SAI reviews in Northern Ireland.

In April 2018, the RQIA was commissioned by the Department of Health (DoH) to examine the effectiveness of the current procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAIs) (November 2016) and its implementation within Health and Social Care services and make recommendations for improvement. A final Terms of Reference for this work was agreed with the DoH in October 2019 and fieldwork on this review concluded in January 2021.

The review was conducted in phases, with interim reports submitted to DoH upon completion of each phase. This document is the culmination of this work and is an overall assessment of the effectiveness of the SAI procedure and its implementation across Health and Social Care in Northern Ireland

1.3 Overview of Regional SAI Procedure

The system for reporting adverse incidents was first introduced in Northern Ireland in 2004 by the former Department of Health, Social Services and Public Safety (DHSSPS), now known as the DoH. Reporting arrangements were transferred to the Health and Social Care Board (HSCB), now the Strategic Planning Performance Group (SPPG) within the DoH, in partnership with the Public Health Agency (PHA), in 2010. Updates to this procedure were implemented in 2010, 2013 and 2016.

The current version of the regional SAI procedure which was last updated in 2016, advises that SAI reviews should be conducted at a level appropriate and proportionate to the complexity of the incident under review.

Incidents which meet the following criteria may be classified as an SAI.

- Serious injury to, or the unexpected/unexplained death of:
 - a service user, (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit)
 - a staff member in the course of their work
 - a member of the public whilst visiting a HSC facility.
- Unexpected serious risk to a service user and/or staff member and/or member of the public.
- Unexpected or significant threat to provide service and/or maintain business continuity.

- Serious self-harm or serious assault (including attempted suicide, homicide and sexual assaults) by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service.
- Serious self-harm or serious assault (including homicide and sexual assaults)
 - on other service users,
 - on staff or
 - on members of the public.
- By a service user in the community who has a mental illness or disorder (as defined within the Mental Health (NI) Order 1986) and/or known to/referred to mental health and related services (including Children and Adolescent Mental Health Services (CAMHS), psychiatry of old age or leaving and aftercare services) and/or learning disability services, in the 12 months prior to the incident.
- Suspected suicide of a service user who has a mental illness or disorder (as defined within the Mental Health (NI) Order 1986) and/or known to/referred to mental health and related services (including CAMHS, psychiatry of old age or leaving and aftercare services) and/or learning disability services, in the 12 months prior to the incident.
- Serious incidents of public interest or concern relating to:
 - any of the criteria above
 - theft, fraud, information breaches or data losses
 - a member of HSC staff or independent practitioner.

Three levels of review are described in the regional procedure. The expectation in respect of each level is summarised below:

Level 1 Review: Significant Event Audit (SEA)

For Level 1 reviews, membership of the SEA review team should include all relevant professionals, yet be appropriate and proportionate to the type of incident and professional groups involved.

The review panel undertakes an SEA of the incident to assess what happened; why it happened; what went wrong and what went well; what has changed or what needs to change; and identify any local or regional learning.

Level 2 Review: Root Cause Analysis (RCA)

For Level 2 reviews, the level of review undertaken will determine the degree of leadership, overview and strategic review required. A core review panel should be comprised of a minimum of three people of appropriate seniority and objectivity. Review panels should be multidisciplinary and have no conflict of interest with the incident concerned. The review should have a chairperson who is independent of the service area involved, while possessing relevant experience of the service area in general and of chairing reviews.

The chairperson should also not have been directly involved in the care or treatment of the individual or be responsible for the service area under review.

The review panel undertakes a RCA to a high level of detail, using appropriate analytical tools to assess what happened; why it happened; what went wrong and what went well; what has changed or what needs to change; and identify any local and regional learning.

Level 3 Review: Independent Review

For Level 3 reviews, the same principles as Level 2 reviews apply; however, team membership must be agreed upon between the reporting organisation and the HSCB/ PHA (PHA) Designated Review Officer (DRO) prior to the review commencing.

The 2016 procedure states that: “The review panel undertakes an in-depth review of the incident, to a high level of detail, using appropriate analytical tools to assess: what happened; why it happened; what went wrong and what went well; what has changed or what needs to change; and identify any local and regional learning.”

In 2016, the Regional SAI procedure was updated to guide SAI review panels in relation to providing patients and families with an opportunity to contribute to the SAI review.

The guidance outlined that:

- The level of involvement depended on the nature of the SAI and the patient and family’s willingness to be involved.
- Teams involved in the review of SAIs should ensure sensitivity to the needs of the patient and family/carer involved.
- Teams should agree on appropriate communication arrangements with the patient and family/carer involved.

To support the involvement process, an SAI leaflet⁵ was designed by the HSCB and PHA for organisations to give to patients and families prior to their initial discussion regarding the SAI which had occurred.

1.4 Patient and Family Involvement and Engagement

Health and Social Care services across Northern Ireland have a legal duty to involve service users and their carers. Personal and Public Involvement (PPI) is a legislative requirement for Health and Social Care organisations as set out in the Health and Social Services (Reform) Northern Ireland Act 2009⁶.

The Act states that service users and carers must be involved in and consulted on:

- The planning of the provision of care.
- The development and consideration of proposals for changes in the way that care is provided.

- Decisions to be made by the body that has the responsibility for the provision of that care.
- The efficacy of that care.

PPI is the active and meaningful involvement of service users and carers in the planning, commissioning, delivery and evaluation of Health and Social Care (HSC) services, in ways that are relevant to them. It is the process of empowering and enabling those who use services and their carers to make their voices heard, ensuring that their knowledge, expertise and views are listened to.

Given this statutory duty, service user and family involvement were considered a pivotal aspect of this review. Throughout the review, the effectiveness and extent of patient and family engagement have been examined from the perspective of patients and families, frontline staff and managers.

2.0 Terms of Reference

The terms of reference for this review, as agreed with the Department of Health, were as follows:

- 1) To review the systems/ processes in place for reporting and follow-up of Serious Adverse Incidents (SAIs) across the six HSC Trusts, the HSCB and Public Health Agency in Northern Ireland, between 30 November 2016 and 31 March 2018.
- 2) To engage with families affected by SAIs reported between 30 November 2016 and 31 March 2018, to determine their level of involvement in the Serious Adverse Incident process.
- 3) To assess the process for the classification of the severity of SAIs and to determine whether incidents are appropriately classified through this process.
- 4) To assess the level of independence of the SAI reviews progressed and assess whether a multi-disciplinary systems-wide approach to reviews has been undertaken.
- 5) To assess the development and effectiveness of action plans and recommendations arising from SAIs reviews.
- 6) To assess whether appropriate learning has been identified from the SAIs and disseminated regionally, and whether the learning can deliver measurable and sustainable improvements in the quality and safety of care.
- 7) To determine current understanding of the role of respective organisations, including the Coroner, in the process for SAI reviews, and how this understanding compares to the published roles and responsibilities as outlined in the procedure for the Reporting and Follow up of Serious Adverse Incidents.

- 8) To assess the level of professional support provided to (i) staff who were delivering care at the time of the SAIs, as well as (ii) staff conducting the review of the SAIs.
- 9) To provide a report of the findings to the Department of Health, making recommendations for improvement as relevant to the overall response to SAIs, their assessment and review, and the learning arising through these processes.

3.0 Review Methodology

The review used a range of methodologies to ensure each term of reference was addressed. Each methodology aimed to optimise the quality of information sought by the expert panel to ensure a robust evidence-base for their recommendations.

The methods included:

- 1) The assessment of SAI review reports, by the Expert Review Team. The criteria for assessment as agreed with the Department of Health.
- 2) The design of a structured assessment questionnaire which was applied by the Expert Review Team to all SAI review reports submitted by the participating HSC Trusts.
- 3) Questionnaires issued to a range of Trust staff, from senior management to frontline practitioners, and SAI panel chairs, seeking their views of their involvement in the SAI review process.
- 4) Engagement of patients and families who had experienced healthcare-induced harm and the offer of face-to-face conversations to learn about their experiences and hear their views as to how these experiences could have been improved.
- 5) Focus groups involving staff involved in an SAI, as well as staff involved in the SAI review process.
- 6) Meetings with individuals and groups of staff in HSC organisations involved in SAI reviews.
- 7) Engagement with other relevant organisations.

It was intended that the effectiveness of implementation of SAI recommendations would be examined in specific detail by the Expert Review Team to explore further the arrangements within services to deliver on sustained and measurable improvements to patient safety. However due to the COVID-19 pandemic, this aspect of the methodology was unable to be performed in full, but was explored through other aspects of the methodology.

3.1 The Identification and Selection of SAIs

For the aspect of this review SAIs selected had been conducted between 30 November 2016 and 31 March 2018 and fell within the following categories:

- Deaths of women and babies related to pregnancy and childbirth: maternal deaths, stillbirths and neonatal deaths. Serious illness of women and babies where this has been related to pregnancy and childbirth.
- Sepsis
- Choking on Food
- Never Events¹
- Cases where private hospitals or private nursing homes feature in the care pathway.
- People with a learning disability who have died from a treatable physical condition.
- People with a learning disability in residential care.
- Primary Care
- Any other categories RQIA considered appropriate for inclusion the review.

The information relating to these SAIs was obtained from the HSCB. After validation, 54 SAIs were identified for inclusion. A total of 12 additional SAIs were subsequently selected, comprised of Level 2 and Level 3 reviews, resulting in a total of 66 SAIs being selected for expert review (Appendix A).

3.2 The Structured Assessment of SAI Reports

A structured assessment tool was developed and applied to each SAI report reviewed. The assessment captured the perspectives of members of the Expert Review Team who were:

- Experienced investigators.
- Clinicians.
- Lay and family representatives.

Two distinct types of structured assessment tools were developed, one for use by the lay members of the Expert Review Team and one for the technical assessment of the SAI reports by other Expert Review Team members. This approach ensured consistent and objective assessment of each SAI report.

Due to the differences in templates used and levels of review required, for Level 1 and Level 2 SAI reviews set out in the regional procedure, the core assessment tool, which applies to Level 2 SAIs, was modified to meet the requirements of a Level 1 SAI report.

¹ Never Events are serious, wholly preventable safety incidents that should not occur if the available preventative measures are implemented. They include things like wrong site surgery or foreign objects left in a person's body after an operation. The full scope of Never Events is detailed in the Care Quality Commission report, [Learning from Never Events \(July 2018\)](#).

To ensure a robust approach, members of the Expert Review Team with either a clinical qualification or extensive prior experience in the conduct of SAI review were grouped in pairs. This resulted in each pair reviewing a total of 33 SAI reports.

The lay members of the Expert Review Team reviewed all 66 SAI reports individually before comparing their assessments and discussing any differences of opinion. This resulted in three subgroups with two members of the Expert Review Team in each, assessing the SAI review reports.

Table 1 below shows the breakdown of trusts and reports allocated to each technical team.

Table 1: Breakdown of trusts and reports allocated to each technical team

Team	Organisation	Number of SAI reports for review
Team 1	Northern Trust	10
	South Eastern Trust	13
	Western Trust	10
Team 2	Belfast Trust	11
	Southern Trust	14
	NIAS	4
	Integrated Care Team, HSCB	4
TOTAL		66

Source: RQIA Structure Assessment Exercise

3.2.1 Quality Assurance of the Structured Assessments

The structured assessment tool developed by the Expert Review Team considered the extent to which the SAI report described:

- The incident under review and why it was being reviewed.
- The level of independence of the review panel members and the competencies and skills they had to conduct the review.
- The degree of patient and family engagement with the review process.
- The nature of the recommendations made and their relevance to improving patient safety.
- The robustness of the action plans constructed to deliver the recommendations and whether they would deliver a measurable and sustained improvement in quality and safety.

3.2.2 Technical Assessment

To ensure reliable and accurate assessments of the SAI reports, two quality assurance exercises were undertaken.

Firstly, for each of the three technical teams referenced above, an intra-team reliability exercise was undertaken. This required the assessors to submit a sample of four assessments to each other for a repeat assessment to ascertain the similarity or differences in assessment outcome. This process demonstrated a high level of consistency between the assessments. Where there were significant differences in the assessments, these were presented and discussed at a round table conversation between the technical assessors to reach consensus. A lay member of the Expert Review Team was included in this process.

The second quality assurance exercise was undertaken upon completion of the assessment of all SAI reports.

This involved a sample of four completed assessments being selected from each technical assessment team and reassessed by the other team. Following this, the technical assessment teams met to compare findings. There were few discrepancies between the teams which confirmed a high level of consistency. Any discrepancies were discussed, and a consensus position was reached.

3.2.3 Lay Assessment

The lay members of the Expert Review Team assessed all 66 SAI reports adopting the perspective of a family member who might receive these reports. To achieve a comparable process of quality assurance, each lay member assessed all 66 reports and subsequently met with their lay counterpart to discuss each report, including any differences in perspective.

As with the technical assessments, there were few discrepancies between the assessments conducted by the two lay members of the Expert Review Team, and any differences were resolved by discussion thereby reaching a consensus view.

3.2.4 Analysis of the SAI Report Assessments

Themes were extracted from SAI report assessments and collated to inform key findings. These findings informed engagement with the HSC organisations during subsequent phases of this review. During the review, emerging findings and key messages were shared with the Department of Health via interim reports.

3.3 How each Trust responds to Significant Unexpected Harm Events

Questionnaires were developed for and issued to each HSC Trust, the HSCB and the PHA. These were designed to gather information from each organisation about their respective approaches to SAI review and the related structures and processes in place, including the extent of patient and family involvement.

A thematic analysis of the responses received was subsequently undertaken.

3.4 Patient and Family Engagement

Initially, it was intended that the Expert Review Team would make direct contact with those patients and/or families affected by the 66 SAIs which were included in the structured review undertaken in the first phase of this review. Recognising the potential for further psychological impact, the Expert Review Team agreed the following patients and/or family members would not be contacted:

- Where there had been an expressed wish by the patient and family not to be contacted further or where there were issues of confidentiality.
- Families of cases who were subject to a coroner's investigation.
- Patients/families of cases which were subject to legal proceedings.
- Patients/families of those involved in significantly distressing SAIs (including suicide of a family member).

This resulted in 38 out of the 66 patients/families being contacted to seek their involvement in the review process. Of the invitations sent to each patient and family, only six responses were received. Following this, two decided not to be involved. This resulted in four out of 38 individuals contacted agreeing to become involved. Individuals subsequently met with RQIA staff members. This number was considered too few for the purposes of this review. As such a decision was made to supplement the engagement and further seek experiences via several additional routes, including approaching the Department of Health and the Patient Client Council (PCC) to supplement the experiences of those four initially contacted. Both organisations had previously engaged with patients/families who have had an experience of the SAI process following an incident of unexpected harm.

The PCC agreed to meet with the Expert Review Panel to share the views of patients/families with whom they had engaged. Communication with the Department of Health also resulted in three additional families agreeing to participate and share their experiences.

3.4.1 Additional information considered on engagement with patients and families

Experiences of patients and families involved in SAI reviews were also ascertained through engagement with other groups and work streams:

- In November 2019, the Inquiry into Hyponatraemia-related Deaths Implementation Programme (Work stream 5, Serious Adverse Incidents), held a workshop in conjunction with the PCC to engage with families on their experience of the region's SAI review process. The findings from the workshop were shared with RQIA and considered by the Expert Review Team.
- In October 2019, the PCC shared its Serious Adverse Incident Complaints A Thematic Review of Client Support Service Cases 2014-2018 report. It outlined the experiences of families who had been through the region's SAI review process and the findings were considered by the Expert Review Team.

- In December 2020, the Expert Review Team met with staff from Cause NI² who shared the experiences of families they had supported through the SAI review process and provided insight into how to achieve quality family engagement in the process.

These findings were articulated in the Expert Review Team's interim report on Patient and Family Engagement. .

3.5 Staff Engagement

As part of this review, the Expert Review Team engaged with those staff involved in the care of the 66 patients who were the subject of the SAI review reports involved in the structured assessment undertaken in the earlier phase of the review. Several methods of staff engagement were utilised:

- Focus group meetings using a café style approach.
- A private post box method.
- An online survey.
- One-to-one telephone interviews.

3.5.1. Focus Groups

Focus groups were held between 5 November and 21 November 2019. To accommodate the range of staff involved in the SAI process, each focus group had a different emphasis:

- Staff involved in the care of the patient who was harmed.
- Staff involved in the SAI review process.
- Staff involved in a named SAI review.

The focus groups focused on three primary areas:

- The experience of staff who had been involved in the SAI process.
- Their experience of engaging and involving patients/families in the SAI process.
- The views of staff in relation to how the SAI process could be improved.

Table 2 below shows the number of staff who attended each of the focus groups.

² Cause NI is an organisation which supports people with a mental health problem and their family members.

Table 2: Staff Engagement Focus Groups by Participation and Organisation

Source: Information recorded by RQIA during the focus groups

	Focus Group 1	Focus Group 2	Focus Group 3	
Organisation	Staff involved in an incident	Staff involved in reviewing an incident	Team involved in reviewing an incident	Total number of staff by organisation
Belfast Trust	5	12	4	21
Northern Trust	19	16	2	37
South Eastern Trust	14	15	4	33
Southern Trust	12	10	3	25
Western Trust	5	19	4	28
NIAS	2	8	n/a	10
Integrated Care	n/a	8	n/a	8
Total number of staff by focus group	57	88	17	162

3.5.2 Confidential Post-Box Feedback

At each staff focus group, a confidential post-box was provided to enable staff to share their experiences of the SAI process should they not be comfortable with speaking out in front of a group.

3.5.3 Online Survey

The third method to support staff engagement was via an online survey. All staff working within HSC Trusts were offered an opportunity to respond, provided they had experienced the SAI review process.

Overall, 201 staff completed the survey. However, 114 of those had not been involved in an SAI process, either as a member of a care team involved in an incident or as a member of the SAI review panel. Their responses were therefore not included in these analyses.

Of 87 respondents who had an experience of the SAI review process, 40 staff members had been involved in care and treatment related to an incident and 47 staff members had been part of the panel reviewing an incident.

3.5.4 Telephone Interview

All staff who attended the focus group meetings were also offered the opportunity to speak confidentially with a member of the Expert Review Team by telephone interview. Four staff members were subsequently interviewed.

3.6 Meetings with HSC Organisations

The Expert Review Team met with Senior Managers in each of the HSC Trusts. The meetings focused on the management and oversight of the SAI review process within the organisations and included a discussion on potential improvements to the SAI review process.

The Expert Review Team also met with the HSCB and PHA to discuss their regional responsibilities, their roles in oversight of the SAI review process and the role of the Designated Review Officer. This meeting also included a discussion on potential improvements to the SAI review process.

3.7 Engagement with other Organisations

The Expert Review Team met with representatives of the RQIA's Mental Health inspection team and the Coroners Service in NI, both of which were identified as having had frequent engagement with the SAI process. The purpose of this discussion was to gain an insight into their experience of the SAI process and what improvements they considered could be made.

A broad range of organisations are involved and impacted by the regional SAI review process. Engagement with these organisations focussed on those that had most frequently experienced the process. Other organisations, such as other regulatory bodies, trade unions, and the Police Service for Northern Ireland were provided with information about the review and asked if they would like to make a written submission regarding their views and opinions in relation to the current SAI process and their suggestions for change to the SAI process.

Of the organisations contacted, the following eight responded. These were; the Royal College of Nursing, the Eastern Local Medical Committee, the Pharmacy Forum, the Coroner's Service, the Northern Ireland Public Sector Alliance, the Northern Ireland Medical and Dental Training Agency, the Information Commissioners Office and the Health and Safety Executive Northern Ireland.

The full list of organisations contacted is outlined in Appendix B.

4.0 Findings

4.1 Overall findings of the Expert Review Panel

After full consideration of all the evidence gathered from each of the contributors to this review, the Expert Review Team was confident in their determination that the current regional policy for SAI review in Northern Ireland must change. It was clear that the current procedure and its implementation does not support:

- Fulfilment of the statutory duty of PPI as set out in the Health and Social Care (Reform) Act (Northern Ireland) 2009.
- Reasonable application of the principles of effective review practice.
- Confidence in the independence of Chairs of SAI reviews at Level 2, or Level 3 - particularly so for Level 3 reviews where the appointed chair is a former employee of an HSC Trust.
- Health and Social Care organisations embracing their accountability for:
 - decisions made regarding the level of review conducted
 - how they involve and engage with a patient and family
 - the quality of review conducted, acceptance of its findings and approval processes
 - demonstrating how HSC Trust services have improved and are safer because of the reviews conducted
 - ensuring that issues requiring regional attention to improve safety are escalated to the right people/organisations.
- The formulation of evidence-based recommendations.
- The design of action plans that will enhance the safety and quality of healthcare provision across the region both in the short and longer-term.
- Review reports that are well-formulated, evidence-based and readable.

The Expert Review Team identified a number of reasons for this:

- The implementation of the regional procedure focuses too heavily on process and non-attainable timescales instead of focusing on consistently delivering the practice of conducting high quality SAI reviews.
- There was an absence of clear regional guidance on PPI duties in relation to patient rights within the serious adverse incident process.
- There was no defined regional patient safety training strategy and curriculum.
- There were not defined competencies required of lead investigating officers and serious adverse incident panel chairs.
- There were insufficient numbers of trained independent advocates to support family involvement in the process.
- There was a regional lack of effective training in how to conduct a meaningful review. Furthermore, even where training had been delivered, the appointed chair or investigative leads did not have sufficient authority to independently devise a review plan that fully delivers the required quality of a review.

The evidence underpinning these findings was derived across a broad range of engagements and is detailed further in the following sections under three key themes.

- 1) Patient and family engagement.
- 2) Staff engagement.
- 3) The effectiveness of the procedure and approach for delivery of SAI reviews.

4.2 Patient and Family Engagement

A hallmark of success in any approach to the review and learning from incidents of unexpected and avoidable harm is the manner in which a health provider organisation engages with the patient and their family through the review process. The families who provided information to the Expert Review Team, the PCC and the lay members of the Expert Review Panel (who themselves have lived experience of healthcare induced harm) provided consistent reflections on how this aspect of SAI Reviews is delivered in Northern Ireland.

The Expert Review Team identified several of themes after listening to the views and experiences of patients and families:

- There was inconsistency in the practice of HSC Trusts in when and how they informed families about:
 - the incident
 - the decision to conduct an incident review process
 - the rights of patients and families to be engaged at all stages of the review, including shaping the terms of reference or lines of enquiry
 - sharing of the interim findings of the review process to allow commenting and feedback from the patient and family to be incorporated.
- There was inconsistency in the quality and frequency of communications with the patient and their family. This includes written correspondence as well as verbal communications. A common concern was the level of empathy, respect in the nature and tone of communications and levels of planning with the patient and their family about what mode of communication was best and with what frequency.
- Families reported there was not sufficient transparency about the process.
- There was a deficit in the availability of independent support or advocacy for patients and families.
- There were concerns about the timeliness and amount of information provided about the plan for the review process and its intended conclusion date.
- They described HSC organisations across the region were unable to apologise for the harm that had occurred. In their words, it was not enough to say, “sorry, we are at fault”. Rather, the apology should say: “Sorry this has happened to you. We will look after you and help you understand what happened”.

- They experienced an unwillingness to seek the testimony of the patient and family members as an integral component of the review process, thus diminishing the status of the patients and their families.
- Many stated that the interim findings of the review process were not shared with the patient or their family members so that they could contribute constructive comments and ensure their voice is appropriately represented and heard.
- There was not a sufficient level of openness and candour about what had happened and why. They described the shrouding of the SAI review findings in technical language which was not accessible and perceived it to be defensiveness.
- There were some who were concerned about potential 'cover-ups' and a lack of transparency in the process, as well as in the report subsequently written.
- Several described Chairs of the SAI review whose communication skills and ability to work constructively with a family were poor.
- Several were not confident in the independence of Chairs of the SAI review.

Of particular note was the view expressed by Cause NI, a charity that specialises in offering practical and emotional support to families whose loved ones have experienced harm as a result of serious mental illness or suicide. They considered that the current requirement within the SAI procedure, for the investigation of all deaths that have occurred as a result of mental illness (where the individual who dies was known to Mental Health Services in the preceding 12 months), was not the best approach. It was suggested SAI reviews would be most appropriate in those cases where it was suspected there were care deficits preceding the death.

The Expert Review Team reflected, that overall, the expressed views of patients of families in Northern Ireland regarding their experiences of involvement, were similar to findings of independent reviews and inquiries elsewhere in the UK, such as the Care Quality Commission (CQC) review, '*Learning, Candour and Accountability 2016*⁷', the *Mid Staffordshire NHS Foundation Trust Inquiry* and *The Report of the Morecambe Bay Investigation*. It was therefore disappointing that in Northern Ireland, more progress had not been made in implementing best practice in how HSC organisations work with families after unexpected harm.

The Expert Review Team was impressed with the attitude of staff who expressed a willingness to have greater engagement and involvement with the patient and their family in the process. Most staff appreciated that patients and families are an important component of a successful approach to learning from harm. They reported feeling constrained by an overly bureaucratic process, which they perceived placed completion of arbitrary timescales and narrow performance targets above the requirement for meaningful involvement.

The most significant barriers to achieving meaningful involvement of patients and their families were described as:

- Uncertainty about what staff could and could not say to a family and what constitutes an acceptable level of disclosure.
- How to achieve realistic expectations with a patient and their family about what the SAI process can and cannot deliver.

- The time allowed for the delivery of the SAI process, and the time available to an SAI review panel chair, who would have additional managerial or frontline clinical duties and which is not conducive to meaningful patient and family engagement.
- The availability of dedicated support for patients and their families through the SAI process. Without support, it is difficult for Chairs of SAI reviews to also attend properly to the needs of the patient and family.
- Absence of constructive guidance on how to capture family involvement and engagement within the SAI review report, exacerbated by lack of space within the review report template to record the level of family involvement.
- Staff were concerned about legal issues and reported anxiety about how to describe the findings that then might result in a claim for damages. A small number of staff described instances where legal services have requested modifications to a report which diluted the findings of the SAI review panel.

The Expert Review Team is clear that concerns regarding future claims for damages must not interfere with conduct of an SAI review or with the integrity of the resulting report. It is wholly unacceptable that report authors could be asked by a manager or by legal services to dilute their findings. Furthermore, such action should have serious implications for health professionals who have breached their professional duty of candour.

However, there are good reasons for a legal services team to review an internal SAI review report document:

- To sense check the use of language.
- To test the strength of the evidence base underpinning the report's findings and conclusions.
- To determine a report's readability.

Feedback made to a report author in the context of the above must be considered and acted upon.

Across the HSC, it was not the cultural norm to share interim findings of an SAI review with a patient and their family. Enabling the patient and family to have a voice in the report, to comment on the report content, and to influence the content and tone of the final report appears not to be a primary consideration. Ineffective and insufficient patient and family engagement can cause further harm. Families report having experienced some of the following adverse effects:

- Increase in stress.
- Delay in starting the grieving process.
- Post-traumatic stress disorder.
- Loss of income.
- Feelings of anger.
- Loss of life enjoyment.

The Expert Review Team considered that, for many families, it is possible to avoid causing further harm if HSC organisations engage in a compassionate process. The

founders of the Harmed Patients Alliance⁸, a campaign group founded to raise awareness of harmed patients and families, effectively communicate the kind of compassion families need following healthcare harm.

“In the aftermath of our loss, we needed healthcare to fully acknowledge and thoroughly understand our experience of what had happened to our children and the impact it had on us. We needed answers to all of the questions that we had, that were important to us, and we needed those regardless of whether anyone else felt our question relevant or important. We needed staff to be supported to give us honest accounts of their actions and their reflections. We needed a collaborative approach to reach a truthful and evidence-based explanation of events. We needed help and support to understand what all the processes were that were happening and how to engage with them. We needed the system to learn and to see meaningful change, but we also needed the system to help us heal, recover, and restore our trust. Meaningful engagement coming from a place of care could have provided that.”

Harmed Patients Alliance

4.2.1 Working with patients and their families in a way that delivers a restorative process and maintains candour

The Expert Review Team determined that the Department of Health with associated stakeholders must describe the region’s statement of intent regarding how patients and families are involved in the SAI review process and the core objectives in relation to patient and family involvement for which each HSC provider must evidence achievement.

Examples of objectives relating to patient and family involvement are:

- Families and patients are supported as active partners in the review process as much as they wish to be engaged, including the involvement of an appointed advocate.
- Patients/families experience a compassionate and empathetic approach, which is demonstrated by the nature and frequency of contact throughout the review process.
- The voice of the patient and family is heard, their testimony captured, and they have the same status as any professional contributing information to the review process.
- The patient and family has a named source of support, outside of the review panel. The role of this individual is clearly defined, including the basis authority to act as advocates in the best interests of the family.

- Questions asked by the patient and family are responded to fully, with honesty, integrity and candour.
- The patient and family are encouraged to contribute to the terms of reference for incidents identified as requiring in-depth review.
- Patients/families are taken through the interim findings of the review and are provided with enough time to read, comment on, and influence the content of the final report.

In the event of new information becoming available after the conclusion of an SAI review, or if there is a change in conclusion or material findings from such review, then this information must be shared with the patient/families as soon as possible.

How individual HSC organisations undertake to deliver the objectives should be for them to determine. However, what is required from all HSC organisations is clear evidence that they have achieved the objectives. In particular, they should provide evidence that patients and families are given the same opportunity for involvement in an SAI review as the staff and others involved in an incident. This evidence should be validated by patients and families who have experienced unexpected healthcare harm of the nature that warrants an SAI review. The Expert Review Team considered that a co-production model for development and further improvement of the SAI procedure, involving frontline staff and patients and their families, should be adopted going forward.

4.3 Staff Engagement (staff engaged in the care and management of the patient who experienced harm)

Every SAI review must involve the collection and analysis of a sufficient amount of information from multiple sources. This requires the active engagement of staff involved in the care and treatment of the harmed patient and the engagement of a wider sphere of individuals who have experience in the field and understand the system at work.

The purpose of the SAI review process is to:

- Find out what happened.
- Understand how and why it happened.
- Implement any appropriate early remedial actions to address any identified deficits in care.
- Identify areas for improvement in order to support the delivery of safe patient care.
- Implement appropriate improvements based on the findings of the SAI review.

In circumstances where patients have been harmed, it is understandable that frontline staff may feel vulnerable and experience emotional pain, as well as feelings of anger, shame, fear, sorrow or regret.

To enable HSC staff to fully inform the review process, they must feel safe to do so. They must also have confidence in both the competence the appointed review panel and feel secure that the information they provide will be used fairly.

What staff employed within Health and Social Care trusts across the region had to say

Comments about the SAI procedure and its implementation:

In the online survey completed by HSC staff:

- 89% (179) said they agreed, or strongly agreed, that SAI reviews were an essential activity for a learning organisation.
- 74% of respondents (149) said SAI reviews generated improvement for safety within their organisations.
- 64% (129) said they agreed or strongly agreed that they were aware of more than one improvement resulting from an SAI review.
- 61% (123) said outcomes from SAI reviews were regularly discussed at team or service meetings.

While the survey results cannot definitively conclude whether or not SAI reviews enabled the collection of quality information upon which to formulate evidence-based findings, face-to-face meetings conducted with staff in HSC organisations did, however, provide a useful insight into the experiences of staff involved in SAI reviews.

The information gathered at staff focus groups, for example, highlighted that the principle of a 'just culture' was not embedded across the region.

Staff consistently reported:

- Insufficient openness about the process and the standards of conduct expected of the SAI review panel members.
- Insufficient communication about the progress of an SAI review and why it was being conducted. The key lines of enquiry, progress, findings, and recommendations were frequently unknown by staff who had been involved in the care and treatment of the patient to which the SAI review related.
- The experience of the review felt like it was designed to apportion blame.
- Terms of reference for SAI reviews did not suggest they were grounded in a constructive or learning process.
- There was variable engagement in the process, with some staff unaware the SAI review was even being conducted, only to find out at a later point in time. Some staff described an over-emphasis on the collection of written submissions and a lack of detailed exploratory conversations being conducted by SAI review panels.
- Some staff described insufficient notice of, or information about, SAI panel meetings or interviews staff were asked to attend.
- Some staff did not have an opportunity to read the interim findings before these were finalised in the SAI report.

- Some staff said they were not able to respond to any criticisms made in the SAI report before it was signed off as completed.

Regarding the constitution of the SAI review panel, and how those panels operated, the following concerns were described by frontline staff who participated in this review:

- Concerns about the appropriateness of members of the panel in terms of technical and subject matter competency and insight.
- Concern about the lack of factual accuracy checking by review panels, both in terms of the sequence of events leading to the incident under review, but also regarding the accuracy of notes of face-to-face meeting. Staff said that this meant they were unable to correct the SAI review panel's misinterpretation of words spoken at interviews, or during panel meetings.
- Some staff described too narrow a field of focus by SAI review panels, with little consideration of the system within which frontline staff work. For example, workload, workplace design, task design, skill mix, staffing issues, team dynamics, and cultural factors, leadership and factors which may contribute to an incident.

Although negative experiences were reported, some staff reported a more positive experience and had been involved fully throughout the SAI review. These staff reported that they felt they had been involved throughout the SAI review, in terms of being kept up to date with progress of the SAI review and were able to contribute to the learning from the SAI review.

During discussions with the Expert Review Team, frontline staff reflected on the support mechanisms available to them in coming to terms with the SAI event and its subsequent review. Although we received many comments about a lack of support, a small number of staff did share positive experiences of being supported by both managers and colleagues. These staff highlighted that the people who had provided the support, had themselves been previously part of a SAI review. The overwhelming message from all focus groups across all Trusts was that staff had experiences of inadequate support as they went through the SAI process.

Frontline staff acknowledged that it was not the role of the chair of the SAI panel or the Trust staff member who oversees the review to provide appropriate support for staff as their role was to deliver an effective, unbiased review process. However, they did consider that better quality support ought to be forthcoming from:

- Their own line managers.
- Independent providers of psychological support.
- Their employer via staff supports and counselling services.

In several focus groups, the Expert Review Panel members were struck by the level of emotion expressed by staff who had participated in an SAI reviews. It was evident that these staff had not been through a supportive, reflective process of learning.

4.3.1 Achieving a way of working with staff that delivers a supportive, learning-orientated process within a 'Just Culture'.

The Expert Review Team determined that the Department of Health, working with appropriate stakeholders, must set out, in its strategic direction, its expectations for how staff in HSC organisations and those they report to are engaged and when participating in an SAI review. As with family engagement, the principles for effective staff engagement must be developed and defined before an effective process can be designed.

An example of a statement of success could be:

'Staff are treated well, their voice is heard, and they actively contribute to the SAI review process.'

The core objectives for HSC organisations which will ensure this is delivered could be:

- 1) Staff experience a compassionate and empathetic approach.
- 2) The voice of the staff involved in an incident is heard, including their experience of the incident, and the context in which it occurred.
- 3) Staff are well informed throughout the review process.
- 4) Staff are treated fairly and equitably, in line with the principle of a 'just culture', including having the opportunity to read any criticisms made about them and to respond.
- 5) Staff involved in the incident (and other key staff) are given the opportunity to read the interim findings of the SAI review panel and to provide feedback in relation to factual accuracy, tone, and style.
- 6) Staff involved in the incident and service in which the incident occurred are actively engaged in designing the action plan to deliver measurable and sustained improvement.

Again, individual HSC organisations should determine for themselves how to deliver these objectives but should be able to evidence achievement of the objectives. This evidence should be validated by staff that have experienced the SAI process. Perspectives of staff who have delivered the SAI process should also be gathered and evaluated. The Expert Review Team again advises that a cooperative approach be adopted for involving frontline staff, patients and their families in designing of these improvements.

4.4 Staff Engagement (staff with experience undertaking SAI reviews)

A robust SAI review requires staff delivering the process to have the right technical knowledge, along with a range of non-technical skills and attributes. At the time of this review there was no competency framework in place to ensure the required competencies to deliver the review process. It cannot be assumed individuals have these skills simply because of their professional background or seniority. Implementing an effective approach for SAI reviews will require upskilling of staff before it can be practised and evaluated.

For the implementation of the review procedure to be effective and for optimal learning to be achieved, a structured and feasible policy framework needs to be embedded alongside cultural change.

The consistent messages provided to the Expert Review Panel from staff engaged in the delivery of the SAI procedure and its implementation were:

- It was challenging to undertake the SAI reviews alongside their pre-existing professional duties. There was no protected time for this, nor any account taken of their day-to-day workloads or frontline patient care duties.
- There was insufficient supervision and mentorship by experienced reviewers who hold the necessary technical and non-technical skills and attributes.
- There was a lack of training in conducting SAI reviews and related methodologies.
- There were challenges in engaging with staff involved in the care giving, such as established off duty rotas, the need to provide a 6–8-week lead time to medical staff before meeting with them, challenges in locating agency and locum staff, and the delay between the incident occurring and the SAI review being commissioned.
- Communication with all relevant parties was described as a persistent challenge.
- The classification of an SAI, and how it was determined that an incident met Level 1 or Level 2 criteria, was difficult for staff to understand. There was not always full understanding that the current procedure directs reviews should be conducted at a level appropriate and proportionate to the complexity of the incident and significance of event under review rather, that the impact or outcome for the patient. Most staff considered that the criteria for classification were not clear.
- The current approach of imposed regional terms of reference does not support an effective review practice. Staff understood effective reviews require the right technical questions to be asked about the patient's care and treatment; this is not supported by the current process. When asked why the terms of reference were not changed to something more relevant, staff reported that they did not believe they had the authority to do so.
- The regional report template did not support the formulation of an evidence-based, well-structured or readable report. Participants reported that the design of the regional template made it difficult to reflect the level of an engagement that an SAI review panel may have achieved with the family. Overall, the template was considered to be not fit for purpose.
- Recommendations were a particular source of concern for participating staff, with many reporting their perspective that recommendations often did not get implemented due to a lack of resources. Staff also displayed some frustration members of review panels felt obliged to make recommendations even if they suspected that nothing would happen as a result.

In addition to the above, staff with experience in conducting SAI reviews provided insights into the review methodology of Root Cause Analysis (RCA) and the extent to which learning is implemented. The information provided by staff indicated that there is confusion about what constitutes an RCA method. The fact that many staff believed completion of the regional report template constituted a valid review and an

RCA is concerning. Staff did not demonstrate an informed understanding of what constituted a review and were not aware of the broad range of tools and approaches they could employ to deliver this. The tools that participating staff were aware of were simple chronology, the 'five-whys' technique, and the 'fishbone' diagram.

The Expert Review Team was left with an impression that HSC Trusts across Northern Ireland are using the language of RCA without an embedded understanding of what this means, or where RCA fits into a structured and auditable review. The regional guidance does not address this, nor does it provide practical advice on how to conduct a review to an acceptable standard.

The Expert Review Team could not be confident that across the HSC Trusts, consistent systems based learning was happening, and that changes were embedded or that there was a robust system in place for sharing learning beyond the investigating organisation. The issuing of regional learning letters by the HSCB was referred to, but most frontline staff were not aware of this and only two of those interviewed had ever seen a learning letter.

Staff with experience as an SAI reviewer understood why staff asked to provide information to the review panel may suspect the existence of a 'blame culture'. They considered that most of the staff they interviewed often appeared anxious about the process and were sometimes defensive when questioned. Some staff who had undertaken several SAI reviews considered that the level of anxiety among staff being interviewed had increased over time.

The Expert Review Team considers from their assessment of the 66 review reports that the language used in SAI review reports might also contribute to a sense of blame. For example, root causes of incidents were described as 'human error', which may unfairly suggest that an individual member of staff is responsible. This is further compounded by the lack of deconstruction of events from a systems perspective, meaning that the true root causes and contributory factors which underlie errors in care and treatment are not identified, placing an unreasonable weight of responsibility on frontline staff.

Staff acting as SAI reviewers on behalf of their employer also considered the way the media in Northern Ireland reported on incidents that had reached the public domain. Subsequent media interest and commentary fuelled their feeling of a blame-driven approach and culture, alongside concerns about medico-legal consequences.

As with staff involved in care delivery, those who had an experience of conducting SAI reviews also believed that there was a lack of constructive support. Staff asked to chair SAI review panels were particularly concerned. They considered that there was no account taken of the true time required to deliver the role well, or how the time required conflicted with their other professional responsibilities. Some staff reported having to write SAI reports in their own time and late into the night, which then impacted their wellbeing and concentration levels at work the next day.

The Expert Review Team considers this situation to be wholly unacceptable. If the objective is to learn and improve safety, the system cannot overload staff already working at full capacity. Failing to provide protected time to lead the SAI review

process infers that it lacks importance. In the rail, marine, and airline industries, where an incident merits careful analysis, only trained individuals with time to undertake the work are appointed to the task.

The lack of administrative assistance for review chairs was also cited by staff as evidence of lack of support. There is considerable administration associated with the conduct of an SAI review. The Expert Review Team considers that it is not appropriate for a frontline clinician, who has been asked to lead an SAI review process, to also be responsible for administering it.

4.4.1 How to ensure chairs and members of SAI review panels are equipped to deliver the job adequately and with enough time

The Expert Review Team considers that the first step in achieving a sustainable situation across the region is to review how decisions are made regarding the level of SAI review required. This should be informed by:

- The frequency by which the incident type occurs.
- Whether there is a safety review already ongoing to explore and address any safety issues.
- Whether the conduct of the review is likely to deliver more learning than has already been achieved by previous reviews.
- Whether there is a safety improvement plan already underway.

It is widely recognised that many individual reviews involving the same incident type often do not lead to tangible safety improvements. Therefore, the practice of defining the need for an SAI review on the basis of adverse patient outcomes should be discouraged and is not in line with the current guidance contained within the SAI procedure which states,

“SAI reviews should be conducted at a level appropriate and proportionate to the complexity of the incident under review. In order to ensure timely learning from all SAIs reported, it is important the level of review focuses on the complexity of the incident and not solely on the significance of the event”.

An approach that allows a sensible period of time for the early assessment of ‘what happened’, and consideration of early information gathered about the care and incident, might enable a more structured and evidence-based approach to deciding which cases require an in-depth systems analysis. Treating the review as a process, where reviewers and chairs can determine an evidenced-based stop point, might be more successful than a static approach which assumes that all incidents can be treated the same. One of the expert review panel members has supported several NHS Trust mental health teams to implement such an approach. As a result, mental health teams reported a reduction in the number of in-depth reviews, greater engagement from staff and a formalised process whereby the review is led by the team lead; now recognised to be an important aspect of the process.

A more flexible approach is required to enable families to understand the process and what it can deliver. For example, it can deliver learning and provide answers to questions but it cannot provide justice.

In terms of the time allocated to conduct an SAI review, it will always be necessary to stipulate timescales, but it is important that they are realistic. They must allow at least to six-months for complex cases, and it would be reasonable to require a structured project management approach that can be monitored and quality assured.

The second step is to define the core competencies required of:

- People acting as review leads and/or chairs of review panel.
- The subject advisors supporting the process.

Furthermore, a regional training curriculum and certification process must be agreed. All training providers across the region should meet the minimum content requirement in order to enable competency achievement. For such an approach to work well, all HSC Trusts and independent providers responsible for delivering training should be required to demonstrate their competency and knowledge in order to be approved as training providers. Requiring all training providers to apply to be on a regional register or preferred provider list would support the achievement of this.

Finally, to support the implementation of a training curriculum it was considered that a mentorship and coaching approach could also be adopted. A person independent of the HSC Trust in which the incident occurred could provide external support to the lead reviewer/chair. This has the added advantage of providing an independent quality assurance check of the process and its outcomes.

4.5 SAI Reports: The extent they demonstrated a reasonable standard of review and positive contribution to patient safety in Northern Ireland

As previously outlined in the methodology in section 3.0, the Expert Review Team reviewed 66 SAI reports as part of this review.

In undertaking the review of reports, it was evident to the Expert Review Team that having two separate report templates for Level 1 and Level 2 reviews is not working. The design of the templates also does not support staff to write up their findings in a way that delivers confidence in the standard of the review or in the appropriateness of the level of review undertaken. Furthermore, the templates are designed in a way that limits important information being included, such as the questions that have been asked by patients and family members.

Upon assessing the report of a significant adverse incident review, the expectation is that it demonstrates that an effective method has been used to underpin the review. Indicators of an effective methodology are:

- The methods, tools and techniques used by the SAI review panel are clearly stated and appropriate to the incident under examination.
- The evidence upon which findings and conclusions are based have been clearly triangulated.
- An appropriate range of subject advisers have been engaged in the review process

- The SAI review report outlines the key elements of the processes and procedures relevant to the expected standards of care and treatment.
- There is a clear account of:
 - what happened
 - where policy, process or procedural expectations were met
 - where there was a deviation from procedural expectations.
- Where deviation from procedural expectations is identified, there is an explanation of:
 - whether the deviations were reasonable and justified based on the presentation of the patient, their clinical needs at the time, and the unfolding situation
 - whether the deviations were not reasonable and therefore not justifiable.
- In the instance of a non-justifiable deviation from the expected standard of care, there should be an indication of whether this contributed to or caused the harm to the patient, and whether the deviation represents a breach in standards to such an extent as to pose an ongoing threat to the safety of another patient should it reoccur.
 - In all such instances, a report should outline a human factor and systems-based explanation of how and why the deviation(s) occurred.
- Recommendations should address the most significant factors identified which contributed to or directly caused the incident.

In addition to the above, all significant adverse incident reports should deliver the following:

- Clarity about the questions posed by the family. The answers to these questions should be included in the findings section of the report.
- A good standard of writing with correct use of grammar, punctuation, and syntax. There should be no abbreviations, unless already in common usage in Northern Ireland.
- A readable report written in non-technical language.

4.5.1 Expert Review Team Findings following review of 66 significant adverse incident reports, comprising Level 1 and Level 2 reviews

The Expert Review Team found that all HSC Trusts utilised the relevant regional templates for the Level 1 or Level 2 review reports. Therefore, the Expert Review Team's findings are as much a reflection of the design of the templates as the quality of the reports assessed.

Style and structure of the reports

The Expert Review Team considered the presentation of the review reports and there was consensus that both report templates would benefit from a basic front page that simply states the name of the reviewing organisation, the title of the report and the publication date. It was proposed that any demographic information required for regional collection purposes could be accommodated within an appendix.

In both the Level 1 and level 2 report templates, space is provided to record 'what happened'. Mostly, this was comprehensively completed. However, in many reports, the sequence of events was recorded in too much detail and at the expense of the detailed analysis expected in the findings section of both reports, accepting that the Level 1 report is intended to be more succinct than the Level 2 report.

In the Level 1 report, there is no 'findings' section but instead, a section titled 'why it happened'. This title is erroneous. It implies that 'why' is determinable and automatically infers that the incident was preventable. It does not promote a balanced, constructive, analytical process.

In the Level 2 reports, there was a 'findings' section, but this was not structured. There were no uniform subheadings to guide a report author about what they should be recording. For example:

- Evidence that shows that expected standards of care were delivered as intended.
- Evidence of deviations from the expected standards of care.

Some reports made statements of policy and procedural compliance but did not say what these were and did not present an evidence base for the reported levels of compliance.

Some review reports stated their findings in relation to human factors, such as team elements, education and training. However, in the majority of instances the Expert Review could not link these findings to a systematic analysis of these areas of concerns in keeping with the approach of the National patient Safety Agency.⁹ This indicates that the review panel, the author of the SAI review report and those signing off the reports did not fully understand how to effectively implement a human factors approach.

Some reports reviewed by the Expert Review Team did outline deviations in the care and management of the patient but did not make clear the significance or seriousness of these in relation to the patient outcome. As stated above, rarely was this accompanied by any structured or evidence-based explanation regarding how and why these deviations occurred. As a result, there was a lack of outcome-focused recommendations within the reports reviewed.

In stating the above, the Expert Review Team is not inferring that staff who undertook the reviews or wrote the reports were failing to deliver what was required of them, rather, the lack of structure and quality of the reports is a consequence of:

- A lack of investment in those tasked with leading the reviews in terms of their knowledge, skill base and time required to do the job adequately.
- A report structure that is not fit for purpose (Level 1 and Level 2 templates).
- A lack of effective quality assurance of reports at senior management levels across HSC Trusts.
- A lack of empowerment in HSC Trusts to adopt a more comprehensive approach and a better style of report, based on the principles outlined in regional policy and guidance.
- A lack of an effective quality assurance process within each HSC organisation and at a regional level. There appears to be no reliable process through which reports are peer reviewed to ensure delivery of an acceptable standard of review, including outcome-focused recommendations. Nor are they quality assured with a view to ensuring that there is a standard of report writing suitable for sharing with patients and their families.

Expert Review Team findings in relation to specific indicators of a robust SAI review

These are the findings from the Expert Review Team's structured assessment of the 66 review reports.

Indicator 1: The methods, tools and techniques used by the review panel are clearly stated and appropriate to the incident under examination

The following list describes what was found to be commonly recorded in terms of the methodology and approach to reviewing SAIs:

- The patient's notes were reviewed.
- A tabular timeline established.
- Relevant staff were interviewed.
- Family was invited to participate in the review.

The above elements are not sufficient to be considered a methodology, nor do they provide clarity regarding the approach taken by the relevant review panel. As previously articulated in this report, the primary reason for this is a lack of understanding about what constitutes a fair and reasonable review, with a regional approach that is too limiting and not embracing a tool-kit method.

Indicator 2: The evidence upon which findings and conclusions are based has a clear triangulated evidence-base

None of the reports reviewed satisfied the Expert Review Team that there was a triangulated, and thus validated, evidence-base for what was written in the findings section of the reports. This represents an unacceptable situation. A credible review aims to establish what happened, how it happened and why it happened.

An SAI Review Panel Chair understands the importance of triangulating and validating information and understands the dangers of not delivering this standard of practice. The SAI reports reviewed demonstrated a region-wide lack of adherence to

defendable review practice. This is mostly due to a lack of training, an unclear competency framework and insufficient professional supervision.

Indicator 3: An appropriate range of subject advisers have been engaged in the process

Regarding the independence and appropriateness of subject advisers, in 93% of reports this was either unclear or absent. Regarding relevant experience of subject advisers, this was unclear in 45% of the reports reviewed. The lack of clarity was in part influenced by the design of the regional report template which did not require precision in the recording of this information.

Indicator 4: The key elements of processes and procedures relevant to the effective care and management of the patient's condition are recorded

This was missing from almost all reports reviewed. It is not a current requirement of the regional report template, and its absence underlines the lack of appreciation about what is necessary for a structured and credible review.

Each report should give a clear account of:

- 1) What happened.
- 2) Where policy/process/procedural expectations were delivered as expected.
- 3) Where there was deviation from policy/process/procedural expectations and an explanation for such deviations.

Although there was a clear account of what happened, few reports provided an analysis that enabled the reader to know where expectations were delivered, where they were not, and where the design of the process for care delivery and management was incomplete.

This is a significant shortcoming in the SAI protocol which does not require systems based analysis as part of its approach to conducting SAI reviews or within its regional report template.

Reports of reviews must determine:

- What was expected.
- Where the evidence supports that the standard of care was delivered as expected.
- Where the evidence shows deviation from what was expected.
- Where the evidence shows there was a pre-existing deficiency in the design of care and treatment requirements and associated systems and processes.

Where deviation from policy, process or procedural expectations is identified, there is an explanation of any or all of the following:

- Whether the deviations were reasonable and justifiable based on the presentation of the patient, their clinical needs at the time and the unfolding situation.

- Whether the deviations were not reasonable and therefore not justifiable.

Where deviations in care standards and the care and treatment delivered were identified, there was little evidence regarding the reasonableness of such deviations. It is accepted across all domains of clinical practice that sometimes it is necessary to do things differently than what is outlined in policy and procedure. Clinical professionals are trained to apply their clinical skills and to have a clear reason why a different approach in any given situation is right for the patient under their care. It is possible to make a correct decision at the time care is delivered to alter the normal plan and for this to be later contemplated as a contributor to an incident that occurred later. The rights and wrongs of these decisions must be carefully contemplated, alongside the application of principles such as the substitution test (that is, what would a similarly qualified group of professionals, providing care under the same/similar set of circumstances, reasonably have done). There was no evidence from the reports reviewed that these core principles have been applied.

The situation is uncomplicated if the review panel and the care team agree that an unjustifiable deviation occurred. The problem arises when there is a difference of opinion between the care team and the SAI review panel. In all such instances, the SAI review panel must apply the substitution test.

There was no indication in any of the reports reviewed as to whether the care teams had agreed or disagreed with the findings and conclusions of the SAI review panel.

Many report authors and SAI review panels tried to draw conclusions regarding contributory factors and causal factors. However, there was a lack of robustness in the evidence-base on which such important conclusions were being made. In some cases, where a finding of causality had been made, it was clear from the content of the report and the Expert Review Team's clinical knowledge that the conclusion of causality would not stand up to independent scrutiny. It is the lack of a robust evidence base for such conclusions that contributes to the widely-held view, supported by some members of staff during focus groups, that a culture of blame pervades reviews.

Regarding the human factors and systems-based analysis, report authors and the review panels clearly tried to undertake this analysis and present its outputs in the review report. However, based on most of the reports assessed by the Expert Review Team, there is a lack of understanding about how this needs to be approached, and how the findings need to be structured and presented. The design of the regional report template will have further compounded this.

Indicator 5: Recommendations to address the most significant influencing factors to the identified contributory and causal factors

The quantitative assessment of the 66 SAI reports reviewed by the Expert Review Team revealed:

- There was a lack of clarity about whether the report made recommendations. This was found in 14 (21%) of the SAI reports.

- Recommendations were only made in 26 (39%) of the SAI reports, but what they were trying to achieve was unclear.
- In terms of whether there was a correlation between the incident, the report content, and the recommendations, in 30 (45%) of the SAI reports this was clear, in 32 (48%) it was unclear, and in 4 (6%) it was difficult to make a judgement about this.
- In terms of the appropriateness of recommendations, in 22 (33%) of the SAI reports the recommendations seemed reasonable, but in 40 (61%) they did not. In 4 reports (6%) it was difficult to make a judgement about this.
- Regarding any correlation between recommendations and the subsequent action plan, this was clear in 29 (44%) of SAI reports while in 36 (55%) it was not. In 1 report (2%) it was difficult to make a judgement about this.

In no report was there evidence that a structured approach was taken to the formulation of recommendations. The regional guidance on SAIs does not describe any requirements for this and neither do the regional report templates.

An example of a structured approach to recommendations is:

- Clear identification of the intended recipient of the recommendation.
- A clear statement of what is required.
- A clear statement about what the recommendation should deliver.
- A clear statement of what risk the recommendation is meant to contain.
- A clear statement of the scope of the recommendation (local, regional).

Indicator 6: Regarding the non-technical aspects of SAI reports

SAI review reports should adhere to the following non-technical requirements:

- Clarity about the questions posed by the family and the answers to these questions.
- A good standard of writing, with the correct use of grammar, punctuation, and syntax, with no abbreviations, unless already in common usage within the population of Northern Ireland.
- A readable report, written in non-technical language.

Each of the reports was assessed in relation to these factors. Regarding the level of family engagement and understanding, it is the Expert Review Team's perspective that most SAI review reports did not deliver any evidence, or at least convincing evidence, of compliance with candour.

The standard of writing was variable as was the use and non-use of technical language.

Regarding the degree of satisfaction a patient and family might have with the report presented, the lay members of the Expert Review Team considered that they would be satisfied with 16 (24)% of SAI reports reviewed. They considered that they would not be satisfied with (23) 35% of the SAI reports and were unable to determine an opinion of their satisfaction with the remaining 27 (41%).

Regarding the inclusion of evidence that patient and/or family questions had been asked and responded to during the SAI review process, there was evidence in 15 (23%) of SAI reports reviewed that this had happened. In 44 (66%) of SAI reports, there was no such evidence, while in 7 (11%) of SAI reports it was unclear.

Regarding readability and comprehension of SAI review reports, the lay members of the Expert Review Panel considered most reports 89 of 132³, (67%) as easy to read in terms of structure and flow, but this dropped to 26 of 66 (39%) in terms of ease of comprehension of report contents.

Wider Consideration from Structured Assessment of 66 SAIs

On consideration of the implications of the overall findings of the structured assessment of the 66 SAI review reports, the Expert Review Team considered the necessary steps to ensure SAI reviews and their reports are of good quality, readable, respond to family questions and provide evidence an acceptable standard of review.

They agreed on a number of general issues that need to be addressed regarding the procedure and its implementation, if the overall standard and credibility of the SAI report, which sets out the findings, conclusions and recommendations of the significant adverse incident review process, are to improve. These include:

- A regional framework that makes clear what the approach to learning from unexpected and unintended harm is intended to deliver; that is, what are its measurable markers of success.
- A regional approach to SAI reviews that delivers recognised international good practice in the science of review.
- A reasonable amount of time to conduct an effective review and include the patient and family in the process in an empathetic, meaningful, and respectful way.
- A single, new report template and regional style guide that enables a consistent approach to SAI reviews across the region but is flexible enough to allow SAI review report writers to remove and add sections to the template.

There is no single activity that will achieve the above. The Expert Review Team wish to make clear that re-writing the regional standards will not achieve the standard of practice that harmed patients and their families are rightfully demanding of this specialist field across the HSC. This is a standard of practice that is comparable to other industries where the activity of reviewing and learning from unexpected harming incidents deliver the core components necessary for an evidence-based review, undertaken by investigators who are skilled for the job, so the right lessons are learned and the right safety improvements are implemented.

³ The denominator in this indicator is 132 as there was not consensus. 132 reviews were undertaken 2 of each 66 reports. One by each lay reviewer.

It is the Expert Review Team's assertion that there must be a comprehensive recalibration of the approach to the requirement for, and delivery of, SAI reviews across Northern Ireland.

A new approach must achieve:

- Greater flexibility in an approach that focuses on the opportunity for learning and safety improvement.
- A lower number of in-depth reviews. Where early assessment indicates that this depth of review is necessary, there should then be capability and capacity in the system to do this well.
- A process by which individuals and/or organisations who want the opportunity to deliver 'Investigating Well' training to HSC staff, are asked to undertake an assessment process so that it can be determined that they have the right knowledge and skills to deliver such training. This would preferably then lead to a regional register of preferred providers from which individual HSC Trusts can source training.
- A register of individuals and organisations who are authorised and have been assessed as competent to lead the review of unexpected harm events that meet the threshold for an in-depth fully independent review - for example, mental health homicide, removal of a body part in error, in-patient suicide.

Northern Ireland is in the envious position of having only six HSC Trusts. This provides an opportunity to reset the compass in a way that is not possible in regions with larger populations. Achieving this reset and designing a fit-for-purpose approach to reviewing and learning from SAIs will require unified and cooperative work across all involved organisations. Furthermore, it will require frontline senior clinicians to be prepared to provide straightforward, peer-to-peer assessment, reflection and feedback to colleagues in neighbouring Trusts about the care and treatment provided to patients when the outcome constitutes unexpected and unintended healthcare harm. This is a core element of professionalism and clinicians of all disciplines need to meet this challenge head-on. It should not be the case that trusted independent clinical opinion has always to be sought from outside of Northern Ireland.

5.0 Conclusion

The work undertaken for this review has, alongside other related projects, determined that the SAI procedure and its implementation across Northern Ireland is not working as intended.

It frequently fails to:

- Answer patient and family questions.
- Determine where safety breaches have occurred.
- Achieve a systemic understanding of those safety breaches.
- Design recommendations and action plans to reduce the opportunity for the same or similar safety breaches in future.

Patients and their families are not fully enabled to engage with the process as partners and their questions are not always sought. They do not always receive open, honest and straightforward answers to their questions. The witness testimonies of patients and families are not routinely collected and, when they are, they are not treated as they should be; that is, as evidence in the same way staff testimonies are treated. The current situation is not tenable and must change.

Frontline staff, who come to work to help and support patients to achieve the best quality of health they can, consider the current process to be blame-orientated and not learning-orientated. It does not embrace the basic principles of a credible review process, a reasonable expectation of fair treatment, or the right to know of any criticism that is to be made and its relevant evidence-base. Staff are most frequently engaged as passive recipients to the process, which is not a good platform for learning and positive change.

The SAI review reports largely do not evidence a defensible approach to the review and identification of learning arising from unexpected patient harm. There are several contributory factors, including:

- Staff asked to lead the reviews are mostly asked to do this on top of pre-existing work commitments, including frontline patient care duties.
- The level of training provided to staff that are tasked with leading SAI reviews is insufficient and is not informed by regionally agreed competencies or a core patient safety training strategy or curriculum.
- The regional timescales allowed for undertaking a complex review, including meaningful engagement with a patient and their family, are unrealistic and lead to a bureaucratic process.
- The regional report templates are not designed to support the delivery of a quality, evidence-based report.

It is worth noting that since this review was commissioned, a number of Public Inquiries, patient recall and lookback exercises have been initiated in Northern Ireland. The Expert Review Team considers that such lengthy inquiries and large-scale pieces of work could be avoided by a robust system for deriving and implementing learning from SAIs. Ineffective systems and processes for review

and identification of learning emerging from SAIs, not only damage public confidence and trust in the SAI process, but also adversely impact on the trust of patients, their families and the public in the healthcare system as a whole.

There is now an important opportunity to achieve better for patients, for staff and for Health and Social Care services across the region. It is patently evident that continuing as we have been is not an option. The Expert Review Team has made five recommendations that, if implemented, should transform the current approach to learning from and preventing recurrence of harm within Health and Social Care in Northern Ireland. The RQIA look forward to working in partnership with DoH, PHA, HSC Trusts, patients, families and carers to deliver on a new and improved regional system for optimising the learning from adverse incidents which occur in Health and Social Care services and ensuring every opportunity is seized to improve the safety of Health and Social Care services.

6.0 Recommendations

The following recommendations are intended to deliver a new regional policy for reporting, investigating and learning from adverse events.

Recommendation 1:

The Department of Health should work collaboratively with patient and carer representatives, senior representatives of Trusts, the Strategic Performance and Planning Group, Public Health Agency and Regulation and Quality Improvement Authority to co-design a new regional procedure based on the concept of critical success factors. Central to this must be a focus on the involvement of patients and families in the review process.

Recommendation 2:

Health and Social Care organisations should be required to evidence they are achieving these critical success factors to the Department of Health.

Critical success factors

Appendix D provides an example of the critical success factors the Department of Health may wish to use to commence the work of redesigning the region's approach to learning from SAIs.

An example of a critical success factor and its core objectives:

- Families and patients are supported as active partners in the review process as much as they wish to be involved, including the involvement of an appointed advocate.
- Patients/families experience a compassionate and empathetic approach, which includes the method and frequency of contact throughout the review process.
- The voice of the patient and family is heard, their testimony is captured and they have the same status as any professional contributing information to the review process.
- The patient and family have a named source of support outside of the review panel. The role of this individual is clearly defined, including their authority to act in the best interest of the family.
- Questions asked by the patient and family are responded to fully, with honesty and integrity.
- The patient and family are encouraged to contribute to and influence the terms of reference for incidents identified as requiring in-depth.
- Patients/families are taken through the interim findings of the review and they are provided with enough time to enable them to read, comment on and influence the content of the final report.

How individual HSC organisations deliver these objectives is for them to determine. However, what must be required from all HSC organisations is evidence of achievement and an equal opportunity to be involved. This must be validated by patients and families who have experienced unexpected healthcare harm of a nature that warrants a dedicated review.

The Expert Review Team recommends that a co-production model, involving frontline staff, patients and their families, be adopted regionally to shape any way forward.

Implementing this recommendation will achieve:

Meaningful involvement of patients and families as partners in the SAI review process. This should incorporate a restorative process delivered within a culture of learning and improvement. The incident of harm and its resulting impact is one which the patient and their family must manage and live with. Therefore, it is essential that the patient and their family are at the centre of the review process if their trust in the Health and Social Care service concerned is to be retained.

This recommendation should address the risk of:

Further loss of public confidence in the systems of learning from healthcare harm and, importantly, risk of unnecessary harm to patients/families.

Recommendation 3:

The Department of Health should implement an evidence-based approach for determining which adverse events require a structured, in-depth review. This should clearly outline that the level of SAI review is determined by significance of the incident and the level of potential deficit in care.

What is required:

RQIA has found throughout its inspection and review work, widespread practice, where adverse outcome for the patient often drives the requirement for a Level 2 or Level 3 review. This practice must change. Not all unexpected harm, irreversible harm, and unexpected deaths are attributed to mistakes in the care or treatment provided.

Clear guidance is necessary which includes the implementation of a system of early, structured case assessment, taking place within one to two weeks of the incident occurring. This will deliver a greater degree of clarity regarding the degree of variance from expected care and treatment standards, and, on this basis, a proportionate decision can be made regarding the subsequent level of review required.

The Expert Review Team suggests:

- In all cases where there is concern that an identified variance may have contributed to the outcome for the patient, an in-depth examination of those variances is required.
- Where a serious breach in the expected standards of safe care is identified, an in-depth examination is warranted – even if the variance itself is not considered to have contributed to the patient’s outcome.
- Where the incident represents issues known to have been previously examined individually, that consideration is given to conducting a structured, in-depth, whole system review rather than repeating another individual incident review which, by its nature, is unlikely to include systems-based learning and improvement.

In all the above suggestions, it is expected that there will be involvement and engagement with the harmed patient and their family.

Other considerations that should be incorporated into a decision-making process:

- It should be considered whether a further Level 2 or Level 3 review will achieve more learning than has already been achieved by a previous review.
- It should be considered whether a safety improvement plan, regarding issues relevant to this SAI, is already underway. If yes, then the value of an individual incident review should be determined. Consideration must be given to incorporating this case into the pre-existing safety improvement project.

Implementing this recommendation will achieve an approach that:

- Is proportionate.
- Makes appropriate use of public funds.
- Allows review panels to focus in-depth reviews on those cases where there is the greatest opportunity for learning and improvement.
- Enables the relevant clinical teams and service managers to retain ownership of incidents that do not reach the threshold for a level 2 or 3 review. This ensures recognition of the skill, competence and integrity of staff that are entrusted with the delivery of safe patient care.

In summation, this recommendation should address the risk of perpetuating a situation where the volume of level 2 reviews required exceeds the capacity and capability to deliver to a credible standard. The resulting proportionality will also support measurable improvements in safety and quality. This will also serve to address the risk of prolonging the dissatisfaction with the process that has been expressed by patients, their families, and frontline staff.

Recommendation 4:

The Department of Health should ensure the new Regional procedure and its system of implementation is underpinned by 'just culture' principles and a clear evidence-based framework that delivers measurable and sustainable improvements.

Recommendation 5:

The Department of Health should develop and implement a regional training curriculum and certification process for those participating in and leading SAI reviews.

What is required:

There are several issues that must be addressed if the overall standard of how serious incidents are reviewed and learnt from is to improve. These include:

- A regional framework that makes clear the key factors for success⁴, against which each Trust/DoH (SPPG) is performance managed.
- A regional approach that delivers international good practice in the science of review. The development of a standard operating procedure that focuses on the practice of investigating rather than performance targets would support this.
- A process that embraces a just and fair culture where staff are supported through a constructive learning process and not scapegoated should deficiencies in systems or processes be found.
- A quality assurance system that makes explicit the accountability of senior managers within each Trust/DoH (SPPG) organisation, alongside a mechanism for holding them to account for SAIs signed-off as acceptable.
- A regional training curriculum, competency framework, certification or accreditation process and mentorship programme.
- Investigators of SAIs must demonstrate that they have the competencies to do so and have completed a programme of training in line with regional curriculum requirements.
- Educators/trainers and mentors must demonstrate that they have the right knowledge and competencies. Furthermore, they must complete an assessment process in order to be included on a region-wide approved provider register. Only providers on this register can provide review training to Trusts/DoH (SPPG).
- A fair and reasonable amount of time to conduct a credible review must be provided. This must include time to engage and involve the family/patient in an empathetic, meaningful and respectful way.
- A single new report template and regional style guide must be designed. This must facilitate a consistent approach to report formulation and presentation, with enough flexibility to allow a report writer to adapt it to meet the needs of the review conducted.

⁴ That is the critical success factors and the core objectives for each success factor are agreed, and adopted by all Trusts and HSCB.

A new approach must achieve:

- Greater flexibility in approach, that focuses on the opportunity for learning and safety improvement.
- A lower number of in-depth RCA reviews. However, where early assessment indicates that this depth of review is necessary, there must then be the capability and capacity in the system to do this well.

Implementing this recommendation will achieve:

An approach to learning from harm that HSC staff and the public can have confidence in, in terms of:

- Learning lessons.
- Measurable safety improvement.
- Transparency.
- Alignment with the core principles and hallmarks of a robust review process.
- Restoration and reconciliation.

This recommendation should address the risk of:

A system of learning that is overwhelmed by too many reviews, few of which lead to measurable improvements in safety or learning of any significance. This will enable the HSC Trusts to develop a flexible and innovative approach to learning from harm; one which engages the patient and their family in the process and mitigates the risk of perpetual mistrust.

There is no single activity that will achieve the above recommendations. There must be a comprehensive recalibration of the approach to the requirement for, and delivery of, SAI reviews across the region.

Appendix A: SAIs by Category and by HSC Organisation

	SAI Level	Belfast Trust	Northern Trust	South Eastern Trust	Southern Trust	Western Trust	NIAS	Primary Care	Total
Maternity related	Level 1	2	5	3	0	4	0	0	14
	Level 2	0	0	1	1	0	0	0	2
Sepsis	Level 1	1	0	2	0	0	0	0	3
	Level 2	0	0	0	1	0	0	0	1
Choking	Level 1	0	0	1	0	0	0	0	1
	Level 2		1	0	0	0	0	0	1
Never Event	Level 1	1	0	3	0	1	0	0	5
Reference to Private Hospital/Nursing Home	Level 1	1	1	0	0	1	1	0	4
Person with a learning disability who died from a treatable condition	Level 1	0	0	0	0	0	0	0	0
Primary Care	Level 1	0	0	0	0	0	0	4	4
Reference to a person with a learning disability in Residential Care	Level 2	0	0	0	1	0	0	0	1
Other Level 1 SAIs	Level 1	0	0	1	0	0	3	0	4
Other Level 2 SAIs	Level 2	5	3	2	11	4	0	0	25
Other Level 3 SAIs	Level 3	1	0	0	0	0	0	0	1
Total SAIs reports to be assessed		11	10	13	14	10	4	4	66

Source: Information provided by HSCB and HSC Trusts. Categories suggested by DoH

Appendix B: Other Organisations that were offered the Opportunity to Input Into this Review

Organisation
Medicines & Healthcare products Regulatory Agency (MHRA)
Northern Ireland Adverse Incident Centre (NIAIC)
Health and Safety Executive Northern Ireland (HSENI)
Police Service for Northern Ireland (PSNI)
Safeguarding Board for Northern Ireland (SBNI)
Northern Ireland Adult Safeguarding Partnership (NIASP)
Information Commissioner Office (ICO)
British Medical Association (BMA)
General Medical Council (GMC)
General Dental Council (GDC)
Northern Ireland Medical and Dental Training Agency (NIMDTA)
Pharmaceutical Society Northern Ireland (PSNI)
Northern Ireland Social Care Council (NISCC)
Royal College of Nursing (RCN)
Nursing and Midwifery Council (NMC)
Health Care Professional Council (HCPC)
Northern Local Medical Committee (NLMC)
Eastern Local Medical Committee (ELMC)
Southern Local Medical Committee (SLMC)
Western Local Medical Committee (WLMC)
UNISON
Unite the Union
Northern Ireland Public Sector Alliance (NIPSA)

Appendix C: Improvements Suggested by Staff

During the engagement process, staff were asked to share any suggestions they felt would improve the SAI review process or patient and family engagement. Staff suggestions were used to formulate the following suggested improvements.

Suggested improvements to the SAI process

Classification of incidents

- The identification of incidents requiring an in-depth review must be driven by a structured assessment, which identifies:
 - a significant learning opportunity
 - the presence of significant care lapses, or care concerns
 - the depth and range of family questions

Eliminating the determination for an in-depth review based on incident type and/or patient outcome alone can minimise the number of reviews with little impact on improving safety.

- Incidents involving suicide should not automatically be classified within the SAI process.

Timescales for Conducting SAI reviews

- Overwhelmingly, HSC staff consider that the timescales for conducting SAI reviews need to allow greater flexibility and take account of the complexity and the needs of the patient and family.
- A structured timescale approach that outlines the importance of capturing factual accounts and situational context within the first 48 hours post-incident, and early capture of information from families followed by a realistic period to allow an initial assessment of the information before determining what subsequent review is required, along with its depth and approach.

Terms of Reference

- The terms of reference for SAI reviews should be specific to the incident and referred to as key lines of enquiry to reflect a more learning-based approach.
- Terms of reference must include patient and family questions, where the patient and family have questions.
- The practice of pre-determined terms of reference that are used for all SAIs should desist as it provides no meaningful structure for the review process.

Staff Involvement

- Staff said that to achieve a 'just culture' and optimal learning they needed to be more involved in the process, specifically:
 - Their team leaders need to be involved in decisions over what to review, at what depth, and why

- Involved staff need an early invitation to capture a full account of what had happened and the situational context of the day, shift, or relevant period
- There needs to be a shift away from only reviewing documents to engaging involved staff in conversation about what had happened
- More group learning approaches could be utilised, such as after-action review
- Providing feedback on a high quality draft of the review report, that their comments are listened to and taken account of by the review panel
- In formulating recommendations
- In contributing to the design of action plans
- In participating in a post review learning event.

Communication with Staff

- Staff involved in an incident should receive notification that an SAI has been requested and be provided with a copy of the agreed terms of reference or key lines of enquiry, as well as information about who is conducting the review.
- Staff involved in an SAI ought to expect their team leader to receive update reports regarding the progress of the review so that the whole team is informed about this.
- Several staff thought a website or shared area should be established to keep those staff involved in an incident up to date on the progress of the SAI review while maintaining confidentiality.

SAI Review

- Currently, the SAI process is perceived as a negative review that does not support a 'just culture'. It must be mandated that the aspects of care that met or exceeded care standards, as well as those aspects that could have been improved, are reported on. This includes interventions that may have mitigated the impact of the incident.

SAI Review Panel

- Where it is identified that there were, or may have been significant care lapses, staff considered a dedicated SAI review panel from outside the Trust was required. This includes the lead reviewer and the subject advisors/field experts. Staff considered that such a team needed to be appointed by an external agency such as the HSCB/PHA.
- There should be a set of competencies, skills and knowledge required of the chair of an SAI review panel/lead reviewer, and the subject advisors/field experts asked to work with this individual.

Independence

Staff recognised that achieving complete independence was not feasible. However, they considered that:

- The lead reviewer/chair should not come from the service involved in the incident.
- Mentorship should be available for lead reviewers/chairs to support them in maintaining objectivity and impartiality.
- Ideally, a non-clinician with the right investigatory skills and competencies should chair the SAI review panels.
- A lay person or trained family advocate should be included in the SAI review panels. This would support meeting family needs and writing a report that is understandable by a non-technician.
- Optimal use of interventions such as web-conferencing and remote web-based interviews could be utilised to support involvement of independent technicians without the excessive cost often associated with this.

Staff Support

- Staff involved in an incident must be given protected time to prepare and attend interviews or meetings during the SAI review.
- Staff involved in an incident must be given the opportunity for pastoral/psychological support to deal with traumatic incidents.
- A rapid team debrief post incident must become normal practice.
- All SAI teams must include an administrator to support its smooth delivery and to ensure that the time of frontline, professionally qualified staff is used appropriately.
- Corporate teams responsible for patient safety must have the necessary competencies required to provide support and mentorship to SAI leads/chairs.
- Staff asked to lead SAIs must have received a minimum of two days training, plus mentorship and coaching support so that they can lead the process competently.
- Staff required to conduct the initial reviews of incidents before a decision is made to progress to SAIs need to know how to conduct a structured review, and what information is required to do this competently.

Advocacy

- Northern Ireland needs to engage with patient advocacy organisations to develop a system where lay people can become accredited advocates for families following patient safety incidents.
- Publicly funded independent advocacy should be available for patients/families that require this and where there are concerns about the adequacy of care and/or treatment offered.

Recommendations

- Staff need protected time to participate/lead in Quality Improvement Action plans emerging from SAI reviews.
- Multidisciplinary staff should be brought together to help develop outcome-focused recommendations. This should not be the sole domain of the SAI review panel.

- Recommendations from SAI reviews should be benchmarked against core criteria, and the teams and services involved in the incident must be invited to comment on the appropriateness of the recommendations made.
- When contemplating whether a recommendation is or is not accepted and how it is treated, due consideration must be given to pre-existing safety and quality improvement projects already underway or planned.
- Recommendations from SAI reviews need to be outcome-focused and drive action plans that deliver measurable and sustainable improvements in the quality and safety of care.

Learning

- There must be more formal processes for disseminating learning from SAI reviews. The Oxford Model developed in the 1990's and successfully utilised by Mersey Care NHS Trust is an example of this.
- Each Trust must be required to demonstrate not only what it has learnt but how it has improved. This will drive disseminated learning.
- RQIA and other regional bodies must show how the learning within individual Trusts is captured and used for learning across Northern Ireland.

SAI Review Reports

- Feedback from all key staff involved should be considered in the finalisation of an SAI review report. This assures factual accuracy and greater engagement by frontline professionals.
- A meeting with all staff associated with the incident, and who provided information to the SAI review panel, should be conducted to enable findings, conclusions and recommendations to be discussed and agreed.
- The SAI review report template should be revised to include a section that allows greater articulation of patient and family engagement.

Action Plans

- How action plans are developed must be in line with good practice, rather than copying and pasting recommendations into an action plan template. This does not deliver sustainable or measurable change.

General

- The practice of retrospective recordkeeping in the 72 hours post incident needs to be enabled. Where this is not possible for whatever reason, accounts of involvement must be collected.
- SAI reviews should focus less on assigning blame and scapegoating, and instead embrace the principles of a 'just culture' and justifiable accountability.
- The SAI process should be reviewed to examine how best to review future incidents in a more proportionate way.

Suggested improvements for patient and family engagement

Information for Patients/Families

- Patients/families should be better informed of the SAI review process. For example, there could be better quality information leaflets available, or a video or podcast explaining the process on the DoH or RQIA's website.
- The SAI process must be explained to patients/families before the process commences so they can have realistic expectations.

Communication with Patients/Families

- There must be clear standards of how a patient and family should be communicated with during the SAI process, with patients/families asked for formal feedback at the end of the process via a questionnaire or online survey tool. This should also accommodate requests for anonymity.
- The terms of reference/key lines of enquiry must be shared with patients/families prior to an SAI review commencing, and these must include the patient and family questions alongside technical clinical/process-based questions.

Patient and Family Engagement

- Trusts must demonstrate their commitment to the SAI process and to the patients/families affected by SAIs by ensuring senior management are actively involved in communications with families. This is particularly important at the start and end of the process.
- Staff must receive training from experienced advocates and families who have experienced the SAI review process so they know how to achieve and maintain positive engagement with a family.

Appendix D: Examples of Critical Success Factors

The factors listed below are examples of critical success factors (CSF), previously developed by an HSC organisation in the UK and provided to this review by Maria Dineen, member of the Expert Review Team. This list is not intended to serve as a definitive list; rather, its purpose is to provide an initial starting point for a wider conversation about what the critical success factors could look like in Northern Ireland.

Critical Success Factor 1:

We consistently value and engage meaningfully with patients and their families through the entire review (including complaints) process.

The core objectives for this CSF are proposed as:

- Patients/families experience a compassionate and empathetic approach.
- The voice of the patient and family is heard.
- The patient and family are well informed throughout the process.
- Questions asked are responded to with honesty and integrity.
- Patients/families are provided with the opportunity to contribute to and /or influence the terms of reference for incidents identified as requiring in-depth review.
- Patients/families are taken through the draft review report, and provided enough time to enable them to read, comment on and influence the content of the final report.

Critical Success Factor 2:

We consistently value and engage meaningfully with staff throughout the entire review (including complaints) process

The core objectives for this CSF are proposed as:

- Staff experiences a compassionate and empathetic approach.
- The voice of the staff involved in an incident is heard. This includes their experience of 'the day', and the 'context' in which the incident occurred.
- Staff involved are well informed throughout the review process.
- Staff are treated fairly and equitably, in line with NHS Improvements Just Culture Guidance.
- Staff involved in the incident, and other key staff informants to the review, are facilitated in reading the draft report and providing feedback on it relating to factual accuracy, tone and style.
- Staff involved in the incident and service(s) in which the incident occurred are actively engaged in designing the action plan to deliver measurable and meaningful improvement.

Critical Success Factor 3:

We will consistently show that measurable improvements in standards, safety and quality occurs, is sustained, and known about by staff.

The core objectives for this CSF are proposed as:

- There is a corporate action planning/lessons learnt group that acts as a repository for those issues identified in one division, but which have wider implications for other services / divisions within the Trust. A central approach will ensure these issues are assessed and addressed corporately.
- Within each division the safety governance group, lessons learnt and recommendations arising from reviews are a standing agenda item.
- Recommendations are targeted towards i) the local team ii) the local service/division and iii) corporate wide. Further they are mostly addressing systems improvement and not individual practice.
- There is an action planning method/approach that facilitates engagement of staff involved in service delivery and sets out clearly the range of activities required to deliver the intent of the recommendation.
- All action plans include how success is to be measured and at what frequency to assure sustainability.
- Recommendations are formulated to make clear their intent (i.e. what needs to be achieved if they are accepted and implemented).
- Staff are aware of the improvements implemented in their service and division as a consequence of reviews conducted, and more widely across the organisation.

Critical Success Factor 4:

Incidents will be reviewed proportionately i.e.: right level, right depth, and right breadth of review according to the volume and magnitude of errors (if any).

The core objectives for this CSF are proposed as:

- The Trust has an achievable and defined method/process through which harming incidents that meet the threshold for Duty of Candour (i.e. moderate harm and above) are assessed to determine the depth of review required and with what degree of independence.
- The Trust has a clear categorisation system for incidents that meet the threshold for Duty of Candour (and above) so that there is clarity between those that occurred despite good care, and those that were caused by mistakes in care delivery. (E.g. Category A means care and treatment was appropriate, and category D means there were several lapses in care and treatment that may have contributed to the outcome).
- The Trust assigns the review of cases where there may have been a contribution to the harm because of mistake to a case reviewer who has the right competencies to lead and deliver a more complex review.

- Terms of reference for reviews are bespoke and make clear the relevant technical questions that must be asked and answered, alongside any family questions that have been posed.
- The Trust has a review framework, and approach, that allows a range of methods and tools to be employed to meet the discrete requirements of each review.
- The Trust has in place a process to enable early preservation of information including memory capture, so that the assessment of incidents and any subsequent review is well informed and can be explored to the right depth and breadth.

Critical Success Factor 5:

Reviews are conducted using appropriate methods and tools, and in line with good project management principles, assuring delivery within an agreed and realistic timescale.

The core objectives for this CSF are proposed as:

- The Trust will have enough staff trained to undertake the case screening element of the review journey within 10 working days of incident occurrence.
- The Trust will have enough staff trained to a higher level of knowledge and competency to delivery those reviews that are categorised C or D (i.e. care/management a bit 'hit or miss' or serious lapses are identified).
- The Trust will commit to a stepped review process including clear boundaries for the review arising from carefully formulated terms of reference that make clear the necessary technical questions as well as including family questions.
- Staff asked to act in a case screening or lead reviewer/case reviewer capacity will have the necessary adjustments made to their pre-existing diary commitments so that they have a fair amount of dedicated time to deliver the review project.
- Specialist advisors will be allocated to the appointed case reviewer in a timely manner so that avoidable delays do not occur.
- The Trust will ensure for all category C and D reviews that there is reasonable administrative support provided to the case investigator so that working practices are as efficient as possible. (Category C and D - i.e. care/management a bit 'hit or miss' or serious lapses are identified).

Critical Success Factor 6:

Review reports are consistently produced and meet the following standards:

- Well written.
- Understandable by a non-technician.
- Reasoned (i.e. evidence and not opinion orientated).
- Clear findings, conclusions and recommendations.
- Answer all family questions where it is possible to do so.
- Accessible.
- Validated.

The core objectives for this CSF are proposed as:

- The Trust has a practical approach to proof reading reports that includes insights from:
 - a technical advisor
 - a lay person
 - someone who has good grammar, and spelling
 - someone who is good at formatting documents, using 'smart report' technology.

- The Trust has a well-designed report template that includes:
 - acknowledgements
 - contents list
 - an executive summary
 - introduction (case over view and context of care, as well as outcome and reasons for the review)
 - a family section
 - a findings section (what was delivered to a reasonable standard, what could have been improved, any significant or serious lapses in care standards.)
 - what has changed / improved since the incident
 - what additional lessons learnt arose from this review
 - conclusions
 - recommendations
 - appendices

- Both the patient / family and the staff involved are provided with the opportunity to read and comment on the report when in good draft format. Their comments are listened to and incorporated into the final report document as far as it is possible to do so. Where it is not, they are advised of this and why not.
- Review reports are written empathetically and compassionately.
- Review reports are written in plain language so they understandable by all readers.
- Staff required to write review reports have a mentor who can support the development of their writing and presentation skills.

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