Urology Services Inquiry

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Mr Peter May
Department of Health C5
Castle Buildings
Stormont Estate
Belfast
BT4 3SL

5th October 2022

Dear Mr May,

The Inquiry has been provided with a copy of the "RQIA Review of the Urology Structured Case Record Review Southern Health and Social Care Trust" dated September 2022, commissioned by the SHSCT in March 2022.

I am concerned that recommendation 13 of that report is formulated in the following terms:

"*That the Department of Health should commission the RQIA to undertake a review of Governance arrangements within Urology Services in the SHSCT*."

If the Department were to accede to this recommendation so as to commission the RQIA to undertake this task, it seems to me to that it would encroach upon on the work of the Inquiry. This view is supported by my reading of the text in the second half of page 24 of the report before recommendation 13 is described.

The Inquiry has recently received a statement from Dr O'Kane wherein she states:

"8.17 In a letter to the Trust in July 2022, Mr Peter May, Permanent Secretary DoH, has asked RQIA to undertake a Quality Assurance of Governance Processes in Urology in the Southern HSC Trust."

She attaches a letter of 7th July (a copy of which was stated to be attached to a letter from Minister Swann to me on the same date, although on checking I now realise it was not attached) wherein you stated:

"*We have concluded that the matters raised relating to "Urology Clinician Assurance" and the "Investigation into accurate information provided to patients by SHSCT" should be subject to an independent review. I can therefore advise that the Department will be commissioning the RQIA to undertake an urgent review of the SHSCT Urology Services and Lookback Review. The Terms of Reference for this review will be shared with you in due course."*

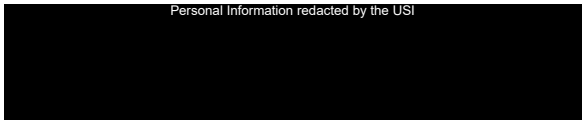
I was told of this determination by Minister Swann in his letter to me and understood it to mean that any review by RQIA related to the issues I raised in my letter to Minister of 16th May 2022.

Are you in a position to share with the Inquiry the Terms of Reference for RQIA? Can you also confirm that the Department does not intend to accept recommendation 13 of the RQIA report?

In fulfillment of its Terms of Reference the Urology Services Inquiry is clearly looking at systems of governance within the Trust and when we conclude our work we will report to the Minister making recommendations regarding those governance arrangements. It seems to me that to ask another body to carry out a similar task would clearly risk undermining our work.

I look forward to hearing from you in clarification of each of these issues.

Yours sincerely



Christine A Smith KC
Chair of the Urology Services Inquiry

From the Permanent Secretary and HSC Chief Executive

Department of Health
An Roinn Sláinte
Männystrie O Poustie
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CHRISTINE A SMITH KC
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Our ref: SCORR-0211-2022
PM-264

Date: 9 November 2022

Dear Christine

Thank you for your letter, dated 6 October 2022.

I would firstly like to acknowledge your concern that the RQIA Review relating to the SHSCT Urology and Lookback Review may encroach on the work of the USI. I would like to reassure you that the Department intends that the RQIA Review should not encroach on the work of the Inquiry.

I can confirm that the decision to commission the RQIA to undertake a review was in response to the issues you raised in your letter to Minister Swann of 16 May 2022. Our priority is to ensure that any issues that may potentially impact patient safety are explored at pace to ensure appropriate remedial measures can be effected if deemed necessary.

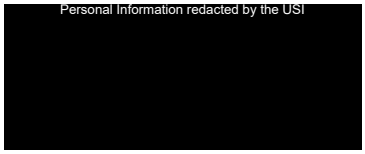
I can advise you that the Terms of Reference for the RQIA Review have now been finalised between the Department and the RQIA, and are attached for your information. I hope that you will accept that this has been an appropriate response by the Department, following the concerns raised by the Inquiry and that this now provides you with the required clarity and reassurance regarding this work. The Department will also be happy to share the outcome of the RQIA Review with the Inquiry on completion.

The RQIA Review is scheduled to commence by the end of November 2022. If you have any further or continuing concerns regarding the RQIA Urology Review and the work of the Inquiry, I would be happy to arrange a meeting with you and the Inquiry Team, if you feel that would be beneficial.

I would like to thank you for raising your concern with me and I hope you find this response helpful.

I hope you find this response helpful.

Yours sincerely



Peter May

Annex C

RQIA REVIEW OF SOUTHERN HSC TRUST UROLOGY SERVICES AND LOOKBACK REVIEW

Terms of Reference

The Terms of Reference for this RQIA Review have been developed within the context of the patient safety concerns raised by the Urology Services Inquiry (USI), and to ensure that the concerns for patient safety are addressed in an appropriate and timely manner, whilst ensuring the Review does not infringe on the work of the USI.

1. **Undertake an assessment of the current Southern Health and Social Care Trust Urology Lookback Review process, to include arrangements for its delivery and oversight.**

   To include:

   - Progress on the implementation of the recommendations made by the Southern Health and Social Care Trust's earlier investigation relating to the Urology Lookback Review and assess the robustness of the current Lookback Review.
   - Identify learning which can be applied to any further extension to the current Lookback Review.
   - Assess the extent to which Southern Health and Social Care Trust members of the Urology Assurance Group (UAG) have fulfilled requirements set out within the UAG Terms of Reference.

2. **Assess the effectiveness of current arrangements to assure the delivery of safe care within Urology Services in the Southern Health and Social Care Trust.**

   To include:

   - An assessment of the arrangements to monitor the delivery of care against all relevant standards.

3. **To seek the views and experiences of patients in relation to the care received from Urology Services in the Southern Health and Social Care Trust, in so far as they relate to 1 and 2.**

4. **To provide a report on the findings and, where relevant, make recommendations to the Department of Health.**

5. **To escalate any emerging concerns identified during the course of the Review to the Department of Health and to notify the Southern Health and Social Care Trust on any emerging patient safety concerns.**

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Personal Information redacted by the USI

9 November 2022

By email only to: Personal Information redacted by the USI

For the attention of Christine Smith QC
Chair of Urology Services Inquiry

Dear Chair,

RE: Section 21 Notice 50 of 2022 follow up on the production of documents referred to in the statement.

The Permanent Secretary of the Department of Health, Peter May, in response to Section 21 Notice, Schedule 50 of 2022 submitted his witness statement on 18 August 2022. Within his statement he gave a commitment to provide the Inquiry with certain documentation when available. This material is now available.

The relevant paragraphs within the statement are set out below, accompanied by an overview of the associated documents now made available to the Inquiry:

Paragraph 116

In relation to paragraph 116, the following documents are now available and will be uploaded to the Inquiry server by Naomi Roberts today:

1. IHRD Implementation Programme Update – Departmental Statement October 2022. Published 28 October 2022.

This has been downloaded from the following website: https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-ihrd-imple-prog-update-statement-oct-2022.PDF and has been sent to the Inquiry.

2. IHRD Recommendations Phase 1 and 2. Published 28 October 2022

This has been downloaded from the following website: https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-ihrd-recommendations-phase-1-2.PDF and has been sent to the Inquiry.

3. IHRD Co-Production Report 2022. Published 28 October 2022

This has been downloaded from the following website: https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-ihrd-co-production-report-2022.PDF and has been provided to the Inquiry.

4. IHRD briefing note to Urology Services Inquiry. Dated 2 November 2022.

This is in relation to the Department's continuing work to implement the recommendations arising from the Inquiry into Hyponatraemia-related Deaths (IHRD). [WIT-42402]

Paragraph 131

The following document is now available to the Inquiry:

5. RQIA Review of the Systems and Processes for Learning from Serious Adverse Incidents in Northern Ireland. Dated June 2022.

This has been downloaded from the following website: https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-rqia-review-systems-processes.pdf and has been sent to the Inquiry.

This is in relation to the RQIA review of serious adverse incidents in Northern Ireland intended to deliver a new regional policy for reporting, investigating, and learning from adverse events. [WIT-42407]

Paragraph 110

In relation to paragraph 110, the Department are providing a copy of the submission to the then Health Minister on 21 October 2022 providing options for a review of the Maintaining High Professional Standards policy. [WIT-42400]

On this basis, the following document is now available to the Inquiry:

6. Sub-xxxx-2022_Review of Maintaining High Professional Standards (MHPS). Dated 21 October 2022

Separately, the Department instruct that they would welcome clarification on the approach to disclosure of minutes of the Urology Assurance Group meetings post 23 May 2022. We would appreciate guidance on your preferred approach to the provision of such to the Inquiry.

Many thanks

Sarah Wilson

Principal Legal Officer, DOH Inquiries Team

Departmental Solicitor's Office

WEBSITE STATEMENT

Update from the Department of Health on the implementation of the report of the Inquiry into Hyponatraemia-related Deaths

The Department of Health is today providing a detailed update on the progress made to date to implement the report of the Inquiry into Hyponatraemia-related deaths ("the IHRD Report").

The report was published on 31 January 2018. Mr Justice O'Hara, the Chair of the Inquiry, concluded that the culture of the health service, the arrangements in place to ensure the quality of services, and the behaviour of certain individuals within the health service at the time were not acceptable.

We must never forget Adam Strain, Claire Roberts, Lucy Crawford, Raychel Ferguson and Conor Mitchell. Over four years after the publication of the IHRD Report, the details in relation to each of the cases make for distressing reading. We pay tribute to the courage of their families, and we must honour their suffering by ensuring we continue to work on and implement the recommendations arising from the IHRD report.

In his report Mr Justice O'Hara acknowledged that progress had been made in the guidance and practice of hyponatraemia management, but that a more comprehensive approach for learning from error was needed for further unnecessary harm to be avoided. He set out 96 recommendations across ten themes where he had identified failings in competency in fluid management, honesty in reporting,

professionalism in investigation, focus on leadership and respect for parental involvement.

In response to this report, the Department initiated a comprehensive IHRD implementation programme. The 96 recommendations were broken down into 120 actions, and nine Workstreams were established to take this work forward. From the outset, the Department has been committed to using a co-production approach to ensure that the input of all stakeholders, especially service users and carers, has been central to the decision-making processes. Whilst full implementation of the 96 recommendations is by no means complete, significant progress has been made in many areas over the past four years.

Mr Justice O'Hara's primary recommendations were that a statutory duty of candour should be introduced for healthcare organisations and everyone working for them, so that they are open and honest in all their dealings with patients and the public, and that there should be supports and protections in place to ensure this happens. As a reflection of the seriousness of this, Mr Justice O'Hara also recommended that criminal sanctions should apply to organisations and individuals for serious and intentional breach of these duties.

After considering all the evidence, including the findings of a 20-week public consultation that yielded 334 responses, the Duty of Candour Workstream provided its assessment earlier this year.

As a first step, and in order to understand the barriers to an open and candid culture, officials are developing the policy for a "Being Open Framework" for the health and

social care system. Initial work on the "Being Open Framework" will initially focus on an exploratory exercise in a Trust to establish an understanding of the:

- perceptions of openness;
- barriers to openness;
- levers of power in relation to openness;
- enablers of openness.

This work will include engagement with relevant stakeholders to develop guidance and proposals for the design and rollout of Being Open training across the HSC.

Officials are also carrying out further study on how a duty of candour might work in practice, including additional analysis of the impact of such a duty on the health and care service, both legally, and in workforce terms.

Officials will also engage with counterparts across the UK on duty of candour developments. Earlier this month, the Kirkup Review – *Reading the Signals* – was published. It examined maternity and neonatal services in two hospitals in East Kent between 2009 and 2020. That review "found a clear pattern. Over that period, those responsible for the services too often provided clinical care that was suboptimal and led to significant harm, failed to listen to the families involved, and acted in ways which made the experience of families unacceptably and distressingly poor." It made a recommendation that "the Government reconsider bringing forward a bill placing a duty on public bodies not to deny, deflect and conceal information from families and other bodies." Candour and openness are live issues and the Department of Health

will share its experience and learn from others to put the best possible system in place in Northern Ireland.

All work by the Department of Health in Northern Ireland on candour and openness will focus on patient safety and an ongoing commitment to ensuring that individuals and organisations are provided with the support they need to fulfil their responsibilities.

The Department is committed to this cultural change, but recognises that it will not happen overnight. The Being Open Framework will allow organisations to put in place the support and systems required to ensure that individuals will be fully empowered to exercise their individual duty of candour.

Agreeing on a Being Open Framework and implementing its principles will ensure that the public can have confidence that individuals within the health service will have the support and protection of their organisations and legislation to be open and candid in all that they do.

Another significant recommendation from the IHRD Report is the introduction of an Independent Medical Examiner office to scrutinise those hospital deaths not referred to the Coroner.

A non-statutory prototype Independent Medical Examiner service is now operating across all five Health and Social Care Trusts. This means that when a doctor completes a Medical Certificate of Cause of Death, an Independent Medical

Examiner reviews the certificate together with the patient's clinical record and has a discussion with the certifying doctor about the circumstances of the death.

This helps to ensure that deaths occurring in hospital are appropriately reported to the Coroner when there is a need to do so. It also assures the family that the death certificate is reasonable and accurate and that if any safety or governance issues are identified, these are brought to the attention of the relevant Trust in order that immediate action can be taken if this is required.

In the coming months, the prototype non-statutory Independent Medical Examiner office will consider the most appropriate way in which a statutory service might interact with bereaved families, and how such an IME system can include reviews of those deaths occurring in community settings which are usually certified by GPs.

The IME prototype will provide all the required information to inform the development of a statutory Independent Medical Examiner service for Northern Ireland.

The IHRD report also makes ten recommendations regarding Serious Adverse Incident (SAI) reviews, which take place when death or serious harm occurs. The report on the RQIA Review of the Systems and Processes for Learning from Serious Adverse Incidents was published on the 7th July 2022 and is available on the Department for Health Website (RQIA Review of Systems and processes | Department of Health). The report makes five recommendations and clearly highlights the need to co-design a new evidence-based, regional procedure, which

delivers an approach to learning from reviews where harm has occurred, and in which the HSC, and the public, can have confidence.

Work on both sets of recommendations and the excellent work already completed by the SAI Workstream will carry forward into a new work programme, which will be led by the Department's dedicated policy team on Serious Adverse Incidents.

Turning to the wider IHRD implementation programme, the Department can confirm that 63 of the 120 actions arising from the 96 recommendations in the IHRD report have been fully actioned. This reflects a huge amount of work by members of the various Workstreams established following the Report's publication, and the Department would like to take this opportunity to thank all of them for their invaluable input and effort. While this was a complex process, there is no doubt that the magnificent contribution of service users, carers and others has provided much added value to the quality and effectiveness of the outcomes. This is borne out by the findings of an independent report commissioned from Mr Peter McBride, the former Chair of the IHRD Being Open Workstream. His report acknowledges the considerable effort put into the co-production process within the overall IHRD Programme, the challenges the process faced and recommendations for future co-production exercises such as the one undertaken in this context.

Whilst there has been significant progress across many areas of the IHRD programme, the work has undoubtedly been impeded by the impact of Covid-19. As we hopefully emerge from the worst of the pandemic, there is renewed momentum.

There has also been ongoing progress on the 57 actions that remain outstanding from the IHRD report, but more work is required. These will be dealt with in what the Department is describing as Phase Two of the IHRD implementation programme. Phase Two of the programme will deal with

- the 20 actions, to be overseen by the IHRD Programme Team, where initial work has been completed by the Workstreams and Sub-groups, but where further work is now required to ensure appropriate implementation at service level. There has been much progress in identifying solutions, new procedures and issuing relevant guidance in the areas of Death Certification, Board Effectiveness, Clinical and Social Care Governance, Training and Workforce issues. This work will continue to ensure that HSC organisations continue to adhere to good practice and that there is a consistent approach across the region; and

- the 37 actions, where initial work has been completed, but where it is now appropriate to transfer responsibility for these recommendations from the IHRD implementation programme to the appropriate DoH policy area. Examples of these actions include those where detailed policy and scoping work is well under way but where primary legislation will be required to go through the Assembly, such as on the Duty of Candour, Serious Adverse Incidents and the Independent Medical Examiner service. Other examples are where there is a need to work on detailed policy, for example, the Being Open Framework.

A new Programme Management Structure, with the Department's Permanent Secretary as the Senior Responsible Owner, has been put in place to drive forward the work needed to complete implementation of all the recommendations.

Detail of the progress on each of the 120 actions is being published today on the Department's website, together with the report on co-production commissioned by the Department.

In concluding, the Department would like to take this opportunity to thank everyone involved in the programme to implement the recommendations set out in Mr Justice O'Hara's IHRD report; in particular, the service users and carers who gave freely of their time to make this work a success. Their continued support will be very welcome as we move into Phase Two of the IHRD Programme.

The improvements that have been and will be achieved will in no way assuage the grief of the families of the children who tragically died, or relieve the sense of injustice. However, it is the hope and intention of all in the Health and Social Care family that the service will be all the better when the recommendations arising from the report have been implemented.

IHRD Phase 1 Recommendations – ACTIONED

Workstream/ Sub-Group	Number	Recommendation
Duty of Quality Workstream	9	The highest priority should be accorded the development and improvement of leadership skills at every level of the health service including both executive and non-executive Board members
Paediatric Clinical Workstream	10	Health and Social Care ('HSC') Trusts should publish policy and procedure for ensuring that children and young people are cared for in age-appropriate hospital settings
Paediatric Clinical Workstream	11	There should be a protocol to specify the information accompanying a patient transfer from one hospital to another
Paediatric Clinical Workstream	12	Senior paediatric medical staff should hold overall patient responsibility in children's wards accommodating both medical and surgical patients **Revised Definition - "Paediatricians hold responsibility when children are admitted to paediatric medical wards. However, it recognised that this arrangement would not be in the best interests of the safest clinical care for the child where consultants from other specialties are responsible for the direct delivery of care and treatment to the child. In such cases adequate arrangements need to be put in place to ensure that senior paediatric advice is available, particularly in prescribing fluids for children and in managing the deteriorating patient"**
Paediatric Clinical Workstream	13	Foundation doctors should not be employed in children's wards **Revised Definition - "No Foundation Year 1 (F1) doctors (previously known as Junior House Officers JHO) are employed in Paediatric Wards. Foundation Year 2 (F2) doctors (previously known as Senior House Officers SHO) rotate through Paediatric units and sufficient supervision must be put in place to ensure safe practice in the care and treatment of children"**
Paediatric Clinical Workstream	14	The experience and competence of all clinicians caring for children in acute hospital settings should be assessed before employment
Paediatric Clinical Workstream	15	A consultant fixed with responsibility for a child patient upon an unscheduled admission should be informed promptly of that responsibility and kept informed of the patient's condition, to ensure senior clinical involvement and leadership
Paediatric Clinical Workstream	16	The names of both the consultant responsible and the accountable nurse should be prominently displayed at the bed in order that all can know who is in charge and responsible
Paediatric Clinical Workstream	17	Any change in clinical accountability should be recorded in the notes
Paediatric Clinical Workstream	18	The names of all on-call consultants should be prominently displayed in children's wards
Paediatric Clinical Workstream	19	To ensure continuity, all children's wards should have an identifiable senior lead nurse with authority to whom all other nurses report. The lead nurse should understand the care plan relating to each patient, be visible to both patients and staff and be available to discuss concerns with parents. Such leadership is necessary to reinforce nursing standards and to audit and enforce compliance. The post should be provided in addition to current staffing levels
Paediatric Clinical Workstream	20	Children's ward rounds should be led by a consultant and occur every morning and evening
Paediatric Clinical Workstream	21	The 'accountable' nurse should, insofar as is possible, attend at every interaction between a doctor and child patient
Paediatric Clinical Workstream	22	Clinicians should respect parental knowledge and expertise in relation to a child's care needs and incorporate the same into their care plans
Paediatric Clinical Workstream	23	The care plan should be available at the bed and the reasons for any change in treatment should be recorded
Paediatric Clinical Workstream	24	All blood test results should state clearly when the sample was taken, when the test was performed and when the results were communicated and in addition serum sodium results should be recorded on the Fluid Balance Chart

Paediatric Clinical Workstream	25	All instances of drug prescription and administration should be entered into the main clinical notes and paediatric pharmacists should monitor, query and, if necessary, correct prescriptions. In the event of correction the pharmacist should inform the prescribing clinician
Paediatric Clinical Workstream	26	Clinical notes should always record discussions between clinicians and parents relating to patient care and between clinicians at handover or in respect of a change in care
Paediatric Clinical Workstream	27	Electronic patient information systems should be developed to enable records of observation and intervention to become immediately accessible to all involved in care
Paediatric Clinical Workstream	28	Consideration should be given to recording and/or emailing information and advice provided for the purpose of obtaining informed consent
Paediatric Clinical Workstream	29	Record keeping should be subject to rigorous, routine and regular audit
Paediatric Clinical Workstream	30	Confidential on-line opportunities for reporting clinical concerns should be developed, implemented and reviewed
Clinical and Social Care Governance Sub-Grou p	40	Learning and trends identified in SAI investigations should inform programmes of clinical audit
Clinical and Social Care Governance Sub-Group	41	Trusts should publish the reports of all external investigations, subject to considerations of patient confidentiality
HSC Bereavement and Pathology Network Sub-Group	44	Authorisation for any limitation of a post-mortem examination should be signed by two doctors acting with the written and informed consent of the family
HSC Bereavement and Pathology Network Sub-Group	45	Check-list protocols should be developed to specify the documentation to be furnished to the pathologist conducting a hospital post-mortem
HSC Bereavement and Pathology Network Sub-Group	46	Where possible, treating clinicians should attend for clinico-pathological discussions at the time of post-mortem examination and thereafter upon request
HSC Bereavement and Pathology Network Sub-Group	47(i)	In providing post-mortem reports pathologists should be under a duty to: Satisfy themselves, insofar as is practicable, as to the accuracy and completeness of the information briefed them
HSC Bereavement and Pathology Network Sub-Group	47(ii)	In providing post-mortem reports pathologists should be under a duty to: Work in liaison with the clinicians involved
HSC Bereavement and Pathology Network Sub-Group	47(iii)	In providing post-mortem reports pathologists should be under a duty to: Provide preliminary and final reports with expedition
HSC Bereavement and Pathology Network Sub-Group	47(iv)	In providing post-mortem reports pathologists should be under a duty to: Sign the post-mortem report
HSC Bereavement and Pathology Network Sub-Group	47(v)	In providing post-mortem reports pathologists should be under a duty to: Forward a copy of the post-mortem report to the family GP
HSC Bereavement and Pathology	54	Professional bereavement counselling for families should be made available and should fully co-ordinate bereavement information, follow-up service and facilitated access to family support groups

Network Sub-Group		
ALB Board Effectiveness Sub-Group	55	Trust Chairs and Non-Executive Board Members should be trained to scrutinise the performance of Executive Directors particularly in relation to patient safety objectives.
ALB Board Effectiveness Sub-Group	56	All Trust Board Members should receive induction training in their statutory duties
Education and Training Workstream	57	Specific clinical training should always accompany the implementation of important clinical guidelines
Education and Training Workstream	58	HSC Trusts should ensure that all nurses caring for children have facilitated access to e-learning on paediatric fluid management and Hyponatraemia
HSC Bereavement and Pathology Network Sub-Group	59	There should be training in the completion of the post-mortem examination request form
HSC Bereavement and Pathology Network Sub-Group	60	There should be training in the communication of appropriate information and documentation to the Coroner's office
Education and Training Workstream	61	Clinicians caring for children should be trained in effective communication with both parents and children
Education and Training Workstream	62	Clinicians caring for children should be trained specifically in communication with parents following an adverse clinical incident, which training should include communication with grieving parents after a SAI death
User Experience and Advocacy Workstream	63	The practice of involving parents in care and the experience of parents and families should be routinely evaluated and the information used to inform training and improvement
Education and Training Workstream	64	Parents should be involved in the preparation and provision of any such training programme
Education and Training Workstream	65	Training in SAI investigation methods and procedures should be provided to those employed to investigate
Clinical and Social Care Governance Sub-Group	67	Should findings from investigation or review imply inadequacy in current programmes of medical or nursing education then the relevant teaching authority should be informed
Clinical and Social Care Governance Sub-Group	68	Information from clinical incident investigations, complaints, performance appraisal, inquests and litigation should be specifically assessed for potential use in training and retraining
ALB Board Effectiveness Sub-Group	69(ii)	Trusts should appoint and train Executive Directors with specific responsibility for: Child Healthcare
ALB Board Effectiveness Sub-Group	69(iii)	Trusts should appoint and train Executive Directors with specific responsibility for: Learning from SAI related patient deaths
ALB Board Effectiveness Sub-Group	70	Effective measures should be taken to ensure that minutes of board and committee meetings are preserved
Clinical and Social Care Governance Sub-Group	71	All Trust Boards should ensure that appropriate governance mechanisms are in place to assure the quality and safety of the healthcare services provided for children and young people
Clinical and Social Care Governance Sub-Group	76	Clinical standards of care, such as patients might reasonably expect, should be published and made subject to regular audit
Clinical and Social Care Governance Sub-Group	77	Trusts should appoint a compliance officer to ensure compliance with protocol and direction

Clinical and Social Care Governance Sub-Group	78	Implementation of clinical guidelines should be documented and routinely audited
Clinical and Social Care Governance Sub-Group	79	Trusts should bring significant changes in clinical practice to the attention of the HSCB with expedition
Clinical and Social Care Governance Sub-Group	81	Trusts should ensure that all internal reports, reviews and related commentaries touching upon SAI related deaths within the Trust are brought to the immediate attention of every Board member
ALB Board Effectiveness Sub-Group	84	All Trust Boards should consider the findings and recommendations of this Report and where appropriate amend practice and procedure
Departmental	85	The Department should appoint a Deputy Chief Medical Officer with specific responsibility for children's healthcare
Departmental	88	The Department should engage with other interested statutory organisations to review the merits of introducing a Child Death Overview Panel
User Experience and Advocacy Workstream	89	The Department should consider establishing an organisation to identify matters of patient concern and to communicate patient perspective directly to the Department
Clinical and Social Care Governance Sub-Group	90(i)	The Department should develop protocol for the dissemination and implementation of important clinical guidance, to include: The naming of specific individuals fixed with responsibility for implementation and audit to ensure accountability
Clinical and Social Care Governance Sub-Group	90(ii)	The Department should develop protocol for the dissemination and implementation of important clinical guidance, to include: The identification of specific training requirements necessary for effective implementation
Clinical and Social Care Governance Sub-Group	92	The Department should review healthcare standards in light of the findings and recommendations of this report and make such changes as are necessary
Assurance Workstream	93	The Department should review Trust responses to the findings and recommendations of this Report

TOTAL **63 actions**

IHRD Phase 2A Recommendations

Workstream/ Sub-Group	No	Recommendation
Workforce and Professional Regulation Workstream	5	Trusts should review their contracts of employment, policies and guidance to ensure that, where relevant, they include and are consistent with the duty of candour
Workforce and Professional Regulation Workstream	7	Trusts should monitor compliance and take disciplinary action against breach
Workforce and Professional Regulation Workstream	32	Failure to report an SAI should be a disciplinary offence
Workforce and Professional Regulation Workstream	35	Failure to co-operate with investigation should be a disciplinary offence
Preparation for Inquests Sub-Group	36	Trust employees who investigate an accident should not be involved with related Trust preparation for inquest or litigation
User Experience and Advocacy Workstream	37(iv)	Trusts should seek to maximise the involvement of families in SAI investigations and in particular a fully funded Patient Advocacy Service should be established, independent of individual Trusts, to assist families in the process. It should be allowed funded access to independent expert advice in complex cases
Death Certification Implementation Workstream	43	A deceased's family GP should be notified promptly as to the circumstances of death to enable support to be offered in bereavement
Death Certification Implementation Workstream	48	The proceedings of mortality meetings should be digitally recorded, the recording securely archived and an annual audit made of proceedings and procedures
Death Certification Implementation Workstream	49	Where the care and treatment under review at a mortality meeting involves more than one hospital or Trust, video conferencing facilities should be provided and relevant professionals from all relevant organisations should, in so far as is practicable, engage with the meeting
Preparation for Inquests Sub-Group	50	The Health and Social Care ('HSCB') should be notified promptly of all forthcoming healthcare related inquests by the Chief Executive of the Trust(s) involved
Preparation for Inquests Sub-Group	51	Trust employees should not record or otherwise manage witness statements made by Trust staff and submitted to the Coroner's office
Preparation for Inquests Sub-Group	52	Protocol should detail the duties and obligations of all healthcare employees in relation to healthcare related inquests
Preparation for Inquests Sub-Group	53	In the event of a Trust asserting entitlement to legal privilege in respect of an expert report or other document relevant to the proceedings of an inquest, it should inform the Coroner as to the existence and nature of the document for which privilege is claimed
Workforce and Professional Regulation Workstream	73	General Medical Council ('GMC') 'Good Medical Practice' Code requirements should be incorporated into contracts of employment for doctors.
Workforce and Professional Regulation Workstream	74	Likewise, professional codes governing nurses and other healthcare professionals should be incorporated into contracts of employment
Workforce and Professional Regulation Workstream	75	Notwithstanding referral to the GMC, or other professional body Trusts should treat breaches of professional codes and/or poor performance as disciplinary matters and deal with them independently of professional bodies
Clinical and Social Care	80	Trusts should ensure health care data is expertly analysed for patterns of poor performance and issues of patient safety.

Governance Sub-Group		
Departmental	94	The interests of patient safety must prevail over the interests engaged in clinical negligence litigation. Such litigation can become an obstacle to openness. A government committee should examine whether clinical negligence litigation as it presently operates might be abolished or reformed and/or whether appropriate alternatives can be recommended
Preparation for Inquests Sub-Group	95	Given that the public is entitled to expect appropriate transparency from a publically funded service, the Department should bring forward protocol governing how and when legal privilege entitlement might properly be asserted by Trusts
Preparation for Inquests Sub-Group	96	The Department should provide clear standards to govern the management of healthcare litigation by Trusts and the work of Trust employees and legal advisors in this connection should be audited

TOTAL **20 actions**

IHRD Phase 2B Recommendations

Workstream/ Sub-Group	No	Recommendation
Duty of Candour Workstream	1(i)	A statutory duty of candour should now be enacted in Northern Ireland so that: Every healthcare organisation and everyone working for them must be open and honest in all their dealings with patients and the public
Duty of Candour Workstream	1(ii)	A statutory duty of candour should now be enacted in Northern Ireland so that: Where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or duly authorised representative) should be informed of the incident and given a full and honest explanation of the circumstances.
Duty of Candour Workstream	1(iii)	A statutory duty of candour should now be enacted in Northern Ireland so that: Full and honest answers must be given to any question reasonably asked about treatment by a patient (or duly authorised representative)
Duty of Candour Workstream	1(iv)	A statutory duty of candour should now be enacted in Northern Ireland so that: Any statement made to a regulator or other individual pursuant to statutory duty must be truthful and not misleading by omission
Duty of Candour Workstream	1(v)	A statutory duty of candour should now be enacted in Northern Ireland so that: Any public statement made by a healthcare organisation about its performance must be truthful and not misleading by omission
Duty of Candour Workstream	1(vi)	A statutory duty of candour should now be enacted in Northern Ireland so that: Healthcare organisations who believe or suspect that treatment or care provided by it, has caused death or serious injury to a patient, must inform that patient (or duly authorised representative) as soon as is practicable and provide a full and honest explanation of the circumstances
Duty of Candour Workstream	1(vii)	A statutory duty of candour should now be enacted in Northern Ireland so that: Registered clinicians and other registered healthcare professionals, who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare organisation by which they are employed has caused death or serious injury to the patient, must report their belief or suspicion to their employer as soon as is reasonably practicable
Duty of Candour Workstream	2	Criminal liability should attach to breach of this duty and criminal liability should attach to obstruction of another in the performance of this duty
Being Open Sub-Group	3	Unequivocal guidance should be issued by the Department to all Trusts and their legal advisors detailing what is expected of Trusts in order to meet the statutory duty
Being Open Sub-Group	4	Trusts should ensure that all healthcare professionals are made fully aware of the importance, meaning and implications of the duty of candour and its critical role in the provision of healthcare
Being Open Sub-Group	6	Support and protection should be given to those who properly fulfil their duty of candour
RQIA Remit Sub-Group	8	Regulation and Quality Improvement Authority ('RQIA') should review overall compliance and consideration should be given to granting it the power to prosecute in cases of serial non-compliance or serious and wilful deception
Serious Adverse Incident Workstream	31	Trusts should ensure that all healthcare professionals understand what is expected of them in relation to reporting Serious Adverse Incidents ('SAIs')
Serious Adverse Incident Workstream	33	Compliance with investigation procedures should be the personal responsibility of the Trust Chief Executive
RQIA Remit Sub-Group	34	The most serious adverse clinical incidents should be investigated by wholly independent investigators (i.e. an investigation unit from outside Northern Ireland) with authority to seize evidence and interview witnesses
Serious Adverse Incident Workstream	37(i)	Trusts should seek to maximise the involvement of families in SAI investigations and in particular Trusts should publish a statement of patient and family rights in relation to all SAI processes including complaints
Serious Adverse Incident Workstream	37(ii)	Trusts should seek to maximise the involvement of families in SAI investigations and in particular families should be given the opportunity to become involved in setting the terms of reference for an investigation
Serious Adverse Incident Workstream	37(iii)	Trusts should seek to maximise the involvement of families in SAI investigations and in particular families should, if they so wish, engage with the investigation and receive feedback on progress
Serious Adverse Incident Workstream	37 (v)	Trusts should seek to maximise the involvement of families in SAI investigations and in particular families in cases of SAI related child death should be entitled to see relevant documentation, including all records, written communication between healthcare professionals and expert reports
Serious Adverse Incident Workstream	37(vi)	Trusts should seek to maximise the involvement of families in SAI investigations and in particular all written Trust communication to parents or family after a SAI related child death should be signed or co-signed by the chief executive

Serious Adverse Incident Workstream	37(vii)	Trusts should seek to maximise the involvement of families in SAI investigations and in particular families should be afforded the opportunity to respond to the findings of an investigation report and all such responses should be answered in writing
Serious Adverse Incident Workstream	37(viii)	Trusts should seek to maximise the involvement of families in SAI investigations and in particular family GPs should, with family consent, receive copies of feedback provided
Serious Adverse Incident Workstream	37(ix)	Trusts should seek to maximise the involvement of families in SAI investigations and in particular families should be formally advised of the lessons learned and the changes effected
Serious Adverse Incident Workstream	37(x)	Trusts should seek to maximise the involvement of families in SAI investigations and in particular Trusts should seek, and where appropriate act upon, feedback from families about adverse clinical incident handling and investigation
Serious Adverse Incident Workstream	38	Investigations should be subject to multi-disciplinary peer review
Serious Adverse Incident Workstream	39	Investigation teams should reconvene after an agreed period to assess both investigation and response
Serious Adverse Incident Workstream	42	In the event of new information emerging after finalisation of an investigation report or there being a change in conclusion, then the same should be shared promptly with families
Serious Adverse Incident Workstream	66	Clinicians should be afforded time to consider and assimilate learning feedback from SAI investigations and within contracted hours
Duty of Candour Workstream	69(i)	Trusts should appoint and train Executive Directors with specific responsibility for: Issues of Candour.
ALB Board Effectiveness Sub-Group	72	All Trust publications, media statements and press releases should comply with the requirement for candour and be monitored for accuracy by a nominated Non-Executive Director
Serious Adverse Incident Workstream	82	Each Trust should publish policy detailing how it will respond to and learn from SAI related patient deaths
Serious Adverse Incident Workstream	83	Each Trust should publish in its Annual Report, details of every SAI related patient death occurring in its care in the preceding year and particularise the learning gained therefrom
RQIA Remit Sub-Group	86 (i)	The Department should expand both the remit and resources of the RQIA in order that it might: Maintain oversight of the SAI process
RQIA Remit Sub-Group	86 (ii)	The Department should expand both the remit and resources of the RQIA in order that it might: be strengthened in its capacity to investigate and review individual cases or groups of cases.
RQIA Remit Sub-Group	86 (iii)	The Department should expand both the remit and resources of the RQIA in order that it might: scrutinise adherence to duty of candour.
Independent Medical Examiner Sub-Group	87	The Department should now institute the office of Independent Medical Examiner to scrutinise those hospital deaths not referred to the Coroner
Serious Adverse Incident Workstream	91	The Department, HBSC, PHA, RQIA and HSC Trusts should synchronise electronic patient safety incident and risk management software systems, codes and classifications to enable effective oversight and analysis of regional information

TOTAL **37 actions**

Inquiry Into Hyponatraemia Related Deaths (IHRD)

Review of the Co-Production Experience

1. Introduction

The implementation of the 96 recommendations made by Justice O'Hara in the IHRD report began shortly after its launch on the 31st January 2018. At the outset, the Department of Health (DOH) made a clear commitment to use a co-production model. On the 31st August 2018 it published the Co-Production guide for Northern Ireland – Connecting and Realising Value Through People. The ambition within the guide is clear:

"Our goal is to support transformational change through a co-productive approach and promote the opportunity for all sections of the Northern Ireland community to partner with health and social care staff in improving health and social care outcomes. "(p.7)

The work of the IHRD implementation programme was overseen by the Implementation Programme Management Group (IPMG). The Chairs of each of the programme work streams sat on this group and it was led by senior departmental officials. The membership of the workstreams contained representation from various groups including:

- Department of Health Officials
- Health Service Personnel from Trusts, The Board and various Arm's Length Bodies
- Third Sector Representatives
- Service Users / Carers
- Other specialists

As well as the workstreams the DOH also engaged the Public Health Agency (PHA) to provide experienced personnel to support the involvement of Service Users and Carers within the programme. In addition, the Service User / Carer Liaison Group (SUCLG) was established by the Service Users and Carers members to develop deeper knowledge-sharing across the programme, to act as an additional support mechanism and to provide representation on their behalf at the programme Board level. This was not in the original design but was adopted by the programme management as a welcome augmentation to the programme structure.

2. The Purpose and Scope of This Review

Having started in 2018, the IHRD implementation programme is the largest and most ambitious programme undertaken by the DOH using co-production as an approach. With 17 work streams working on the 120 actions that arose from the 96 recommendations, and hundreds of people involved it has been a huge administrative undertaking. The purpose of this review is to evaluate the experience of co-production primarily from the perspective of the Service Users and Carers who were involved. Additional information has also been gathered from other workstream members and departmental officials. As well as an exploration of the co-production experience, this review will provide some recommendations for how the co-production approach can be enhanced in future programmes, learning from the experiences of IHRD.

3. Methodology

Over November and December of 2021, individual interviews were held. All Service Users and Carers were offered the opportunity to be interviewed, 16 agreed. 3 independent work stream chairs were interviewed as well as 13 other workstream members, these included departmental officials and independent workstream members. 4 of the departmental officials also chaired some of the workstreams, and independent members of workstreams were randomly selected for interview. All interviews were carried out with the agreement that the identity of participants would remain anonymous.

A semi-structured approach to the interviews was used with the interview template attached as Appendix 1. The template was designed with the assumption that there was significant activity across all the work streams after the outbreak of COVID-19, however there is very little data relating to the post-covid experiences with most of the information relating to the experience up to March 2020. The main exception to this is the work of the Duty of Candour work stream that continued through a very significant public consultation in 2021. The template also used some numerical scales to determine levels of engagement. These were useful conversations starters but were too abstract to provide useful comparative data, and so the responses are reported in a narrative rather than numerical form.

4. Results of the Service User / Carer Interviews

a) The Service User / Carer Experience. (Pre and Post COVID)

- **A general appreciation of the intention to use co-production.** Most Service User / Carer respondents recognised that this was a laudable effort on the part of the DOH to involve them in a co-production approach. There was also positive appreciation of the scale and ambition of the programme.

- **The effectiveness of induction.** There was the recognition that attempts had been made to have an induction programme. The experience of respondents was varied. The elements of the induction discussed in the interviews were:

    - **Inter-personal.** Respondents welcomed meeting new people and the excitement of starting a new ambitious venture. Some identified the difficulty of feeling like the "outsider" at the table when the other members of the group seemed to know each other and worked together in the health service. Many respondents mentioned how overwhelming and intimidating it was for them to join a group with people they didn't know. While some mentioned large induction meetings which were general, there seemed to be less time spent at work stream level allowing people to get to know one another, acknowledging these inter-personal challenges.

    - **Work stream expertise.** Many Service User / Carer respondents reported experiencing a power differential between them and the perceived "experts" in the groups, feeling themselves to be at a disadvantage because of their lack of specialist knowledge. For some, this eased as they began to work together, and many described the benefit of being able to study meeting papers well in advance. Others mentioned the benefit of meeting the Chair of the work stream in advance of meetings to discuss any questions they might have about the material.

b) Positive themes in the Service User /Carer Experience:

Respondents gave a variety of answers, they...

- felt very supported by the system, specifically mentioning the work of the involvement co-ordinator.
- mentioned the introduction of the Service User and Carer Liaison Group as a very positive support for their involvement.
- mentioned the positive benefit of meeting new people.
- mentioned the warmth of the welcome they received, the benefit of the support provided to them inside and outside the work stream meetings, and how this helped them participate.
- mentioned the openness of others to what they were saying and suggesting, and the willingness they experienced of others to take on board and incorporate their views.
- expressed their appreciation of the opportunity to challenge and debate these important issues and to have their views meaningfully incorporated.
- mentioned the value of the diversity of work stream members and how this benefitted the breadth of discussion.
- mentioned the benefit of receiving their papers well in advance of meetings with the opportunity to seek clarification before the work stream met.
- mentioned the benefit of the support they received from DOH officials in providing additional information and helping with practical challenges.

c) Negative Themes in the Service User Carer Experience

Respondents gave a variety of answers, they...

- felt intimidated joining work streams where other members knew each other and had already worked together and "spoke their own special language".
- did not think that there was adequate preparation, training, and induction.
- doubted the genuine willingness of the DOH/health system to take on their views and incorporate meaningful change.
- described a power differential they experienced in relation to the other group members.
- described the hurdles they experienced in trying to get their point across and the effort that was required to be heard and taken seriously.
- reflected on the challenges and inertia of the large-scale bureaucracy of the system.
- feared that their involvement could be tokenistic.
- felt that "the system" was defensive and unwilling to listen to challenge or change.
- spoke of the differential contributions of work stream members, with some dominating and others saying nothing.

- spoke of the problems with the lack of contact from the DOH after the outbreak of COVID – they did not feel that their ongoing engagement was facilitated.
- thought that the questions they posed in the work streams were thought to be too difficult to deal with and that the intention was merely to "tweak" around the edges of the system, rather than meaningful substantial change.
- thought that there should have been wider engagement with the public.
- thought that there should have been more support:
    - practical support - in relation to transport and accessibility. Some expressed the view that there was a lack of understanding of the constraints experienced by active carers that made participation difficult. The use of ZOOM was seen to be a positive move.
    - support for engagement – in relation to the dissemination of information in accessible forms. Respondents generally appreciated the additional engagement with officials and Chairs to explain and discuss the issues.
    - support for co-production – in relation to service user / carer participation in shared decision making. Respondents referenced a lack of ongoing reflection on the success or otherwise of the co-production process.
- thought that there were decisions being made outside of the workstream meetings that should have been discussed and agreed by the workstream.
- thought that there was a general lack of understanding of the co-production process and that there was a significant variation in the ability and competence of Chairs to manage service user / carer engagement.

d) Service User Evaluation of Co-Production

Feedback from service users and carers on what worked.

- the direct support of staff.
- there was a genuine effort to incorporate all views.
- there was a friendly environment.
- it was enjoyable and people were not condescending.
- resources were invested in the process.
- service users and carers were encouraged to lead the discussions.
- the process started off extremely well.
- there was a respectful approach.
- this was the first time something like this had been tried.
- good chairs and good support from DOH officials.

Feedback from service users and carers on what didn't work.

- there should have been more induction / training at the start.
- there was a lack of understanding of the difference between consultation and shared decision making.

- there was an unhelpful power differential between service users/carers and the system.
- there needed to be more ongoing reflection on what was and wasn't working.
- it appeared that some decisions were being made or vetoed outside of the workstreams without service user / carer involvement.
- it appeared that everything was "set-up" in advance therefore it wasn't co-designed.
- there was the fear that the outcomes were predetermined – it was a "done deal".
- there was a lack of appreciation in "the system" of the scale of change required.
- there was defensiveness in the system to change because it might threaten jobs
- the same volunteers were involved.
- there was a tendency to focus on the work of specific work streams and lose sight of the work of the whole programme.

e) Views on the benefits of Service User / Carer Involvement:

- Lived Experience. Most respondents mentioned the value of "lived experience" of using health services and the insight this provided into the issues patients would be experiencing.
- Real "on the ground" experience. Respondents mentioned the value of input from those who had good and poor experiences of services on the ground to challenge assumptions about how these are being delivered.
- The authentic voice of the service user. Respondents noted the value of the authentic voice of the service user in decision making about service development. It was thought that this provided additional authenticity to the discussions.
- Challenge. Respondents thought that service user / carer involvement brought a significant challenge to assumptions by the system about the effectiveness of its service delivery.
- The human touch. Respondents thought that the involvement of service users and carers retained a focus on the human experience of services, not just the systems.
- Specialist service user experience. Respondents recognised the specific value of people who had used specific services being involved in the improvement of those services.
- Holding to account. Some respondents saw the role of service users / carers as holding the system to account for the delivery of services. For some, this was in the context of a lack of confidence in the willingness or ability of the health service to engage in meaningful change or transformation.
- Some respondents spoke of the distinction between the role of service users and the role of carers and some of the difficulties this can cause.

f) Service Users / Carers views on the next stage of IHRD Implementation.

- All the service users / carers were asked if they would like to remain involved in some capacity in the next stage of IHRD implementation, and without exception they all indicated their willingness to help.

There were a variety of responses, respondents...

- spoke of their frustration at the lack of engagement since the outbreak of COVID-19, and the hope that the momentum for implementation would not be lost.
- reflected on the positive impact of the IHRD implementation process and the hope that the model would be replicated for other issues – with the lessons from it being learned and incorporated.
- spoke of the public view of the IHRD implementation and the need to show progress and completion.
- recognised the significant changes in the system since the IHRD implementation programme started and the need to take these into account.
- identified the need for an ongoing assurance process to ensure that the changes that had been made persisted.
- mentioned the practical benefits of using ZOOM technology to facilitate engagement with service users and carers
- mentioned the importance of linking system change with culture change – this was specifically in relation the The Duty of Candour and Being Open work stream.
- mentioned the importance of role clarity for any future involvement of service users and carers, along with clear expectations of support and ongoing reflection of the effectiveness of the co-production approach.
- reflected on the different requirements of different types of work when considering service user and carer involvement. The specific distinction was between the requirements of technically specialist areas of work, and those areas that are more general in nature.
- mentioned the need to focus on the introduction of new legislation to precipitate meaningful change.
- highlighted the need for better communication both within the system as well as with the public.

5. Results of the interviews with other workstream members, Chairs and DOH officials.

Some work stream Chairs, DOH officials and other workstream members were selected at random for interview. The same interview template was used for these semi-structured interviews but adapted to seek respondents' views on the co-production process as they observed and experienced it.

a) Other work stream members views of the co-production experience:

- **A positive view of the effort to co-produce.** There was a general appreciation of the commitment to co-production and an acknowledgement of the effort and resource that had been committed to the process. There was recognition of the effort put in by Chairs and DOH officials to engage with service users /carers to support them to engage with the process.

- **Changes over time.** There was some reflection on changes in service user / carer engagement over time with more engagement at the start of the process, followed by a gradual falling off. This was then exacerbated by COVID-19. Some respondents reported a lack of continuity in attendance by service users / carers at meetings. Others reported the numbers of service users / carers expanding over time as the need for representation increased.

- **Different challenges depending on the topic of the work stream.** There was reflection on different experiences of co-production depending on the topic of the workstreams. Where the experience of the service users / carers aligned directly with the focus of the work stream, there were high levels of engagement and input. Where the topic of the work stream was of a more general or principled nature, it appeared to be more difficult to engage service users / carers in a focused way.

- **The impact of COVID-19.** There was a general acceptance that in effect, the work of the programme had been on hold for most of the work streams from March 2020 because of the profound disruption caused by COVID.

- **The benefit of support.** There was recognition of the positive impact of providing support to service users / carers. Specific reference was made to the positive influence of direct support staff on the programme, as was the recognition of the benefit of Chairs and departmental officials taking the time outside the work stream meetings to work with and support service user / carer workstream members.

- **Un-managed expectations.** Several respondents spoke of their perception that some of the service users / carers expectations about their role in the programme were in their view at times unrealistic. This was in relation to decisions that may have been outside the scope of the programme, or that may have been deemed to be impossible or impractical to implement. It seems that there were occasions when these expectations were mis-matched what was thought to be possible. In these circumstances, some staff felt reticent to directly challenge these expectations.

- **Anxiety about challenge.** Several of the respondents spoke of their concern about challenging or disagreeing with service users / carers because of the perception of their status as volunteers in the programme. Some also spoke of their fear that a robust challenge may result in criticism or complaints being raised by service users / carers against them, the possible public reaction, and the possible negative impact on the programme. The consequence of this appears to be that difficult or controversial discussions were sometimes avoided and that it was therefore difficult at times to deal with some important issues in the work streams.

- **Confusion between Patient and Public Involvement (PPI) and Co-Production.** There were some of the respondents who spoke of their perception of a confusion within the system between the requirement to involve and consult service users and carers on important changes within the health service (PPI) and the process of co-production. At its core was confusion around the issue of shared decision making and a lack of experience in involving service users / carers as partners in the complex decision-making processes involved in developing significant health service reform.

- **Shared decision-making challenges.** Some respondents described difficulties in balancing the input of service users / carers with the input of other group members. The main concern was that on occasion, there was a perception that service users / carers appeared to expect their views to carry more weight than the views of other group members. This resulted in either a mismatch of expectations, confusion and conflict, or the avoidance of important issues. The consequence was that sometimes there were significant challenges in achieving genuinely shared decision making.

b) Perceptions of other members, Chair and DOH Officials about what worked.

- the commitment of service users / carers to the process was impressive.
- the benefit of a very explicit commitment on the part of the DOH to co-production across all its initiatives.
- service users / carers added significant value to the decision-making process of the IHRD implementation programme.
- service users / carers brought a broader view to the issues, that ultimately resulted in better policy decisions being made.
- service users / carers brought reality of experience and personal life stories to the attention of policy makers, that enhanced the process.
- service users / carers reflected the views of the public and kept the core issues at the top of the agenda.

c) Perception of other members, Chairs and DOH Officials about what didn't work.

- Confusion about the role of service users / carers. Some respondents reported challenges with how highly specialised technical issues were dealt with. It was perceived that some service users / carers felt out of their depth with some of these issues, and there was some effort to provide additional support to help

them understand. Some thought this reflected a misunderstanding of the role of service users / carers in making decisions about these issues.

- Shared decision making. Some respondents identified a confusion between co-production and the inherently shared nature of decision making within it, and the legal duty of involvement and consultation associated with PPI.
- The avoidance of conflict and anxiety about challenge and disagreement. There was significant feedback from respondents about their anxiety about challenging service users / carers, and their fear of the implications of complaints being made against them. Respondents felt that on occasion, some of the service users / carers expected their opinions to take precedence.
- The dominance of negative personal experiences. Some of the respondents, reflecting on the benefit of the lived experience of service users / carers, noted that most of those involved had negative experiences of using health services and that this influenced the way they contributed to the process.
- The challenge to trust. Respondents identified trust as a significant issue in the process. This was both the perception of a lack of trust on the part of some service users / carers in the ability of the system to meaningfully change, and a lack of trust on the part of some of those working in the system that service users / carers could contribute meaningfully to pragmatic service delivery improvements.
- Time and progress. Some of the respondents expressed the view that too much time was spent in circular discussions, and that more clarity about expected outcomes and timescales would have helped expedite decision making.

d) Views of other members, Chairs and DOH Officials on the benefits of Service User / Carer Involvement:

- asked questions and raised issues that would not otherwise be raised.
- brought a very different perspective and healthy debate.
- were a litmus test for the public reaction to issues.
- challenged the assumptions of policy makers to create better policy decisions.
- maintained the focus of the IHRD issues.
- the specialist experience of service users / carers gave a valuable insight into how services were experienced on the ground

e) Other work stream members, Chairs and DOH Officials views on the next stage of IHRD Implementation.

Respondents identified:

- the need for role clarity in the co-production process, for chairs, service users /carers and all other members.
- the importance of a selection process that matched experience with the objectives.

- the importance of the distinction between service users / carers with specific experience and those with general interests; and the need to ensure appropriate skill matching within relevant work streams.
- the importance of some sort of selection to ensure appropriate matching of skills and experience with the task required.
- the importance of recognising the benefit of positive experiences of using the health service as well as negative experiences.
- the importance of support for all of those involved to maintain a focus on the core principles of co-production.
- the importance of investing in building trust and a sense of "common purpose" in the group.
- the importance of managing the expectations of group members about the challenges and limitations of the work.
- the importance of facilitating honest conversations within the group.
- smaller more focused working groups would work better.
- clear and co-designed terms of reference for the work of each group.

6. Discussion and Analysis

The feedback from those who were interviewed as part of this review can be aggregated under the following headings:

- **The benefits of co-production**. There was general agreement among both service users /carers and the other workstream members that the co-production approach for IHRD implementation was beneficial and that it resulted in better policy decisions. There was also the recognition that it was difficult, and that the system would benefit from support and development to make full use of it as a model of policy development or service transformation. There was also the acknowledgement that in the IHRD Implementation Programme, the Department of Health had embarked on a hugely ambitious co-production exercise, and that it had invested significantly in the human and other resources required to make it a success. The commitment to co-production for IHRD implementation was impressive, and that commitment continues with the department's openness to learning from the experience so that insightful local experience informs future HSC co-production initiatives.

- **The challenges of co-production.** While there is no doubt that there is an appreciation of the benefits of co-production, it is also important to have a full understanding of the challenges of this model. The feedback from this review would suggest that there were some issues about the management of the process that, with hindsight, could have been improved to produce a better result. Primary among these is that as a process co-production needs to be actively managed. It is a dynamic process that is arguably inherently conflictual and therefore needs ongoing support and engagement to maintain focus and efficacy. The focus of the management of a co-production project needs to be split between attention to the work plan and expected outcomes, alongside a focus on the group process and the relational dynamics.

- **The architecture of co-production.** From the feedback received within this review, it is possible to construct a framework for understanding the different components of a successful co-production process. They can be characterised as a sequence of:

    - preparation,
    - selection,
    - negotiation and
    - agreement setting, and reflection.

    These are described in more depth in the recommendations. The involvement of service users / carers in a process does not necessarily make that process co-production and working within a framework for co-production helps make explicit some of the more complex challenges associated with it.

- **Managing expectations.** One of the phrases most frequently heard in the feedback for this review was the importance of managing expectations. It was used most

often when speaking about the challenges of "shared decision making", and the anxieties of those within the system about the expectations of service users /carers about what could or could not be done. This reflected a much deeper issue which was the challenge of creating a "common purpose".

Much of the feedback in this process was predicated on a "them and us" assumption – a false division, that when left unchallenged had the potential to cause misunderstanding:

- From a service users /carer perspective, it was expressed as the sense that they held sole responsibility for ensuring change happened, "holding the system to account" – with the view that those within the system were perceived to be resistant to change and resistant to making the meaningful and radical changes that were required.

- For those within the system, it was expressed as the sense that they held responsibility for maintaining the stability of fragile and strained services, containing staff who were over-stretched, deeply committed to doing a good job but intensely conscious of the constraints within which they had to work.

At its most extreme each side of this false division, felt the other to be defensive, antagonistic, and not committed to doing the right thing. This was of course manifestly not true of either "side" but was a very real perception. The solution to this is to work hard to find "common purpose", a way of describing the work that allows those involved to connect with what they agree is important, and then work on the issues upon which they disagree. This reinforces two key components of co-production:

- **Role clarity** – it is important that in the preparation for a co-produced project, effort and thought is put into who really are the key stakeholders. Service users / carers are an obvious group, but it is important also to include others for whom the issue carries real importance and relevance. Some of these people will come from within the system, some from the wider health service community, the third sector and at times the general public. The purpose of convening such as group is to create a "common purpose", where there is clarity about the contribution that each can make.

- **Equality around the discussion table** – in the feedback for this review individuals across all groups expressed anxiety that others' views were given more importance than theirs. This was said both by service users / carers as well as other group members such as officials, clinicians etc. It is reflective of the need to make absolutely clear to all group members the value of all contributions, the acceptance that at times all will not agree, the possibility of conflict and finally the acceptance that decisions may not always be unanimous. By holding this tension within the group, decisions can be maintained within the group – rather than made elsewhere where there may be no conflict, but neither is there any consultation or consensus.

- **The Importance of Co-Design at the start of Co-Production.** Some respondents reflected that, because of the timing of their involvement, there were some important decisions about the design of the programme that had been taken before their inclusion. They understood that the extraordinary scale of the Hyponatremia Inquiry necessitated a robust but timely process of implementation but with hindsight, the desire to get a process up and running may well have overshadowed the need for a wider co-design phase at the start. In this instance, co-design began when the workstreams began their work and it continued throughout the remainder of the programme. The delay at the start clearly had an impact on the process, where some of the challenges could possibly have been predicted and avoided. The learning from this programme is that co-design is best introduced as early as possible to maximise a sense of common purpose, ownership and understanding expectations of the project.

- **It's difficult but it's worth it...**
  The purpose of this review was to explore the experience of co-production with a particular focus on the experience of service users / carers. In doing so it is necessary to identify both what worked well and what could have been improved. It is clear from these findings that co-production is not easy, however there was unanimous agreement from those who were involved that it made for better outcomes – that it was difficult but worth it.

7. Recommended model for the stages of a co-production project:

The Importance of proportionality

When planning any project where there is an expectation of co-production it is important to determine the level of engagement with other stakeholders that is appropriate. There is no value in a "one size fits all" approach, and the following description of a process is not intended to be formulaic but simply offers a sequence of principles to follow to consider how co-production might be applied. The decisions about how other stakeholders, including service users / carers, might be involved will be determined by factors such as the scale of the task and its nature, for example:

- Service Improvement Projects – will benefit from representation by those who use the services, as well as the wide range of others usually involved in delivery.
- Policy Development projects – will benefit from input from those impacted by the policy at certain stages of the policy development process.

In these circumstances, it is important to determine the stages within the process that require more engagement or less engagement with the wider stakeholder group and the general or specialist nature of the engagement. Consideration should be given to whether a project should be co-produced, or whether the outcomes could better be met with a PPI approach.

The Stages of a Co-Production Approach:

Stage 1 – Co-Design and Preparation – clarifying expectations:

- identification and mapping of the stakeholder groups relevant to the project
- description of the key outcomes expected from the project with timetables
- description of the skills and experience required to add value to the project and identification of the stakeholders needed to help design the process
- this process should involve individual representative stakeholders with experience relevant to each of the identified stakeholder groups to provide specialist insight to recruiting from those groups and maximising the benefit of their involvement

Stage 2 – Leadership – Getting effective people in the right roles:

- Identify if different types of leadership roles are needed within the project
- Match skills and knowledge of leaders to the tasks required
- Reflect the stakeholder make up in the leadership team to ensure a co-design approach is embedded in the project from the beginning.
- Define the project governance and reporting structures
- Identify co-production training for the leadership of the project
- Prepare a draft "terms of reference"

Stage 3 – Selection and training – getting the right skills and experience:

- the formality of the selection process will vary according to the scale and nature of the project. For some it will simply be that thought is put into who can best be involved, for a large-scale project it may be a formal recruitment process
- selection of those who might be involved should be carried out using the criteria of the skills and experience identified in the preparation stage
- the specific skills and experiences required should be explicit in the selection process – thought can be put into the preparation of "person specifications" for the roles depending on the scale of the project
- there should be the capacity allowed for additional skill sets to be recruited later in the project as the understanding of the needs develops

Stage 4 - Negotiation and Agreement – setting the ground rules:

- once participants are identified, time can be taken to negotiate working practices, these are simple questions that the team can take some time to consider together as part of an induction process. The purpose is to encourage discussion about the subjects rather to come up with fixed view on the answers, and the issues can be revisited throughout the process:
    - how will the group get to know one another?
    - how will the group ensure that everyone is able to have a voice?
    - how will the group deal with differences of opinion?
    - how will the group deal with specialist issues where not all members will have specialist knowledge?
    - how will the group share responsibility for decisions?
    - how will the group deal with dissent?
    - what support do individuals need to fully participate in the process?
    - are there any key stakeholders or other relevant groups not represented?
    - are there any required skills missing?

Stage 5 – Reflection and Closure:

- the opportunity for the group regularly to reflect on progress should be built into the timetable:
    - at the end of every meeting there should be a brief discussion and check-in with each member. This informal evaluation of the meeting should provide a check and assurance that everyone was able to participate.
    - there should be the opportunity for regular more formal reviews of progress, making the distinction between reviewing the progress against the task the group is set to achieve as well as the process of co-production.
    - there should be regular one-to-one meetings between the Chair and individual group members to check in with them and ensure they are feeling supported to contribute.
    - when the work of the group is complete, an evaluation should be undertaken of the effectiveness of the co-production process and any learning that needs to be incorporated into future projects

The challenges of each Stage of Co-Production.

STAGES	Service Users/Carers	Departmental personnel leading the project	Others: e.g. 3rd sector, external representatives
Stage 1 Co-Design / Preparation	Service Users/Carer representatives should be involved at this stage to co-design the process and advise on recruitment.	Those leading the project should have clear plans in place to manage the project, and to manage the co-production component of it.	Other personnel, or organisational representatives might be involved at this stage in the co-design of the process and to advise on recruitment.
Stage 2 Leadership	Service Users / Carers should have representation in the leadership of work-streams.	Depending on the nature of the project, there will be occasions where it is best that work is led by departmental personnel.	As with departmental personnel, there will be circumstances where work is best led by external representatives.
Stage 3 Selection	Depending on the person specifications of the service user / carer roles, different sources of recruitment can take place. Public advertisements, PCC etc.	Some specific personnel may be nominated by their departments, other may volunteer or be "head-hunted". As with the selection of service users / carers, clarity should be given about the skills and experience required.	Direct approaches can be made to specific organisations or representative bodies such as NICVA. As with the selection of service users / carers, clarity should be given about the skills and experience required.
Stage 4 Negotiation and Agreement	On the basis that Service Users /Carers may not be familiar with the workings of the systems, extra efforts should be put in to ensuring agreement about how they will feel comfortable participating. Discussion should be had about the supports necessary for them.	It should not be assumed that personnel within the health system are necessarily familiar or comfortable with the co-production process. Time and effort should be spent supporting them to explore what that means in practice.	Personnel from agencies external to the health service will not necessarily be comfortable or familiar with how the system operates. Time and effort should be dedicated to exploring how they can be facilitated to participate fully.
Stage 5 Reflection	As well as whole-group reflection, service users /carers should be given the opportunity to reflect with the Chair on the effectiveness of their participation and any further support they may require.	The impact of managing and participating in a co-production process on core staff should not be underestimated. It can be both challenging and personally demanding. Opportunities should be provided to get advice, support and to process the impact of this work.	Individuals from external organisations should have the same opportunities as others to be involved in reflection on the effectiveness of the project and of the co-production process.
Training Needs	Service users / carers would benefit from orientation training about the health service system, as well as specific training concerning the context of the project – policy, legal framework, clinical context etc. Training in co-production.	Those within the system will benefit from training in co-production.	Those others external to the system will benefit from some orientation training as well as co-production training

The experience and skills required of leadership to manage a co-production project are:

- **Ability to manage difficult conversations**: The co-production process is inherently conflictual. It is normal for there to be very different and conflicting views around the table about how things should be done. It is very important that the articulation of these differences is facilitated in a productive way, that conflict is not avoided but that it is handled sensitively and calmly. The Chair plays a critical role in brokering these discussions providing enough "containment" for the difficult issues to be aired. It can be useful to provide the opportunity for dissent to be recorded and "parked" to allow the discussion to proceed without needing to force immediate resolution.

- **Ability to deal with emotional distress**: It is sometimes the case that service users / carers or other group members, have very personal and distressing experiences of the services that are under discussion by the group, and that while others may view the discussions dispassionately from a policy or systems perspective, service users /carers (and indeed others) may be speaking from very personal, painful, first-hand experience. The Chair needs to ensure that these issues are dealt with sensitively, that painful connections can be acknowledged, and that conversation is facilitated to continue. Sometimes in situations like this, others may feel unwilling to speak if they think they are going to upset another group member – while this sensitivity is important, it is also important that the group is enabled to speak about these difficult and provocative issues. Group members should be facilitated to explore how these issues can be spoken about in a respectful, compassionate and supportive way.

- **Task orientated and focused:** Getting the balance between allowing discussion and exploration of difficult issues with getting agreement on a decision and being able to move on. The Chair is responsible for managing the discussions to come to some sort of consensus in conclusion. This will either be a unanimous group decision, or the group needs to decide how it deals with final disagreement on points. Circular and repetitive discussions should be avoided, and mechanisms such as recording dissent, should be used to progress decision making. Clarity about outcomes and timescales can help drive the decision-making process forward.

- **Compassionate and supportive:** It is the Chair's responsibility to create an appropriate environment in which the challenging process of co-production can take place. This involves both the management of the group process, as well as support for each of the individuals:

    - Group Process: The Chair should ensure that group discussions and activities are focused on the task and inclusive of all members participation. If there are distressing or controversial issues, The Chair is responsible for managing a safe enough environment for these to be explored, as well as ensuring that appropriate boundaries and safeguards are in place for individuals to feel supported to contribute.

- Individual Support: The Chair should be tuned into the well-being of all members of the group, and supportive to individuals who may be feeling excluded, overwhelmed, out of their depth or generally distressed. The Chair should have access to professional services for those who may need some emotional support and should have access to support and advice themselves.

Peter McBride

February 2022

BRIEFING NOTE TO THE UROLOGY SERVICES INQUIRY

PROGRAMME TO IMPLEMENT THE RECOMMENDATIONS OF THE INQUIRY INTO HYPONATRAEMIA RELATED DEATHS (IHRD)

1. Peter May, at paragraph 116 of his witness statement of 18 August 2022 to the Urology Services Inquiry, committed to forward a copy of a written statement that was, at that time, intended to be made to the Northern Ireland Assembly by the then Minister of Health on progress to implement the recommendations of the Inquiry into Hyponatraemia-related Deaths, together with a comprehensive briefing document.

2. There was a change in approach. The statement was not made in written form to the Assembly by the Minister. It was instead published online as a Departmental statement on 28 October 2022. The statement, together with detail on the phased approach taken in relation to the recommendations and actions can be found at: **https://www.health-ni.gov.uk/topics/ihrd-latest-updates**

3. The link also includes a report on the co-production approach used to date to implement the actions.

BACKGROUND ON THE IHRD PROGRAMME

4. On 31 January 2018, Sir John O'Hara published his report following the Inquiry into Hyponatraemia-related Deaths (IHRD), which examined the deaths of five children in hospitals in Northern Ireland. The five children were:
    - Adam Strain, born on 4th August 1991 and died on 28th November 1995 (4 years old);
    - Raychel Ferguson, born on 4th February 1992 and died 10th June 2001 (9 years old);
    - Lucy Crawford, born on 5th November 1998 and died on 14th April 2000 (2 years old);
    - Claire Roberts, born on 10th January 1987 and died 23rd October 1996 (9 years old); and

- Conor Mitchell, born on 12th October 1987 and died 12th May 2003 (15 years old).

5. The report made 96 recommendations which were wide-ranging and have significant implications for the HSC in Northern Ireland. A number of these recommendations include multiple parts and as a consequence there are 120 separate actions to be addressed arising from the Inquiry.

6. Following the publication of the report in 2018, the Department established an Implementation Programme to address these 120 Actions. The programme had 9 workstreams and 7 sub-groups.

7. The workstreams and sub-groups were:

    - Duty of Candour (Being Open Sub-Group)
    - Death Certification (Preparation for Inquests; Independent Medical Examiner; & HSC Bereavement & Pathology Networks Sub-Groups)
    - Duty of Quality (ALB Board Effectiveness; RQIA Remit; & Clinical and Social Care Sub-Groups)
    - Paediatric-Clinical Collaborative
    - Serious Adverse Incidents
    - Training & Education
    - User Experience and Advocacy
    - Workforce and Professional Regulation
    - Assurance

8. It was determined from the beginning that the Department's response to the Inquiry would take a co-production approach involving a wide range of stakeholders. The programme brought together over 200 people from a wide variety of backgrounds to work as members of workstreams. The task of each workstream and sub-group has been to develop an implementation plan for the IHRD recommendations relating to their area/theme.

9. The assurance process was key. Each workstream was to produce an assurance framework which clearly mapped out how a recommendation will be implemented.

10. Membership of the workstreams included: service users and carers; representatives of the voluntary and community sector; staff from health and social care organisations; non-executive directors of health and social care organisations; and Departmental staff from DoH and other Departments. Each member has been able to bring a unique perspective through their expertise and/or personal experience.

11. In addition to the contribution which individual service users/carers make to workstreams, a Service User / Carer Liaison Group was established as an integral part of the IRHD Implementation Programme.

12. From 2018-2020 the Implementation Programme published a number of progress updates setting out the work done and the progress made. The intention has been to be open and transparent in how the recommendations are being developed for implementation.

13. The current position has been established as follows:

	No. of Recommendations	**No. of Actions**
Phase 1 - Actioned: Necessary work has been completed and there is adequate evidence that they have been actioned across the HSC.	57	63
Phase 2A – The initial work of Phase 1 has been completed. However, these recommendations require further input to ensure appropriate implementation at	19	20

service level. This work will be overseen by the IHRD Programme Team, reporting to the Programme Management Board.		
Phase 2B – The initial work of Phase 1 on these recommendations has been completed. It is now appropriate to transfer responsibility for these recommendations from the IHRD implementation programme to the appropriate DoH policy area, with progress reporting to the Programme Management Board.	20	37
TOTALS	**96**	**120**

IHRD Phase 1

14. In total 57 recommendations (63 actions) have been identified as actioned in the first phase of the programme, meaning that there is adequate evidence that they have been implemented across the HSC. Further assessment and monitoring may be required to provide evidence of a consistent regional approach to continued implementation of these recommendations.

15. These include recommendations included in the following Workstreams:

- Paediatric Clinical Workstream (21 recommendations);
- Duty of Quality Workstream (1 recommendation);
- ALB Board Effectiveness sub-group (5 recommendations/6 actions);

- Clinical & Social Care Governance sub-group (12 recommendations/13 actions);
- Education and Training Workstream (6 recommendations/6 actions);
- User Experience and Advocacy Workstream (2 recommendations/2 actions);
- Departmental (2 recommendation/2actions);
- HSC Bereavement Network & Pathology Network Subgroup (9 recommendations/13 actions);and
- Assurance Workstream (1 recommendation).

16. This work will be further monitored as part of Phase 2 of the IHRD Programme to ensure there is a consistent continuing regional approach to action and implementation.

Structure for IHRD Phase 2 Implementation

17. Phase 2 of the IHRD Implementation programme will allow the remaining recommendations to receive focused attention. In preparation for Phase 2, two distinct categories are now being applied to the recommendations on which work is continuing: -

- Phase 2A: The initial work has been completed by the relevant Workstream. However, these recommendations require further work to ensure appropriate implementation across the HSC. This work will be overseen by the IHRD Programme Team.
- Phase 2B: The initial work has been completed by the relevant Workstream. The next stage of the work on these recommendations will reside with the appropriate DoH policy area (as distinct from the IHRD Programme Team).

18. Phase 2B (to run concurrently with Phase 2A) includes recommendations and actions in the areas of:

- Duty of Candour/Being Open (5 recommendations/10 actions);
- Independent Medical Examiner (1 recommendation);
- Death Certification (3 recommendations/3 actions);
- Serious Adverse Incidents (10 recommendation/18 actions); and
- RQIA Remit (5 recommendations).

Co-Production Approach to the IHRD Programme

19. From the outset the ethos of the programme was a co-production/involvement approach, involving a wide range of stakeholders, including service users and carers, HSC staff and third sector organisations. This inevitably means that the pace of progress has taken longer than if the Department had issued instructions but the consultation with all parties and their commitment to the programme and input to the solutions has gained us a valuable perspective, leading to the development of meaningful plans to address the issues raised in the IHRD Report.

20. As the IHRD programme was the largest co-production exercise the Department had committed to and engaged in, it was determined that it would be timely for a review of the approach adopted, as the first phase of work was coming to a conclusion and also to ensure that early thinking on Phase 2 was appropriately informed.

21. The review was led by Mr Peter McBride, an associate of the HSC Leadership Centre, who previously acted as the Chair of the IHRD Being Open Workstream. In undertaking his review, Mr McBride interviewed a large cross-section of the IHRD programme membership, with particular focus on the service users and carers who were members of the various Workstreams and Sub-Groups. Mr McBride's report details both positive and negative feedback from interviewees regarding the co-production approach adopted during the first phase of the programme.

22. The report makes a number of recommendations to improve the co-production approach of the IHRD programme into the future, and it is

suggested that all of the recommendations will be incorporated into planning for and implementation of Phase 2 of the IHRD programme.

23. The Department is happy to provide any further information to the Inquiry.

Department of Health
November 2022

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

The Regulation and Quality Improvement Authority (RQIA) is the independent body responsible for regulating and inspecting the quality and availability of Health and Social Care services in Northern Ireland. RQIA's reviews identify best practice, highlight gaps or shortfalls in services requiring improvement and protect the public interest. Reviews are supported by a core team of staff and by independent assessors who are either experienced practitioners or experts by experience. RQIA reports are submitted to the Department of Health (DoH) and are available on the RQIA website at www.rqia.org.uk.

Acknowledgements

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

Membership of the Expert Review Team

Maria Dineen	Managing Director of Consequence UK, Consultant to the National Patient Safety Agency 2001-2003, approved investigator - NHS England's serious incident framework and author of Six Steps to Root Cause Analysis.
Dr David Evans	Former Medical Director and Interim Chief Executive Northumbria Healthcare National Health Service Foundation Trust, England.
Dr Lourda Geoghegan	Former Director of Improvement and Medical Director, Regulation and Quality Improvement Authority (role in review ceased March 2020)
Emer Hopkins	Director of Hospital Services, Independent Healthcare, Audit and Reviews, RQIA (role in review commenced March 2020)
Mr Hall Graham	Professional Advisor, Regulation and Quality Improvement Authority.
Mrs Vivien Jess	Lay Representative and Independent Expert Advisor to the review
Mr Brian O'Hagan	Lay Representative and Independent Expert Advisor to the review
Dr Richard Wright	Former Medical Director of Southern Health and Social Care Trust and Professional Medical Advisor, Regulation and Quality Improvement Authority.

Table of Contents

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.

Personal Information redacted by the USI

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.

Personal Information redacted by the USI

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 2014[2] 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 2014[3] 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 Ireland[4]. 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 leaflet[5] 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 2009[6].

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 though other aspects of the methodology.

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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 Events[1]
- 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 NI[2] 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 nine responded. These were; the British Medical Association, 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 Alliance[8], 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 undertaken 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 132[3], (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 defendable 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 success[4], 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**	**6**

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

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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[3] Sir Liam Donaldson, The Right Time the Right Place: An expert examination of the application of Health and Social Care governance arrangements for ensuring the quality of care provision in Northern Ireland (December 2014). Available at: https://www.health-ni.gov.uk/publications/right-time-right-place Cited June 2022

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[5] HSCB, PHA. Information Leaflet – What I Need to Know About a Serious Adverse Incident for Service Users/Family Members/Carers. Available at: https://hscboard.hscni.net/download/PUBLICATIONS/QUALITY%20AND%20SAFETY/sai_learning_reports/English-Communication-with-the-Service-User-Family-and-Carers-following-a-Serious-Adverse-Incident.pdf Cited June 2022

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[7] CQC, Learning Candour and Accountability: A review of the way NHS trusts review and investigate the deaths of patients in England (December 2016). Available at: https://www.cqc.org.uk/sites/default/files/20161213-learning-candour-accountability-full-report.pdf Cited June 2022

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The **Regulation** and
Quality Improvement
Authority

FROM **PHIL RODGERS**
WORKFORCE POLICY DIRECTORATE

DATE **21 OCTOBER 2022**

TO **1. PETER MAY**
2. ROBIN SWANN MLA, MINISTER

SUB/XXXX/2022 – REVIEW OF MAINTAINING HIGH PROFESSIONAL STANDARDS (MHPS)

SUMMARY

ISSUE:	
TIMING:	**ROUTINE**
PRESENTATIONAL ISSUES	None at this time. Press Office will liaise with officials regarding a press statement in due course. Cleared by Press Office 21/10/22 (PMcC)
FOI IMPLICATIONS	Not disclosable at this time - Should be considered under sec 35 policy development and 41 information provided in confidence.
EXECUTIVE REFERRAL:	None
FINANCIAL IMPLICATIONS:	There will likely be some costs associated with delivering a review of MHPS but these will be small and can be managed from within existing budgets.
LEGISLATION IMPLICATIONS:	None
EQUALITY AND HUMAN RIGHTS IMPLICATIONS:	None
RURAL NEEDS:	None
SPECIAL ADVISOR COMMENTS:	
RECOMMENDATION:	It is recommended that you: • consider the draft Terms of Reference for this project and note that these will be finalised following discussion with the proposed Project Steering Group • note proposed approach to taking forward the review of Maintaining High professional Standards (MHPS); • note that officials have identified two potential experts who might be suitable to form the review panel to support this work moving forward; and • agree that officials should continue to progress this work including making initial engagement with potential panel members.

Background

1. *Maintaining High Professional Standards in the Modern HPSS* was published by the then Department of Health, Social Services and Public Safety (DHSSPS) in November 2005 and was effective from 1 December 2005. MHPS provides a framework "*for handling concerns about the conduct, clinical performance and health of medical and dental employees"*. The framework covers:

    - Action when a concern first arises;
    - Restriction of practice and exclusion from work;
    - Conduct hearings and disciplinary procedures;
    - Procedures for dealing with issues of clinical performance;
    - Handling concerns about a practitioner's health; and
    - Formal procedures – general principles.

2. Subsequent to its introduction, there have been two separate, but ultimately unfinished reviews of MHPS, each led by the Department, but working with HSS bodies/HSC employers. As both of these reviews were unfinished and therefore unimplemented, no action has been taken by the Department in regard to amending MHPS. The first review took place across the period 2011-2013 with a second review commencing in 2018.

Review of MHPS

3. The Independent Neurology Inquiry makes three specific recommendations with respect to MHPS as well as recommendations as to how the HSC more widely deals with the raising and investigation of concerns surrounding an individual's clinical practice.

4. In his statement to the Urology Services Inquiry, the Permanent Secretary committed to a review of MHPS being commissioned by the Department but conducted by persons external to the Department.

5. Officials have been working to identify an appropriate way forward for a review of MHPS. A draft Terms of Reference for the project is attached at **Annex A** for your consideration, this document includes a proposal as to how the project would be structured for deliver. You will wish to note that, the Terms of Reference will be considered and agreed by the proposed Project Steering Group at the commencement of the project before being finalised.

6. It is proposed that the Review be undertaken by a Panel of up to 3 individuals who would each bring differing expertise to the project. This panel would be supported by a small (secretariat) team of Departmental staff. The project would be overseen by a Steering Group of Departmental officials; local medical and dental leaders; HR expertise drawn from HSC alongside some external representatives. It is considered appropriate that the proposed panel include someone with practical experience of the operation of MHPS; someone who could bring appropriate medical input and perhaps someone with legal experience (in terms of employment law or clinical negligence).

7. The Department has taken soundings from colleagues across the UK and locally and have identified two potential experts that might assist with this project. Personal Informa Personal Information Personal Information redacted by the USI who we understand has undertaken a number of reviews of this nature. Personal Informat has experience with BMA engagement and policy work. Personal Information Personal Information redacted by the USI and is experienced in investigating and case managing concerns around doctors and dentists. Personal Informati on managed a team in Personal Information redacted by the responsible for investigating concerns for many years and more recently is Personal Information redacted by the USI . Personal Information also worked for several years with Personal Information redacted by the USI and has undertaken independent case management and investigations into doctor and dental concerns in Personal Information redacted by the USI Personal Information redacted by the . Officials have not been able to approach either individual yet but it would appear that both would be suitable members of the review panel. Officials are also actively seeking to identify a possible 3rd Panel Member

Recommendation

8. It is recommended that you:

- consider the draft Terms of Reference for this project and note that these will be finalised following discussion with the proposed Project Steering Group;
- note proposed approach to taking forward the review of Maintaining High professional Standards (MHPS);
- note that officials have identified two potential experts who might be suitable to form the review panel to support this work moving forward; and
- agree that officials should continue to progress this work including making initial engagement with potential panel members.

PHIL RODGERS
WORKFORCE POLICY DIRECTORATE

CC list:
Jim Wilkinson
Michael McBride
Caroline Lappin
Lourda Geoghan
Naresh Chada
Andrew Dawson
Robbie Davis
Chris Wilkinson

Review of MHPS – Draft Terms of Reference

Introduction

1. Maintaining High Professional Standards in the Modern HPSS: A framework for the handling of concerns about doctors and dentists in the HPSS, was published by the then Department of Health, Social Services and Public Safety (DHSSPS) in November 2005. It was modelled on a document titled "Maintaining High Professional Standards in the Modern NHS" which was first issued in December 2003 by the English Department of Health. The Northern Ireland MHPS document was effective from 1 December 2005 and remains in force. There have been no updates to the framework since its introduction in 2005.

2. MHPS was issued by the Department's then Human Resources Directorate Pay and Employment Unit on 30 November 2005, promulgated by Circular HSS(TC8) 6/2005. The framework is "*for handling concerns about the conduct, clinical performance and health of medical and dental employees"*. The framework is in six sections and covers:

    - Action when a concern first arises;
    - Restriction of practice and exclusion from work;
    - Conduct hearings and disciplinary procedures;
    - Procedures for dealing with issues of clinical performance;
    - Handling concerns about a practitioner's health; and
    - Formal procedures – general principles.

3. The Department currently has a three-year Service Level Agreement in place with NHS Resolution, which started in April 2020 to provide advice and guidance to HSC on the MHPS process which cover:

    - an advisory service to the Department for advice on cases arising and an assessment service on a case-by-case basis as agreed between the parties;

- an assessment and intervention service, including Professional Support and Remediation (PSR) services when required;
- support to local efforts to improve good practice in relation to the resolution of difficulties and concerns between the Practitioners and their employers and contractors, through policy support and website resources;
- support for reporting at a local level.

4. The Department's operational role in the application of MHPS is extremely limited, covering only the following issues:
    - review of longer term exclusions;
    - the recruitment and selection of appeals panels in clinical performance cases; and
    - provision of process advice to smaller HPSS (now Health and Social Care) organisations, where necessary
5. Subsequent to its introduction, there have been two separate, but ultimately unfinished reviews of MHPS, each led by the Department, but working with HSS bodies/HSC employers. As both of these reviews were unfinished and therefore unimplemented, no action has been taken by the Department in regard to amending MHPS. The first review took place across the period 2011-2013 with a second (incomplete) review commencing in 2018.
6. The Independent Neurology Inquiry makes three specific recommendations with respect to MHPS as well as recommendations as to how the HSC more widely deals with the raising and investigation of concerns surrounding an individual's clinical practice.

Key Issues

7. The Department of Health now wishes to commission a thorough review of MHPS as it operates in Northern Ireland. This review will be carried out by person(s) with relevant experience of MHPS but out with of HSC Northern

Ireland. The project will be overseen by a Project Steering Group. A structure of the project is attached as annex A.

8. The Review should consider:

    a. roles and responsibilities identified within MHPS

    b. the operation of MHPS in particular could the process be made less cumbersome or burdensome for both individuals and employers;

    c. the interaction between the informal and formal investigation stages;

    d. consider the changes made to MHPS in other jurisdictions and provide recommendations as to what improvements could be incorporated into the NI process;

    e. consult a wide range of stakeholders who have been involved in MHPS including those who have used the processes and guidance in HSC organisations

    f. recommendations with respect to the guidance element of the framework to ensure it is fit for purpose, clear to follow and compliments existing organisational policies for performance management of all staff e.g. disciplinary, capability, health and describe their relationship to the Framework.

    g. identify any skills development or training needed for those operating MHPS;

    h. the interaction MHPS has with other codes of conduct and performance management systems as well as other DoH policies such as whistle-blowing and ongoing work in relation to Candour and openness; Serious Adverse Incidents and the Department's Early Alert policy; and

    i. make recommendations as to which groups should be covered by MHPS, e.g. should its scope be extended to also include Pharmacists (not just Doctors and Dentists) directly employed by HSC organisations.

Outputs and Timelines

9. The project should complete within 6 months of commencing. The project should produce a final report setting out key findings and recommendations and a draft revised version of MHPS

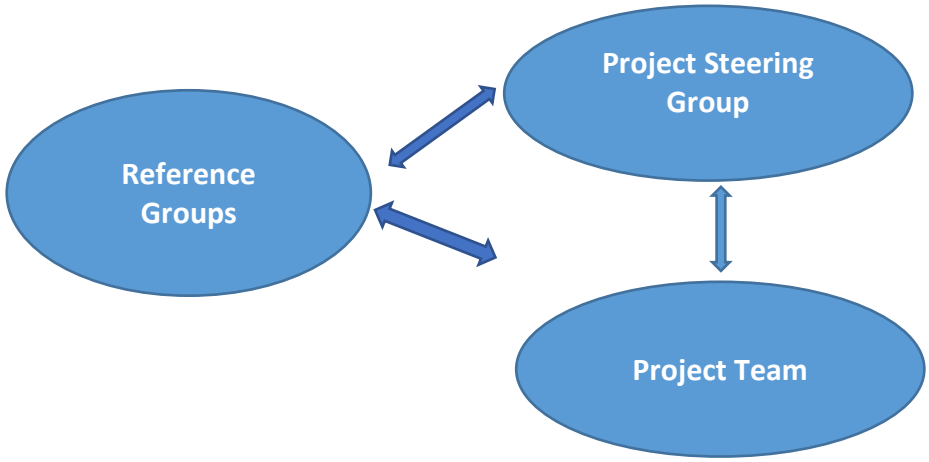
Annex A

Review of MHPS – Suggested Approach

A substantive review of the MHPS policy is overdue and must be made a priority for the Department.

The starting point for a review must be the relevant recommendations identified within the recently published report of the Independent Neurology Inquiry and will also need to consider the issues that had been highlighted previously through the two previous reviews of the policy which began and did not complete.

A review should be commissioned by the Department but conducted by persons external to the Department. The Department's Workforce Policy Directorate, working with the Chief Medical Officer Group, will take responsibility for the commissioning of the review.



Membership/Responsibilities

- **Project Steering Group**

  Oversight of project; ensuring delivered within agreed timescales; advice/guidance to project team/lead; review of draft and emerging reports; review and agreement of revised MHPS policy.

  Director, DoH Workforce Policy
  Deputy CMO
  Director, DoH Quality Safety and Improvement
  Trust Medical Director (* 2)
  Smaller ALB Medical Director (1 on behalf of all)
  Trust HR Director (*2)
  Smaller ALB HR Director (1 on behalf of all)
  Representative nominated by CDO
  External Representatives

- **Reference Groups**

  Existing groups to act as sounding board on key/emerging considerations; support to nominated representatives of Project Steering Group;

Medical Leaders Forum;
HR Directors Forum;
Responsible Officers Forum
Other external stakeholders as appropriate (e.g. GMC; BMA; BDA etc)

- **Project Team**

  Undertaking review; consultation with wide range of stakeholders; preparation of Review reports etc; drafting of amended MHPS policy for HSC.
  Review to be undertaken by a Panel of up to 3 individuals, external to DoH/HSCNI, who would each bring differing expertise to the project covering:

  i. Operational Experience;

  ii. Medical Expertise; and

  iii. Legal Knowledge

  DoH Project Team (Temporary Team for approx. 6 months) would have day to day responsibility for project delivery; supporting designated project team to enable project to be completed etc.

  WPD Grade 7
  Staff Officer/DP to support – possible secondee from HSC