The Regulation and Quality Improvement Authority

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Quality Assurance of the Review of the handling of all Serious Adverse Incidents reported between 1 January 2009 and 31 December 2013

December 2014

Assurance, Challenge and Improvement in Health and Social Care

www.rqia.org.uk

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 (HSC) services in Northern Ireland.

RQIA's reviews are designed to identify best practice, to highlight gaps or shortfalls in services requiring improvement, and to protect the public interest.

Our reviews are carried out by teams of independent assessors, most of whom are either experienced practitioners or experts by experience.

Our reports are submitted to the Minister for Health, Social Services and Public Safety and are available on the RQIA website at www.rqia.org.uk.

RQIA wishes to thank HSC staff, who facilitated this quality assurance exercise by participating in interviews or in providing relevant information.

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1. Introduction and Background to the Look Back Exercise

The vast majority of patients, clients and their families using health and social care services have a positive experience and receive a high quality service. Outcomes for patients and clients are improving on an ongoing basis, despite what can be a very challenging environment in terms of demographic change, new technologies and treatments, rising public expectations and finance.

However, amongst the millions of interactions between HSC Trusts, patients, clients and families there are some cases where things go wrong, or the quality of care falls below the standard which any of us would wish or expect. An important aspect of the quality of services being provided is how organisations and the people working within them respond in these instances.

The Chief Medical Officer, Department of Health, Social Services and Public Safety (DHSSPS), in a letter dated 9 April 2014, stated that recent events and the coverage of these events had shaken public confidence in health and social care services. In response, the Minister for Health, Social Services and Public Safety had decided that a number of actions should be undertaken in order to restore that confidence.

In relation to Serious Adverse Incidents (SAIs), each trust was required to review the handling of all SAIs reported between 1 January 2009 and 31 December 2013, providing the following information for each case:

- The SAI number
- Information on the trust's engagement with the patient/clients, or families/carers. If there was no engagement, details why
- In cases where patients/clients have died, confirmation or otherwise, that the statutory requirement to inform the Coroner had been complied with, where appropriate
- If appropriate, confirmation that the SAI was escalated and reported to other organisations; and
- Highlight any general or specific issues which had not been previously identified, which they now wish to bring to the attention of the DHSSPS/Minister

In respect of the Health and Social Care (HSC) Board's regional role with regard to SAIs, trusts were to liaise with the HSC Board with regard to any emerging issues.

With regard to any identified failures to report cases to the Coroner's office, trusts were to ensure that the proper process was complied with.

The exercise was to be completed and reports provided to the Permanent Secretary by 30 September 2014.

In order to provide independent assurance the Minister asked RQIA to quality assure the work each HSC Trust undertook as part of this look back exercise.

2. Serious Adverse Incidents

Commissioners and providers of health and social care wish to ensure that when a serious event or incident occurs, there is a systematic process in place for safeguarding services users, staff, and members of the public, as well as property, resources and reputation. One of the building blocks for doing this is a clear, regionally agreed approach to the reporting, management, follow-up and learning from serious adverse incidents (SAIs).

Each trust was required to review the handling of all SAIs reported between 1 January 2009 and 31 December 2013. It should be noted that guidance for the reporting and follow up of SAIs was first introduced in 2004 and has been subject to several changes, including during the period of the look back exercise.

These changes have impacted not only on the types of incidents which should be reported but also on the expected levels of family engagement required when an incident occurs. These changes must be taken into consideration when reviewing the work undertaken to review the handling of all SAIs reported between 1 January 2009 and 31 December 2013.

A background timeline detailing these changes is attached at Appendix 1.

2.1 Reporting and Follow up of Serious Adverse Incidents

The current procedure for the Reporting and Follow up of Serious Adverse Incidents (October 2013) was developed by the HSC Board in conjunction with other HSC organisations. This procedure aims to provide a system-wide perspective on serious incidents occurring within the HSC and Special Agencies. The procedure also takes account of the independent sector, where it provides services on behalf of the HSC.

The current HSC definition of a Serious Adverse Incident is:

'Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation'[1] arising during the course of the business of an HSC organisation/Special Agency or commissioned service.

The current criteria used to determine whether or not an adverse incident constitutes an SAI are attached at Appendix 2.

SAI investigations should be conducted at a level appropriate and proportionate to the complexity of the incident under review.

[1] Source: DHSSPS How to classify adverse incidents and risk guidance 2006 www.dhsspsni.gov.uk/ph_how_to_classify_adverse_incidents_and_risk_-_guidance.pdf

There are three levels of investigation:

- Level 1 Investigation: Significant Event Audit (SEA)
- Level 2 Investigation: Root Cause Analysis (RCA)
- Level 3 Investigation: Independent Investigation

While most SAIs will be subject to a Level 1 investigation, for some more complex SAIs, reporting organisations may instigate a Level 2 or 3 investigation immediately following the incident. Guidance on timescales for the completion of SAI investigations is set out at Appendix 3.

2.2 Involvement of Service Users/Relatives/Carers in Investigations

The current procedure for the Reporting and Follow up of Serious Adverse Incidents (October 2013) indicates that investigation teams should provide an opportunity for the service user/relative/carers to contribute to the investigation, as necessary.

The level of involvement clearly depends on the nature of the incident and the service users/relatives/ carers willingness to be involved. Teams involved in the investigation of SAIs should ensure sensitivity to the needs of the service user/relatives/carers involved in the incident and agree appropriate communication arrangements.

On the 31 March 2014 the Interim Chief Executive of the HSC Board wrote to HSC Trust Chief Executives requesting that SAI reports should include more information in relation to contact with families and their involvement in the investigation process.

In response the HSC Board and Public Health Agency (PHA) reviewed the SAI notification form and developed an SAI investigation report checklist, which should accompany all SAI investigation reports. This is designed to ensure that more detailed information about family involvement is consistently recorded.

The SAI investigation report checklist also includes details in relation to notification of the Coroner's office for death related SAIs.

The revised forms were implemented with immediate effect for all newly reported SAIs and for ongoing SAIs for which investigations had not yet been completed.

In April 2014, a group comprising HSC Board, Public Health Agency (PHA), Patient Client Council (PCC) and RQIA representatives was established to develop guidance for HSC organisations on engagement with patients, clients and families as part of the SAI process.

The draft guidance produced refers to the principles of being open with service users, carers and families and specifically highlights the various stages of engagement from recognition that a SAI has occurred, to the conclusion of the process.

The guidance has been informed by the National Patient Safety Agency (NPSA) 'Being Open' framework (2009)[2] and the Health Service Executive – Open Disclosure National Guidelines (2013)[3].

To support the engagement process, an SAI leaflet has been designed for organisations to give to service users, family and carers prior to any initial discussion regarding the SAI.

The draft guidance is currently at the final stages of consultation and once completed it will be formally issued to HSC organisations for implementation.

[2] http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726
[3] http://www.hse.ie/opendisclosure/

3. The Coroners Service for Northern Ireland

It is a statutory legal duty, based on the Births and Deaths Registration (Northern Ireland) Order 1976, for Registered Medical Practitioners to provide a Medical Certificate of Cause of Death (MCCD) without delay if, to the best of their knowledge, that person died of natural causes for which they had treated them in the last 28 days.

All doctors completing MCCDs should be aware of when and how to complete the forms and when deaths should be referred to the Coroner.

Coroners are independent judicial officers, who are available to deal with matters relating to deaths that may require further investigation and to establish the cause of death. Coroners in Northern Ireland can either be barristers or solicitors and are appointed by the Lord Chancellor.

Coroners inquire into deaths reported to them that appear to be:

- unexpected or unexplained;
- as a result of violence;
- an accident;
- as a result of negligence;
- from any cause other than natural illness or disease; or
- in circumstances that require investigation.

The Coroner will seek to establish the cause of death and will make whatever inquiries are necessary to do this e.g. ordering a post mortem examination, obtaining witness statements and medical records, or holding an inquest.

The criteria for reporting to the Coroners Service are attached at Appendix 4.

In March 2013, the DHSSPS issued circular HSS (MD) 8/2013: Investigating Patient or Client Safety Incidents.[4]. This Memorandum of Understanding (MOU) has been agreed between the DHSSPS, on behalf of Health and Social Care (HSC), the Police Service of Northern Ireland (PSNI), the Northern Ireland Courts and Tribunals Service (Coroners Service for NI) and the Health and Safety Executive for Northern Ireland (HSENI). The MOU sets out the general principles to observe when liaising with one another when joint or simultaneous investigations are required into a serious incident. A summary in relation to joint investigation of SAIs is set out at Appendix 5.

[4] Investigating patient or client safety incidents (March 2013)
http://www.dhsspsni.gov.uk/ph_mou_investigating_patient_or_client_safety_incidents.pdf

4. The RQIA Quality Assurance Exercise

In April 2014, each HSC Trust was asked to undertake a review of the handling of all SAIs reported between 1 January 2009 and 31 December 2013. RQIA was asked, by the Minister for Health, Social Services and Public Safety, to provide independent assurance on the process undertaken by HSC Trusts, with the aim of identifying learning points from the work of the review.

4.1 Terms of Reference

The terms of reference for this quality assurance exercise agreed by RQIA with the Department of Health, Social Services and Public Safety (DHSSPS) were to:

1) Document the findings of the review of the handling of all Serious Adverse Incidents reported between 1 January 2009 and 31 December 2013 undertaken by HSC Trusts.

2) Provide independent assurance on the process undertaken by HSC Trusts, to review the handling of all Serious Adverse Incidents reported between 1 January 2009 and 31 December 2013.

3) To identify learning points from the work of the review and make recommendations for improvement in handling of Serious Adverse Incidents in Northern Ireland.

RQIA was asked to complete this exercise in time to inform the wider Review of HSC Governance led by Sir Liam Donaldson. This wider review is due to report by December 2014.

4.2 Methodology

The principal requirement of this RQIA review is to provide independent assurance on the process undertaken by HSC Trusts to review the handling of all Serious Adverse Incidents (SAIs), reported between 1 January 2009 and 31 December 2013. This work has been undertaken with the aim of identifying learning points from the work of the review and making recommendations, where required, for improvement in the handling of SAIs in Northern Ireland.

The methods used included:

a) Collation and analysis of the findings of the look back exercise, undertaken by each of the 5 HSC Trusts, of the handling of all SAIs reported between 1 January 2009 and 31 December 2013
b) Stratified sampling of the SAIs identified by the look back exercise. This methodology allowed the sample to be divided into relevant subgroups. Following this, a fixed number of records were selected proportionally from the different

subgroups, thus ensuring the sample size of each subgroup was consistent across each trust.

c) A file audit quality assurance exercise was designed and carried out to provide independent assurance on the process undertaken by HSC Trusts
d) Discussions took place with staff responsible for the completion of the look back exercise to obtain their views on the process

4.3 The Quality Assurance Process

RQIA's quality assurance exercise took place during October and November 2014. On receipt of the information collated by each HSC Trust an initial analysis was undertaken. The purpose of this was to ascertain if the information returned was consistent across all trusts and to assist RQIA in identifying a suitable sample for the quality assurance exercise.

For the period 1 January 2009 to 31 December 2013 the total number of SAIs reported as part of this look back exercise was **1479.**

Of those, **59** SAIs were identified by trusts as being de-escalated since the original report was produced. In addition to this, an additional **3** SAIs were identified for reporting as a result of the look back exercise.

Figures for SAIs reported are broken down by trust in the table below:

Trust	Total SAIs Reported	SAIs Subsequently De-escalated	SAIs Retrospectively Identified	Total Cohort for RQIA study
BHSCT	381	36		**345**
NHSCT	378	4		**374**
SHSCT	232	0		**232**
SEHSCT	263	0	3	**260**
WHSCT	225	19		**206**
TOTALS	**1479**	**59**	**3**	**1417**

In addition to the HSC Trusts above, the Northern Ireland Ambulance Service HSC Trust reported 12 SAIs.

For the purpose of the RQIA study the case definition for inclusion in the quality assurance exercise was agreed as follows:

- Any SAI reported in the period 2009-2013; which was not subsequently de-escalated;
- SAIs may be open or closed at the time of the look back exercise;
- The study includes SAI reports from trust records which may not have been included on the original regional list.

It was agreed that a fixed number of 30 cases from each trust would be selected for audit. This on average represented a 10% sample size. The cases selected for quality

assurance were pre-notified to the trusts, to provide them with an opportunity to collate the supporting evidence used in the completion of the look back exercise.

Cases were selected using a stratified file sampling methodology, to ensure a balanced sample size across specific key areas relating to family engagement and Coroner contact, in those SAIs which involved a death. It was agreed that the 12 SAIs reported by the Northern Ireland Ambulance Service (NIAS) would not be subject to file audit but that RQIA would visit NIAS to discuss the process.

Following initial analysis and case selection an internal team from RQIA visited each trust. The visit comprised of 3 distinct elements:

- clarification of the trusts' interpretation of the spreadsheet headings,
- a file audit,
- discussion with staff responsible for the completion of the look back exercise.

Where any trust had deviated from the spreadsheet template, the reasons for this deviation were sought.

The file audit was undertaken to provide assurance that the information entered and subsequently submitted to the DHSSPS was recorded accurately. The file auditors were not required to make any determination as to the appropriateness of the actions undertaken or of the quality of the engagement which was documented as having taken place.

The file audit was undertaken using the approach outlined below:

- The RQIA team was briefed on the interpretation and completion of the look back exercise
- For each SAI a brief synopsis of the circumstances was provided, to enable to RQIA team to understand the actions taken

For those cases where family involvement was the primary focus the audit checked the accuracy of information recorded in relation to the following fields:

- if the patient/family/carer had been advised that the incident was being investigated
- if this had not been the case, the reason for non-engagement
- the date that the patient/family/carer had been advised
- the method by which the patient/family/carer had been advised
- if the final report of the investigation was shared with patient/family/carer
- the date that the final report of the investigation was shared
- if the trust had a record of the investigation recommendations
- fields relating to SAI escalation were also checked to ensure they were accurately completed

For those cases where notification of the Coroner was the primary focus the audit checked accuracy of the information recorded in relation to the following fields:

- the date of death
- if applicable, if the statutory requirement to report to the corner was complied with
- the date that the death had been reported to the Coroner
- the reason for any delay in reporting the death
- if the final report of the investigation was shared with the Coroner
- if as part of this review a death is to now be reported to the Coroner
- if applicable, if the family/carer had been informed
- if as part of this review additional information is to be provided to the Coroner
- if applicable, if the family/carer had been informed

Across each of the 30 cases, each entry was checked to ensure that the information contained within the spreadsheet was recorded accurately and that there was sufficient evidence provided to support this.

Following the file audit, the RQIA team spoke with staff responsible for the completion of the look back exercise. This discussion was undertaken using a semi structured interview approach and focused on the process undertaken, the benefits of the look back exercise and the emerging key issues.

5. Summary of Findings

Having completed the quality assurance exercise RQIA can confirm that each trust completed the look back exercise within the specified timeframe and provided their report to the DHSSPS as required.

In each trust, RQIA sampled 30 case files in order to provide assurance on the quality of the overall submission to the DHSSPS. The entries in each cell in the spreadsheet were cross referenced with documentary evidence held by trusts, in either hard copy or electronic format. Where the original documentation was not available the information was sourced from spreadsheets completed and signed off by individual directorates.

Involvement of Service Users/Relatives/Carers in Investigations

For those cases where family involvement was the primary focus, for each of the files sampled the following assurances can be provided:

Criteria	Findings
Was the patient/family/carer advised that the incident was being investigated	In all cases this field was completed correctly. • It was noted that in the South Eastern and Southern HSC Trusts that this would have been completed as a YES regardless of the terminology (SAI/investigation) used. • In the Western and Northern HSC Trusts they were very specific only to complete this as YES where they were certain that the term SAI was used. • In the Belfast HSC Trust they had received assurances that the terminology SAI was used but were unable to confirm this would always have been the case.
If not, the reason for non-engagement	In all cases this field was completed correctly. • It was noted where family engagement was recorded as not having taken place; each HSC Trust provided a valid reason for this decision.
The date that the patient/family/carer had been advised	In all cases this field was completed correctly. • This information was not included in the Southern HSC Trust return. However, RQIA were advised that this information would be available if required.
The method by which the patient/family/carer had been advised	In all cases this field was completed correctly. • This information was not included in the Southern

	HSC Trust return. However, RQIA were advised that this information would be available if required.
Was the final report of the investigation shared with patient/family/carer	In all cases this field was completed correctly. • There were however several differing interpretations of this. • In the Belfast HSC Trust this field would have been completed as YES if the report was shared, even if the method of sharing was by discussing the report in a meeting with the patient/family. • In the Southern HSC Trust this field would have been completed as a YES if the family were offered the final report even if this offer was declined • In the South Eastern HSC Trust this field was completed as YES if the **final** report was shared. However, within Mental Health services draft reports would also be shared with families, especially where they had input to the review. • In the Northern and Western HSC Trusts the focus on completing this field as YES was only for cases where the **final** report was shared but they are unable to confirm this in all cases.
The date that the final report of the investigation was shared	In all cases this field was completed correctly. • Again the issues around the final report criteria were different across each trust.
Does the trust have a record of the investigation recommendations	In all but one case this field was completed correctly. • In the case recorded incorrectly: It was noted that the trust did have a record of the recommendations, however the investigation had not been completed. • As this field was to be completed either YES or NO, variations were noted in relation to investigations where there were no recommendations.
SAI escalation	In all cases this field was completed correctly. • It was noted that this information was presented differently by the Southern HSC Trust. However, RQIA were advised that specific information would be available if required.

Notification of the Coroner

For those cases where notification to the Coroner was the primary focus, for each of the files sampled the following assurances can be provided:

Criteria	Findings
The date of death	In all but one case this field was completed correctly. • In the case incorrectly recorded: It was noted that the error had been the result of a tying error. • This information was not included in the Southern HSC Trust return. However, RQIA were advised that this information would be available if required.
If applicable, was the statutory requirement to report to the Corner was complied with	In all cases this field was completed correctly.
The date that the death had been reported to the Coroner	In all but one case this field was completed correctly. • In the case recorded incorrectly: It was noted that confusion had arisen due to the actual notification date and the date of an initial telephone call to the Coroner to discuss the requirement to report. • The instruction on the spreadsheet in relation to deaths in the community the date of reporting death to the Coroner was to be recorded as 'Not Known'. The Western HSC Trust completed the spreadsheet on this basis. Other trusts provided the date of reporting if this information was available to them.
The reason for any delay in reporting the death	In all cases this field was completed correctly. • It was noted where there had been a delay in reporting to the Coroner (11 cases in 3 different trusts); each trust provided a valid reason for this decision. • This information was not included in the Southern HSC Trust return. RQIA were advised that no such delays were identified by the trust.
Was the final report of the investigation was shared with the Coroner	In all but two cases this field was completed correctly. • In one case, it was noted that the error had been the result of entering the data into the wrong column. • In the other case, it was noted that the final report had been requested but that the request for the report had subsequently been withdrawn.

If as part of this review a death is to now be reported to the Coroner	In all cases this field was completed correctly. • This information was not included in the Southern HSC Trust return. RQIA were advised that no such cases were identified by the trust.
If applicable, had the family/carer been informed	In these remaining categories each field was completed accurately, however the use of NO and N/A was interchangeable. • This information was not included in the Southern HSC Trust return. RQIA were advised that no such cases were identified by the trust.
If as part of this review additional information is to be provided to the Coroner	In these remaining categories each field was completed accurately, however the use of NO and N/A was interchangeable. • This information was not included in the Southern HSC Trust return. RQIA were advised that no such cases were identified by the trust.
If applicable, if the family/carer had been informed	In these remaining categories each field was completed accurately, however the use of NO and N/A was interchangeable. • This information was not included in the Southern HSC Trust return. RQIA were advised that no such cases were identified by the trust.

5.1 The Look Back Exercise

Earlier in this report it has been noted that individual trusts have interpreted the headings in the spreadsheet in slightly different ways. This variation in approach makes it difficult to make any direct statistical comparisons between trust returns.

The time span of the look back exercise covered a five year period. During this period the SAI reporting requirements changed. These changes make any comparison of the data/trends over the time period very difficult.

These caveats need to be taken into account when reviewing the information submitted.

While each trust took a slightly different approach, they each described how they ensured consistency in adhering to that approach. This consistency in approach ensured that each trust spreadsheet was completed accurately.

In terms of the completion of the exercise, trusts described a similar process. In the main, the governance/risk management departments took a coordinating role, including the initial pre-population of the template spreadsheet using central records. The spreadsheet was then forwarded to individual directorates for further completion using their locally held records.

While the exercise was labour intensive in relation to the number of SAIs included, the information was reasonably easy to source, particularly for more recent incidents. While the governance/risk management departments hold central records in relation to SAI reporting and follow up, investigation files are usually held locally within the relevant directorates.

The Datix risk management system is used in each trust. Staff described that this system was helpful in retrieving records and documentation in relation to the later incidents being reviewed. Trusts did indicate that earlier manual systems were also robust, meaning that information could also be sourced from them, although this was a little more time consuming. Currently, the Datix system allows all documentation to be uploaded and linked to the relevant SAI. In addition, it can assist in tracking and cross referencing information across a number of associated modules, including litigation and complaints.

RQIA confirmed that this exercise was subject to quality assurance at a number of levels. Each trust described their own quality assurance processes at both directorate level, including the governance/risk management teams coordinating the look back exercise. Each of the trust teams was very specific about sourcing and/or validating the hard copy evidence to support the information being placed into the spreadsheet and in ensuring that directorates signed off their individual returns, as a true reflection of the handling of each SAI.

The oversight that the governance/risk management teams were able to bring to the process meant that the returns from each directorate were consistent and where there were anomalies, these could be challenged.

In each trust the final return was then signed off for submission to the DHSSPS and these were submitted within the required timescale.

5.2 Involvement of Service Users/Relatives/Carers in Investigations

The current procedure for the Reporting and Follow up of Serious Adverse Incidents (October 2013) indicates that investigation teams should provide an opportunity for the serviceuser/relative/carers to contribute to an SAI investigation. It is the responsibility of each individual trust to decide if such engagement is necessary. Trusts are advised that the level of involvement should be determined by the nature of the incident and the service users/relatives/carers wishes to be involved.

The procedure further advises that teams involved in the investigation of SAIs should ensure sensitivity to the needs of the service user/relatives/carers involved in the incident and agree appropriate communication arrangements.

Each of the trusts reported that family engagement was considered to be of paramount importance and was the default approach. They did however have some specific cases where they felt that a decision not to engage could be justified:

- where medical advice indicates that such contact may pose a risk to a person's health and wellbeing,
- where the person does not have the capacity or support to allow them to engage,
- where there are risks to security or safety or in cases where the subject is also the perpetrator of the incident.

All trusts reflected difficulties with the timescales for Level 1 and 2 investigations, which can make it difficult to effectively involve patients/families/carers in the SAI investigation process.

Trusts felt that families should determine their individual level of engagement in SAI investigations and not the HSC. Making the requirement to involve families so prescriptive may result in the person centred principles of engagement being eroded.

It was felt that further consideration should be given to the timescales for completion of final reports to allow for the involvement of the family in investigations, bearing in mind the individual case. There needs to be a degree of reasonability to ensure full and transparent engagement is possible.

At the time of completing this report, trusts are awaiting the outcome of the draft regional guidance on communicating with patients/clients, families/carers when a SAI occurs. This is currently at the final stages of consultation. The outcome of this review should be taken into account before finalising this guidance.

5.3 Notification of the Coroner

Each of the trusts confirmed that clinical staff are made aware of the responsibility to report deaths to the Coroner in accordance with the DHSSPS guidance on death, stillbirth and cremation certification, at both induction and via regular ongoing training. Guidance in relation to the reporting requirements is available when required.

It is the responsibility of a doctor to contact the Coroner. Such decisions should be recorded on the patient notes. This information can also be recorded on the SAI notification form if it is considered to meet the criteria for reporting as an SAI.

There is no written acknowledgement from the Coroner to confirm that the report has been made. However, if the Coroner then decides to open the case they will write formally to the trust advising of this. If the Coroner decides there is no case and that a death certificate can be issued without an inquest, there is no formal recording or acknowledgment of this decision.

Each trust described systems in place to ensure oversight of decisions to inform the Coroner and that reporting occurs when it is appropriate to do so.

5.4 Escalation of SAIs to other Agencies

The RQIA team was advised that in the majority of cases, escalation to other organisations was undertaken when required. Where there was any exception to this organisations were contacted to see if there was a need to report these cases retrospectively. Where there was such a requirement, reporting has now taken place.

5.5 Learning from the Look Back Exercise

Each trust outlined the benefits of the exercise and how it had helped them to reflect on their work. It has been helpful to give them reassurance that the SAI reporting system is working well and that the requirement for trusts to involve families in the SAI investigation process is being adhered to.

Where any issues have been identified, the exercise has given trusts the opportunity to address these to ensure that, in the future, the process is robust.

It has reinforced the need for family engagement and, for staff responsible for reporting to the Coroner to be aware of their responsibility.

The process has also provided a helpful 'checkpoint' to ensure that all action plans were being completed and collated, thus ensuring that learning was being taken forward.

5.6 General Issues Emerging for Future Consideration

The look back exercise in relation to the handling of all SAIs reported between 1 January 2009 and 31 December 2013 included the requirement for trusts to identify any issues which required trust or regional attention.

During the course of the exercise a number of key generic issues emerged across trusts.

Serious Adverse Incident Reporting Guidance:

The purpose of the procedure for the Reporting and Follow up of Serious Adverse Incidents (October 2013) is to provide guidance to HSC Organisations in relation to the reporting and follow up of Serious Adverse Incidents (SAIs).

Each trust indicated that the guidance is lengthy and can cause confusion. Sometimes it is difficult to clearly establish, from the guidance, what meets the criteria for an SAI and there is a feeling that consequently each trust is reporting things differently. In addition to this the changing criteria and reporting requirements makes the procedure difficult to embed in day to day practice.

Trusts expressed the opinion that the reporting process needs to be quick and easy to use. It must also be a process that supports trust staff and clinicians. It should not be difficult or cumbersome to use.

The following specific issues were raised:

1. Definition of the 'serious' aspect of the guidance.

   In the procedure for the Reporting and Follow up of Serious Adverse Incidents (October 2013) criteria are set out for trusts to determine whether or not an adverse incident constitutes an SAI. These include incidents where there is serious injury; serious self-harm; serious assault or serious incidents of public interest.

   However, in discussions, each trust described difficulties in defining 'serious' and expressed their concerns that interpretation of the term 'serious' may differ both within and across trusts.

   It would be beneficial to provide further guidance regarding definitions of 'serious' incidents that require investigation under the SAI procedure to ensure there is reporting on a consistent basis.

2. Concerns around the terminology used in relation to SAIs.

   The majority of trusts described how the current terminology often causes unnecessary worry and stress to the family. In addition to this it can cause further emotional distress and confusion for families, who because of the terminology think that there has been a deficit in the care provided.

3. Inclusion of the requirement to report "any death of a child in receipt of HSC services" via the SAI reporting procedure.

   In a case where the death of a child/baby has been expected/anticipated, or where they are on a palliative care pathway, their parents have already been supported and advised of the pending outcome. It is perhaps not then appropriate to advise them that the death has been reported as an SAI, unless there have been any specific service or care issues raised. At present, a number of trusts will engage with these families in a different way and without using the specific terminology of SAI.

Parallel Investigation Processes

It was noted that in a number of cases, SAI investigations run in parallel to other investigation processes, such as Vulnerable Adults or Looked after Children. The management of dual processes requires further consideration regarding communication with families and hierarchy of investigation processes. It would be helpful to review the regional approach to prevent duplication of effort and to minimise the potential for lack of clarity for service users.

Interface Incidents

Increasingly the trusts are seeing a rise in the reporting of interface incidents; where one trust makes the decision to report the SAI with the expectation that another trust will

undertake the investigation. It is recognised that in such cases there needs to be clear guidance on which trust should take the lead role in the investigation.

Timescales for Investigation

All trusts reflected difficulties with the timescales for Level 1 and 2 investigations, and the difficulties in ensuing involvement of patients/families/carers in the SAI investigation process. All trusts would welcome further discussion in regard to difficulties in meeting timescales and ensuring effective engagement with families.

Effective Engagement with Families

With an increasing focus on effective engagement with families, some trusts expressed a willingness to further explore parameters for good quality engagement and to have an agreed consistent approach to thresholds and rationales, to determine when family engagement is not appropriate.

The SAI Reporting System

The majority of trusts felt that the SAI system has become increasingly process driven. Concerns were raised that this has the potential to erode the learning element which is the core function of the SAI reporting and investigation procedure.

All trusts were keen to ensure that the SAI reporting system is maintained as an open and honest system, supporting high quality investigations and leading to sharing of learning arising from SAIs.

Trusts emphasised that when any changes to the system are being considered, there needs to be full engagement with all trusts to ensure that any revision is fit for purpose and can be operationalised at trust level. Even small changes in wording of guidance can have a significant impact on the interpretation and operation of the arrangements at local level.

RQIA recommends that the issues identified above should be considered in any future discussions in relation to the procedure for the Reporting and Follow up of Serious Adverse Incidents.

RQIA further recommend that in the future, when any changes to the procedure for the Reporting and Follow up of Serious Adverse Incidents (October 2013) are being considered; the HSC Board should ensure there is full and timely engagement with all HSC Trusts.

6. Conclusions

In conclusion, RQIA can provide assurance that all staff involved in the completion of the look back exercise were diligent in their undertaking to ensure that the work was completed by the required date.

Based on the findings from the quality assurance exercise, RQIA can further confirm that the information submitted provides an accurate reflection of the handling of each SAI reviewed.

All trusts had a multi-level quality assurance process for the exercise in place at both directorate and at corporate level. Information provided was cross referenced with and validated using corporate records, information held centrally in trust governance and risk management departments and also with records held electronically on their Datix Risk Management systems.

In discussion with trusts a number of common issues emerged for further consideration. All trusts view the SAI arrangements as a core part of the overall governance systems. They emphasised the need to ensure that there is a strong focus on identifying learning and sharing this between organisations in a timely manner.

RQIA recommends that the generic issues and the individual reflections of trusts from the exercise are used to inform the future development of the SAI arrangements. This report is being made available to support the work of the wider Review of HSC Governance led by Sir Liam Donaldson.

Serious Adverse Incident Reporting: Background Timeline

Circular HSS (PPM) 06/04 introduced interim guidance on the reporting and follow-up on serious adverse incidents (SAIs). Its purpose was to provide guidance for HPSS organisations and special agencies on the reporting and management of SAIs and near misses.[5]

Circular HSS (PPM) 05/05 provided an update on safety issues; and underlined the need for HPSS organisations to report SAIs and near misses to DHSSPS in line with Circular HSS (PPM) 06/04.[6]

Circular HSS (PPM) 02/2006 drew attention to certain aspects of the reporting of SAIs which needed to be managed more effectively. It notified respective organisations of changes in the way SAIs should be reported in the future and provided a revised reporting pro forma. It also clarified the processes DHSSPS had put in place to consider SAIs, outlining the feedback that would then be made to the wider HPSS.[7]

In March 2006, DHSSPS introduced Safety First: A Framework for Sustainable Improvement in the HPSS. The aim of this document was to draw together key themes to promote service user safety in the HPSS. Its purpose was to build on existing systems and good practice so as to bring about a clear and consistent DHSSPS policy and action plan.[8]

The Health and Personal Social Services (Quality Improvement and Regulation) (Northern Ireland) Order 2003 imposed a 'statutory duty of quality' on HPSS Boards and Trusts. To support this legal responsibility, the Quality Standards for Health and Social Care were issued by DHSSPS in March 2006.[9]

Circular HSC (SQS) 19/2007 advised of refinements to the DHSSPS SAI system and of changes which would be put in place from April 2007, to promote learning from SAIs and reduce any unnecessary duplication of paperwork for organisations. It also clarified arrangements for the reporting of breaches of patients waiting in excess of 12 hours in emergency care departments.[10]

Under the Provisions of Articles 86(2) of the Mental Health (NI) Order 1986, the Regulation & Quality Improvement Authority (RQIA) has a duty to make inquiry into any case where it appears to the Authority that there may be amongst other things, ill treatment or deficiency in care or treatment. Guidance in relation to reporting requirements under the above Order previously issued in April 2000 was reviewed,

[5] www.dhsspsni.gov.uk/hss(ppm)06-04.pdf
[6] www.dhsspsni.gov.uk/hssppm05-05.pdf
[7] www.dhsspsni.gov.uk/qpi_adverse_incidents_circular.pd
[8] www.dhsspsni.gov.uk/safety_first__a_framework_for_sustainable_improvement_on_the_hpss-2.pdf
[9] www.dhsspsni.gov.uk/qpi_quality_standards_for_health___social_care.pdf
[10] www.dhsspsni.gov.uk/hss__sqsd__19-07.pdf

updated and re-issued in August 2007. (Note: Functions of the previous Mental Health Commission transferred to RQIA on 1 April 2009).[11]

Circular HSC (SQSD) 22/2009 provided specific guidance on initial changes to the operation of the system of SAI reporting arrangements during 2009/10. The immediate changes were to lead to a reduction in the number of SAIs that were required to be reported to DHSSPS. It also advised organisations that a further circular would be issued giving details about the next stage in the phased implementation. This would manage the transition from the existing DHSSPS SAI reporting system, through its cessation and to the establishment of the Regional Adverse Incident and Learning (RAIL) system.[12]

Circular HSC (SQSC) 08/2010, issued in April 2010, provided guidance on the transfer of responsibility for SAI reporting arrangements from the DHSSPS to the HSC Board, working in partnership with the Public Health Agency. It also provided guidance on the revised incident reporting roles and responsibilities of HSC Trusts, Family Practitioner Services, the Health & Social Care (HSC) Board and Public Health Agency (PHA), the extended remit of the Regulation & Quality Improvement Authority (RQIA), and the role of the DHSSPS.[13]

Circular HSC (SQSD) 10/2010 advised on the operation of an Early Alert System, the arrangements to manage the transfer of Serious Adverse Incident (SAI) reporting arrangements from the DHSSPS to the HSC Board, working in partnership with the Public Health Agency. It also details the incident reporting roles and responsibilities of Trusts, family practitioner services, the new regional organisations, the Health & Social Care (HSC) Board and Public Health Agency (PHA), and the extended remit of the Regulation & Quality Improvement Authority (RQIA).[14]

In May 2010 responsibility for management of SAI reporting transferred from the DHSSPS to the HSC Board working in partnership with the Public Health Agency (PHA). Following consultation with key stakeholders, the HSC Board issued the procedure for the 'Reporting and Follow up of Serious Adverse Incidents' to HSC Trusts, Family Practitioner Services (FPS) and Independent Service Providers.[15]

In May 2010 the Director of Social Care and Children HSC Board issued guidance on 'Untoward Events relating to Children in Need and Looked after Children' to HSC Trusts. This guidance clarified the arrangements for the reporting of events, aligned to delegated statutory functions and Departmental Guidance, which are more appropriately reported to the HSC Board Social Care and Children's Directorate.

In 2005 the Regional Adult Protection Forum produced standardised, regional policies and procedures in the 'Safeguarding Vulnerable Adults' document, a framework based on

[11] www.dhsspsni.gov.uk/utec_guidance_august_2007.pdf
[12] www.dhsspsni.gov.uk/hsc-sqsd-22-09.pdf
[13] http://www.dhsspsni.gov.uk/index/phealth/sqs/sqsd-guidance.htm
[14] http://www.dhsspsni.gov.uk/hsc__sqsd__10-10.pdf
[15] http://www.hscboard.hscni.net/publications/Policies/101%20Serious%20Adverse%20Incident%20-%20Procedure%20for%20the%20reporting%20and%20followup%20of%20SAI%20-%20April%202010%20-%20PDF%20268KB%20.pdf

best practice. This document represented a major new phase in improving adult protection arrangements across the region.[16]

In February 2011 the HSC Board issued the 'Protocol for responding to SAIs involving an alleged homicide' perpetrated by a service user known to/referred to mental health and/or learning disability services, in the two years prior to the incident. This was revised in the 2013 HSC Board 'Protocol for responding to SAIs involving an alleged homicide'.

Circular HSS (MD) 8/2013 replaced HSS (MD) 06/2006 and advised of a revised Memorandum of Understanding (MOU), between the DHSSPS, on behalf of Health and Social Care (HSC), the Police Service of Northern Ireland (PSNI), the Northern Ireland Courts and Tribunals Service (Coroners Service for NI) and the Health and Safety Executive for Northern Ireland (HSENI), when investigating patient or client safety incidents. This revised MOU was designed to improve appropriate information sharing and coordination when joint or simultaneous investigations were required when a serious incident occurs.[17]

A DHSSPS Memo dated 17 July 2013 from Chief Medical Officer introduced the HSC Board/PHA protocol on the dissemination of guidance/information to the HSC and the assurance arrangements where these are required. The protocol assists the HSC Board/PHA in determining what actions would benefit from a regional approach rather than each provider taking action individually.

[16] www.hscboard.hscni.net/publications/LegacyBoards/001%20Regional%20Adult%20Protection%20Policy%20and%20Procedural%20Guidance%202006%20-%20PDF%20249KB.pdf

[17] http://www.dhsspsni.gov.uk/ph_mou_investigating_patient_or_client_safety_incidents.pdf

Serious Adverse Incident: Reporting Criteria

The following criteria determine whether or not an adverse incident constitutes a SAI.

- Serious injury to, or the unexpected/unexplained death of:
    - a service user (including 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;

- Any death of a child in receipt of HSC services (up to eighteenth birthday). This includes hospital and community services, a Looked After Child or a child whose name is on the Child Protection Register;
- 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 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.

Any adverse incident that meets the criteria of an SAI should be reported within **72 hours** of the incident being discovered using the SAI Notification Form.

Serious Adverse Incident Investigations

Level 1 Investigation: Significant Event Audit (SEA)

Most SAI notifications will enter the investigation process at this level and an SEA will immediately be undertaken to:

- assess why and what has happened
- agree follow up actions
- identify learning

If it is determined this level of investigation is sufficient, an SEA report will be completed and sent to the HSC Board within 4 weeks (6 weeks by exception) of the SAI being reported.

If the SEA determines the SAI is more complex and requires a more detailed investigation, the investigation will move to either a Level 2 or 3 investigation. In this instance the SEA report will still be forwarded to the HSC Board within 4 weeks (6 weeks by exception) of the SAI being reported with additional sections being completed to outline membership and Terms of Reference of the team completing the Level 2 or 3 investigations.

Level 2 Investigation: Root Cause Analysis (RCA)

When a Level 2 or 3 investigation is instigated immediately following notification of a SAI, the reporting organisation will inform the HSC Board within 4 weeks, of the Terms of Reference and Membership of the Investigation Team. A final report must be submitted to the HSC Board either within 12 weeks from the date the incident was discovered or within 12 weeks from the date of the SEA.

In most circumstances, all timescales for submission of RCA investigation reports must be adhered to. However, it is acknowledged, by exception, there may be occasions where an investigation is particularly complex. In these instances the reporting organisation may request one extension to the normal timescale i.e. 12 weeks from timescale for submission of SEA report. This request must be approved by the Designated Review Officer (DRO) and should be requested when submitting the SEA report.

Level 3 Investigation: Independent Investigation

Level 3 investigations will be considered for SAIs that:

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

In some instances the whole team may be independent to the organisation/s where the incident/s has occurred. The timescales for reporting will be agreed by the HSC Board/PHA Designated Review Officer (DRO) at the outset.

Criteria for reporting to the Coroners Service

Not all deaths are reported to the Coroner. In most cases, a General Practitioner (GP) or hospital doctor can certify the medical cause of death and the Registrar of Births, Deaths and Marriages can register the death in the usual way.

However, if a doctor has not seen and treated the deceased for the condition from which they died within 28 days of death, or the death occurred in any of the circumstances detailed below, then the death should be reported to the Coroner (Section 7 of the Coroners Act (Northern Ireland) 1959).

A death is reported to the Coroner in the following situations:

- a doctor did not treat the person during their last illness;
- a doctor did not see or treat them in the 28 days before they died;
- the cause of death was sudden, violent or unnatural such as an accident, or suicide;
- the cause of death was murder;
- the cause of death was an industrial disease of the lungs such as asbestosis; or
- the death occurred in other circumstances that may require investigation.

If a death occurs in hospital it should be reported if:

- there is a question of negligence or misadventure about the treatment of the person who died;
- they died before a provisional diagnosis was made and the general practitioner is not willing to certify the cause; or
- the patient died as the result of the administration of an anaesthetic.

In relation to Prison Healthcare, a death should be reported by the governor of a prison, immediately following the death of a prisoner.

Members of the deceased's family, who have concerns about the cause of death given by a doctor, may contact the Coroner's Office to discuss this with the Coroner.

When a death is reported to the Coroner, initially the Coroner will gather information to investigate whether the death was due to natural causes and if a doctor can certify the medical cause of death. The Coroner will authorise the police to gather this information which means that they will need to speak to relatives and others present when the death occurred or involved in the care of the deceased.

If the reason why a doctor cannot certify the death is simply because they have not treated the patient in the last 28 days, then the Coroner will discuss the cause of death with the doctor. If the Coroner is satisfied that the death was from natural causes and no further investigation is necessary, then the Coroner may accept the medical cause of

death that the doctor gives and issue a Coroner’s notification to enable the death to be registered.

If a doctor cannot certify the medical cause of death then the Coroner will investigate the death and may order a post mortem examination to be carried out.

Joint Investigations of Serious Adverse Incidents

In March 2013, the DHSSPS issued circular HSS (MD) 8/2013: Investigating patient or client safety incidents.[18] It outlined a Memorandum of Understanding agreed between the DHSSPS, on behalf of Health and Social Care (HSC), the Police Service of Northern Ireland (PSNI), the Northern Ireland Courts and Tribunals Service (Coroners Service for NI) and the Health and Safety Executive for Northern Ireland (HSENI). It set out the general principles to observe when liaising with one another when joint or simultaneous investigations are required into a serious incident, and applies to people receiving care and treatment from HSC in Northern Ireland.

The principles and practices promoted in the document apply to other locations, where health and social care is provided e.g. it could be applied when considering an incident in a family doctor or dental practice, or for a person receiving private health or social care provided by the HSC.

The purpose of the MOU is to promote effective communication between the organisations. The MOU takes effect in circumstances of unexpected death or serious untoward harm requiring investigation by the PSNI, Coroners Service for NI or HSENI separately or jointly. This may be the case when an incident has arisen from or involved criminal intent, recklessness and/or gross negligence, or in the context of health and safety, a work-related death.

The MOU intended to help:

- Identify which organisations should be involved and the lead investigating body.
- Prompt early decisions about the actions and investigations thought to be necessary by all organisations and a dialogue about the implications of these.
- Provide an understanding of the roles and responsibilities of the other organisations involved in the memorandum before high level decisions are taken.
- Ensure strategic decisions are taken early in the process and prevent unnecessary duplication of effort and resources of all the organisations concerned.

HSC Organisations should note that the MOU does not preclude simultaneous investigations by the HSC and other organisations e.g. Root Cause Analysis by the HSC when the case is being investigated by the Coroner's Service and/or PSNI/HSENI.

In these situations, the Strategic Communication and Decision Group can be used to clarify any difficulties that may arise; particularly where an external organisation's investigation has the potential to impede a SAI investigation and subsequently delay the dissemination of regional learning.

[18] Investigating patient or client safety incidents (March 2013)
http://www.dhsspsni.gov.uk/ph_mou_investigating_patient_or_client_safety_incidents.pdf

Appendix 6

Detailed Findings for Health & Social Care Trusts

The principal requirement of this RQIA review is to provide independent assurance on the process to review the handling of all Serious Adverse Incidents (SAIs), reported between 1 January 2009 and 31 December 2013, by HSC Trusts.

During November 2014 an internal team from RQIA visited each trust. Each visit comprised of 3 distinct elements:

- clarification of the trusts' interpretation of the look back spreadsheet headings,
- a file audit,
- discussions with staff responsible for the completion of the look back exercise

The quality assurance exercise focused on the work undertaken in each trust, with the aim of identifying learning or key issues emerging for future consideration.

The detailed findings for each trust are reported overleaf.

Belfast Health & Social Care Trust

The Look Back Exercise

In the Belfast HSC Trust, the Governance Manager had the responsibility for the coordination, completion and submission of the look back exercise. The work was undertaken in partnership within a number of directorates which assisted with the collation and validation of the required information. Some administrative support was available.

The spreadsheet was pre-populated as far as possible using centrally held files in the governance department. There was then additional work undertaken to prepare the spreadsheet for circulation to directorates. This included the insertion of names, the service area and a synopsis of the incident. The purpose of this was to assist directorates in tracing the cases.

The information required for the completion of the exercise was easily accessible where the information could be retrieved from the original SAI reporting forms and from final investigation reports or Datix. Where this was not the case, the information was more difficult to retrieve and required follow up with directorates and other records such as associated complaints or litigation cases.

Since 2010, all centrally held SAI documentation has been stored in electronic format. Information is uploaded onto Datix and linked to individual SAIs but it is also retained in the email system and saved in a series of shared folders.

This exercise was subject to quality assurance at a number of levels.

Returns from each directorate were collated by the trust Governance Manager and an initial pre-population of the spreadsheet took place, using detailed documentary evidence held by the SAI/governance team.

Entries in relation to the escalation fields were populated using Datix. These were then sent to the specialist areas responsible for reporting to those external organisations i.e. NIAIC to the Medical Device manager, RIDDOR to the Health & Safety Manager, ICO to the Data Manager, for them to confirm that all additional notifications were appropriate and that nothing had been missed.

Entries in relation to corner engagement were sent to the trust's litigation office to ensure that records were consistent with the information they held.

A first draft of the spreadsheet was shared with the Medical Director and co-director for risk and governance; this was then circulated to directorates for review and QA. On the circulated spreadsheet, any areas where there was no evidence to support specific submissions were highlighted and directorates were asked to provide the necessary evidence and to ensure that all fields were correct. There then followed a period of communication and clarification of entries in conjunction with governance managers in

each directorate. At the close of the process, directorates were asked to sign off their individual returns ensuring this was a true reflection of the engagement/notification for each SAI.

The final return was then sent to directors for finalising prior submission to the DHSSPS. The return was submitted in accordance with the required timescale.

Involvement of Service Users/Relatives/Carers in Investigations

The trust's Being Open policy was introduced in November 2011 and was revised in summer 2014. The Being Open policy has been included in mandatory incident reporting training since March 2014 and the revised policy will be supported by a new e-learning package for staff.

In June 2014, the trust put in place a revised SAI procedure, taking into account the new HSC Board requirements re family engagement. Currently all SAI investigations are treated on a case by case basis as requiring full engagement, unless deemed inappropriate.

The director and co-director for each service area have the overall responsibility for deciding if the family should be informed. Following this, the clinician or the identified link person would be the one who would make initial contact with the family/patient.

Contact with the family can be recorded on the SAI form but it is not always recorded given the timeframe to report the incident.

The trust has developed a Patient/Family/Carer SAI information leaflet which is issued during every SAI investigation. This leaflet gives details of the link person who will be responsible for ensuring continuous communication throughout the investigation process.

At service level if a decision is taken not to engage this is approved by the director/co-director. The director/co-director also approves the SAI reporting form prior to submission, thus giving a further opportunity to challenge decisions on family engagement. The director will also approve the final SAI investigation report and checklist and in doing so approves that appropriate family and Coroner engagement has occurred.

Currently decisions not to engage with families are being more robustly challenged. However, it was noted that there are occasions where the trust decides that family engagement is not appropriate; there is a clear understanding of the types of cases where families would not routinely be involved.

On occasions, where multiple patients have been involved in an SAI the trust has taken a decision that it is not appropriate to inform or share the final report with those affected. However, the trust would welcome some further guidance in such cases.

The level of engagement for all new SAIs is now recorded and reported to the trust internal SAI group. This report, which provides information on the level of family engagement, gives other co-directors and the Medical Director, who chairs this group, a further opportunity to challenge decisions not to engage.

Decisions not to engage can also be discussed at the trust's ethics committee, to ensure further oversight if required.

Notification of the Coroner

There is a trust policy 'Actions Following a Patient's Death', which includes a section on what, when and how to report to the Coroner

A clinician makes the decision to contact the Coroner and this is recorded in the patient notes and also on the SAI reporting form by governance staff, after they have been notified. The Coroner should provide an initial opinion during the first contact with the clinician, whether or not there is to be an inquest. This decision should be recorded in the notes.

To re-enforce appropriate Coroner engagement, the trust has revised its own SAI checklist to add an additional two prompts for staff during investigation:

- was the SAI referred to the Coroner
- should the final report be offered to the Coroner

If the response to either question is YES then the information will be sent to the Medical Director to ensure that this is the correct decision. Closer working between the Litigation Department and the SAI team has ensured improved management of Coroner involvement.

The trust advised that the Coroner is not informed of any expected, anticipated or palliative deaths in keeping with section 7 of the Coroners Act (NI) 1959. In general, unless the investigation highlights any issues of concern which contribute to the person's death, the investigation report will not routinely be shared with the Coroner. However, if the SAI was originally reported to the Coroner they may well request the final report as a matter of course.

Recently, an RCA Forum of Chairs has been set up to help improve the investigation of SAIs. The trust has developed an information pack, for them, which includes guidance on engagement with the Coroner.

The director and the co-director for each service area have oversight of decisions to contact the Coroner; they also approve the SAI reporting form prior to submission, thus giving a further opportunity to challenge decisions on Coroner reporting. It is rare that a case would be identified, where the requirement to contact the Coroner was not met.

Each death is supposed to be reviewed by a Consultant who should examine whether the completion of an Medical Certificate of Cause of Death (MCCD) or referral to the Coroner is correct and appropriate. The local Mortality and Morbidity meeting would review all deaths. If a case, upon review, should have been reported to the Coroner, then it should then be reported.

As a result of the trust's own internal review of SAI handling, 5 deaths in the Emergency Department were considered for reporting retrospectively. The trust was asked to review these cases after the SAI investigation to consider whether they needed to be referred to the Coroner.

Escalation of SAIs to other Agencies

The RQIA team was advised that all SAIs were escalated appropriately to other organisations as required. There was only one exception to this in relation to a RIDDOR report; this has since been reported retrospectively.

Learning from the Look Back Exercise

When the look back exercise was announced the Belfast HSC Trust was in the final stages of completing their own review of SAI handling, which had a specific focus on family and Coroner engagement. As part of this work and the subsequent SAI look back exercise it became clear that several issues were emerging in relation to SAI handling.

This exercise has facilitated a clearer understanding of patient/family/carer engagement in the SAI process. Healthcare associated infections (HCAI), root cause analysis (RCA) and one-off mental health unscheduled care assessments are not now automatically excluded from patient/family engagement but are treated on a case by case basis as requiring full engagement unless deemed inappropriate.

The look back exercise has also provided an opportunity for the trust to reinforce the need for family engagement and Coroner reporting requirements to those staff responsible for this. In addition to this, it has provided an opportunity for the trust to ensure that action plans are being completed and collated.

Key Issues Emerging for Future Consideration

Serious Adverse Incident Reporting Guidance:

The trust felt that the guidance for SAI reporting is lengthy and can cause confusion. The changing criteria make the procedure difficult to embed and allows for variation in interpretation, both within and across trusts.

There is nowhere where the serious part of the SAI guidance is defined. Risks and harm are categorised across the HSC as catastrophic or major. Risk matrices do not have a serious category.

The reporting of child deaths is one area that causes the most difficulty for the trust. For example when a child is on a palliative care pathway their parents, who have already been supported and advised of the pending outcome, are not advised that the death has been reported as an SAI, unless service or care issues have been raised during the review. The trust would welcome some further consideration of the difficulties in relation to these SAIs.

The trust had some problems with the terminology of SAI. This has been raised previously with the HSC Board. It is felt that the use of this terminology causes unnecessary worry and stress for patients and families and that it can also cause emotional distress and confusion.

Timescales for investigation:

The trust outlined some difficulties with the timescales for the investigation of incidents, particularly those which are graded as Level 1. They felt that the timescale of 4 weeks is difficult to achieve. This may in exceptional cases be extended to 6 weeks, however they feel that this is still challenging.

For Level 2 incidents the timescale for investigation is extended to 12 weeks, however these timescales are also difficult to adhere to. Specific difficulties were identified:

- Where independent expertise is required, it is often difficult to source and once secured it can be difficult to get the necessary meetings arranged in the timescales.
- Staff often wish to examine potential legal issues with their advisors before becoming involved in an investigation.
- There needs to be robust scrutiny and approval before final SAI reports are issued, this often takes some time.
- There are routine staffing issues to consider such as sickness and annual leave, all of which have the potential to delay the investigation process.
- Ensuring appropriate family engagement can challenge compliance with timescales.

Until recently, the trust had been performing well in relation to timescales. If they identified a genuine delay the HSC Board would have been willing to grant an extension. However, since May 2014, the HSC Board is applying the extension request process more rigorously.

For Level 2 incidents, the requirement is to ask for an extension when submitting the terms of reference and membership of the investigation team. Requests outside of this are rejected. Often the need for an extension will not be evident until after this time. There has been little or no recognition of the difficulties this creates.

The trust feels that the investigation timescales, particularly in Level 1 investigations, are too short to ensure true engagement with patients/families. The aim of engagement is to hear families' experiences and to ensure the investigation takes account of their views. However sensitivity may be required meaning that immediate contact is not always appropriate.

The trust has commented on the consultation for the HSC guidance on engagement with patients, clients and families as part of the SAI process, outlining their difficulties with the level of family engagement as outlined in the draft guidance. The trust feels it is important for patients/families to determine the level of this engagement and not the HSC. The trust feels that by making the guidance too prescriptive may result in a loss of the person centred approach.

There is a degree of performance management in relation to SAIs and directorates have a record of their performance in relation to response times and they are then held to account regarding adherence to timeframes.

Northern Health & Social Care Trusts

Look Back Exercise

In the Northern HSC Trust, the Head of Governance and Patient Safety and the Senior Risk Coordinator had the responsibility for the coordination, completion and submission of the look back exercise. The exercise was undertaken using a project management structure with a project team consisting of 3 staff, with a nursing background, assisting the team in the collation and validation of the information required.

At the outset of the exercise all trusts met to agree the methodology to be adopted. The DHSSPS developed the spreadsheet for recording the information taking into account the comments from the trusts.

The spreadsheet was pre-populated as far as possible using centrally held files in the governance department. The spreadsheet template was then forwarded to representatives within a number of directorates who verified the information provided, based on the information available in the source files.

In SAIs reported in the earlier years it was difficult to access some of the records. On occasions there was some difficulty in clarifying the information, as the staff involved in the investigation had left the organisation. The level of detail in the documentation improved in the later years. Initially, all governance documentation relating to SAIs was not uploaded on to the Datix system. This is now standard procedure and this has proved beneficial when retrieving information for the later SAIs.

This exercise was subject to quality assurance at a number of levels.

Information relating to Coroner's cases opened with the trust is held centrally by the governance department. This assisted in the validation of the information in templates returned from each directorate, where the information was added as required.

The governance department then reviewed a sample of SAIs, in order to ensure that there was evidence to support the entries in the spreadsheet. Clarification was sought to ensure there had been a consistent interpretation of the question/headings in the spreadsheet. For example, when considering the question around advising a patient/family/carer of an SAI investigation, they ensured that the terminology of SAI was used.

The governance team was able to advise if the case had been investigated through other relevant processes, such as complaints and litigation, meaning that information could be sourced from these records.

This oversight from the governance department ensured there was consistency to the process.

Involvement of Service Users/Relatives/Carers in Investigations

The trust noted that the involvement of patients, families and carers has improved over time.

As part of this look back exercise there has been a process in place to consider the level of patient/ family/carer involvement and a decision has been further taken to review all SAIs reported, back to 2010, to consider the quality of patient/family carer involvement.

The trust Chief Executive has issued a number of memos that have reiterated the duty of transparency and reminding staff that the patient/family/carers should be involved in SAI investigations

It is usually the chair of each SAI investigation that would decide if the patient and/or family should be engaged in the investigation process. Should there be any doubt regarding the impact that this information may have on the health and wellbeing of the patient and/or family, the chair of the investigation would seek advice from relevant clinicians involved in the treatment of the individual.

Following introduction of the new procedure, the trust has developed two leaflets, one for child deaths and one for adult deaths. These are designed to support both staff and patients/families in the discussion around the SAI investigation process. These leaflets very clearly use the terminology of serious adverse incident.

Generally, the trust would not engage with patients and/or families in the following circumstances:

- In the event of a death when no next of kin can be established
- concerns regarding the impact this information may have on health and wellbeing of patient/client
- the case involved suspected or actual abuse by family
- not relevant (for example assault on staff)
- general issue (bad weather, equipment failure affecting a service/multiple clients)

In a small number of cases it was felt that it may be detrimental to share the SAI investigation findings; however this was not noted as a frequently used reason.

On occasions, there are unique circumstances, such as the inability to trace the next of kin in order to advise them that an SAI has been reported. This can be a difficult situation; whilst a number of attempts to contact a relative will be attempted the regional guidance currently in place does not address the expectations regarding this.

When a decision is made not to engage with patients and/or families the rationale for this is now recorded, by the chair of the review, in the family involvement form.

The trust is now progressing a process where operational directors and executive directors from each discipline oversee decisions not to involve the patient and/or family at any stage in the process, in order to assess their appropriateness

Patient/family carer involvement forms are approved by the directors of operational directorates and any particular areas of concern currently would be escalated to the executive director for a second opinion. These are kept under review and contact can be made at a later stage, if further information is acquired indicating that involvement is now appropriate, or that involvement has not been appropriate to date.

The trust governance department also reviews incoming family involvement forms to ensure that the decision to engage appears appropriate. This can also be challenged when involvement is not apparent in the investigation report.

The HSC Board guidance currently issued for consultation states that an ethics committee should be involved in oversight of such decisions, however the trust is implementing the above procedure as they do not currently have access to an ethics committee.

Notification of the Coroner

There is a trust policy on reporting to the Coroner, which is included in induction for medical staff and there is additional information provided on the requirements to report to the Coroner. The Coroner's office has provided awareness raising sessions for trust staff on the requirements to report and there is also guidance on each ward reminding staff of the reporting requirements.

A clinician makes the decision to contact the Coroner and this is recorded in the patient notes. Where necessary, guidance is sought from senior colleagues prior to making contact; this call would be recorded in the case notes

Notification to the Coroner is recorded on the back of the SAI notification form if the death has occurred at the time of reporting an SAI and this contact is also now recorded on the family involvement form.

If the Coroner then decides to open the case they will write formally to the trust advising of this. If the Coroner decides there is no requirement to open a case and that a death certificate can be issued this is recorded in the patient's case notes.

Notifications to the Coroner should be faxed through to the governance department; but they do not have oversight of those cases where there is a decision made that referral to the Coroner is not required.

The trust outlined several areas where further consideration of the reporting requirements would be helpful. They felt there is a need to look at the arrangements for deaths outside the trust, for deaths that have occurred sometime after the actual SAI having taken place and for reporting deaths when further information has come to light, following the SAI investigation.

The trust would also welcome guidance and clarification in relation to the sharing of final SAI investigation reports. Should these be sent to the Coroner for all cases, including those where the particular case has been closed, regardless if any new information has come to light.

Escalation of SAIs to other Agencies

The RQIA team was advised that there were no obvious trends/gaps in meeting the reporting requirement to other organisations.

Learning from the Look Back Exercise

The trust described how the exercise had made them consider the processes in place for the handling of SAIs. They said this had provided an opportunity to review their processes, following the introduction of the guidance in 2013.

The trust has also used the exercise to review SAIs, reported since the guidance was issued, to ensure it was being adhered to. This was helpful as it provided an opportunity to identify any gaps in the system for the reporting and handling of SAIs.

It was noted that the general guidance for this exercise initially advised that patients/families/carers should be informed retrospectively if any new information had come to light. As a result of the look back exercise the Northern HSC Trust has made such contact in one case.

Under this process, further consideration was given to a small number of cases to determine if involvement with the Coroner was appropriate. As a result, there has been retrospective reporting of one death and discussion with the Coroner's office about another.

In view of the questions, asked on the spreadsheet, the trust has suggested several modifications to the HSC Board patient/family/carer involvement form regarding service user involvement, to ensure that this explicitly records the detail required.

Key Issues Emerging for Future Consideration

Serious Adverse Incident Reporting Guidance:

The trust advised that clinical staff can find the Serious Adverse Incident Reporting Guidance difficult to operationalise and that the current definition of SAIs could be more clearly defined.

The changing criteria make the procedure difficult to embed and can result in varying interpretations within the trust. The governance department regularly reviews adverse incident reporting forms to see if anything has been missed that should have been escalated to an SAI.

The trust felt that it would be helpful if service users and the general public had a clearer understanding of the purpose of the SAI reporting system; reinforcing that this is a system to promote learning in order to prevent future harm.

The trust had some problems with the terminology of SAI which they felt implies something going wrong. It is very distressing for both patients and families to hear the term SAI. The SAI terminology is very harsh and blunt, particularly when the service

user has not come to harm but the incident was reported as there was serious risk. It is on occasions not an easy term to use when speaking to distressed/bereaved families.

The trust outlined that the requirement to report a child death as an SAI has caused much difficultly. In cases where deaths of children are expected or not preventable the reporting and investigation process can be very distressing for families, at a time when they are already very upset.

Timescales for investigation:

The trust outlined some difficulties with the timescales for the investigation of incidents, particularly those which are determined as a Level 1investigation. They outlined that the timescale of 4 weeks is on occasions difficult to achieve. New guidance suggests that this may be extended to 6 weeks however they feel that this may still be challenging.

The trust feels that investigation timescales, particularly in Level 1 investigations, are too short to ensure meaningful engagement with patients/families. The timescales do not take into account the vulnerabilities of the patient/families at what can be a difficult time.

The trust has commented on the consultation for HSC guidance on engagement with patients, clients and families as part of the SAI process. The trust described that the information to be shared with the patient/family/carer can be overwhelming. On occasions it is helpful to seek specialist advice so that accurate information can be provided to the patient/family/carer prior to engaging them in the investigation process.

It is hoped that there may be an opportunity to standardise the process. However, even if explicit guidance on engagement is developed there is a need for a mechanism for exclusions from this, in recognition of the needs of the individual.

The current guidance appears to focus on completion of the investigation and sharing learning. However consideration is also required of the impact of the SAI on the affected individual which may prolong the investigation timescales, to ensure the appropriate level of patient/family involvement can occur. While involvement is essential, it is difficult to put a timescale against this, as each case is different and the trust feels that by making the guidance too prescriptive this may result in a loss of the person centred approach. A balance is required between the learning and the family involvement aspects of the SAI process.

Southern Health & Social Care Trust

The Look Back Exercise

In the Southern HSC Trust the Assistant Director of Clinical and Social Care Governance (Acting) and the Patient Safety and Quality Manager had the responsibility for the coordination, completion and submission of the look back exercise. The governance co-ordinators in a number of directorates assisted the team in the collation and validation of the information required. Some administrative support was available.

It was noted that the Southern HSC Trust had developed and completed a modified version of the spreadsheet that was issued for completion by the DHSSPS. The trust advised that in order to ensure this exercise was a true learning experience they felt they needed to adapt and enhance the content of the spreadsheet to ensure the information collated was helpful. A column indicating if the SAI involved a death was added as the trust felt this helped to structure the later questions and therefore improve the flow through the spreadsheet.

Information in relation to SAIs notified to the HSCB since 2010 was easy to access. The trust outlined how processes for recording of information in relation to SAI's were strengthened following its governance review in 2010. Information in relation to earlier SAIs was accessible but was stored on different systems and held in individual directorates. To assist the collection of the required information, each directorate was given a list of its own SAIs and was asked to complete the required information onto the spreadsheet template.

This exercise was subject to quality assurance at a number of levels.

Returns from each directorate were collated by the governance leads, in association with the assistant directors and directors of each programme of care. The information provided was then signed off locally and returned to the governance department.

The governance department took an overarching quality assurance role, challenging any information which they were unhappy with; thus ensuring that the information on the spreadsheet was accurate and consistent.

The exercise was also discussed at Senior Management Team meetings, Governance Committee and Trust Board and updates were given to each of the directorates as the work progressed.

Upon completion of the look back exercise, the submission to the DHSSPS was signed off by the Chief Executive. The return was submitted in accordance with the required timescale.

Involvement of Service Users/Relatives/Carers in Investigations

The trust reported that it is committed to embracing the principles of openness and transparency in relation to engagement with patients, families, services users and staff when SAIs occur and developing a culture in which these principles are embedded.

In 2010, the trust approved a series of actions following a review of their governance arrangements. Restructuring of responsibilities and system changes were subsequently made to reflect and embed the trust commitment to these principles, and they are continuing to refine its systems as governance arrangements evolve and mature.

Since 2012 all incidents identified in the trust as potentially meeting the SAI criteria are subject to screening process. As part of screening, there is a clear requirement to determine who should contact the family and how this should be done. The identified person would then be the key contact who will take the family thought the investigation process. Decisions with respect to family engagement are recorded on the screening form which also records discussion about the level of the investigation, the requirement to escalate to an SAI appropriately to other agencies e.g. RQIA, Coroner and the DHSPPS.

The trust default position is to report all appropriate incidents as SAIs and to engage with the family; unless there is a very good rationale for not informing them. If it is decided that engagement should not take place, the rationale for this is recorded on the screening form.

The trust outlined that a decision not to engage with the patient/family may be made where there are mental health issues or where such engagement could be detrimental to their health. This would include cases when the patient/family member may not have the capacity or support to allow them to handle the engagement at that time.

The look back exercise did uncover some inconsistency in levels of engagement with families between programmes of care. The trust has responded to this by ensuring there is guidance is in place to ensure that family engagement is at the appropriate level, across all areas within the trust.

Decisions around patient and family engagement are taken by multidisciplinary teams and such decisions are clearly recorded. The director involved in these discussions would have oversight of these decisions. These are reviewed on a monthly basis by the governance team in each directorate. Decisions to engage can also be reviewed at a later stage depending on the health of the family/patient.

The trust agreed that engagement of patients and families in SAI investigations is absolutely essential and is the right thing to do. However the new guidance, currently in draft form, puts this into a very rigid framework which may not be appropriate for every individual case.

The trust has a leaflet to guide families through the SAI process; further work is ongoing within the Trust to develop information in a format suitable for children, young people and for patients with learning disabilities.

Notification of the Coroner

The trust was satisfied that clinicians have adequate guidance on when they should report a death to the Coroner. Coroner's guidance is available on each ward and all clinicians are advised of the reporting requirements at induction and through regular communications from the Medical Director.

A clinician makes the decision to contact the Coroner and this is recorded in the patient notes and on the death checklist. At the same time the clinician will also complete a mortality and morbidity screening form. While this information is recorded locally, there is no written acknowledgement provided by the Coroner.

A multidisciplinary group, led by the chair of the Mortality and Morbidity meeting, reviews all screening forms to identify cases for presentation at the trust Mortality and Morbidity meetings. The trust described how the review of cases through this process, provides an additional assurance mechanism to consider if cases meet the SAI incident criteria or should be reported to the Coroner retrospectively. As SAI investigations progress the case may also require to be retrospectively reported to the coroner if new information is identified.

Escalation of SAIs to other Agencies

The RQIA team was advised that all SAIs were escalated appropriately to other organisations as required.

Learning from the Look Back Exercise

The trust described how the exercise was helpful as it provided an opportunity to review information collated at both directorate and corporate levels.

There has been a lot of work undertaken in the trust since the governance review (2011); this exercise didn't uncover any major problems with family engagement or the reporting requirements to the Coroner.

The trust described that, as its governance arrangements have matured, the trust has developed and improved the quality of their patient /family engagement process. The trust fells it would be helpful if there was a regionally agreed benchmark established to define what constitutes good quality engagement. A mechanism such as this would support the trust in ensuring a consistency of approach to thresholds and rationale when engaging with families. The trust would welcome some regional support and guidance on this.

Key Issues Emerging for Future Consideration

Serious Adverse Incident Reporting Guidance:

The trust advised the SAI criteria for reporting incident can be subjective. The trust has arrangements in place to ensure that incidents reported are reviewed with the SAI

criteria in mind. However, the trust cannot be assured that every incident that meets the SAI criteria is reported via incident reporting systems.

There are multiple mechanisms and forums within the trust where incidents/cases discussed are identified as meeting the SAI criteria. The trust supports and encourages staff to consider incidents/cases, with the SAI criteria in mind, through other forums e.g. team meetings, governance meeting, and mortality morbidity meetings. This approach however can sometimes result in delayed reporting outside the 72 hour reporting requirement.

The term 'unexpected/unexplained death' may have a different meaning for families compared with clinicians. In order to address this, the trust has been developing a set of clinical triggers to help their staff determine if deaths meet the reporting criteria associated with 'unexpected/unexplained death'. The trust also described difficulties in defining 'serious' and expressed their concerns that interpretation of the term 'serious' may differ both within and across trusts.

The trust is of the opinion that the SAI criterion with regard to reporting all child deaths is not appropriate. This has caused significant challenges with respect to family engagement. In applying this criterion the trust is required to review all deaths in this category, including the deaths of children that are expected or unpreventable. Reviewing these cases as SAI's, when there is no potential for learning or improvement, can be distressing and confusing for families. The trust would welcome the opportunity to participate in future discussions regarding this criterion.

The importance of having consistency in reporting across the HSC is recognised but this needs to be balanced with flexibility in reporting. If the guidance is too prescriptive there is the potential for important learning to be missed. There are incidents where things haven't gone wrong but there potentially is learning. In its current format the SAI procedure makes these difficult to report as they often do not match the criteria for reporting. This hinders the learning opportunities.

The trust had some problems with the terminology of SAI which they felt can imply that something has gone wrong. It is felt that the use of this terminology can result in unnecessary upset and distress for families.

Timescales for investigation:

The trust outlined some difficulties with the timescales for the investigation of incidents, particularly those which are graded as Level 1SAI investigations. They felt that the level of analysis required to produce a robust report is not possible to do within 4 weeks. The 4 week timescales for completion of Level 1 investigations impact on the quality of patient family engagements and ensuring that the patient/families perspective is included in the report.

The trust explained that decisions on patient/family engagement are made on a case by case basis and depending on the individual circumstances of the case a multi professional decision will be taken on the most appropriate method of communication and the timing of family engagement.

The trust would welcome further discussion with the regards the difficulties in balancing timescales with effective engagement with families; particularly in cases were a death has occurred.

The trust outlined that the content, scope and recommendations of SAI investigations often will not provide families with total resolution. The focus of the SAI process is learning and improvement this should be made clear in all information provided to staff, patients and families involved in the SAI process. The trust feels it is important to acknowledge this within regional and local SAI guidance.

The complexity of cases/incidents reviewed through the SAI process can result in delays occurring in the investigation.

One issue that may cause delay is the sharing of draft reports with the patient/family. The concept of draft SAI reports is a difficult one. Often additional information comes to light through the investigative process, meaning that reports develop and evolve.

The trust advised that patients and families are provided with the opportunity to contribute to the review process through influencing the terms of reference of reports and also identifying to the review team's particular areas which they consider should be included in the review process. The final report represents the independent analysis, learning and recommendations of the review team and this will often look very different to the first draft.

In cases where SAI reports are shared with HSC Board, to ensure timely shared learning across the region, the trust may have to proceed with the submission of the final report without the patient/families comments.

The trust feels that it is essential that review teams are allowed the time required to complete the investigative process to ensure that it is robust and credible. This is particularly important as SAI reports can be referenced and considered outside the HSC processes. The reputation and credibility of the investigation teams can be challenged through these processes.

The trust described how they were keen to ensure that it maintains a system of high quality investigation and associated reports. In view of this the trust would welcome some feedback from the HSC Board on the quality of the reports being submitted, to ensure that quality remains a key focus.

South Eastern Health & Social Care Trust

The Look Back Exercise

In the South Eastern HSC Trust, the Assistant Director, Risk Management & Governance had responsibility for the coordination, completion and submission of the look back exercise. Assistance was provided by the Litigation Services & Systems Manager along with staff from each directorate in the collation of information to populate the spreadsheet. A project management approach was used for the exercise.

The methodology for the exercise was agreed by all trusts following a meeting with representatives from the DHSSPS, HSC Board and RQIA on 13 May 2014. Subsequent to this a blank spreadsheet was issued by the DHSSPS to all trusts for completion by 30 September 2014. Information was also provided by the DHSSPS, the HSC Board and Coroner's office to assist trusts in the population of the spreadsheet.

The spreadsheet was pre-populated as far as possible using centrally held files in the risk management & governance directorate. The spreadsheet was then issued to relevant directorates who were asked to fill in any gaps and to validate the information contained therein.

The mental health directorate maintains central records of their own SAIs and given the large number of SAI reports involved, two staff from the risk management & governance directorate worked alongside a Case Review Officer to assist in the population and validation of this directorate's return.

The coordination from senior risk management & governance directorate staff ensured a consistency of approach to the completion of the exercise and the population of the spreadsheet. In addition it also allowed for the challenge function to be discharged, to ensure the accuracy of the information being returned.

Whilst the majority of information required for the completion of the exercise was accessible it was noted that this was not held in one central location. However, post this exercise, all key documents related to SAIs are now uploaded and stored in Datix for future ease of retrieval.

Since the issue of the family/service user checklist by the HSC Board on the 31 March 2014, the trust is now recording patient engagement on the Datix system, using the categories from the HSC Board checklist. This should allow this information to be easily retrieved in the future.

This exercise was subject to quality assurance at a number of levels.

The initial pre-population of the spreadsheet took place using detailed documentary evidence held by the risk management and governance directorate. Directorates were then asked to populate the gaps in the spreadsheet and to sign off their individual returns ensuring this was a true reflection of the engagement/notification for each SAI.

Returns from each directorate were then scrutinised by the risk management and governance directorate.

Information returned was cross referenced with centrally held files. Where discrepancies were noted by the team, these were amended. In all such cases, it was recorded that the directorate return was challenged and amended as required. This approach was agreed by the directorates.

The risk management & governance directorate was very specific about sourcing the evidence to support the information being placed into the spreadsheet; they described how they checked the spreadsheet to ensure there was consistency to the process.

The Director of Human Resources & Corporate Affairs received regular update reports from the Assistant Director, Risk Management & Governance about the progress of the project. In addition the Executive Management Team (EMT) was also kept apprised of progress throughout the exercise; regular reports were made to the Corporate Control and Governance Assurance Committees, as required.

A final draft of the spreadsheet was presented to the EMT for approval by the relevant directors prior to sign off and submission to the DHSSPS by the Chief Executive. The return was submitted in accordance with the required timescale.

Involvement of Service Users/Relatives/Carers in Investigations

The trust operates the principles of the National Patient Safety Agency (NPSA) Being Open guidance for informing patients, clients and families, as appropriate; their approach is one of openness and transparency.

In line with the HSC Board guidance the trust will notify patients/service users/families, as appropriate, if it is undertaking a SAI investigation. It reviews each SAI at the start of the investigation to determine the level of engagement required. The decision to involve patient/service user/families rests with the assistant director (in conjunction with relevant others) responsible for the SAI investigation. At an early stage, a decision will be made on who should engage and how they should do this.

This decision is normally documented in the SAI checklist; however this is not always the case. The 72 hour reporting deadline, on occasions, means there is not enough time or it may not be appropriate to contact the family before the submission of the SAI reporting form, as they may not be ready for such discussions.

The trust agrees with the principle of engagement with patients and families in SAIs. The new guidance and checklist is welcomed and hopefully the comments returned during the consultation process will be given cognisance by the HSC Board in the final draft version.

There is a need to view family engagement with a degree of sensitivity of approach particularly in view of the timing aspect. Some families are not ready to engage at such an early time, particularly when they are grieving. Applying rigid guidelines to this poses a risk of the person centeredness of the approach being lost.

The trust outlined several cases where it may be appropriate not to engage with families for example in cases where there are mental health issues and/or where such engagement could be detrimental to the patient/client's health.

The application of the HSC Board SAI procedure in prison healthcare has been challenging and a meeting has been arranged with the Designated Review Officer (DRO), to address areas of concern, and to agree a way forward.

Any exceptions to expected involvement are subject to challenge by the risk management and governance directorate. Decisions not to inform can be reviewed and amended, if necessary, following discussion with the relevant director. If there are any issues/concerns about a lack of engagement then this would be reported to the relevant director in the first instance.

Following this exercise, the trust has analysed the results of the information collated in the spreadsheet for their own learning. In the future, the trust may consider adopting a modified version of the spreadsheet as an audit tool to undertake a high level compliance check of adherence to the HSC Board procedure.

Notification of the Coroner

The trust was satisfied that clinicians recognise their professional obligation to report a death to the Coroner when required to do so. They advised that notification to the Coroner is not always the responsibly of the trust to manage, as many of the deaths are in the community setting therefore not the trust's responsibility to report.

In respect of this exercise, the trust was pleased to see their answers were all positive, providing a level of assurance that the reporting procedures were being followed when required.

A clinician makes the decision if it is necessary to contact the Coroner and this is recorded in the patient's notes. The trust may not know such cases have been reported to the Coroner until a request for statements for an inquest is received.

Escalation of SAIs to other Agencies

The RQIA team was advised that all SAIs were escalated appropriately to other organisations, as required.

Learning from the Look Back Exercise

On reflection, the trust stated that they found the process helpful as it identified gaps in the SAI system. The exercise provided an opportunity to conduct a high level audit of SAI information over the past 5 years which in turn allowed the trust to highlight issues for future consideration by the HSC Board.

During the course of this exercise, the trust identified 3 possible cases which had been reviewed but were not reported to the HSC Board at the time. In view of revised reporting arrangements as per the extant guidance, these cases were brought to the EMT for consideration and it was agreed that these should be reported as SAIs

retrospectively. The trust is considering contacting one of the families in light of one of these retrospective cases; a final decision has not yet been taken.

No communication has been received from the HSC Board regarding these additional cases.

Key Issues Emerging for Future Consideration

Serious Adverse Incident Reporting Guidance:

The SAI procedure is implemented across the trust and the responsibility for the decision to escalate an incident as an SAI is that of the assistant director for the particular service area. However, as the guidance is unclear in some cases, the assistant directors can tend to be cautious over the decision to escalate and would often seek support and guidance from the risk management and governance directorate.

Decisions to escalate are then taken following joint deliberation. It is the assistant directors who understand their own service areas and therefore understand the impact/consequences of their own incidents. The risk management and governance directorate can help to interpret the guidance using their overview and knowledge of the reporting system.

Where decisions remain unclear, the risk management and governance directorate will raise the matter with the relevant executive director to ensure that decisions to report or not to report are made, as appropriate, and that these are agreed at that senior level.

In terms of the clarity of the guidance itself, the trust has made some issues known to the HSC Board during various consultation exercises. The question of the definition of what is termed ‘serious’ has not yet been fully addressed. It would be helpful for this to be more clearly defined for staff with very clear parameters. In the past, the SAI reporting guidance did have triggers for reporting. It may be that these could be revisited and considered along with the NPSA guidance. The trust felt that if trigger guidance for SAIs is to be developed, that this should be taken forward and agreed on a regional basis.

In addition, the adoption of the NPSA guidance in terms of descriptors of grading patient safety incidents to determine level of response on a regional basis would also be useful. The trust also considered that if a single regional incident reporting policy was developed for Northern Ireland, this would help to bring consistency to reporting thus removing the issues in relation to varying interpretation.

The trust reported that the requirements to report a child death has caused much difficulty. In cases, where deaths of children are expected, the reporting and investigation process can be very distressing for families, at a time when they are already very upset. The trust has been advised at the regional governance leads meeting that the requirement to notify child deaths is being re-considered and the outcome of this is awaited.

The trust understands that the reporting criteria do have to change over time however they felt that often when the guidance is revised, the feedback from trusts is not always

taken on board. This is essential if the amended procedures are to work from an operational trust perspective.

The issue of interface incidents was also discussed and often there can be differences of opinion in who takes the lead in investigations and this can take time to resolve.

Timescales for investigation:

The trust outlined some difficulties with the timescales for the investigation of incidents, particularly those which are graded as Level 1. They outlined that the level of family engagement required is not possible to achieve within 4 weeks. The 4 week period is too short to ensure true engagement with patients/ families meaning there is a loss of person centeredness.

The 12 week period for Level 2 investigations is also often difficult to achieve. Investigations can often involve multiple directorates meaning that deadlines can be missed.

Decisions on patient/family engagement need to be made on a case by case basis and so there needs to flexibility in the timescales for this. The trust felt that if a deadline is missed in order to allow full and transparent engagement with families then this is the right thing to do.

There are many different reporting procedures that run parallel with the SAI procedure and this can cause confusion and is time consuming for those involved. The requirement to run a parallel SAI investigation, while the other investigation is ongoing (which may be more rigorous and often takes a lot more time to complete), is not an effective use of resources. The trust would welcome some consideration of how these processes could be streamlined.

Western Health & Social Care Trust

The Look Back Exercise

In the Western HSC Trust, the Head of Clinical Quality and Safety and the Corporate Risk Manager had the responsibility for the coordination, completion and submission of the look back exercise. The team worked in partnership with a number of directorates who assisted with the collation and validation of the information required.

The spreadsheet was pre-populated as far as possible using centrally held files in the risk management department. A spreadsheet was received from the Coroner which included date of death and date reported to the Coroner. This was also used to pre-populate the spreadsheet.

The majority of information required for the completion of the exercise was easily accessible. Greater use of Datix-Web to manage SAIs did help to collate the information in relation to the more recent incidents; information can be uploaded onto Datix and linked to individual SAIs making them easily sourced.

Some of the information for the earlier SAIs was recovered from the manual record system; this system was also robust and provided easily accessible information. Some of the information required was sourced from complaints and litigation department records. Datix proved useful, in the cross referencing and tracking of this information.

The spreadsheet was forwarded to relevant directorates and any outstanding questions were answered by relevant staff. The Governance Lead for Adult Mental Health & Disability Services was very involved in the review of relevant SAIs.

This exercise was subject to quality assurance at a number of levels.

The initial pre-population of the spreadsheet took place using detailed documentary evidence held by the risk management department.

Directorates were asked to sign off their individual returns, ensuring this was a true reflection of the engagement/notification for each SAI and returns from each directorate were collated by the risk management department. There then followed a period of communication and clarification of entries in conjunction with senior managers and the governance leads in each directorate. Directors signed off the review for their area of responsibility.

The risk management team was very specific about sourcing the hard copy evidence to support the information being placed into the spreadsheet, and explanations/notes were provided where applicable.

Entries in the spreadsheet were quality assured by the Corporate Risk Manager and a further level of quality assurance was then applied by the Head of Clinical Quality and Safety.

Throughout the process regular updates on progress were provided by the Corporate Risk Manager to the Head of Quality and Safety and the Medical Director. The Medical Director provided a final level of quality assurance to ensure that the information was accurate.

The final return was then sent to the Chief Executive for sign off prior to submission to the DHSSPS. The return was submitted in accordance with the required timescale.

Involvement of Service Users/Relatives/Carers in Investigations

The trust reported that it is committed to the principle of engagement with patient/clients and families and there is a long history of engagement across all directorates, it has updated its internal incident reporting policy to reflect the new procedure introduced in October 2013. Currently the default position for all SAIs is to always engage the family in the investigation, unless it is deemed inappropriate to do so.

A lead investigator is identified for each SAI and they are advised on the process, including patient/family involvement. The lead investigator has the overall responsibility for deciding if the family should be informed. However this decision would normally be taken in conjunction with other professionals involved in the patient/client's care.

An SAI leaflet is also provided for the investigation lead which is then shared with the patient/family. This leaflet provides information on the SAI investigation process. In tandem with the leaflet, the trust has developed a template letter for staff, which provides guidance on how to make the initial contact with families/patient/carers. All contact is adapted as appropriate for the individual case, ensuring it is person centred

Decisions not to engage with families are now being more robustly challenged. If a decision not to engage is taken, this should be clearly documented. The risk management department would quality assure decisions not to engage with families to ensure the reasons for this are appropriate. If there was a pattern emerging where staff were continually not involving families, this would be challenged.

It was noted that there are occasions where the trust would decide that family engagement is not appropriate. The trust outlined that a decision not to engage with the patient/family may be made where the SAI involves an employee, a police investigation or the person involved is the perpetuator. There are also cases where such engagement could be detrimental to their wellbeing; often in suicides the family would decline to be involved and this is respected by the trust. However in all instances, support is offered by the Family Liaison Officer.

There are also incidents which have not led to any harm: e.g. an accidental fire or a general issue such as an electrical failure etc. Often these cases would have affected multiple patients but there has been no harm. Consequently the trust has taken a decision that it is not appropriate to inform or share the final report with those affected.

As a final checking mechanism the HSC Board has oversight of all SAIs including the decision as to where or not to engage families; they can also challenge decisions not to engage.

Notification of the Coroner

Trust staff are regularly reminded of their responsibility to report deaths to the Coroner in accordance with the DHSSPS guidance on death, stillbirth and cremation certification. There is a trust policy on reporting to the Coroner, which is included in staff induction training and guidance on the requirements to report to the Coroner is available on all wards and the trust intranet.

A clinician makes the decision to contact the Coroner and this is recorded in the patient notes and also on the SAI reporting form. While this information is recorded locally there is no written acknowledgement provided by the Coroner. The requirement to report is reinforced at incident reporting training.

All death certificates are now scanned onto the system in the mortuary. The Head of Clinical Quality & the new Associate Medical Director, now review the death certifications for each month to ensure there are none issued without being reported to the Coroner, where required. This also gives the trust an opportunity to check the death certificate to check if something should be reported as an SAI. The trust Mortality and Morbidity Committee may also flag up issues in this regard.

The trust 'lesson of the week' has been used to highlight reporting requirements and to ensure that all staff are aware of the requirement to report.

Escalation of SAIs to other Agencies

The RQIA team was advised that all SAIs were escalated appropriately to other organisations as required.

Learning from the Look Back Exercise

The trust described the look back exercise as being time consuming and difficult to do within current resources. It has however been helpful for the trust to reflect on their handling of SAI investigations and notification to the Coroner.

It has resulted in the trust considering how they could further improve the family engagement process and in particular the use of the SAI terminology.

It has also been helpful to provide reassurance that SAIs have been handled appropriately and to confirm that the culture of the organisation has been to share and involve families.

Key Issues Emerging for Future Consideration

Serious Adverse Incident Reporting Guidance:

The guidance for SAI reporting is lengthy and sometimes it is difficult to clearly establish what meets the criteria for an SAI. This can result in varying interpretation both within and across trusts. There is a feeling that trusts are not consistent in their interpretation of the guidance leading to inconsistencies in reporting across the region.

The changing criteria make the procedure difficult to embed. There is a need to ensure that the process is quick, easy and that it is there to support the clinicians. It should not be made too difficult or cumbersome to use.

There is an ongoing debate as to whether the purpose of the SAI reporting system is about notification or about shared learning.

In the case of recognised complications of procedures, it is unclear if these should all be reported as SAIs.

The reporting of child deaths is the one area that causes the most difficulty for the trust. Implementing the associated SAI investigation process may automatically imply to parents/families that there has been a deficit in the care provided and this can be very distressing for families.

There are many different reporting procedures that run parallel and this can cause confusion and is time consuming for those involved. The trust would welcome some consideration of how these processes could be streamlined.

The trust had some problems with the terminology of SAI. It is felt that the use of this terminology indicates that something has gone wrong in relation to the care provided. This is turn can cause distress and confusion for those involved.

Timescales for investigation:

The trust outlined some difficulties with the timescales for the investigation of incidents, particularly those which are graded as Level 1. Specific difficulties were identified:

- It is difficult to get the time in clinicians' diaries to allow them to be involved in the investigation process. In the main at least 6 weeks (or more) is required to allow for clinician involvement.
- Clinicians will find it increasingly difficult to engage with the process if they do not have time to do this or if the process becomes more labour intensive.

The trust felt that investigation timescales, particularly in Level 1 investigations, are too short to ensure true engagement with patients/families. They feel that the timescales only allow for 'notification' that there is going to be an investigation and does not allow the trust to effectively involve patients/families/carers.

For Level 2 incidents the timescale for investigation is extended to 12 weeks however these timescales are also difficult to adhere to, particularly where the SAI is related to a

suicide. It is always a very difficult time for families and often they are not ready to meet with the trust. Situations such as this need to be handled with sensitivity and the time and level of involvement must be something driven by the families' wishes.

The trust believes that the patient and/or family involved should be at the centre of engagement, however the targets in relation to timescales make this difficult and have the potential to make the process less patient centred.

The trust described the new guidance on family engagement as being lengthy and repetitive. There is a concern that the paperwork associated with the new guidance may hinder the completion of the SAI investigation. The trust has provided comment back to the HSC Board raising these concerns and specifically querying the level of engagement required.

Northern Ireland Ambulance Service Health & Social Care Trust

The Look Back Exercise

In the Northern Ireland Ambulance Service, the Risk Manager had the responsibility for the coordination, completion and submission of the look back exercise.

It was noted that some headings on the spreadsheet contained multiple questions which made interpretation difficult. In response to this the NIAS did take some time to discuss and understand the questions, coming to an agreed interpretation. The NIAS also discussed the spreadsheet at the Regional Governance Network in order to confirm their understanding and interpretation. A single interpretation was settled upon and due to the small numbers of SAIs the trust was able to ensure that completion was consistent.

The NIAS advised that pulling together the information required was relatively simple however a lot of cross checking was required to quality assure the submission.
The NIAS uses Datix to record information in relation to SAIs and this has proved to be a useful document management system from which information can be easily retrieved. All documentation relating to an SAI can be linked to the SAI and even the caller conversations between ambulance control and the caller can also be stored in this way.

This exercise was subject to quality assurance at a number of levels.

The initial population of the spreadsheet was completed by the risk manager using documented evidence held by the risk management department. The Medical Director was then involved in the quality assurance of the exercise ensuing oversight and sign off of the whole exercise at a senior level.

The final return was then finalised for onward submission to the DHSSPS. The return was submitted in accordance with the required timescale.

Involvement of Service Users/Relatives/Carers in Investigations

The underlying ethos reported by the NIAS is to ensure that all contact is appropriate and that the timing is right for the individual family involved. When the NIAS does have a SAI, the Medical Director and the Chief Executive will normally discuss contacting the patient, and/or their family, and reach a conclusion as to whether it is appropriate to do so.

In general, the NIAS time with the patient is limited and therefore when there is an incident they would not always engage with the family, as it may not be appropriate to do so. Due to the nature of incidents involving the NIAS e.g. road traffic accidents, other family members are often involved in the same incident and therefore may not be not be able to engage at that time.

Where a decision is taken not to engage with the patient and/or family this decision is taken by the Medical Director and the Chief Executive. The NIAS would also report decisions to not engage with patients and families to their Assurance Committee and ultimately to the Trust Board, this provides an element of oversight and discharge of the challenge function when required.

Notification of the Coroner

The NIAS would very rarely report a death to the Coroner as it is not within their remit. The NIAS can establish death but can't certify it. They notify the GP or to the PSNI medical officer who would act as the Coroner's office link. If there was any case where they held the requirement to contact the Coroner, the decision to do so would be taken by the Medical Director.

Escalation of SAIs to other Agencies

As the result of the look back exercise the NIAS can give reassurance that all SAIs were escalated appropriately to other organisations as required.

Learning from the Look Back Exercise

The NIAS described how they took an element of reassurance out of the process. It gave assurance that incidents were being reported appropriately and investigations were being carried out when required.

Partly as a result of this exercise, NIAS has now put links in place with their complaints management system in order to cross reference these with a view to identifying possible SAIs. As part of this new process complaints are now reviewed on a weekly basis to help identify any potential SAIs. As part of this new process, two complaints have been identified which may require to be reported as SAIs. At the time of the review these were under consideration for further action.

In general, the NIAS feels its approach to SAI handling has improved over the last number of years particularly since the new guidance was issued in October 2013. The NIAS is finding that trusts are involving them in their SAI investigations on a more routine basis and often a representative for the NIAS is included in trust investigation teams. This input is beneficial to both parties as it means that recommendations for learning are well founded and are applicable to both the hospital and the ambulance trust.

Designated Review Officer's (DROs) involved in the investigation of SAIs take account of the role of the NIAS and there is a good level of engagement to ensure that actions/recommendations are appropriate to the service.

One area of difficulty for the NIAS when involved in an incident investigation is securing independent experts, as there is no peer organisation within NI. They have got round this by approaching the other UK countries and the ROI ambulance service.

Key Issues Emerging for Future Consideration

Serious Adverse Incident Reporting Guidance:

Recently the NIAS has reviewed its own incident reporting policy and procedure to include a direct link from this into the SAI process.

At front line level, staff struggle with the definition of an SAI, so the governance department oversight of all reported incidents is vital to ensure they are escalated when appropriate. The trust indicated that as long as a staff member knows how to report an incident it will be elevated to an SAI by the risk management department if required to do so.

All operational managers have had training to help to identify those incidents which meet the SAI reporting requirements, however to ensure the process is managed correctly all SAI reporting and follow up is handled centrally by the risk manager.

In relation to the SAI guidance the NIAS has some difficulties with the terminology of 'unexpected' deaths. Due to the nature of their work all deaths are considered to be 'unexpected'. In order to address this difficulty the NIAS has made a decision that they will only report an incident as a SAI if the death is/or could be the result of an action or inaction. This reflects the daily business of the NIAS.

The trust also raised the issue around the definition of an SAI including the use of the serious classification. This makes it difficult to identify which incidents should be deemed as serious as this does not link easily to the catastrophic and major classifications currently in use within the HSC risk matrix.

The trust outlined their difficulties with the terminology SAI, which has been a concern for them for some time and they have previously brought this to the attention of the HSC Board. The terminology used at present implies fault and this can often cause upset and confusion for those persons involved in an incident.

Timescales for investigation:

The trust outlined some difficulties with the timescales for the investigation of incidents, particularly those which are graded as Level 1. The 4 week period is considered to be an unachievable target which does not allow time for a full and transparent investigation to take place.

The timescales for the completion of an investigation often do not allow appropriate time to ensure meaningful engagement with all parties. This causes particular difficulties in ensuring there is meaningful family engagement. Often the initial contact may be too soon for families to deal with meaning they find it difficult and stressing to engage.

It is felt that the new guidance for family engagement, currently in draft form, is too prescriptive and that it continues to make SAI investigation procedure very process driven. It does not take into account the needs and wishes of the families. This system may have the potential to cause more harm than good and has the potential to erode the learning element at the heart of the process.

In addition to this, when initial contact is required at such an early stage, there may be a lack of information available and this be perceived as the trust trying to hide something or keeping something back from the families.

The NIAS felt that the SAI system needs to be maintained as an open and honest system for shared learning. The SAI reporting procedure needs to be something that is helpful for staff, not something that becomes detrimental to them.

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