



## Policy for the management, review of and regulatory response to intelligence deriving from Serious Adverse Incident Notifications and Investigation Reports received by RQIA

Title:	Policy for the management, review of and regulatory response to intelligence deriving from Serious Adverse Incident Notifications and Review Reports received by RQIA		
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## 1.0 Introduction

RQIA provides independent assurance about the quality, safety and availability of Health and Social Care (HSC) services, including independent sector services, that fall under our legislative remit, in Northern Ireland, while encouraging continuous improvements in these services and assisting in promoting the safety and rights of services users.

Effective regulation requires the collection and assessment of data, information, and intelligence used effectively to support our core purpose of securing and improving the safety and quality of health and social care services in Northern Ireland. Making best use of regulatory intelligence is central to tailoring RQIA's actions to individual services and targeting its resources where it can have the greatest safety and quality improvement impact. RQIA is committed to using all relevant information, including information from Serious Adverse Incidents (SAI), to drive its regulatory and improvement actions.

The role of monitoring the Health and Social Care Trust's compliance with the [Procedure for the Reporting and Follow up of Serious Adverse Incidents \(2016\)](#), and following up on the Investigation Reports, within the required timescales, from the investigation of those incidents, is held by the Strategic Planning and Performance Group.

In addition to RQIA's regulatory role set out in [The Health and Personal Social Services \(Quality, Improvement and Regulation\) \(Northern Ireland\) Order 2003](#), (the 2003 Order) under the Provisions of Article 86 (2) of the Mental Health (NI) Order 1986 (the MH Order), RQIA has a duty to make inquiry into any case where it appears to RQIA that there may be, amongst other things, ill treatment or deficiency in care or treatment for a patient living with mental disorder, in any setting.

This policy has been developed in accordance with the regional HSCB<sup>1</sup> Procedure for the Reporting and Follow up of Serious Adverse Incidents, November 2016.

The purpose of this policy is to set out RQIA's arrangements for considering the intelligence held within SAI Notifications and Reports sent to RQIA. In doing so, we will work jointly with the HSC Trusts, the Strategic Planning and Performance Group of the Department of Health (SPPG) and the Public Health Agency (PHA) to drive improvements in the safety and quality of care provided across community services and hospital settings.

## 2.0 Scope of the policy

This policy applies to RQIA Inspectors and any other RQIA staff who receive and need to record SAIs using the iConnect SAI module. The policy should be read in conjunction with:

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<sup>1</sup> In accordance with the Health and Social Care Bill 2021, the Health and Social Board (HSCB) closed on 31 March 2022. Responsibility for the functions of the HSCB transferred to the Department of Health's Strategic Planning and Performance Group (SPPG) from 1 April 2022.

- [Procedure for the Reporting and Follow up of Serious Adverse Incidents \(2016\)<sup>2</sup>](#)
- RQIA Procedure to support RQIA staff in the management, collation and sharing of learning from Serious Adverse Incidents, October 2023 (*in development*)

From 1 October 2019, the decision was taken by RQIA to suspend commentary to SPPG in relation to SAI Investigation Reports. The background to this decision is detailed in the correspondence from RQIA to the Public Health Agency attached at Appendix 1. This remains RQIA's position.

For the purposes of this policy, an adverse incident is defined as:

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

A Serious Adverse Incident (SAI) is defined as:

**“Any event or circumstance that led or could have led to unintended or unexpected harm, loss or damage.”**

The criteria below define those incidents that must be dealt with as a Serious Adverse Incident (SAI).

Any adverse incident which meets one or more of the following criteria should be reported as a SAI:

- Serious injury to, or the unexpected/unexplained death of:
  - a service user, (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit)
  - a staff member in the course of their work
  - a member of the public whilst visiting a HSC facility;
- Unexpected serious risk to a service user and/or staff member and/or member of the public;
- Unexpected or significant threat to provide service and/or maintain business continuity;
- Serious self-harm or serious assault (including attempted suicide, homicide and sexual assaults) by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service;
- Serious self-harm or serious assault (including homicide and sexual assaults) on other service users/on staff or on members of the public by a service user in the community who has a mental illness or disorder

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<sup>2</sup> This procedure is currently under review

- 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; and
  - a member of HSC staff or independent practitioner.

### **3.0 Policy Statement**

RQIA promotes an open and positive approach to sharing the learning from SAI's and encourage a learning reflective environment.

The responsibility for ensuring regional learning from SAI's rests with the Strategic Performance and Planning Group (SPPG) of the Department of Health. RQIA may meet with SPPG periodically to discuss any emerging patterns of concern arising from SAIs.

Within the regional SAI procedure, there is a requirement on HSC organisations to notify RQIA of all mental health and learning disability SAI and any SAI that occurs within a registered service<sup>3</sup> that has been commissioned/funded by a HSC organisation. In this regard the following SAIs should be notified to RQIA at the same time of notification to the SPPG:

- All mental health and learning disability SAIs reportable to RQIA under Article 86.2 of the Mental Health (NI) Order 1986; and
- Any SAI that occurs within a registered service that has been commissioned/funded by a HSC organisation.

RQIA have a statutory obligation to investigate some incidents that may be reported to RQIA via other processes (e.g. safeguarding or a notification from a registered service provider) are also reported to RQIA under the SAI regional procedure. In order to avoid duplication of incident notification and review, RQIA will work in conjunction with the SPPG/PHA with regard to the review of pre-defined categories of SAI.

It is acknowledged that some incidents should already have been reported to RQIA as a 'notifiable event' by the registered service provider where the incident has occurred (in line with relevant reporting regulations). This notification will alert RQIA that the incident is also being reviewed as a SAI by the HSC organisation who commissioned the service.

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<sup>3</sup> The HSCB procedure describes these services as "regulated". The wording in this policy has been changed to better reflect RQIA's statutory requirements under the 2003 Order.

## **SAI Process Stages**

There are 3 levels of SAI investigation (detail of criteria for each is available in the [Procedure for the Reporting and Follow up of Serious Adverse Incidents \(2016\)](#)). At each level there is a different type of investigation approach. These are:

Level 1 – Significant Event Audit (SEA)

Level 2 – Root Cause Analysis (RCA)

Level 3 – Independent Review.

All SAIs should be referred to as SAI. The investigation approach, for example, SEA, should not be used when referring to the SAI incident.

There are two stages of the Regional SAI Procedures.

### Notification

Any adverse incident that meets the SAI criteria should be reported to SPPG within 72 hours of the incident being discovered.

### Report

Subsequently the SAI Review Report is completed and submitted to SPPG within the timescales specified within the [Procedure for the Reporting and Follow up of Serious Adverse Incidents \(2016\)](#).

## **RQIA Receipt of SAI Notifications and Reports**

Upon receipt of SAI notification and review reports, the information is logged by an administrator against the patient and/or service on RQIA's iConnect document/information management system. This allows tracking of the individual incident and enables themes and trends over time to be assessed, allowing RQIA to identify and respond if similar incidents are recurring in a particular Trust or service.

With the exception of MHLA related SAIs, the information should be managed in line with the [RQIA Regulatory Intelligence Concerns Policy](#).

## **SAI as a Source of Intelligence**

The analysis and risk assessment of intelligence at both stages of the process (Notification and Report) is critical to targeting RQIA's resource where it can have the greatest impact.

Information contained within SAIs should be reviewed in terms of its value as regulatory intelligence and a determination should be made regarding engagement with other relevant third party organisations and/or making a determination regarding whether a regulatory response is required. That could involve making

further enquiries with the Trust or Service Provider to seek assurances that patient safety risks have been addressed, whether any early learning has been identified and actions taken while the investigation is ongoing, through to deciding that an unannounced inspection is required.

SAI information, along with wider intelligence analysis, is part of preparing for an inspection of a service. The inspection team have access to relevant intelligence held by RQIA in advance of inspections and examine the information in seeking to develop lines of inquiry for the inspection. This must include consideration of SAIs relating to that service.

## **4.0 Legislative Framework**

### **Registered Services**

All registered establishments and agencies are required to comply with [The Health and Personal Social Services \(Quality, Improvement and Regulation\) \(Northern Ireland\) Order 2003](#) (the 2003 Order) and the relevant regulations. The 2003 Order and the associated regulations are available on [RQIA's website](#). Registered Person/Trust's Responsible Individual/s are required to ensure that their establishment/agency/trust provide a standard of care and service in accordance with the Department of Health, Social Services and Public Safety (DHSSPS) standards. A list of relevant standards is available on RQIA's website.

### **HSC Trust/Statutory Services**

Aside from services registered under Part III of the 2003 Order, RQIA also have a regulatory role relating to HSC bodies who have a Statutory Duty of Quality set out in Part IV of the 2003 Order. HSC services are required to meet the Quality Standards for Health and Social Care (2006). It is against these Standards that RQIA inspect or review HSC statutory services. SAIs are reported by the HSC Trusts to the SPPG for all SAIs which relate to HSC Trust Services. RQIA are not required, under the regional SAI procedure nor under the MH Order, to be routinely notified of SAIs in statutory services, with the exception of Mental Health and Learning Disability services due to our role under the MH Order.

### **Mental Health Services**

In accordance with Article 86 of the [Mental Health \(Northern Ireland\) Order 1986](#), RQIA has a duty to keep under review the care and treatment of patients (with a 'mental disorder') and to make inquiry into any case where it appears there may be ill treatment, deficiency in care and treatment, or improper detention in hospital or reception into guardianship, or where the property of any patient by reason of his mental disorder be exposed to loss or damage. The reporting of all Mental Health and Learning Disability related SAIs to RQIA further enables us in undertaking this duty.

### **Regulatory Action**

Where RQIA identifies an establishment/agency/Trust is failing to comply with regulations or failing to comply with any statement of minimum standards, RQIA will consider the various options to enable that establishment/agency/trust to secure compliance. Depending on the circumstances and an assessment of the associated risks and the response from the Registered Person/Trust's

Responsible Individual/s, RQIA will consider a range of actions. This is detailed in the [RQIA Enforcement Policy](#) and Procedures.

## **5.0 Role and Responsibilities of RQIA in relation to SAIs**

**The RQIA Authority** has responsibility for the approval of the SAI Policy. The RQIA Authority will monitor SAIs through the Chief Executive's Report and as necessary be advised of any significant regulatory activity in a timely manner.

**The Chief Executive** is responsible for the implementation of the policy and associated procedure and will be advised by Directors of any SAIs that lead to regulatory activity. Through the monthly performance activity reports, the Chief Executive will be informed of SAI related activity.

**Directors/Assistant Directors** will ensure that matters, which require escalation, are brought to the attention of the Chief Executive in a timely manner. Directors will be responsible for implementing assurance systems within their directorate teams for the monitoring of SAI reports and notifications received.

**Senior Inspectors** have the responsibility to ensure that all Inspectors in their teams are aware of their duties and responsibilities in respect of the SAI Policy and Procedure. This includes ensuring that SAI policies and procedures are included in the induction, supervision and appraisal processes.

Senior Inspectors will utilise SAI data from validation reports, Performance Activity Reports (PARs) and the SAI dashboard to monitor the accurate recording, inspector review and closure of SAIs. Inspectors and/or Senior Inspectors will escalate regulatory intelligence captured within SAIs that may trigger a regulatory response to their line manager/Assistant Director in a timely manner.

Following analysis of information, any actions taken should be recorded within the SAI record on iconnect.

When recording and/or updating SAIs, staff must record the nature, content and outcomes in an accurate and comprehensive manner; this record should include what actions were taken including any relevant timeframes.

**Inspectors** are responsible for maintaining a level of professional knowledge regarding incident management, reporting investigation processes and participating in any training made available. Inspectors' judgements and skills in analysing SAIs are critical. Inspectors must use the intelligence to identify patterns and trends, which may indicate: quality failures, poor practice, safety concerns or matters of a safeguarding nature and act to promote service user safety, drive improvement and assure quality standards. Any such trend analysis should inform inspection preparation and be discussed during supervisions.

When an SAI is received, the significance of the information and any potentially negative impact on service user/s must be considered against information already held – there may be previous instances of similar issues being raised from other sources. In addition, inspectors should ensure that the provisions set out in Article 86 of the [Mental Health \(Northern Ireland\) Order 1986](#) are upheld.



**The Information Team** will ensure that the information system is maintained and updated to support the implementation of this policy and associated procedures. The information team will work with the operational teams to ensure that reporting is available to monitor compliance with agreed internal Key Performance Indicators (KPIs) and provide trend analysis, as specified by Directors, relating to SAIs within RQIA's remit.

The Information Team will also provide validation reports to operational teams on a regular basis to ensure that data relating to SAIs is captured accurately and in line with RQIA's SAI Policy and Procedure.

## **6.0 Training and Support**

Senior Inspectors must ensure that Inspectors have successfully undergone induction training taking into account the capturing of SAIs as outlined in this Policy and the associated Procedure.

It is the responsibility of the Senior Inspector to ensure that all Inspectors are competent to undertake these duties and responsibilities in line with this Policy and the associated Procedure.

## **7.0 Equality**

This policy was equality screened using section 75 groups and was considered to have a neutral impact for equality of opportunity, the policy does not require to be subjected to a full equality impact assessment.

## **8.0 Monitoring:**

This policy will be reviewed through the RQIA policy sub-group and at relevant EMT meetings for review and update, as necessary.

## **9.0 Review Arrangements**

This policy will be reviewed in 12 months.

Our Ref: LG/LB

27 September 2019

Assurance, Challenge and Improvement  
in Health and Social Care

**Private and Confidential**

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Dear <>

**RE: Regional Procedure for Reporting and Follow up of Serious  
Adverse Incidents**

I am writing to advise you of a temporary amendment to arrangements relating to **RQIA's** input to the regional Procedure for the Reporting and Follow up of Serious Adverse Incidents, as published by the Health and Social Care Board, November 2016.

You will be aware that the above regional procedure includes a section addressing 'Reporting of SAIs to RQIA'. Specifically Section 3.6 on Page 12 of the procedure outlines the current context in which SAIs will be notified to RQIA as well as to HSCB, and advises that RQIA will work in conjunction with HSCB/PHA with regard to review of certain categories of SAI.

Appendix 15 of the regional SAI procedure is an administrative protocol describing operational arrangements between **RQIA** and HSCB to enable the above joint working. It sets out arrangements for the Designated Review Officer (DRO) in HSCB/PHA to seek and receive written comments from RQIA in relation to SAI review reports or learning summaries submitted by a Trust to HSCB/PHA (and subsequently shared with RQIA).

I am writing to advise that we have decided to temporarily suspend, from 1<sup>st</sup> October 2019, our provision of written commentary on SAI review reports and/or learning summaries shared with us. I would reassure you that we plan to continue to meet all other arrangements as set out in the regional SAI protocol except for those described under Point 3 in Appendix 15, which refers to *'a 3 week timescale from receipt of review report/learning summary report, for RQIA to forward comments for consideration by the DRO'*.

This decision has been influenced by learning arising from our work in reviewing and providing commentary on SAI learning summaries and review reports. In some instances we do not feel we/our staff are sufficiently well informed about the SAI itself, the context in which the SAI occurred and/or the particular arrangements relating to the SAI review progressed to provide sufficiently well-informed written commentary to the DRO. I know you will agree that each SAI is likely to have contextual information which is important to both understanding the events that occurred and to identifying important learning arising. It is our assessment that providing written commentary in the absence of a fully informed picture may not serve the learning process appropriately.

We have had a number of changes to our Mental Health and Learning Disability (MHL) Team this year; each year we receive a considerable number of SAI review reports and/or learning summaries in this programme area. We have strengthened our leadership of this programme area and we are also in the process of augmenting the size and skillset available within our MHL Team.

In this context I would reassure you that Inspectors across all our Teams within Improvement and Assurance Directorates in RQIA and our Assistant and Deputy Directors remain available to DROs, to discuss individual SAIs and to provide all/any assistance we can offer to the SAI review and learning process. Our preference is that we contribute through ongoing discussion and engagement with DROs and related learning groups, and we look forward to continuing our collaborative working in this regard.

As you are aware DoH has commissioned RQIA to facilitate a Review of Serious Adverse Incidents in Northern Ireland, an Expert Review Team has been established and fieldwork for this Review has commenced. We expect the Expert Review Team will be engaging with all HSC organisations in the coming months as this Review progresses. We plan to reassess our decision regarding provision of written commentary on SAI learning summaries and review reports when this Review is completed and has published its report.

I would emphasise that we wish to continue to receive information relating to SAIs as per the current regional protocol/arrangements. RQIA uses intelligence from a variety of sources to inform our approach to inspection and oversight of services. The information contained within SAI notifications and SAI learning summaries and review reports is an important source of intelligence. We use this information to inform and shape our inspections across the range of health and care services we visit.

You may wish to discuss this further; to this end I would be happy to meet with you and colleagues. Please do not hesitate to contact me if you require any further information.

Yours sincerely

**Dr Lourda Geoghan**  
**Director of Improvement and Medical Director**

cc:

Olive MacLeod, Chief Executive, RQIA

Emer Hopkins, Deputy Director, RQIA

Lynn Long, Assistant Director, RQIA

Fergal Bradley, Director of Quality, Regulation & Improvement Unit, DoH