

Title:	Serious Adverse Incident (SAI) Procedure		
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1.0 Introduction

This procedure covers the reporting, investigating and management of Serious Adverse Incidents for Belfast HSC Trust staff and is based on the HSCB Procedures for the Reporting and Follow up of Serious Adverse Incidents October 2013. It should be read in conjunction with the BHSCT Adverse Incident Reporting & Management Policy and other associated procedures.

2.0 Purpose and scope of this procedure

2.1 Purpose

The purpose of this procedure is to enable a robust and systematic approach to the management of Serious Adverse Incidents that will be consistently applied across the Trust. This will contribute to ensuring that the Trust meets the SAI reporting and management requirements as defined by the HSCB within “Procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAI’s), October 2013” (and amended criteria effective from 1st February 2016) through guiding staff on their duties and responsibilities regarding:-

- Reporting a Serious Adverse Incident
- Informing the Service User / family / carer
- Coroner Involvement
- Investigating a Serious Adverse Incident to identify any learning and recommendations
- Completing an action plan on any actions identified

2.2 Scope of this procedure and definitions

This procedure applies to all staff in the Belfast Health and Social Care Trust. This includes BHSCT employees, students, agency, contractors and volunteers.

Adverse Incident:

“Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation.”

(How to Classify Adverse Incidents and Risk, HPSS 2006)

Harm is defined as ‘injury (physical or psychological), disease, suffering, disability or death’. In most instances can be considered to be unexpected if it is not related to the natural cause of the patient illness or underlying condition.

(Doing Less Harm. NHS. National Patient Safety Agency 2001)

Serious Adverse Incident (SAI) is an adverse incident that must be reported to the Health and Social Care Board (HSCB) because it meets at least one of the criteria as defined by the HSCB within “Procedure for the Reporting and Follow-up of

Serious Adverse Incidents (SAI's), Oct 2013" (see section 3.0). The criteria were then amended with effect from 1st February 2016. The Trust will be responsible for the onward reporting of SAI's relevant internally, and to their Independent Service Providers (ISPs) and contractors, and will ensure the appropriate investigation, learning and sharing of lessons regarding same.

3.0 Reporting a Serious Adverse Incident (SAI)

3.1 What is an SAI?

An SAI is an adverse incident that must be reported to the Health & Social Care Board (HSCB) because it meets at least one of the following criteria:

- 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.
 - 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 which meets one or more of the above criteria should be reported as an SAI.

3.2 How to Report an SAI

If an adverse incident occurs which meets or seems to meet any of the above criteria it should be reported immediately through the reporters management line and ultimately to Director or Co-Director for consideration for reporting as an SAI (the directorate Governance & Quality Manager or equivalent, should also be included in any communication). This should be done urgently and in the form of verbal as well as email communication.

When Director/Co-Director agrees to report the incident as an SAI, the relevant Manager or Governance & Quality Manager (or equivalent) should then complete the [SAI Notification Form](#), send it to the Director / Co-Director for approval and forward the approved copy (including details of who approved it) to the Corporate Governance Department SAI mailbox (address below) for onward reporting to the Health & Social Care Board (HSCB).

The form can also be obtained by emailing your request to Serious Adverse Incident mailbox SeriousAdverseIncident@belfasttrust.hscni.net (also in Outlook address book) or by contacting Corporate Governance Services on Tel: 028 950 48098.

(The Serious Adverse Incident mailbox should also be used for all SAI correspondence with Corporate Governance and external bodies.)

Corporate Governance will then check and redact the SAI Notification form of personal identifying information and give it a BHSCCT SAI reference number. The form will then be forwarded to the HSCB and if applicable to the Regulation and Quality Improvement Authority (RQIA).

A Trust Incident Report Form should also be completed as soon as possible (if not already done so) as per Trust procedures.

(All Adverse Incident policies and procedures can be found in the Policies & Guidelines page of Trust Intranet under the Medical Directorate/Risk & Governance sub folders.)

3.3 Timescale

All SAIs are required to be reported to HSCB within 72 hours of the incident being discovered.

3.4 General guidance on completing the SAI Notification form

Guidance on completing the [SAI Notification Form](#) can be found at Appendix 1. The following points should be read in conjunction with those procedures:-

Sections to complete

Complete all of the following sections (Corporate Governance will complete the remainder)

Sections 3, 4, 5, 6, 8 (excluding CCS coding), 9, 10, 11, 12, 13, 14, 15, 16, 17 and 18.

Section 8: Incident Description:

- Provide a brief factual description of what has happened and a summary of the events leading up to the incident. Please ensure sufficient information is provided so that the HSCB/PHA is able to come to an opinion on the immediate actions, if any, that they must take.
- Where relevant include D.O.B, Gender and Age.
- All reports should be anonymised – the names of any practitioners or staff involved must not be included. Staff should only be referred to by job title.

3.5 Informing the service user / family / carer

The principles of the [Being Open Policy](#) must be adhered to when communicating to service users, their families or carers regarding the reporting of a Serious Adverse Incident. Where it is clear or suspected that an SAI has resulted in unexpected serious harm or death to a service user, rapid and open disclosure and emotional support must be given.

The Co-Director responsible for the SAI is also responsible for ensuring the service user / family / carer is communicated with appropriately regarding the SAI and subsequent investigation. They will nominate the appropriate person to speak with the service user / family / carer initially and also ensure the service user / family / carer has a link person to contact throughout the SAI process as required. An information leaflet¹ covering “What do I need to know about Serious Adverse Incidents” should be given to the service user / family / carer to include contact details for the link person. **NB -This leaflet should only be used when it is confirmed that an SAI has been reported.**

If the Service User/Family/Carer has been notified of the incident before completing the SAI notification form, the appropriate date of notification must be included in section 15 of the form (see appendix 1). If notification is planned and not yet complete at the time of reporting, or not planned, the reason(s) should be explained in the “Others” free text field in section 15 of the form, or where relevant in any updated form the HSCB subsequently issues.

3.6 Coroner Involvement

Details of involvement with the Coroner must where applicable, be included in the description section 8 of the SAI Notification form. It is also important to include date of notification of the Coroner if applicable in section 17. When it is known that a death is to be investigated as an SAI the Coroner must be notified of this even if previously notified of the death.

Ensure the form is forwarded by email to the Trust SAI email address seriousadverseincident@belfasttrust.hscni.net along with confirmation of approval by the relevant Director or Co-Director (name of whom must be provided).

3.7 Interface Incidents

Interface incidents are those incidents which have occurred in one organisation, but where the incident has been identified in another organisation. In such instances, it is possible the organisation where the incident may have occurred is not aware of the incident; however the reporting and follow up investigation may be their responsibility. It will not be until such times as the organisation, where the incident has occurred, is made aware of the incident; that it can be determined if the incident is a SAI.

¹ There are two Trust leaflets informing service users / family / carers about SAIs. One is specifically for Adult Social and Primary Care and the other is general and should be used in all other areas.

In order to ensure these incidents are notified to the correct organisation in a timely manner, the organisation where the incident was identified will report to the HSCB using the HSC Interface Incident Notification Form (see Appendix 3). The HSCB Governance Team will upon receipt contact the organisation where the incident has occurred and advise them of the notification in order to ascertain if the incident will be reported as a SAI.

3.8 “Query Serious Adverse Incidents” (QSAIs)

The responsibility for identifying and the decision to report an SAI is primarily with the directorate responsible for that incident. To support directorate incident review processes and to act as a further control to delayed reporting, the Corporate Governance department may query any incident report where an SAI criteria seems to have been met but where the date for reporting the incident as an SAI is overdue and with no indication that it is being reported or considered. This is known as a Query SAI (QSAI) and “QSAI” is added to the incident reference until closed.

Once an incident is identified as being a query SAI (QSAI) it is forwarded to the relevant Governance & Quality manager or alternative for consideration for reporting as an SAI. The incident will remain open as a QSAI until Corporate Governance receives either:-

- A completed approved SAI Notification form relating to the incident, or
- An investigation report or if not applicable, a clear explanation of why the incident does not meet the criteria for reporting as an SAI. The investigation report should include any learning and actions taken to prevent re-occurrence where applicable. Please note that the decision not to report as an SAI may be subject to challenge from the Medical Directorate’s office.

The response to the QSAI should be sent to the Trust SAI mailbox and any report should also be included within the Datixweb incident record and referenced in the investigation section.

4.0 Procedure for investigating Serious Adverse Incidents (SAI)

The following procedures for the investigation of Serious Adverse Incidents (SAI) are based on, and should be read in conjunction with, the HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents October 2013.

When reporting an SAI, the responsible Director / Co-Director (in conjunction with the Medical Director if considering a level 3) must decide on the level of investigation required and this must be indicated on section 18 of the SAI Notification form. There are 3 levels of investigation available for SAIs and these are explained below with a summary table for quick reference (table 1).

4.1 Level of SAI Investigation

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

SAIs will be investigated using one or more of the following:

4.1.1 Level 1 Investigation – Significant Event Audit (SEA)

A level 1 investigation requires the use of Significant Event Audit (SAE) investigation methodology to investigate the incident. For guidance on using SEA methodology please see [NPSA Significant Event Audit](#).

SAI notifications which indicate a level 1 investigation will enter the investigation process at this level and a SEA will immediately be undertaken to:

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

The possible outcomes may include:

- no action required
- identification of a learning need and actions
- sharing the learning
- Requires Level 2 or 3 investigation.

The SEA report must be completed, approved by the relevant Director or Co-Director and sent to the Trust SAI mailbox for onward reporting to the HSCB within 4 weeks of the SAI being reported.

If during or on completion of the SEA the investigating team determines the SAI is more complex and requires a more detailed investigation, the investigation will move to either a level 2 or 3 investigation.

If a Level 2 investigation is required, the SEA report must still be forwarded to the HSCB within 4 weeks of the SAI being reported along with completed sections 2 and 3 of the Level 2 template to include Team Membership and Terms of Reference. The level 2 investigation process will then need to be initiated (see section 4.1.2). It may be possible to retain the same team but the level of independence needs to be considered and the Director / Co-Director may wish to contact Corporate Governance for assistance in identifying suitable members from other Directorates or external to the Trust if required.

In most circumstances, completed SEA investigations at this level will be adequate for incidents where the circumstances are of a less complex nature. In these instances it is more proportionate to use a concise SEA to ensure there are no unique factors and then focus resources on implementing improvement rather than conducting a comprehensive investigation that will not produce new learning. NB Family Involvement, see section 4.4.

Learning

Any learning from these investigations should be shared as appropriate within the Directorate governance structures and in accordance with the Trust Policy for Sharing Learning. If there is significant learning at any stage of the SEA process which requires urgent sharing outside the directorate, this should be brought to the next SAI Group meeting by the relevant Co-Director on a Shared Learning Template (see Policy for Sharing Learning).

4.1.2 Level 2 – Root Cause Analysis (RCA)

Level 2 Investigations will usually be conducted for incidents of actual or potential serious harm or death and/or where the circumstances involved are relatively complex and may involve multiple processes/teams/disciplines.

The investigation should include use of appropriate RCA analytical tools (see section 4.3 below and NPSA [Root Cause Analysis \(RCA\)](#) guidance). They will normally be conducted by a multidisciplinary team (not directly involved in the incident) with a degree of independence determined by the complexity of the incident. The investigation should be chaired by someone independent to the service area involved as a minimum. The investigation report should be completed using the HSCB RCA report template (see appendix 6 & 7 of HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents October 2013).

Team membership for level 2 investigations is the responsibility of the Director / Co-Director who commissioned the SAI. The Director / Co-Director should select the Chair from an established Trust wide pool of RCA Chairs maintained by Corporate Governance, and should consider team membership to include members independent of the directorate concerned where appropriate. Where the

Commissioning Director / Co-Director requires team member(s) external to the Trust, and is having difficulty obtaining these, they should liaise with Corporate Governance who may contact the HSCB/PHA for further advice if required.

Level 2 SAI investigations may involve two or more organisations. In these circumstances, it is important a lead organisation is identified but also that all organisations contribute to the final investigation report. If required Corporate Governance will liaise with the other organisation(s) to propose a team member(s) and agree who leads the SAI. Refer to Appendix 12 of [\(HSCB\) Procedures for reporting and managing SAIs, October 2013](#) for further guidance.

Sections 2 and 3 of the Level 2 investigation template must be completed and forwarded to the HSCB via the SAI Mailbox by, or on behalf of the Director / Co-Director within 4 weeks of the level 2 SAI being notified, detailing the membership and terms of reference for the level 2 investigation. NB Family Involvement, see section 4.4.

Learning

Any learning from these investigations should be shared as appropriate within the Directorate governance structures and in accordance with the Trust Policy for Sharing Learning. If there is significant learning at any stage of the SEA process which requires urgent sharing outside the directorate, this should be brought to the next SAI Group meeting by the relevant Co-Director on a Shared Learning Template (see Policy for Sharing Learning).

4.1.3 Level 3 – Independent Investigation (RCA)

Level 3 investigations will be considered for highly complex SAIs where a high degree of external/independent representation on the investigation team is required. In some instances all team members may be independent to the organisation/s where the incident/s has occurred.

The timescales for reporting, Chair and membership of the review team will be agreed with the HSCB/PHA Designated Review Officer (DRO) at the outset. The Commissioning Director / Co-Director and Medical Director should liaise with the DRO through Corporate Governance to agree timescales, team membership and terms of reference.

Level 3 investigation reports will take the same format as level 2 and use the same template structure for the final report.

Any SAI which involves an alleged homicide perpetrated by a service user known to/referred to mental health and/or learning disability services will be investigated as a level three incident. In these instances, the Protocol for Responding to an SAI in the Event of a Homicide, issued in 2010 and revised in 2013 should be followed (see appendix 13 of HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents October 2013).

4.2 Timescales

4.2.1 Notification

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

4.2.2 Investigation Reports

- Level 1 – SEA

SEA reports must be completed using the SEA template and submitted to the HSCB within 4 weeks (6 weeks by exception) of the SAI being notified.

Note: Corporate Governance will ask for the final report to be submitted to their office 2 days prior to submission date to HSCB to allow for redacting and final checks.

- Level 2 – RCA

Sections 2 and 3 of the Level 2 & 3 report template must be forwarded to the SAI Mailbox for onward forwarding to HSCB no later than 4 weeks after notification to HSCB of a level 2 investigation.

RCA investigation reports must be completed using the level 2 & 3 report template and submitted to the HSCB no later than 12 weeks from the initial notification of the SAI to HSCB, or if previously a level one investigation, 12 weeks from submission of the level one SEA report.

Note: Corporate Governance will ask for the final report to be submitted to their office 2 days prior to submission date to HSCB to allow for redacting and final checks.

- Level 3 – Independent Investigations

Timescales for completion of level 3 investigations will be set by the HSCB/PHA lead officer and/or DRO in agreement with the Trust.

Note: Corporate Governance will ask for the final report to be submitted to their office 2 days prior to submission date to HSCB to allow for redacting and final checks.

4.2.3 Investigation Report Extensions

- Level 1 Investigations – SEA

HSCB and PHA will not accept extension requests for this level of investigation. When reporting the SEA, an additional 2 weeks can be sought by exception only, giving the reason for the delay.

- Level 2 Investigations - RCA

In most circumstances, all timescales for submission of RCA investigation reports must be adhered to. However, it is acknowledged there may be some occasions where an investigation is particularly complex, perhaps involving two or more organisations. In these instances the reporting organisation may request an extension to the normal timescale i.e. 12 weeks from timescale for submission of interim update report. However, this request must be approved by the DRO and should be requested when submitting sections 2 & 3 of the report at 4 weeks.

- Level 3 Investigations – Independent

As per above, all timescales (including possible extensions) must be agreed with the DRO at the outset of the investigation.

4.2.4 Queries the Designated Review Officer (DRO) at HSCB may have regarding the submitted report

- Level 1 Investigations – SEA

DRO queries must be responded to within 1 week of the query being received

- Level 2 Investigations - RCA

DRO queries must be responded to within 4 weeks of the query being received

- Level 3 Investigations – Independent

DRO queries must be responded to within 4 weeks of the query being received

4.2.5 Monitoring

The commissioning Director / Co-Director is responsible for ensuring that investigation progress is monitored and timetables are met. A performance report will be tabled at each SAI Group identifying any SAs where progress issues have been identified. The relevant Co-Director will be required to provide explanations for any delays.

When the draft final report is complete, the Investigation team chair is advised to share the report with a Trust colleague independent to the directorate for review. The reviewer may have comments/feedback which should then be considered by the Investigation team before finalisation of the report for approval by relevant Director/Co-director.

4.2.6 Actions

The level 2 & 3 report template (appendix 6 & 7 of HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents October 2013) indicates that an action plan should be included within the Final report for submission to HSCB.

This should be done as far as possible. A final draft Action Plan must be forwarded as soon as approved. Actions do not need to be complete when submitting the action plan to the HSCB. Further details on the Action Plan can be found in section 5.0 below.

4.3 Completion of Level 1 (SEA) & level 2&3 report (RCA) templates

Guidance on completing the level 1 and level 2 & 3 report templates for can be found at Appendix 5 & 6 respectively of the HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents October 2013. The following points should be read in addition to those procedures:-

- Jargon or unexplained abbreviations must not be used within the report. Although clinical shorthand would be understandable to other clinicians, a SEA or RCA report is a formal report and not a clinical record. As such it should be understandable to non-clinicians including the service user / family members / carers and the Coroner.
- All reference to services, organisations, facilities etc should be explained fully if not otherwise obvious to the reader e.g. it is not sufficient to include the name of a client accommodation building without explaining the purpose/function of the building.
- The HSCB RCA template is in tabular form. This may cause formatting difficulties. It is acceptable to use a blank word document instead but the HSCB section headings from the RCA template must be included.

4.4 Service User/Family/Carer involvement

HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents October 2013 Paragraph 5.4 should be adhered to and states the requirement for service user / family / carer involvement in SAI investigations is as follows:-

“It is important that teams involved in investigations in any of the above three levels ensure sensitivity to the needs of the service user/relatives/carers involved in the incident and agree appropriate communication arrangements, where appropriate. The Investigation Team should provide an opportunity for the service user / relatives / carers to contribute to the investigation, as is felt necessary. The level of involvement clearly depends on the nature of the incident and the service users/relatives/carers wishes to be involved.”

The Co-Director responsible for the SAI should ensure the appropriate level of involvement of service user / family / carer throughout the investigation including discussion / sharing of the final report with the service user / family / carer and this should be agreed with the investigation team from the outset.

The Director / Co-Director responsible for the SAI should ensure the completion of an SAI Investigation Report checklist (appendix 2) when submitting Investigation reports to HSCB via the BHSCCT SAI mailbox. This checklist will explicitly describe the involvement (and if not, the circumstances where it has not happened) of Service Users/Relatives/Carers in the Investigation and whether they received a final report.

Approved SAI final reports should be shared or talked through with the service user/relatives/Carer as appropriate and where this is not done, an explanation must be submitted within the SAI checklist and if pending, this should be included as an action in the subsequent Action Plan for that SAI (see below).

In all cases the principles of consent and patient confidentiality must be upheld.

For guidance on how to involve families in the SAI investigations please refer to the RCA Chairs Guidance on the hub.

Involvement specific to level 1 (SEA) reports

Under the HSCB timeframe for completing level 1 investigations it may not be possible to involve the service user / family / carer in the investigation process before the final report is submitted to the HSCB. In such cases, where family involvement is deemed appropriate, the approved report should be discussed / shared with the family at a date as soon as possible after submission of the report and any issues addressed and those requiring material changes to the level 1 report should be added as an addendum and forwarded to Corporate Governance for sending to HSCB in a revised report.

Where an SAI is also a Complaint

Where a Serious Adverse Incident is also a Complaint, the investigation under the SAI process will take precedence and the Complaints investigation will be put on hold until the SAI investigation is complete. The Complaints department should notify the Complainant of this as soon as possible. The leaflet '*What do I need to know about SAIs*' should be given to the Complainant along with an explanation of the change in process.

Note that communication through the complaints process with the Complainant should continue regarding timescales and any associated delays. The SAI investigation process as per above will also have a link person identified to communicate with the service user / family / carer and will communicate through this process as appropriate. When complete the SAI final report will be shared with the

Complainant and the complaints process remains open until the complaint is formally closed with all complaints issued addressed.

4.5 Coroner engagement

Reports should also routinely include in their chronology details of all engagements with the Coroner where a death has occurred and if the Coroner has not been involved this should be stated and the decision explained.

The Director / Co-Director responsible for the SAI should also ensure the completion of an SAI Investigation Report checklist (appendix 2) when submitting Investigation reports to HSCB. This checklist will seek information regarding notification to the Coroner and current status of the case.

4.6 Safeguarding Children and Adults

Any incident involving the suspicion or allegation that a child or adult is at risk of abuse, exploitation or neglect should be investigated under the procedures set down in relation to a child and adult protection.

If during the investigation of one of these incidents it becomes apparent that the incident meets the criteria for an SAI, the incident will immediately be notified to the HSCB as an SAI.

It should be noted that, where possible, safeguarding investigations will run in parallel as separate investigations to the SAI process with the relevant findings from these investigations informing the SAI investigation and vice versa. However, all such investigations should be conducted in accordance with the processes set out in the Protocols for Joint Investigation of Cases of Alleged or Suspected Abuse of Children or Adults.

In these circumstances, the Trust should liaise closely with the DRO on the progress of the investigation and the likely timescales for completion of the SAI Report.

On occasion the incident under investigation may be considered to meet the criteria for a Case Management Review (CMR) for children, set by the Safeguarding Board for Northern Ireland; a Serious Case Review (SCR) for adults set by the Northern Ireland Adult Safeguarding Partnership; or a Domestic Homicide Review.

In these circumstances, the incident will be notified to the HSCB as an SAI. This notification will indicate that a CMR, SCR or Domestic Homicide Review is underway. This information will be recorded on the Datix system, and the SAI will be closed.

If a CMR is being considered the SAI process may be suspended and the HSCB notified of this whilst a notification and decision regarding CMR is made. If it is approved as a CMR then the SAI process will close.

4.7 Memorandum of Understanding (MoU) March 2013.

Incidents involving unexpected death or serious harm and requiring investigation by the police and/or Health and Safety Executive (HSENI) need to be handled correctly for public safety reasons as well as maintaining confidence in the HPSS, Police, Coroner and the HSENI. The Department's MoU between these four organisations seeks to ensure effective arrangements are in place to facilitate these complex interactions. The MoU compliments existing joint procedures in relation to the protection of children and vulnerable adults.

Table 1: SAI Investigation process – Teams, tools and timescales

For further details please see HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents October 2013

SAI type <i>(guide only)</i>	Inv. level	Inv. tool/ Template	Timescale	Chair	Team	Extension	Responsible officer			DRO Queries timescale
							Approval	Action Plan	Learning	
Not complex	Level 1	SEA	4 weeks	Outside Service Area. SEA trained	Local multi-disciplinary.	No (2 additional weeks when reporting SAI, by exception)	Director/Co-Director	Director/Co-Director	To SAI group if sharing beyond Directorate	1 week
SEA not sufficient, more complex issues	Level 2	RCA	12 weeks from SAI level 2 Notification. ToR & Team membership by 4 weeks	Outside Service Area/Dir. or Trust. RCA trained	Multi-disciplinary / Trust independent input possible.	1 extension by exception, sought at 4-6 weeks.	Director	Director/Co-Director & SAI Group	To SAI group if sharing beyond Directorate	4 weeks
Particularly complex/ multiple orgs involved; requires significant degree of independence; high profile.	Level 3	RCA	To be agreed with HSCB	Outside Dir or Trust. RCA trained	Highly independent multi organisational	To be agreed with HSCB	Director/ Chief Executive	Director & SAI Group	To SAI group if sharing beyond Directorate	4 weeks

5.0 Action Plans

5.1 Introduction

These procedures outline the responsibilities and requirements to ensure appropriate actions are taken to prevent/minimise re-occurrence and share learning.

The Director / Co-Director responsible for the SAI investigation has responsibility for ensuring any recommendations and lessons learned are incorporated into a plan of appropriate and realistic actions (SAI Action Plan).

An action plan is an important tool to improve systems and implement recommendations from investigations into adverse incidents:

Action plans for SAIs should be approved by the Director / Co-Director responsible for the Investigation. When all actions are completed they should be signed off by the Director/ Co-Director and in the case of Level 2 & 3 SAIs noted as closed at SAI Group.

A robust Action Plan should be:-

- explicit
- time bound
- deliverable
- assign responsibility for the action
- measurable

Avoid actions such as *remind staff* or *promote awareness*, but if they have to be used, explain how this will be done e.g. a poor action would be – *share updated policy with staff*.

Be more specific – *send staff the specific section which has changed highlighting the change and drawing their attention to it*.

SAI Action Plans should include actions for sharing lessons learned from SAI investigations as appropriate.

5.2 Generating actions from the Final Report

Whilst recommendations in a final report are drawn up and are the responsibility of the Investigation team, the corresponding actions are the responsibility of the relevant Director or Co-Director. Action Plans must address all recommendations within the Final Report as deemed appropriate. Where actions are at variance with what has been recommended within the Investigation report the reason should be given to justify the differing course of action or no action.

If recommendations include actions external to the Trust, the Action Plan should identify who will take these forward and have sought agreement for this with the named person(s).

Additional actions

- It may be appropriate to include an action in the action plan in relation to sharing the action plan with the service user / family / carer as appropriate and the progress of this should be monitored until complete.
- Actions should be included as appropriate on how the learning from the SAI is being shared.

5.3 Developing an Action Plan

- Overall responsibility for the SAI Action Plan must be with the Director / Co-Director responsible for the SAI Investigation.
- The Director / Co- Director responsible for the investigation must determine who draws up the actions.
- Where the action identified is within the area of responsibility of the Director / Co-Director responsible for the investigation, the person identified to take the action forward must be instructed to do so and have the capacity required.
- Where a recommendation is outside the area of responsibility of the Director / Co-Director, discussion and agreement must be reached with the relevant manager for drawing up and taking any action(s) forward as appropriate. The Director / Co-Director must ensure agreement is reached.
- Timescales for each action must be agreed with the person/area responsible for implementing the action.
- A draft action plan should be submitted if possible with the Final Report to the HSCB with a final draft submitted when approved. Actions do not need to be completed when submitting the action plan to the HSCB.

5.4 Documentation

- Every Action Plan must be documented using the [SAI Monitoring / Tracking Report template](#) which complies with the minimum standard for Action Plans (appendix 8 HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents October 2013).

- The SAI Monitoring / Tracking Report template for recording Action Plans includes the following:-
 - The reference number of the SAI
 - Date of the SAI Investigation report
 - Date of the latest version of the Action Plan
 - Version number and how often the Action Plan is to be reviewed
 - Who will monitor the implementation of the Action Plan.
 - Who will sign off the Action Plan when all actions are complete
- Each action on the “SAI Monitoring / Tracking Report template” must include:-
 - An associated recommendation, Contributory factor or lesson learned from the Investigation report.
 - A reference or sub-reference number.
 - The current position – this should provide the latest position in relation to progressing the action to date.
 - A description of the action to be taken.
 - Name of the responsible lead for that action (not only their job title).
 - A timescale for completion (if unknown an estimate should be made).
 - Evidence of progress/completion (including any intended Action Plan reviews or audits).
 - Indication of current status which must be one of the following:-
 - RED – Action agreed but not yet commenced
 - AMBER – Action in progress
 - GREEN – Action complete

5.5 Monitoring

- The Director / Co-Director who commissioned the investigation is responsible for setting up directorate level monitoring and review processes to ensure actions are progressed as planned.

- Where actions cannot be completed, the Director / Co-Director who commissioned the investigation is responsible for ensuring that any associated risks are identified and managed in line with the Trust Risk management strategy and brought to the SAI Group for consideration, along with any other unresolved issues.
- The relevant Co-Director responsible for the SAI should notify the SAI Group of the closure of any Action Plans which are complete and have no outstanding issues. Action Plans will not normally be required to be tabled at SAI Group.
- The SAI Group will in respect of its provision:-
 - Provide independent review to agree learning points for sharing;
 - Note closure of action plans through exception reporting;
 - Directorate membership will provide assurance of appropriate debriefing and sharing of learning at Directorate level;
 - Agree appropriate escalation of learning to the Learning from Experience Steering Group;
 - Review status reports from external bodies, such as HSCB/RQIA/HSCNI, as and when required;
 - Members will report on identified risks/issues associated with SAIs and agree appropriate escalation to the Learning from Experience Steering Group;
 - Make recommendations to corporate and operational risk registers as appropriate.
- The Corporate Governance department of the Medical Director's Office will have responsibility for administering a central monitoring process to facilitate SAI Group monitoring.
- Directorate senior managers responsible for governance are responsible for ensuring Corporate Governance has the latest version of action plans held centrally.
- The Corporate Governance department will have responsibility within the central monitoring process for providing a final check on Action Plan progress and will provide liaison with external organisations as required.

6.0 Closure of the SAI

The SAI is closed when signed off by the SAI Group. This will be done when the Action Plan is complete and no outstanding issues remain and will usually include ensuring that the HSCB has also closed the SAI (which they do via email to Corporate Governance and notification of this will be forwarded to the commissioning Director / Co-Director). When closed, a confirmation email is sent to the Director / Co-Director to include a final version of the Final report and Action Plan. Up until this stage, the version used will be a “final approved draft” and subject to change due to further material changes for example after comments received from family members. Any change will be under strict version control through Corporate Governance, approved by the commissioning Director / Co-Director and presented as an addendum to the report and forwarded to HSCB and any other relevant stakeholders.

7.0 Monitoring

The process for monitoring the effectiveness of all of the above will be managed via the following arrangements:

- Accountability/Performance Management Reviews
- Adverse Incident Training records
- Assurance Framework
- Belfast Risk Audit & Assessment Tool (BRAAT)
- Controls Assurance Standards
- Directorate Assurance meetings
- Serious Adverse Incident Group

8.0 Consultation process

Serious Adverse Incident Group

9.0 Evidence base

- Adverse Incident Reporting & Management Policy
- HSCB Procedures for the Reporting and Follow up of Serious Adverse Incidents October 2013
- Being Open Policy
- Policy for Sharing Learning

10.0 Equality Statement

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this procedure should be subject to a full impact assessment has been carried out.

The outcome of the Equality screening for this procedure is:

Major Impact ☐

Minor Impact ☐

No impact ☒

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

Date: _____

Author

Date: _____

Director

APPENDIX 1

Guidance Notes

HSC SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

All Health and Social Care Organisations, Family Practitioner Services and Independent Service Providers are required to report serious adverse incidents to the HSCB within 72 hours of the incident being discovered. It is acknowledged that not all the relevant information may be available within that timescale, however, there is a balance to be struck between minimal completion of the proforma and providing sufficient information to make an informed decision upon receipt by the HSCB/PHA.

The following guidance designed to help you to complete the Serious Adverse Incident Report Form effectively and to minimise the need for the HSCB/PHA to seek additional information about the circumstances surrounding the SAI. This guidance should be considered each time a report is submitted.

1. ORGANISATION: <i>(to be completed by Corporate Governance department)</i>		2. UNIQUE INCIDENT IDENTIFICATION NO. / REF NO. <i>(to be completed by Corporate Governance department)</i>	
3. HOSPITAL / FACILITY / COMMUNITY LOCATION <i>(where incident occurred)</i>		3. DATE OF INCIDENT: DD / MMM / YYYY <i>Insert the date incident occurred</i>	
5. DEPARTMENT / WARD / LOCATION EXACT <i>(where incident occurred)</i>			
6. CONTACT PERSON: <i>Insert the name of lead officer to be contacted should the HSCB or PHA need to seek further information about the incident</i>		7. PROGRAMME OF CARE: <i>(to be completed by Corporate Governance department)</i>	
8. DESCRIPTION OF INCIDENT: <p>Provide a brief factual description of what has happened and a summary of the events leading up to the incident. <u>PLEASE ENSURE SUFFICIENT INFORMATION IS PROVIDED SO THAT THE HSCB/ PHA ARE ABLE TO COME TO AN OPINION ON THE IMMEDIATE ACTIONS, IF ANY, THAT THEY MUST TAKE.</u> Where relevant include D.O.B, Gender and Age. <u>All reports should be anonymised</u> – the names of any practitioners or staff involved must not be included. Staff should only be referred to by job title.</p> <p>In addition include the following:</p> <p>Secondary Care – recent service history; contributory factors to the incident; last point of contact (ward / specialty); early analysis of outcome.</p> <p>Children – when reporting a child death indicate if the Regional Child Protection Committee have been advised.</p> <p>Mental Health - when reporting a serious injury to, or the unexpected/unexplained death (including suspected suicide or serious self-harm of a service user who has been known to Mental Health, Learning Disability or Child and Adolescent Mental Health within the last year) include the following details: the most recent HSC service context; the last point of contact with HSC services or their discharge into the community arrangements;</p> <p>whether there was a history of DNAs, where applicable the details of how the death occurred, if known.</p> <p>Infection Control - when reporting an outbreak which severely impacts on the ability to provide services, include the following: measures to cohort Service Users; IPC arrangements among all staff and visitors in contact with the infection source; Deep cleaning arrangements and restricted visiting/admissions.</p> <p>Information Governance –when reporting include the following details whether theft, loss, inappropriate disclosure, procedural failure etc.; the number of data subjects (service users/staff) involved, the number of records involved, the media of records (paper/electronic), whether encrypted or not and the type of record or data involved and sensitivity.</p>			
DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING			
STAGE OF CARE: <i>(to be completed by Corporate Governance department)</i>		ADVERSE EVENT: <i>(to be completed by Corporate Governance department)</i>	
DETAIL: <i>(to be completed by Corporate Governance department)</i>			

9. IMMEDIATE ACTION TAKEN TO PREVENT RECCURANCE:			
<i>Include a summary of what actions, if any, have been taken to address the immediate repercussions of the incident and the actions taken to prevent a recurrence.</i>			
10. CURRENT CONDITION OF SERVICE USER: <i>Where relevant please provide details on the current condition of the service user the incident relates to.</i>			
11. HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? (please select)	YES	NO	N/A
12. HAVE ALL RECORDS / MEDICAL DEVICES / EQUIPMENT BEEN SECURED? (please select and specify where relevant)	YES	NO	N/A
13. WHY INCIDENT CONSIDERED SERIOUS: (please select relevant criteria from below)			
serious injury to, or the unexpected/unexplained death of:			
<ul style="list-style-type: none"> - 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) <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> • any of the criteria above • theft, fraud, information breaches or data losses • a member of HSC staff or independent practitioner 			
14. IS ANY IMMEDIATE REGIONAL ACTION RECOMMENDED? (please select)	YES	NO	
if 'YES' (full details should be submitted):			
15. HAS THE SERVICE USER / FAMILY BEEN ADVISED THE INCIDENT IS BEING INVESTIGATED AS AN SAI	YES - Date informed	No – Specific reason? <i>If the service user suffered harm but was not informed of the SAI, or if the SAI involves the death of a Service</i>	

		<i>User and their family / carer were not informed, please include here the reason for this.</i>		
16. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? <i>where there appears to be a breach of professional code of conduct</i>			YES	NO
GENERAL MEDICAL COUNCIL (GMC) GENERAL DENTAL COUNCIL (GDC) PHARMACEUTICAL SOCIETY NORTHERN IRELAND (PSNI) NORTHERN IRELAND SOCIAL CARE COUNCIL (NISCC) LOCAL MEDICAL COMMITTEE (LMC) NURSING AND MIDWIFERY COUNCIL (NMC) HEALTH PROFESSIONALS COUNCIL (HPC) REGULATION AND QUALITY IMPROVEMENT AUTHORITY (RQIA) OTHER – PLEASE SPECIFY BELOW				
if 'YES' (full details should be submitted including date notified):				
17. OTHER ORGANISATION/PERSONS INFORMED: <i>(please select)</i>		DATE INFORMED:	OTHER: <i>(please specify where relevant).</i>	
DHSS&PS EARLY ALERT			Date informed:	
HM CORONER				
INFORMATION COMMISSIONER OFFICE (ICO)				
NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)				
NORTHERN IRELAND HEALTH AND SAFETY EXECUTIVE (NIHSE)				
POLICE SERVICE FOR NORTHERN IRELAND (PSNI)				
REGULATION QUALITY IMPROVEMENT AUTHORITY (RQIA)				
SAFEGUARDING BOARD FOR NORTHERN IRELAND (SBNI)				
NORTHERN IRELAND ADULT SAFEGUARDING PARTNERSHIP (NIASP)				
18. LEVEL OF INVESTIGATION REQUIRED <i>(please select)</i>		Level 1 <i>SEA</i>	Level 2 <i>RCA – Can be Trust and/or independent</i>	Level 3 <i>RCA Complex / Multi organisational</i>
19. I confirm that the designated Senior Manager and/or Chief Executive has/have been advised of this SAI and is/are content that it should be reported to the Health and Social Care Board / Public Health Agency and Regulation and Quality Improvement Authority. (delete as appropriate)				
Report submitted by: _____		Designation: _____		
Email: _____	Telephone: _____	Date: DD / MMM / YYYY		

20. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION (refer to Guidance Notes)

Use this section to provide updated information when the situation changes e.g. the situation deteriorates; the level of media interest changes

The HSCB and PHA recognises that organisations report SAIs based on limited information, which on further investigation may not meet the criteria of an SAI. Use this section to request that an SAI be de-escalated. When a request for de-escalation is made the reporting organisation must include information on why the incident does not warrant further investigation under the SAI process.

The HSCB/PHA will review the de-escalation request and inform the reporting organisation of its decision within 5 working days. The HSCB / PHA may take the decision to close the SAI without a report rather than de-escalate it. The HSCB / PHA may decide that the SAI should not be de-escalated and a full investigation report is required.

Use this section also to provide updates on progress with investigations – e.g. where the reporting organisation knows that the investigation report will not be submitted within the 12 week timeframe, this will be communicated to HSCB via Corporate Governance Dept with the unique incident identification number/reference in the subject line and provide the rationale for the delay and revised timescale for completion .

PLEASE NOTE PROGRESS IN RELATION TO TIMELINESS OF COMPLETED INVESTIGATION REPORTS WILL BE REGULARLY REPORTED TO THE HSCB/PHA REGIONALGROUP. THEY WILL BE MONITORED ACCORDING TO THE 12 WEEK TIMESCALES. IT IS IMPORTANT TO KEEP THE HSCB INFORMED OF PROGRESS TO ENSURE THAT MONITORING INFORMATION IS ACCURATE AND BREECHES ARE NOT REPORTED WHERE AN EXTENDED TIME SCALE HAS BEEN AGREED

Additional information submitted by: _____

Designation: _____

Email:

Telephone:

Date: DD / MMM / YYYY

Completed proforma should be sent to: seriousincidents@hscni.net
and (where relevant) seriousincidents@rquia.org.uk

Checklist for Engagement / Communication with Service User¹ / Family/ Carer following a Serious Adverse Incident

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report
for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		HSCB Ref Number:	
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INFORMING THE SERVICE USER¹ / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates only to a HSC Child Death notification (SAI criterion 4.2.2) Please select as appropriate (✓)	Single Service User		Multiple Service Users*		HSC Child Death Notification only
Comment: <i>*If multiple service users involved please indicate the number involved</i>					
2) Was the Service User ² / Family / Carer informed the incident was being investigated as a SAI? Please select as appropriate (✓)	YES		NO		
If YES , insert date informed :					
If NO , please select only one rationale from below, for NOT INFORMING the Service User / Family / Carer that the incident was being investigated as a SAI					
a) No contact or Next of Kin details or Unable to contact					
b) Not applicable as this SAI is not 'patient/service user' related					
c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user					
d) Case involved suspected or actual abuse by family					
e) Case identified as a result of review exercise					
f) Case is environmental or infrastructure related with no harm to patient/service user					
g) Other rationale					
If you selected c), d), e), f) or g) above please provide further details:					
For completion by HSCB/PHA Personnel Only (Please select as appropriate (✓))					
Content with rationale?	YES		NO		

SHARING THE REVIEW REPORT WITH THE SERVICE USER¹ / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

3) Has the Final Review report been shared with the Service User ¹ / Family / Carer? Please select as appropriate (✓) <i>Continued overleaf</i>	YES		NO		
If YES , insert date informed:					
If NO , please select only one rationale from below, for NOT SHARING the SAI Review Report with Service User / Family / Carer					
a) Draft review report has been shared and further engagement planned to share final report					
b) Plan to share final review report at a later date and further					

¹ Service User or their nominated representative

SHARING THE REVIEW REPORT WITH THE SERVICE USER¹ / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

	engagement planned	
	c) Report not shared but contents discussed (if you select this option please also complete 'l' below)	
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user ¹ family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
k) other rationale		
l) If you have selected c), h), i), j), or k) above please provide further details:		
For completion by HSCB/PHA Personnel Only (Please select as appropriate (✓))		
Content with rationale?	YES	NO

SECTION 2

INFORMING THE CORONER'S OFFICE

(under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? Please select as appropriate (✓)	YES		NO	
	If YES, insert date informed:			
	If NO, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? Please select as appropriate (✓)	YES		NO	
	If YES, insert date informed:			
	If NO, please provide details:			
3) If you have selected 'YES' to any of the above '1' or '2' has the review report been shared with the Coroner? Please select as appropriate (✓)	YES		NO	
	If YES, insert date report shared:			
	If NO, please provide details:			

DATE CHECKLIST COMPLETED

HSC INTERFACE INCIDENTS NOTIFICATION FORM

1. REPORTING ORGANISATION:

2. DATE OF INCIDENT:

3. CONTACT PERSON AND TEL NO:

[SeriousAdverseIncident@belfasttrust.hscni.net](mailto:SeriouAdverseIncident@belfasttrust.hscni.net)

4. UNIQUE REFERENCE NUMBER:

5. DESCRIPTION OF INCIDENT:

DOB:

GENDER:

AGE:

(complete where relevant)

6. ARE OTHER PROVIDERS INVOLVED?

(e.g. HSC TRUSTS / FPS / OOH / ISP / VOLUNTARY / COMMUNITY ORG'S)

if 'YES' *(full details should be submitted in section 7 below)*

7. PROVIDE SUFFICIENT DETAILS TO ALLOW FOLLOW UP:

8. IMMEDIATE ACTION TAKEN BY REPORTING ORGANISATION:

9. WHICH ORGANISATION/PROVIDER *(FROM THOSE LISTED IN SECTIONS 6 AND 7 ABOVE)* SHOULD TAKE THE LEAD RESPONSIBILITY FOR THE INVESTIGATION AND FOLLOW UP OF THIS INCIDENT?

10. OTHER COMMENTS:

REPORT SUBMITTED BY:

DESIGNATION:

Email:

Telephone:

Date:

Completed proforma should be sent to: seriousadverseincident@belfasttrust.hscni.net

