



Health and Social
Care Board

Procedure for the reporting and follow up of Serious Adverse Incidents

April 2010

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1.0 BACKGROUND

Circular HSS (PPM) 06/04 introduced interim guidance on the reporting and follow-up of 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.

[www.dhsspsni.gov.uk/hss\(ppm\)06-04.pdf](http://www.dhsspsni.gov.uk/hss(ppm)06-04.pdf)

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

www.dhsspsni.gov.uk/hssppm05-05.pdf

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 report pro forma. It also clarified the processes DHSSPS had put in place to consider SAIs notified to it, outlining the feedback that would then be made to the wider HPSS.

www.dhsspsni.gov.uk/qpi_adverse_incidents_circular.pdf

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.

http://www.dhsspsni.gov.uk/safety_first_-_a_framework_for_sustainable_improvement_on_the_hpss-2.pdf

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.

www.dhsspsni.gov.uk/qpi_quality_standards_for_health_social_care.pdf

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.

http://www.dhsspsni.gov.uk/hss_sqsd_19-07.pdf

Under the Provisions of Articles 86(2) of the Mental Health (NI) Order 1986, the Mental Health Commission has a duty to make inquiry into any case where it appears to the Commission 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, updated and re-issued in August 2007.
www.dhsspsni.gov.uk/utec_guidance_august_2007.pdf

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 which would be put in place to manage the transition from the DHSSPS SAI reporting system, through its cessation and to the establishment of the RAIL system.
www.dhsspsni.gov.uk/hsc-sqsd-22-09.pdf

Circular HSC (SQSD) Phase 2 – Learning from Adverse Incidents and Near Misses reported by HSC organisations and Family Practitioner Services April 2010 advises on the operation of an Early Alert System, the arrangements to manage the transfer of SAI reporting arrangements from the Department to the HSC Board, working in partnership with the Public Health Agency and 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).

2.0 INTRODUCTION

The purpose of this procedure is to provide guidance to Health and Social Care (HSC) Trusts, Family Practitioner Services (FPS) and Independent Service Providers (ISP) in relation to the reporting and follow up of Serious Adverse Incidents (SAIs) arising during the course of the business of an HSC organisation/Special Agency or commissioned service.

The requirement on HSC organisations to routinely report SAIs to the Department of Health, Social Services and Public Safety (DHSSPS) will cease from 1 May 2010. From this date, the arrangements for the reporting and follow up of SAIs, pending the full implementation of the Regional Adverse Incident Learning (RAIL) system, will transfer to the Health and Social Care Board (HSCB) working in close partnership with the Public Health Agency (PHA) and the Regulation Quality Improvement Authority (RQIA).

This new process aims to:

- Focus on service improvement for service users¹;
- Recognise the responsibilities of individual organisations and support them in ensuring compliance;
- Clarify the processes relating to the reporting, investigation, dissemination and implementation of learning arising from SAIs which occur during the course of the business of an HSC organisation / Special Agency or commissioned service;
- Keep the process for the reporting and review of SAIs under review to ensure it is fit for purpose and minimises unnecessary duplication;
- Ensure trends, best practice and learning is identified, disseminated and implemented in a timely manner, in order to prevent recurrence;
- Provide a mechanism to effectively share learning in a meaningful way across the HSC;
- Maintain a high quality of information and documentation within a time bound process.

¹ The term service user also refers to patients, clients, children and young people under 18 years and carers

3.0 APPLICATION OF PROCEDURE

3.1 Who does this procedure apply to?

This procedure applies to the reporting and follow up of SAIs arising during the course of the business of an HSC organisation / Special Agency or commissioned service specifically within:

HSC organisations including

HSC Trusts
HSCB, PHA and Business Services Organisation (BSO)
Special Agencies

Family Practitioner Services (FPS)

General Medical Services
Pharmacy
Dental
Ophthalmic

Independent Service Providers (ISPs)

Legal contract (for treatment and care) with HSCB or PHA
Legal contract (for treatment and care) with HSC Trust (*HSC Trust will be responsible for onward reporting to HSCB*)

3.2 Incidents no longer part of process

This procedure no longer requires the reporting of incidents relating to statutory functions required under The Children (Northern Ireland) Order 1995 such as:

- the admission of under 18s to adult mental health and learning disability facilities;
- children from a looked after background who abscond from care settings, which includes trafficked children and unaccompanied/ asylum seeking children;
- children from a looked after background who are admitted to the Juvenile Justice Centre or Young Offenders' Centre;
- Placements outside of the regulated provision for 16-17 year olds;
- serious incidents necessitating calling the police to a children's home.

Where any of the above incidents meet the SAI criteria as detailed in Section 4.2 these should **also** be notified in the manner set out in Section 5 of this procedure.

NOTE: FROM 1 MAY 2010 HSC TRUSTS MUST CONTINUE TO REPORT THE ABOVE STATUTORY FUNCTIONS NOTIFICATIONS DIRECTLY TO HSCB SOCIAL CARE AND CHILDREN (SCC) DIRECTORATE. THE MECHANISM FOR NOTIFICATION TO SCC WILL BE CONTAINED IN SEPARATE NEW GUIDANCE FROM SCC.

3.3 Other Reporting Arrangements

The reporting of Serious Adverse Incidents to the HSCB is without prejudice to reporting requirements to other statutory agencies and external bodies. It is not practical to list all relevant agencies/external bodies; however, examples include notifications to:

- Health and Safety Executive Northern Ireland (HSENI),
- Northern Ireland Adverse Incident Centre (NIAIC),
- Pharmaceutical Society of Northern Ireland (PSNI),
- Police Service of Northern Ireland (PSNI),
- DHSSPS Northern Ireland Head of Inspection and Enforcement (Pharmaceutical Branch).

All existing local or national reporting arrangements, where there are statutory or mandatory reporting obligations, will continue to operate in tandem with this procedure.

This guidance does not provide for the DHSSPS Early Alert System which will be the subject of separate DHSSPS guidance.

4.0 DEFINITION AND CRITERIA

4.1 Definition of an Adverse Incident

‘Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation’.²
arising during the course of the business of an HSC organisation / Special Agency or commissioned service.

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

4.2 SAI criteria

- serious injury to, or the unexpected/unexplained death (*including suspected suicides and serious self harm*) of :
 - a service user
 - a service user known to Mental Health services (including Child and Adolescent Mental Health Services (CAMHS) or Learning Disability (LD) within the last two ³ years)
 - a staff member in the course of their work
 - a member of the public whilst visiting an 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 assault (*including homicide and sexual assaults*) by a service user
 - on other service users,
 - on staff or
 - on members of the publicoccurring within a healthcare facility or in the community (where the service user is known to mental health services including CAMHS or LD within the last two years).
- serious incidents of public interest or concern involving theft, fraud, information breaches or data losses.

IT SHOULD BE NOTED ANY ADVERSE INCIDENT WHICH MEETS ONE OR MORE OF THE ABOVE CRITERIA SHOULD BE NOTIFIED TO HSCB (AND WHERE RELEVANT RQIA) AS AN SAI.

² 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

³ Mental Health Commission 2007 UTEC Committee Guidance

5.0 PROCESS

Reporting Serious Adverse Incidents

- 5.1 SAI occurs within an HSC organisation / Special Agency, an Independent Service Provider or Family Practitioner Service.
- 5.2 SAI to be reported within **72 hours** of the incident being discovered or in the case of an unexpected/unexplained death, (*where it is understood this poses a significant risk to service users, staff or the public*) where possible within **24 hours**. (*Existing out of hours arrangements to be used*). Reporting mechanisms will vary depending on organisation/practice:
- **HSC Trusts** – Complete the HSC SAI Report Form (Appendix 1) and forward to seriousincidents@hscni.net inserting the Unique Incident Reference/Number in the subject line. (*where relevant HSC Trusts to copy RQIA mhld@rqia.org.uk in line with notifications relevant to the functions, powers and duties of RQIA⁴*)
 - Where HSC Trusts have been informed of an SAI from an ISP with whom they directly commission services, the Trust will liaise with the ISP to complete the HSC SAI Report Form and the HSC Trust will forward to the HSCB at seriousincidents@hscni.net inserting the Unique Incident Reference/Number in the subject line.
 - **HSCB / PHA / BSO** – The Senior officer⁵ within the Directorate, where the SAI has occurred, will complete the HSC SAI Report Form and forward to seriousincidents@hscni.net inserting the Unique Incident Reference/Number in the subject line.
 - **FPS** – Practices to continue to report SAIs to senior officers within the Integrated Care Directorate using adverse incident forms. The senior officer will determine (*in conjunction with PHA Nursing and Midwifery Officers, where relevant*) if the incident meets the criteria of an SAI and will complete the HSC SAI Report Form and forward to seriousincidents@hscni.net inserting the Unique Incident Reference/Number in the subject line.
 - **ISPs** – (*for services directly commissioned by HSCB/PHA*) continue to report directly to Assistant

⁴ Notifications reported to both HSCB and RQIA - the management and follow up with HSC Trusts will be coordinated by the HSCB who will liaise with RQIA.

⁵ Senior Officer is considered officer at Assistant Director Level or above

Director (AD) Contracting within the HSCB Commissioning Directorate using the adverse incident form. The AD Contracting will determine (*in conjunction with relevant officers from PHA*) if the incident meets the criteria of an SAI and will liaise with the ISP to complete the HSC SAI Report Form and forward to seriousincidents@hscni.net inserting the Unique Incident Reference/Number in the subject line.

NOTE: APPENDIX 2 PROVIDES GUIDANCE NOTES TO ASSIST IN THE COMPLETION OF THE HSC SAI REPORT FORM.

Management and follow up of Serious Adverse Incidents

- 5.3** Governance Lead⁶ will record the SAI on the DATIX risk management system, assign to HSCB/PHA Designated Review Officer (DRO) and copy the SAI Report to:
- HSCB/PHA DRO for review and follow up
 - Relevant Directors and AD's within the HSCB and PHA, for information
 - Other relevant officers, for information.
- 5.4** The DRO will consider the SAI notification and ensure that immediate actions, if required, are put in place.
- 5.5** Governance Lead will electronically acknowledge receipt of the SAI report, issuing HSCB unique identification number, confirming the DRO and requesting the completion of an investigation report within **12 weeks** from the date the incident is reported. Where relevant RQIA will be copied into this receipt. (All investigation reports should be completed in line with the HSC Regional Template and Guidance for Incident Investigation/ Review Report - Appendix 3)
- 5.6** Governance Lead will complete Section 1 of the DRO Form (Appendix 4) and forward to DRO.
- 5.7** It is recognised that organisations/practices report SAIs based on limited information and the situation may change which could result in:
- the situation deteriorating or
 - the incident reported no longer meeting the SAI criteria
- in such instances an update should be provided by completing Section 14 of the initial SAI report and the revised/updated SAI report should be re-submitted to seriousincidents@hscni.net.

⁶ Governance Lead refers to Governance Lead within HSCB Local Offices

- 5.8** Where the reporting organisation/practice has determined that the incident reported no longer meets the criteria of an SAI a request to de-escalate the SAI must be submitted by completing Section 14 of the initial SAI report providing the rationale on why the incident does not warrant further investigation under the SAI process.
- 5.9** The DRO will review the de-escalation request and inform the reporting organisation of the decision within **10 working days**. The DRO may take the decision to close the SAI without a report rather than de-escalate it or may decide that the SAI should not be de-escalated and a full investigation report is required.
- 5.10** Investigation reports must be submitted within **12 weeks** from the date the incident is reported. If it is likely that the organisation /practice cannot complete the investigation within this timescale an update should be provided by completing Section 14 of the initial SAI report detailing the reason for the delay and the expected date for completion.
- 5.11** If an investigation report is not received within the 12 week timeframe and an explanation has not been provided the Governance Lead will ensure a reminder is issued to the relevant organisation/practice requesting the full report or where this is not possible a detailed progress report.
- 5.12** If the investigation report or progress report is still not received within **10 working days** or there has been no explanation for delay, the HSCB Chief Executive will write to the organisation/practice requesting an explanation for the delay in forwarding the report.
- 5.13** When the investigation report is received, the DRO will consider the adequacy of the investigation report and liaise with relevant professionals/officers including RQIA (*where relevant*) to ensure that the reporting organisation/practice has taken reasonable action to reduce the risk of recurrence and determine if the SAI can be closed.
- 5.14** If the DRO is not satisfied that the report reflects a robust and timely investigation s/he will continue to liaise with the reporting organisation/practice and/or other professionals /officers, including RQIA (*where relevant*) until a satisfactory response is received.
- 5.15** When the DRO is satisfied (*based on the information provided*) that the investigation has been robust and recommendations are appropriate, s/he will complete the DRO Form validating their reason for closure. The DRO (*in conjunction with relevant professionals/officers*) will agree that recommendations identified are appropriately addressed including development of any action

/implementation plan. The DRO will advise on any additional performance monitoring arrangements which need to be put in place.

5.16 The DRO will identify any learning arising from the SAI that should be brought forward by the HSCB/PHA SAI Review Group. The completed DRO Form will then be forwarded to the Governance Lead.

5.17 Governance Lead will forward a letter to the organisation/practice advising the SAI has been closed by HSCB and, where relevant, any additional action to be taken. A copy of this will also be forwarded to RQIA (where relevant)

5.18 The HSCB/PHA SAI Review Group will meet on a bi-monthly basis to consider:

- number and breakdown of reports received, by programmes of care;
- specifics of any significant SAIs;
- identification of trends;
- any problematic issues relating to specific SAIs;
- any implications in respect of procedure;
- any learning identified by DRO;
- the correct mechanisms to share learning in a meaningful way and in a timely manner.

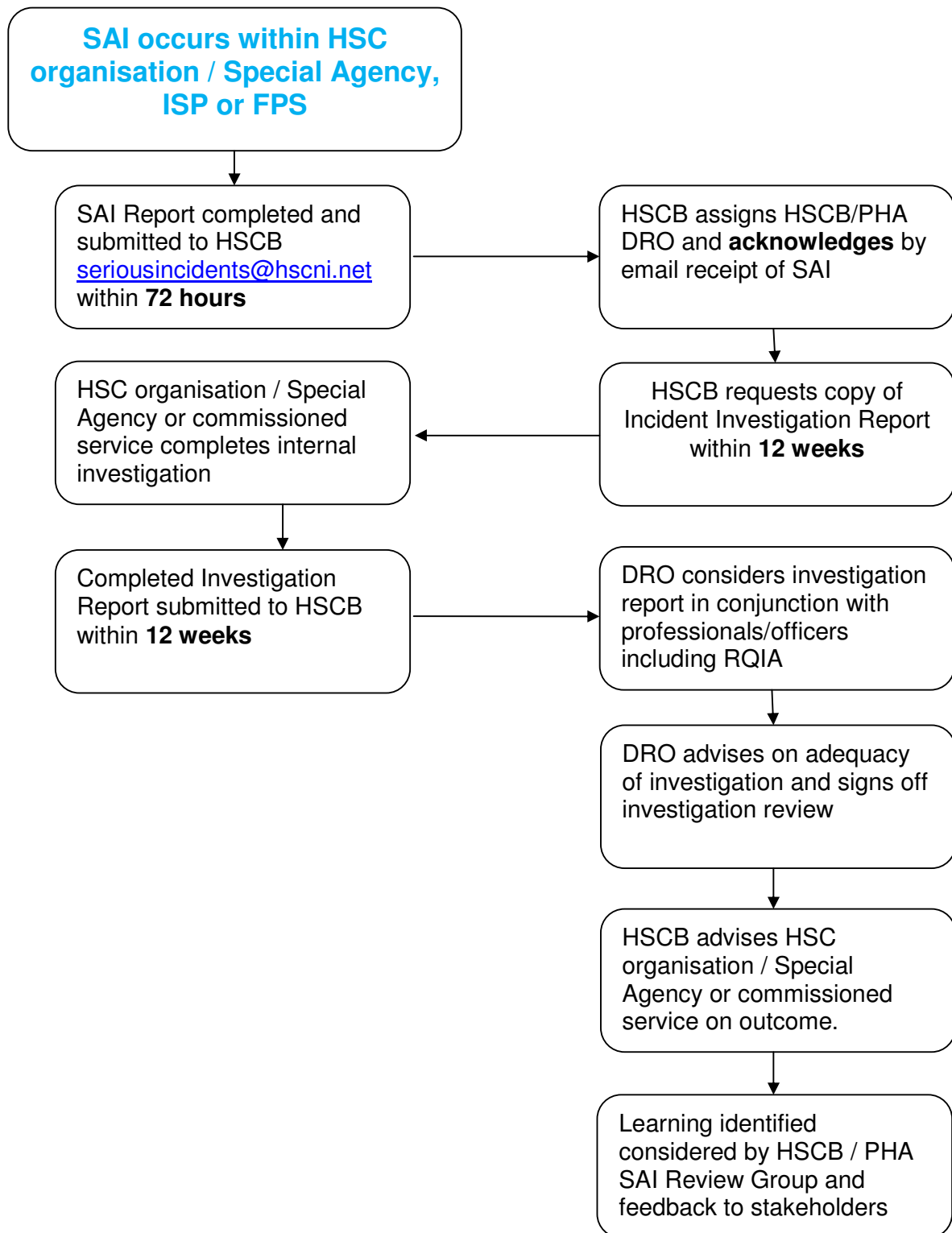
6.0 EQUALITY

This procedure has been screened for equality implications as required by Section 75 and Schedule 9 of the Northern Ireland Act 1998. Equality Commission guidance states that the purpose of screening is to identify those policies which are likely to have a significant impact on equality of opportunity so that greatest resources can be devoted to these.

Using the Equality Commission's screening criteria, no significant equality implications have been identified. The procedure will therefore not be subject to equality impact assessment.

Similarly, this procedure has been considered under the terms of the Human Rights Act 1998 and was deemed compatible with the European Convention Rights contained in the Act.

7.0 PROCESS FLOW CHART – KEY STAGES



APPENDIX 1

HSC SERIOUS ADVERSE INCIDENT REPORT FORM													
1. ORGANISATION:	2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE												
3. DATE OF INCIDENT: DD / MMM / YYYY	4. CONTACT PERSON: <i>(Name of lead officer to contact for further details)</i>												
6. DESCRIPTION OF INCIDENT:													
<p>DOB: DD / MMM / YYYY GENDER: M / F AGE: years <i>(complete where relevant)</i></p>													
7. IMMEDIATE ACTION TAKEN:													
HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? <i>(please select)</i>			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; text-align: center;">YES</td> <td style="width: 33%; text-align: center;">NO</td> <td style="width: 33%; text-align: center;">N/A</td> </tr> </table>	YES	NO	N/A							
YES	NO	N/A											
HAVE ALL RECORDS / MEDICAL DEVICES / EQUIPMENT BEEN SECURED? <i>(please specify where relevant)</i>			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; text-align: center;">YES</td> <td style="width: 33%; text-align: center;">NO</td> <td style="width: 33%; text-align: center;">N/A</td> </tr> </table>	YES	NO	N/A							
YES	NO	N/A											
8. WHY INCIDENT CONSIDERED SERIOUS: <i>(please select relevant criteria below)</i>													
<ul style="list-style-type: none"> • serious injury to, or the unexpected/unexplained death, <i>(including suspected suicides or serious self harm)</i> of: <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%; padding-left: 20px;"> <ul style="list-style-type: none"> – a service user; – a service user who has been known to Mental Health services (including Child and Adolescent Mental Health Services (CAMHS) or Learning Disability (LD) within the last two years); – a staff member in the course of their work; – a member of the public whilst visiting a Health and Social Care facility </td> <td style="width: 20%;"></td> </tr> <tr> <td style="width: 80%; padding-left: 20px;"> <ul style="list-style-type: none"> • unexpected serious risk to service user and / or staff member and / or member of the public </td> <td style="width: 20%;"></td> </tr> <tr> <td style="width: 80%; padding-left: 20px;"> <ul style="list-style-type: none"> • unexpected or significant threat to provide service and / or maintain business continuity. </td> <td style="width: 20%;"></td> </tr> <tr> <td style="width: 80%; padding-left: 20px;"> <ul style="list-style-type: none"> • serious assault <i>(including homicide and sexual assaults)</i> by a service user <ul style="list-style-type: none"> – on other service users, – on staff or – on members of the public occurring within a healthcare facility or in the community (where the service user is known to mental health services <i>(including CAMHS or LD)</i> within the last two years). </td> <td style="width: 20%;"></td> </tr> <tr> <td style="width: 80%; padding-left: 20px;"> <ul style="list-style-type: none"> • Serious incidents of public interest or concern involving theft, fraud, information breaches and data losses </td> <td style="width: 20%;"></td> </tr> </table> 				<ul style="list-style-type: none"> – a service user; – a service user who has been known to Mental Health services (including Child and Adolescent Mental Health Services (CAMHS) or Learning Disability (LD) within the last two years); – a staff member in the course of their work; – a member of the public whilst visiting a Health and Social Care facility 		<ul style="list-style-type: none"> • unexpected serious risk to service user and / or staff member and / or member of the public 		<ul style="list-style-type: none"> • unexpected or significant threat to provide service and / or maintain business continuity. 		<ul style="list-style-type: none"> • serious assault <i>(including homicide and sexual assaults)</i> by a service user <ul style="list-style-type: none"> – on other service users, – on staff or – on members of the public occurring within a healthcare facility or in the community (where the service user is known to mental health services <i>(including CAMHS or LD)</i> within the last two years). 		<ul style="list-style-type: none"> • Serious incidents of public interest or concern involving theft, fraud, information breaches and data losses 	
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9. IS ANY IMMEDIATE REGIONAL ACTION RECOMMENDED? <i>(please select)</i>			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">YES</td> <td style="width: 50%; text-align: center;">NO</td> </tr> </table>	YES	NO								
YES	NO												
if 'YES' <i>(full details should be submitted):</i>													

APPENDIX 2

Guidance Notes HSC SERIOUS ADVERSE INCIDENT REPORT 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 (*24 hours if the incident involves a death*). It is acknowledged that not all the relevant information may be available within that timescale; however, there is a balance to be made 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.

2. ORGANISATION: <i>Include the details of the reporting organisation (Trust, FPS, ISP)</i>	2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE <i>Unique incident number / reference generated by the reporting organisation / practice</i>			
3. DATE OF INCIDENT: DD / MMM / YYYY <i>Date incident occurred</i>	4. CONTACT PERSON: <i>(Name of lead officer to be contacted should the HSCB or PHA need to seek further information about the incident)</i>			
5. DESCRIPTION OF INCIDENT: <i>Provide a brief factual description of what has happened and a summary of the events leading up to the incident, 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. 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.</i> <i>In addition include the following:</i> Secondary Care – recent service history; contributory factors to the incident; last point of contact (ward / specialty); early analysis of outcome Children – when reporting a child death indicate if the Regional Child Protection Committee have been advised 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 2 years) 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; whether there was a history of DNAs, where applicable the details of how the death occurred, if known. 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. 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 DOB: DD / MMM / YYYY GENDER: M / F AGE: years <i>(complete where relevant)</i>				
6. IMMEDIATE ACTION TAKEN: <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 reoccurrence</i>				
HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? (please select)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; text-align: center;">YES</td> <td style="width: 33%; text-align: center;">NO</td> <td style="width: 33%; text-align: center;">N/A</td> </tr> </table>	YES	NO	N/A
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YES	NO	N/A		
7. WHY INCIDENT CONSIDERED SERIOUS: (please select relevant criteria below)				
<ul style="list-style-type: none"> • serious injury to, or the unexpected/unexplained death, (including suspected suicides or serious self harm) of: <ul style="list-style-type: none"> – a service user; – a service user who has been known to Mental Health services (including Child and Adolescent Mental Health Services (CAMHS) or Learning Disability (LD) within the last two years); – a staff member in the course of their work; – a member of the public whilst visiting a Health and Social Care facility 				
<ul style="list-style-type: none"> • unexpected serious risk to service user and /or staff member and/or member of the public 				
<ul style="list-style-type: none"> • unexpected or significant threat to provide service and / or maintain business continuity. 				

<ul style="list-style-type: none"> serious assault (<i>including homicide and sexual assaults</i>) by a service user <ul style="list-style-type: none"> on other service users, on staff or on members of the public occurring within a healthcare facility or in the community (where the service user is known to mental health services (<i>including CAMHS or LD</i>) within the last two years). 				
<ul style="list-style-type: none"> Serious incidents of public interest or concern involving theft, fraud, information breaches and data losses 				
8. IS ANY IMMEDIATE REGIONAL ACTION RECOMMENDED? (<i>please select</i>)			YES	NO
if 'YES' (<i>full details should be submitted</i>):				
9. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? (<i>please select</i>) (<i>e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HPC etc</i>) <i>where there appears to be a breach of professional code of conduct</i>			YES	NO
if 'YES' (<i>full details should be submitted</i>):				
10. OTHER ORGANISATION/PERSONS INFORMED: (<i>insert date informed</i>)		DATE INFORMED:	OTHER:	
DHSS&PS EARLY ALERT			Please specify: Date informed:	
FAMILY/CARER				
HM Coroner				
ICO				
NIAIC				
NIHSE				
PSNI				
RQIA				
11. 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. (<i>delete as appropriate</i>)				
Additional information submitted by: _____			Designation: _____	
Email: _____		Telephone: _____	Date: DD / MMM / YYYY	
14. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION				
<i>Use this section to provide updated information when the situation changes e.g. the situation deteriorates; the level of media interest changes</i>				
<i>The HSCB and PHA recognises that organisations report SAI's 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 and send to seriousincidents@hscni.net with the unique incident identification number/reference in the subject line. 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.</i>				
<i>The HSCB/PHA will review the de-escalation request and inform the reporting organisation of its decision within 10 working days. The HSCB / PHA may take the decision to close the SAI without a report rather than deescalate it. The HSCB / PHA may decide that the SAI should not be de-escalated and a full investigation report is required.</i>				
<i>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 should be communicated to seriousincidents@hscni.net with the unique incident identification number/reference in the subject line and provide the rationale for the delay and revised timescale for completion .</i>				
PLEASE NOTE PROGRESS IN RELATION TO TIMELINESS OF COMPLETED INVESTIGATION REPORTS WILL BE REGULARLY REPORTED TO THE HSCB/PHA SAI REVIEW GROUP. THEY WILL BE MONITORED IN ACCORDANCE WITH THE 12 WEEK TIMESCALE. IT IS IMPORTANT TO KEEP THE HSCB INFORMED OF PROGRESS TO ENSURE THAT MONITORING INFORMATION IS ACCURATE AND BREACHES ARE NOT REPORTED HSCB/PHA SAI REVIEW GROUP WHERE AN EXTENDED TIME SCALE HAS BEEN AGREED.				
Additional information submitted by: _____			Designation: _____	
Email: _____		Telephone: _____	Date: DD / MMM / YYYY	

Completed profroma should be sent to: seriousincidents@hscni.net
and (where relevant) mhld@rqia.org.uk

APPENDIX 3



Department of
**Health, Social Services
and Public Safety**

An Roinn
**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

www.dhsspsni.gov.uk

Health and Social Care Regional Template and Guidance for Incident Investigation/Review Reports

September 2007

Introduction

This work has been commissioned by the DHSSPS Safety in Health and Social Care Steering Group as part of the action plan contained within “*Safety First: A Framework for Sustainable Improvement in the HPSS*” (under 5.1.2 Agreeing Common systems for Data Collection, Analysis and Management of Adverse Events). The following work forms part of an on-going process to develop clarity and consistency in conducting investigations and reviews. This is an important aspect of the safety agenda.

This template and guidance notes should be used, in as far as possible, for drafting all HSC incident investigation/review reports. It is intended as a guide in order to standardise all such reports across the HSC including both internal and external reports. It should assist in ensuring the completeness and readability of such reports. The headings and report content should follow as far as possible the order that they appear within the template. Composition of reports to a standardised format will facilitate the collation and dissemination of any regional learning.

All investigations/reviews within the HSC should follow the principles contained within the National Patient Safety Agency (NPSA) Policy documents on “*Being Open – Communicating Patient Safety Incidents with Patients and their Carers*”.

http://www.npsa.nhs.uk/site/media/documents/1456_Beingopenpolicy111.pdf

It is also suggested that users of this template read the guidance document “*A Practical Guide to Conducting Patient Service Reviews or Look Back Exercises*” – Regional Governance Network – February 2007.

http://www.dhsspsni.gov.uk/microsoft_word_-_hss_sqsd_18-07_patient_service_review_guidelines_-_final_feb07.pdf

This template was designed primarily for incident investigation/review however it may also be used to examine complaints and claims.

The suggested template can be found in the following pages.

Template Title Page

Date of Incident/Event

**Organisation's Unique Case Identifier (for
tracking purposes)**

Introduction

The introduction should outline the purpose of the report and include details of the commissioning Executive or Trust Committee.

Team Membership

List names and designation of the members of the Investigation team. Investigation teams should be multidisciplinary and should have an independent Chair. The degree of independence of the membership of the team needs careful consideration and depends on the severity / sensitivity of the incident. However, best practice would indicate that investigation / review teams should incorporate at least one informed professional from another area of practice, best practice would also indicate that the chair of the team should be appointed from outside the area of practice. In the case of more high impact incidents (i.e. categorised as catastrophic or major) inclusion of lay / patient / service user or carer representation should be considered. There may be specific guidance for certain categories of adverse incidents, such as, the Mental Health Commission guidance

http://www.dhsspsni.gov.uk/mhc_guidance_on_monitoring_untoward_events.pdf

Terms of Reference of Investigation/Review Team

The following is a sample list of statements of purpose that should be included in the terms of reference:

- To undertake an initial investigation/review of the incident
- To consider any other relevant factors raised by the incident
- To agree the remit of the investigation/review
- To review the outcome of the investigation/review, agreeing recommendations, actions and lessons learned.
- To ensure sensitivity to the needs of the patient/ service user/ carer/ family member, where appropriate

Methodology to be used should be agreed at the outset and kept under regular review throughout the course of the investigation.

Clear documentation should be made of the time-line for completion of the work.

This list is not exhaustive

Summary of Incident/Case

Write a summary of the incident including consequences. The following can provide a useful focus but please note this section is not solely a chronology of events

- Brief factual description of the adverse incident
- People, equipment and circumstances involved
- Any intervention / immediate action taken to reduce consequences
- Chronology of events
- Relevant past history
- Outcome / consequences / action taken

This list is not exhaustive

Methodology for Investigation

This section should provide an outline of the methods used to gather information within the investigation process. The NPSA's "Seven Steps to Patient Safety" is a useful guide for deciding on methodology.

- Review of patient/ service user records (if relevant)
- Review of staff/witness statements (if available)
- Interviews with relevant staff concerned e.g.
 - Organisation-wide
 - Directorate Team
 - Ward/Team Managers and front line staff
 - Other staff involved
 - Other professionals (including Primary Care)
- Specific reports requested from and provided by staff
- Engagement with patients/service users / carers / family members
- Review of Trust and local departmental policies and procedures
- Review of documentation e.g. consent form(s), risk assessments, care plan(s), training records, service/maintenance records, including specific reports requested from and provided by staff etc.

This list is not exhaustive

Analysis

This section should clearly outline how the information has been analysed so that it is clear how conclusions have been arrived at from the raw data, events and treatment/care provided.

Analysis can include the use of root cause and other analysis techniques such as fault tree analysis, etc. The section below is a useful guide particularly when root cause techniques are used. It is based on the NPSA's "Seven Steps to Patient Safety" and "Root Cause Analysis Toolkit".

(i) Care Delivery Problems (CDP) and/or Service Delivery Problems (SDP) Identified

CDP is a problem related to the direct provision of care, usually actions or omissions by staff (active failures) or absence of guidance to enable action to take place (latent failure) e.g. failure to monitor, observe or act; incorrect (with hindsight) decision, NOT seeking help when necessary.

SDP are acts and omissions identified during the analysis of incident not associated with direct care provision. They are generally associated with decisions, procedures and systems that are part of the whole process of service delivery e.g. failure to undertake risk assessment, equipment failure.

(ii) Contributory Factors

Record the influencing factors that have been identified as root causes or fundamental issues.

- Individual Factors
- Team and Social Factors
- Communication Factors
- Task Factors
- Education and Training Factors
- Equipment and Resource Factors
- Working Condition Factors
- Organisational and Management Factors
- Patient / Client Factors

This list is not exhaustive

As a framework for organising the contributory factors investigated and recorded the table in the NPSA's "Seven Steps to Patient Safety" document (and associated Root Cause Analysis Toolkit) is useful.

www.npsa.nhs.uk/health/resources/7steps

Where appropriate and where possible careful consideration should be made to facilitate the involvement of patients/service users / carers / family members within this process.

Conclusions

Following analysis identified above, list issues that need to be addressed. Include discussion of good practice identified as well as actions to be taken. Where appropriate include details of any ongoing engagement / contact with family members or carers.

Involvement with Patients/Service Users/ Carers and Family Members

Where possible and appropriate careful consideration should be made to facilitate the involvement of patients/service users / carers / family members.

Recommendations

List the improvement strategies or recommendations for addressing the issues above. Recommendations should be grouped into the following headings and cross-referenced to the relevant conclusions. Recommendations should be graded to take account of the strengths and weaknesses of the proposed improvement strategies/actions.

- Local recommendations
- Regional recommendations
- National recommendations

Learning

In this final section it is important that any learning is clearly identified. Reports should indicate to whom learning should be communicated and copied to the Committee with responsibility for governance.

APPENDIX 4 DESIGNATED SAI REVIEW OFFICER FORM

SECTION 1 TO BE COMPLETED BY HSCB GOVERNANCE LEAD

UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE	HSCB IDENTIFICATION NUMBER
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SECTION 1: RECEIPT AND PROCESSING OF SAI			
DATE SAI NOTIFIED	DD / MMM /YYYY	DATE ACKNOWLEDGED	DD / MMM /YYYY
DESIGNATED REVIEW OFFICER ASSIGNED		DATE ASSIGNED	DD / MMM /YYYY
INVESTIGATION REPORT DUE:		DD / MMM / YYYY	

SECTIONS 2 to 6 TO BE COMPLETED BY DESIGNATED REVIEW OFFICER

SECTION 2: IMMEDIATE ACTION TAKEN BY DESIGNATED REVIEW OFFICER:

SECTION 3: RECEIPT OF INVESTIGATION REPORT		
INVESTIGATION REPORT RECEIVED WITHIN 12 WEEKS?	YES	NO
	<i>complete 4</i>	<i>complete 3b</i>

SECTION 3b: INVESTIGATION REPORT OVERDUE (not submitted within 12 weeks)		
HAS AN EXPLANATION/UPDATE BEEN PROVIDED?	YES	NO
DRO COMMENTS:		
DRO REMINDER SENT TO REPORTING ORGANISATION?	DD / MMM /YYYY	
CHIEF EXECUTIVE LETTER TO REPORTING ORGANISATION?	DD / MMM /YYYY	

SECTION 4: INVESTIGATION REPORT	
DATE INVESTIGATION REPORT RECEIVED	DD / MMM / YYYY
DATE INVESTIGATION REPORT FORWARDED TO RQIA <i>(where relevant)</i>	DD / MMM / YYYY
DRO COMMENTS ON ADEQUACY OF INVESTIGATION REPORT: <i>(in conjunction with other professionals and RQIA where relevant):</i>	

SECTION 5: CLOSURE OF SAI		
BASED ON INFORMATION PROVIDED IS DRO CONTENT TO CLOSE? <i>(confirm in conjunction with other professionals and RQIA where relevant):</i>	YES	NO <i>Continue to liaise with organisation/practice</i>
DRO'S COMMENTS INCLUDING HOW IDENTIFIED RECOMMENDATIONS SHOULD BE MONITORED: <i>(in conjunction with other professionals and RQIA where relevant):</i>		
DRO CLOSURE LETTER SENT TO REPORTING ORGANISATION?	DD / MMM /YYYY	
SIGNATURE OF DRO:	DATE: DD / MMM /YYYY	
DESIGNATION:	ORGANISATION/DIRECTORATE:	

SECTION 6 : LEARNING
LOCAL, REGIONAL, NATIONAL LEARNING IDENTIFIED: <i>(please specify)</i> <i>(learning identified will be submitted to HSCB/PHA SAI Review Group)</i>