Department of
Health, Social Services
and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí

www.dhsspsni.gov.uk

SAFETY FIRST:
A Framework for Sustainable Improvement in the HPSS

March 2006

DHSSPS
333-117-001

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POLICY STATEMENT ON SAFETY

The Department of Health, Social Services and Public Safety, together with the Health and Personal Social Services (HPSS), is committed to the ongoing development of a safer service, as part of its drive to improve clinical and social care, service user experience and outcomes.

No health and social care environment will ever be absolutely safe and without risk; however, more can always be done to improve the safety and quality of care provided.

High safety standards are key indicators of a high quality service. Over the next few years, the policy focus will be on linking quality and safety. Particular attention will be on:

- Creating an informed, open and fair safety culture within the HPSS;
- Raising awareness of risk and promoting timely reporting of adverse incidents;
- Investigating serious incidents;
- Sharing the learning across HPSS environments;
- Implementing change;
- Developing skills, knowledge and expertise; and
- Involving and communicating with the public.

In support of the policy, an action plan has been developed, which places "Safety First" as the philosophy which all organisations, practitioners and staff should promote and adopt.

The action plan will be reviewed in 2007.

SECTION 1 – AIM OF FRAMEWORK

1.1 INTRODUCTION

Safety has to be the first concern of everyone who works in or manages the Health and Personal Social Services (HPSS) in Northern Ireland. It is an integral part of quality in health and social care - diminished standards of safety reflect poor quality of service for people. Effective care, therefore, has to place an emphasis on efforts to improve safety processes in order to prevent adverse outcomes, and to improve the service user and carer experience. Safety is, therefore, an integral part of clinical and social care governance.

This document aims to draw together key themes to promote service user safety in the HPSS. It intends to build on existing systems and good practice, to bring about a clear and consistent DHSSPS policy and action plan, which can be reviewed in light of advances and developments. It does not aim to identify or replace existing policies and procedures, particularly those relating to statutory health and safety functions, or staff or visitor safety, but rather focuses on safety in terms of improvement of quality of care through enhanced clinical and social care governance.

The major policy focus and action will be on:

- creating an informed, open and fair safety culture across HPSS organisations;
- raising awareness of risk and promoting timely reporting of adverse incidents;
- sharing the learning across HPSS environments;
- implementing change;
- investigating serious incidents; and
- involving and communicating with the public.

Appendix A sets out the Terms of Reference and scope of this safety document. The action plan (section 5) will be reviewed in 2007, to determine progress and map future priorities.

1.2 ERROR – A PART OF THE HUMAN CONDITION

No health and social care environment is one hundred percent safe. Some adverse incidents which occur may be the inevitable complication of treatment or care. Many treatment decisions are made in a busy working day, using a range of technologies and

activities (e.g. medicines, medical devices, equipment, procedures) and in different environments, which can, in themselves, be the subject of error. The factors which influence quality and safety of care, include:

- the context, e.g. HPSS, regulatory frameworks;
- the organisation and its management e.g. financial resources, priorities, policies, safety culture;
- the work environment e.g. staffing levels, skill mix, workload;
- the team e.g. structure, communication, supervision arrangements;
- the individual (staff) e.g. knowledge and skills, motivation, health;
- the task e.g. task design, use of protocols, accuracy of test results; and
- patient characteristics e.g. complexity of condition, language and communication, personality and social factors.[1]

Given the multiplicity of factors which influence the care of an individual, health and social services will never be totally error-free. But what can be achieved is the minimisation of risk, a greater knowledge and understanding of why human error and systems failures occur and the fostering of a culture which supports learning in order to prevent reoccurrence.

1.3 DEFINITION OF AN ERROR OR INCIDENT

It is important to have a common understanding of what constitutes an error or incident, regardless of the source. Errors can occur at all stages of the process of care, from diagnosis to treatment, to preventive care. Not all errors result in harm; these errors are often described as "near misses". These too, represent an opportunity to identify systems improvements and have the potential to prevent adverse incidents in the future. All types of errors and incidents should be included in a common definition - social care, clinical, health and safety, fire, infection control etc., as they could potentially impact on the health and social care of service users, staff and visitors.

For the purposes of the Department and the HPSS, the regional definition of an error or incident is as follows:

[1] Adapted from; Vincent, Taylor-Adams and Stanhope 1998

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

The definition acts as a common working definition for HPSS organisations. It acknowledges that not all errors result in harm to patients and service users, but some do. Where the potential for harm/loss/damage is detected and the incident is prevented thus resulting in no harm to the individual, it is considered a "near miss" and can yield valuable learning.

The definition also supports the view that damage to property, environment or reputation can have both a direct and indirect impact and cost on health and social care. For example, faulty equipment may require tests to be repeated, potential for mis-diagnosis and concern for service users and staff. In addition, an incident may lead to loss of trust on behalf of the public and reduced satisfaction and morale among staff, with consequent negative impact on workforce recruitment and retention. More generally, employers and society may pay because of loss of worker productivity, school attendance, and a reduction in population health status. So, the human, social and economic costs resulting from adverse incidents are potentially high, but especially when a death occurs which may have been preventable.

1.4 THE HUMAN, SOCIAL AND ECONOMIC COSTS

The National Patient Safety Agency in England and Wales has produced its first report based on findings of the National Reporting and Learning System from November 2003 to March 2005. It shows a rate of five adverse incidents reported per 100 admissions in acute hospitals. In acute hospital settings, about three in every 1,000 reported incidents resulted in death[2].

Although many HSS Trusts and Boards have local incident reporting systems, the health and social services in Northern Ireland do not have a common reporting or data analysis system for adverse incidents; therefore, neither the number of adverse incidents in health and social care environments is known nor can the order of magnitude of untoward deaths be estimated. However, as with other developed healthcare systems, it can be reasonably assumed that the problem exists in our health and social care environment.

[2] Building a Memory: preventing harm, reducing risks and improving patient safety – The first report of the National Reporting and Learning System and the Patient Safety Observatory – July 2005 – www.npsa.nhs.uk

What is known is the fact that any adverse incident, whether or not it results in injury, harm or death, has the potential to cause considerable distress not just to service users and carers but also to health and social care staff. For the families of those who have suffered the loss of a loved one, that loss can be made worse by the knowledge that death may have been preventable and that past lessons may not have been learnt.

The human, social and economic costs to individuals and families, the Health and Social Services and society are enormous. For example, in the HPSS:

- in 2004, via the Northern Ireland Adverse Incident Centre[3], 166 adverse incidents reports were received with 4 relating to circumstances involving fatalities;
- in 2004/05, a total of 10,107 medication-related patient safety incidents[4] were reported by staff in eight of Northern Ireland hospitals alone, although 89% of these were considered not to have caused harm (i.e. a near miss);
- in 2004/05, the frequency of MRSA[5] among hospital patients has shown a first and significant annual downturn during four years of monitoring, 242 patients were recorded as having MRSA in 2004/05 a decrease of 21% when compared to the same period in 2003/04;
- 15 suspected suicides and 3 suspected homicides occurred involving people in or who had just been discharged from mental health settings in the HPSS and were reported to the Department in 2004/05[6]; and
- in 2003/04, £15 million was paid in settlement of clinical negligence claims (HSS Boards and Trusts) with a future potential liability of around £100 million for current claims[7].

[3] Northern Ireland Adverse Incident Centre records and investigates, as appropriate, reported adverse incidents involving medical devices, non medical equipment, plant and building items used in the HPSS
[4] Source – Northern Ireland Medicines Governance Team
[5] Source - Communicable Disease Surveillance Centre – Northern Ireland – www.cdscni.org.uk
[6] Source – DHSSPS – Circular HSS (PPM) 06/2004. Reporting and follow-up of serious adverse incidents
[7] Source - DHSSPS

1.5 LEADERSHIP AND ORGANISATIONAL CULTURE

The culture of an organisation is about "how we do things around here" and this is significantly influenced by the leadership of senior management. But for senior management to demonstrate leadership, it has to have the knowledge, skills and information to promote a safety culture.

An informed safety culture has four major sub-components[8]:

- *a reporting culture* - in which people are prepared to report their errors and near misses;
- *a just culture* – where an atmosphere of trust and fairness is created in which staff are encouraged to engage in safety related activities;
- *a flexible culture* - which respects the skills, abilities and limitations of frontline staff; and
- *a learning culture* – the willingness and competence to draw the appropriate conclusions from its safety information systems and to implement major reforms.

The DHSSPS endorses the approach that all organizations should have an informed safety culture, which should be given the highest priority at senior management level and promoted throughout as "everyone's business".

1.6 AN INFORMED SAFETY CULTURE

At present, there is no internationally accepted definition of patient safety incidents. Different definitions, information sources and methods of collection and analysis will affect findings. Appendix B provides examples of potential sources of information about the frequency of patient safety incidents and some of the strengths and weaknesses of each system. These include incident reporting systems, medical records review, surveys of patients and staff, and routine data collection. These illustrate the potential breadth of information sources, which contribute to knowledge of safety incident rates. However, for health and social care, the sources of reporting and data collection are even wider. What is needed is the systematic approach to data analysis and intelligence gathering from a range of sources, building on local, national and international capacity and capability, for example:

[8] Reason, J. Managing the risks of organisational accidents. Ashgate. Aldershot 1997

- published literature for health and social care environments e.g. NICE, SCIE and NPSA;
- National Inquiries - e.g. Confidential Inquiries: CEMACH, NCISH, NCEPOD;
- statutory and voluntary reporting systems - e.g. local medicines and devices reporting, MHRA, child protection, Mental Health Commission;
- hospital and social care episode statistics;
- health and social care complaints;
- local and national Inquiries, e.g., Lewis, Ombudsman, Hyponatraemia, Climbié, Shipman and Bristol Inquiry Reports;
- regional and local audit findings;
- Regulation and Quality Improvement Authority (RQIA) reviews and reports;
- Social Services Inspectorate reports;
- claims and litigation findings;
- coroner's findings; and
- death certification data.

Building a comprehensive picture on safety as part of improved quality of care can be complex. However, given the relatively small population size in Northern Ireland and the integrated nature of health and social care services, this provides us with a unique opportunity to draw together the different strands of learning and disseminate it in a positive way - to improve quality of health and social care, rather than in a punitive way to blame and shame individuals or organisations.

Yet being a small region also has its disadvantages in that incidents may occur relatively infrequently here to make their detection and monitoring meaningful. We must also learn from errors detected nationally; we cannot "reinvent the wheel" in terms of national and international expertise and resources when trying to draw together all the variety of sources of information to enhance learning. So, a balance has to be struck between the need for local intelligence mechanisms and expertise, and building on national and international capacity and capability. Hence the need for links with national organisations such as the National Patient Safety Agency (NPSA), Social Care Institute For Excellence (SCIE) and the National Institute for health and Clinical Excellence (NICE) - to enhance both quality and safety in health and social care.

KEY POINTS

- No health and social care service will ever be 100% error-free but what we can do is reduce the risk, enhance systems and expertise, and learn from adverse incidents and near misses.
- Strong leadership, a focus on systems and on organisational safety culture will reduce error.
- A regional definition of an adverse incident is identified covering health, social care, people, property, environment and reputation.
- A systematic approach to information gathering and data analysis is needed locally, which builds on national and international capacity and capability.
- No single source of information will provide all the data that is needed for safety analysis. For example, complaints, litigation, and death certification, together with adverse incidents reporting systems, audit and performance data need to be linked to enhance quality of care and be linked to evidence of effectiveness.

SECTION 2 – CURRENT SYSTEMS TO PROMOTE SUSTAINABLE IMPROVEMENT IN THE HPSS

2.1 INTRODUCTION

Sustainable improvement is at the forefront of the development of health and social care services in Northern Ireland. This is being undertaken through a multi-faceted approach to modernising and reforming organisational structures and delivery of care, together with a greater emphasis on quality, safety and accountability for the commissioning and delivery of that care.

Although healthcare systems from around the world vary considerably, many developed countries, such as the United States of America, Australia and the United Kingdom are leaders in the field of patient safety initiatives. Last year the UK European Union Presidency had a major focus on patient safety.

This section of the Safety Framework recognises that quality and safety are part of the continuum of local service improvement and are integral to good governance of an organisation. It sets out:

- the local commitment to quality and service improvement;
- safety and risk management systems underpinning good governance;
- local examples of organisational cultural change;
- links to national standard-setting bodies;
- examples of learning from local serious adverse incidents;
- changes to HPSS complaints procedures;
- serious adverse incident interim reporting arrangements; and
- the need for education, workforce development and regulation.

2.2 A COMMITMENT TO QUALITY AND SERVICE IMPROVEMENT

In 2001 the Northern Ireland Executive gave a commitment in the first Programme for Government to put in place a framework for raising the quality of services delivered and for tackling poor performance in the HPSS. Since then, much work has been undertaken to bring forward this programme.

The consultation document "Best Practice – Best Care"[9], issued in April 2001, was the first step towards fulfilling this commitment. It set out proposals to put in place a framework to raise the quality of services provided to the community and tackle issues of poor performance across the HPSS. The aim was to provide a high quality system of health and social care, which was easy and convenient to use, was responsive to people's needs and provided a service that instilled confidence in those who used it.

The quality improvements in "Best Practice – Best Care" are centred on five main areas:

- setting of standards: to improve services and practice;
- improving governance in the HPSS: in other words, the way in which organisations manage their business;
- improving the regulation of the workforce, and promoting staff development through life-long learning and continuous professional development;
- changing the way HPSS organisations are held to account for the services they commission and/or provide: the Duty of Quality; and
- establishing a new, independent body to assess the quality of health and social care - the Regulation and Quality Improvement Authority (RQIA).

From 1 April 2003, a statutory duty of quality was placed on HSS Boards and Trusts. Under this duty, each Board/Trust is required to[10] "*put and keep in place arrangements for the purpose of monitoring and improving the quality of the health and personal social services which it provides to individuals and the environment in which it provides them*". This requirement to deliver on the quality of services is similar to the requirements already placed on the HPSS to ensure financial probity.

RQIA came into operation from April 2005. RQIA's principal role includes the registration, regulation and inspection of a wide range of services delivered by the independent sector and the HPSS, and to report to the Department on the quality of care provided by the HPSS. In addition, it has a general role to promote and facilitate quality improvement in health and social care.

[9] Best Practice – Best Care: a framework for setting standards, delivering services and improving monitoring and regulation in the HPSS

[10] Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 (S.I. 2003 No.431 (N.I.9))

In order to provide greater consistency and accountability in the quality of care provided, and to facilitate the RQIA in its role, a range of standards have been developed, including:

- controls assurance standards[11], to assist HPSS organisations to demonstrate that they are doing their reasonable best to manage risk effectively;
- minimum care standards[12], applicable to agencies and establishments in the independent, voluntary and statutory sectors and to certain HPSS services; and
- generic quality standards[13], applicable to primary, secondary and tertiary care in the HPSS.

The above developments all contribute to good governance within the HPSS.

2.3 SAFETY AND RISK MANAGEMENT AS PART OF GOOD GOVERNANCE

All HPSS organisations are required to have a system of internal control to help facilitate the flow of information about risk both up and down and across the organisation. Part of this system is the recording of risks on risk registers. These are held at key points within the organisation depending on its size and structure. When most effective, a system of risk management involves every member of staff, and the organisation as a whole being aware of the key risks that affect them.

The function of risk registers is to inform key decision-makers of the risks they need to know about in order to fulfill their role in the commissioning and delivery of care. The recently-produced "Establishing an Assurance Framework: a practical guide for management boards of HPSS organisations[14]" is written to help HPSS board members, directors and senior managers within the HPSS to further improve their systems of internal control and to embed the principles of whole-organisation risk management as an integral part of quality health and social care. It acknowledges

[11] Controls assurance standards available on: http://www.dhsspsni.gov.uk/index/health_and_social_services/governance/governance-controls.htm
[12] Draft care standards available on: http://www.dhsspsni.gov.uk/index/consultations/previous_consultations.htm
[13] The Quality Standards for Health and Social Care: supporting good governance and best practice in the HPSS available on: http://www.dhsspsni.gov.uk/qpi_quality_standards_for_health_social_care.pdf
[14] Establishing an Assurance Framework: a practical guide for management boards of HPSS organisations – http://www.dhsspsni.gov.uk/publications/2006/assurance_framework.pdf

that decisions by individuals, managers and directors can positively or negatively affect the delivery of care to the individual.

Knowledge and skills in the assessment and appropriate management of risk in an often rapidly changing environment of care are essential to organisational health, to ensure safety and to improve outcomes in clinical and social care. Clear roles, policies, procedures and systems will help facilitate appropriate risk decisions and minimise inappropriate and potentially damaging decisions. This includes a system for assuring that each organisation has available information about key elements of risk:

- at the right time;
- in the right way; and
- to the right person(s).

This enables the most appropriate decisions to be made and facilitates the promotion and delivery of improvements in care.

2.4 SUPPORTING CULTURAL CHANGE

Having appropriate procedures to identify, assess and manage risk is central to organisational health, but this has to be complemented by cultural change in order to demonstrate a commitment to good practice, drive quality and enhance organisational performance. The following four initiatives are all examples which support cultural change:

The Clinical and Social Care Governance Support Team (CSCG) was established by the DHSSPS in 2004. In establishing the CSCG Support Team, the Department's aim was to promote the longer-term cultural change and organisational development that it considered necessary to ensure that the statutory duty of quality could be implemented successfully and consistently in the HPSS. In turn, this would lead to a continuous improvement in health and social care services in Northern Ireland. A decision to link with the NHS Clinical Governance Support Team in developing these local arrangements was taken on the basis that the HPSS would have access to the experience, knowledge and tools already developed in the NHS. The CSCG Team has developed an extensive work programme across primary, community and secondary care. This programme has included specific training initiatives and topic specific programmes, such as in elderly care, to facilitate a multidisciplinary approach to learning and to champion

quality improvement. It complements the many other local initiatives, some of which have been ongoing for a number of years, such as the Clinical Resource Efficiency Support Team (CREST) which aims to drive up standards in clinical practice by the production of specific guidance.

Regional Governance and Risk Management Adviser - The post of Regional Governance and Risk Management Adviser, sponsored by the Department from October 2003, was initially focused on supporting the HPSS in embedding the fundamental structures and processes of risk management. The post promotes a joined-up approach to governance arrangements in HPSS organisations. Integral to this is the involvement of the adviser in a range of safety, quality and risk management initiatives. A major project is underway relating to the standardisation of definitions and coding to enhance incident management (see Appendix D).

The Northern Ireland Medicines Governance Team aims to improve medication-related patient safety by a systematic regional approach to medication risk management through the deployment of six senior pharmacists dedicated to medicines risk management in Northern Ireland hospitals. Beginning in August 2002, the team has addressed three main areas: the development of the risk management process itself, including identification, analysis and evaluation of risk, the development of 'good practice' initiatives and risk education. In November 2004, the Team was awarded the Health Service Journal Award for Patient Safety. As part of the Pharmaceutical Services Improvement Projects currently underway, funding has been secured to extend the Medicines Governance Team, with the aim of enhancing medicines governance arrangements in the primary care sector of the HPSS.

The Safer Patient Initiative, promoted and funded by The Health Foundation Trust, in collaboration with the Institute for Healthcare Improvement (IHI) in the USA, aims at making hospitals safer for patients in the UK. Following rigorous assessment of applications, Down Lisburn Trust was one of four UK Trusts selected to start work on the safety initiative in October 2004. This provides the Trust with an opportunity to work with an expert team from IHI and world experts to promote safety and quality. The four UK Trusts were selected for this prestigious project on the basis of their exceptionally high level of commitment to improving patient

safety. The project will last for two years; the selected trusts are expected to become exemplars in patient safety so that other hospitals can learn from their success.

2.5 LINKING WITH NATIONAL BEST PRACTICE

Whilst HSS Boards and Trusts in Northern Ireland have the capacity to be leaders in the field of quality and safety, given our relatively small size and limited resources, we must draw on the wide range of skills, knowledge and expertise that is available at national and international level. The establishment of appropriate links with national best practice and standard setting bodies is a key element in the framework for raising the quality of health and social services in Northern Ireland. These links are necessary to secure access to independent evidence-based guidance to promote safe, effective and efficient care.

It is recognised that guidance developed in Great Britain should generally have universal application and that local duplication is unnecessary.

Current progress on the Department's links with national bodies is outlined below.

- **National Patients Safety Agency (NPSA)** - A formal agreement with NPSA to extend its services to Northern Ireland is planned from April 2006. This will provide access to the whole range of NPSA's training material, tools and guidance to promote and facilitate safety in the HPSS. This will include access to the NPSA's *Seven Steps to Safety* programme for both primary and secondary care, adapted to meet the need of our integrated health and social care environment. In addition, the HPSS will eventually join with the National Reporting and Learning System, to facilitate an integrated approach to reporting and learning from adverse events (see section 3). The NPSA's Patient Safety Observatory will bring together many sources of information and facilitate benchmarking on safety across the HPSS with other regions.

- **National Clinical Assessment Service (now part of NPSA but previously the autonomous National Clinical Assessment Authority)** - Since October 2004, NCAS provides advice, support, and assessment for HPSS organisations where a doctor's or dentist's performance is called into question (see section 3). This was one of the key

recommendations in *Confidence in the Future for Patients, and for Doctors*[15]. This document set out proposals for the prevention, recognition and management of poor performance of doctors.

- **Social Care Institute for Excellence (SCIE)** – SCIE was developed to identify and promote dissemination of knowledge about what works in social care. A service level agreement was established with SCIE in June 2004 extending the Institute's remit to cover Northern Ireland. Local social care practitioners and academics are now actively involved in SCIE projects and the development of best practice guidelines.

- **National Institute for health and Clinical Excellence (NICE)** - Whilst NICE guidance has no formal status in Northern Ireland, many parts of the HPSS draw on the material produced by the Institute. The Department has had negotiations with NICE on formal links and is represented, in observer capacity, on the committee that provides advice on the selection of topics for NICE appraisal and guidance programmes. A process for reviewing the applicability of NICE guidance to Northern Ireland and, where appropriate, endorsing it for uptake in the HPSS is being put in place. In addition, the HPSS will link with NICE new interventional procedures programme to ensure that new procedures used for diagnosis and treatment are safe enough and work well enough for routine use in the HPSS.

2.6 LEARNING FROM LOCAL ADVERSE INCIDENTS

The provision of health and social care will never be error free due to the complexity of factors which contribute to that care. It is acknowledged that the majority of errors do not lead to any harm for patients, staff or service users, but unfortunately some will. Recent examples of adverse incidents which continue to receive much attention, because of potential severity of outcome are:

- **The Independent Review of Endoscope Decontamination,** was established in June 2004, following concerns about the effectiveness of decontamination of endoscopes in some locations in Northern Ireland. This was chaired by Dame Deirdre Hine. It examined the systems and processes in Trusts to ensure the effective cleaning and

[15] www.dhsspsni.gov.uk/publications/archived/2000/confuture.pdf

high-level disinfection of flexible endoscopes before and after their use on patients, and found a number of areas in which procedures could be improved. Implementation of the recommendations is currently underway.

- **Inquiry into Hyponatraemia – Related Deaths[16].** In November 2004, the Department appointed Mr John O'Hara QC to hold an Inquiry into the events surrounding and following the deaths of three young children, with particular reference to their care and treatment in relation to fluid balance, and the role that individuals and organisations played following their deaths.

- **The Management of Hyperkalaemia in Adults.** Following recent serious adverse incidents relating to blood electrolyte abnormalities involving potassium, the Clinical Resource Efficiency Support Team (CREST) produced guidelines and wall charts for every local organisation to provide clear and concise information to enable clinicians to safely and effectively manage patients presenting with hyperkalaemia.

- **Post operative care following laparoscopic abdominal surgery.** An independent review team produced a report on lessons arising from the death of Mrs Janine Murtagh. It contained a number of recommendations covering consent, patient care, leadership and communication, and the implementation of policies and procedures.

2.7 ARRANGEMENTS FOR MONITORING AND LEARNING FROM SERIOUS ADVERSE INCIDENTS

In July 2004, interim guidance was issued to the HPSS, including family practitioner services, on the circumstances where particular serious adverse incidents or near misses must be reported to the DHSSPS (Circular HSS (PPM) 06/04). These are where the episode is considered:

- to be serious enough for regional action to be taken to ensure improved care or safety for patients, clients or staff;
- to be of such seriousness that it is likely to be of public concern; or
- to require independent review.

[16] www.ihrdni.org

The guidance complements existing local and national reporting systems, both mandatory and voluntary, which have been established over the years. These provide for specific incidents relating to, for example, medical devices, equipment, medicines, mental illness, child protection, communicable disease and the safety of staff to be reported to various points in the DHSSPS.

The new interim reporting arrangements on serious adverse incidents (SAI) were developed to try and ensure that lessons are learned across the HPSS and that serious local incidents are not repeated. The DHSSPS plans to collate learning from reported SAIs and produce an annual report. DHSSPS will also hold SAI briefings for the HPSS at regular intervals. HPSS directors and senior officers responsible for safety and quality will attend these meetings in order to gain information on the emerging current picture of SAIs across the HPSS. This will present an opportunity for the service to share learning and discuss possible improvements to the current reporting mechanisms in order to facilitate further sharing and learning.

It is recognised that different sources and types of data on adverse incidents all contribute to our knowledge of adverse incidents. Examples include "near misses", complaints, social care inspections, litigation, audit, records review, confidential inquiries etc., together with information about relatively infrequent incidents, which occurred in other health and social care systems. Through the NPSA's National Learning and Reporting System, and Patient Safety Observatory, the triangulation of data sources and analysis will be facilitated. However, there will remain a need to have some local reporting arrangements to ensure timely dissemination of local adverse incidents and near misses. Work will be done to clarify arrangements and avoid duplication.

2.8 EDUCATION, WORKFORCE DEVELOPMENT AND REGULATION

Staff and HPSS organisations must be able to justify the trust that the public places in them. For this to happen, the DHSSPS and the HPSS need to be able to demonstrate that good standards of practice and care are being maintained and that respect for service users is being shown. It is recognised that when safety and quality are introduced early into educational programmes, this has a positive impact on the future delivery of safe and effective care. Consequently, the content of this framework will be of use to educational providers.

The maintenance of good standards of practice and care requires individuals and organisations to have a learning culture, and one which supports training and development of staff. Training and development needs analyses, linked to regional, local, organisational and individuals' priorities and objectives, are essential for the ongoing enhancement of quality and safety within the HPSS. The introduction of quality assured appraisal systems which facilitate review of performance and the identification of development needs have the capacity to improve treatment and care and reduce error.

The regulation of the workforce has a major part to play in the promotion of quality and safety. Regulation and responsibility should take place at different levels[17], for example:

Personal level – based on a commitment to quality of care that puts the safety and care of the patient and service user first;

Team level – based on the concept of the importance of team working and the requirement to take responsibility for the performance of the team, and to act if an individual's conduct, performance or health is placing the public at risk;

Workplace level – which reflects the responsibility that HPSS organisations have for ensuring that staff, equipment and facilities are fit for purpose in the commissioning and provision of care. This is expressed through the Duty of Quality, clinical and social care governance, performance management systems and compliance with legislation; and

Professional level – which is undertaken by statutory regulators, for example, working through the development of standards, education, registration and licensing, and fitness to practise procedures.

Examples of professional regulators include the General Medical Council, General Dental Council, Nursing and Midwifery Council, Pharmaceutical Society of Northern Ireland, the Health Professions Council, General Optical Council and the Northern Ireland Social Care Council. All of these organisations have a major part to play in the promotion of quality of care and in the identification and management of fitness to practise. The Council for Healthcare Regulatory Excellence was formed in April 2003 to

[17] Adapted from Developing Medical Regulation: A Vision for the Future – April 2005 - GMC

ensure consistency of approach and good practice among nine "health" regulators. Several of the professional regulatory organisations identified above are undergoing development and change. Many of the drivers for change in the regulation of the workforce are as a consequence of national inquiries such as, the Bristol, Shipman, and Climbié Inquiry Reports.

Locally, a number of organisations also promote best practice and enhanced clinical and social care performance, including:

Northern Ireland Social Care Council (NISCC) – As part of the Northern Ireland Assembly's commitment to raising the status of the whole social care workforce, raising the standards of social care practice and ensuring proper protection of the public against persons who are unsuitable to carry out the work, NISCC was established in 2001 to regulate the social care workforce and to regulate the training of social workers.

Northern Ireland Practice and Education Council for Nursing and Midwifery (NIPEC) – In 2002, NIPEC was established to shape practice, education and performance within the professions of nursing and midwifery in Northern Ireland and to equip nurses and midwives in such a way as to enable them to provide better care for patients and service users.

KEY POINTS

- Sustainable improvement in health and social care requires a multifaceted approach, including service reorganisations and reform, and an emphasis on safety and quality as part of good governance.
- Systems and procedures for the identification, assessment and management of risk are important but have to be supported by organisational cultural change to promote sustainable quality improvements.
- Much work had already been undertaken locally to support quality and safety.
- National links are an important way of gaining access to knowledge, skills and best practice.
- Linkage with the National Patient Safety Agency, National Institute for health and Clinical Excellence, and the Social Care Institute for Excellence are pivotal to the promotion of quality and safety.
- Education, workforce development and regulation occur at individual, team, organisational, regional, and national levels; it is part of the drive to promote quality and protect the public.
- Recent local adverse incidents emphasise the need to put *safety first.*

SECTION 3 – PROMOTING SERVICE USER AND STAFF SAFETY

3.1 INTRODUCTION

Section 2 identified the progress that has been made to date to promote and embed quality and safety within HPSS environments. This section builds on this work and identifies other key elements to promote service user and staff safety. These include:

- creating an informed, open and fair safety culture across the HPSS;
- raising awareness of risk and promoting timely open reporting of adverse incidents;
- sharing the learning across HPSS environments and implementing solutions; and
- investigating serious incidents.

To facilitate implementation of these key elements requires co-ordinated action involving individuals, the HPSS including family practitioner services and the DHSSPS. Actions to promote and support a safer service are identified in section 5. This section is written for managers, educationalists and practitioners to clearly document high level work which needs to occur between 2006 and 2007. The action plan is outcome focused and attributes responsibilities.

3.2 CREATING AN INFORMED, OPEN AND FAIR SAFETY CULTURE ACROSS ORGANISATIONS

An informed organisational culture that promotes safety and quality should be at the centre of every stage of prevention, treatment and care. Section 1 identified four main components of an informed safety culture as:

- a reporting culture;
- a just culture;
- a flexible culture; and
- a learning culture.

A just culture is one that is seen to be open and fair to staff. Creating such a culture encourages the reporting of incidents, which is essential to the success of data collection and subsequent improvement in activity, systems, and care.

An "open and fair" organisation can be defined as a one where staff are not blamed, criticised or disciplined as a result of a

genuine slip or mistake that might have lead to an incident. Disciplinary action would, however, follow an incident that occurred as a result of misconduct, gross negligence or an act of deliberate harm. In determining 'blameworthiness', a 'fair' approach is one that separates the actions of individuals involved from the patient outcomes. A 'fair' culture advocates the systems approach, recognising that accidents may occur as a result of a series of system failures rather than through a deliberate malicious act on the part of an individual. Moving to the systems approach will be an important challenge. Research has shown that currently 85% of health care incidents are caused by systems failures yet, 98% of remedial action focuses on the person or people involved in the incident[18].

Organisations that operate a 'fair' culture are more likely to gather useful information about their organisation that can be used to further improve safe practice and pre-empt future incidents. In this way the organisation can acknowledge mistakes, learn from them and take action to put things right. This is an integral part of what the public wants the HPSS to achieve.

But being "open and fair" also means that the organisation should encourage staff to be open and fair when communicating with patients, service users and carers. This is a part of the redress that people can and should expect when things go wrong and where harm has been caused. This includes an organisational commitment to providing an explanation of what happened, an apology, a reassurance of speedy remedial treatment and, where appropriate, financial compensation.

Any change in culture requires sustained commitment at the most senior level in the organisation. Frank and open discussion needs to occur within senior management and agreement reached on what an open and fair culture will mean in practice for their organisation and this needs to be cascaded throughout the organisation as part of an overarching policy on safety. There are many tools which can assist HPSS organisations in assessing organisational safety culture in terms of underlying beliefs, attitudes and behaviours. In addition, tools such as root cause analysis and NPSA's Incident Decision Tree can assist in distinguishing between poor performance of the individual and a systems failure.

[18] Overveit J. Health Service Quality. Brunel University, 1998

3.3 RAISING AWARENESS OF RISK AND PROMOTING TIMELY REPORTING

Raising awareness of risk implies that all members of an organisation should have a good understanding of the factors that contribute to human and organisational error. In addition, there is a need for individuals to recognise that no-one is perfect; that there is always the capacity to reflect on one's work and to improve. Key tools to enhance this reflection are, for example, professional appraisal, audit and significant event analysis, and multidisciplinary team discussion and analysis.

Raising awareness of risk has to happen at all levels within an organisation. Whilst much work has been done to promote risk assessment and risk management within HPSS organisations within recent years, there remain opportunities which the HPSS will have, in the near future, including access to all NPSA material, tools and guidance.

Recent HPSS adverse incidents, highlighted through the coroner's service, have emphasised the need to pay particular attention to risk awareness and action within undergraduate and post graduate training programmes, newly appointed staff and at vulnerable interfaces such as the transfer of patients to different parts of the HPSS or at the interface between secondary, community and primary care. Specific action to raise awareness in these vulnerable areas needs to be undertaken. In particular, risk awareness should be incorporated into education and training programmes; there should be mandatory training for all newly recruited staff on basic organisational risk awareness, policies and procedures, risk within their specific areas of work, and on incident reporting systems. This should be seen by senior management as an integral part of a new recruit's induction into the organisation. In addition, all existing staff should have in-service education and training to support the continual awareness of risk. Appendix C provides an example of a training programme to promote risk awareness.

It must be explicit in all training and incident reporting and management policies that a staff member's responsibility for patient and service user safety comes before any responsibility to other staff, for example, in their own team or profession. This is supported by the codes of conduct for each profession and must be observed regardless of the severity of the incident(s) concerned.

Promoting a reporting culture is an important challenge for all sections of the HPSS and one which is essential if organisations and individuals are to learn from errors. Timely and open reporting is part of individual and organisational responsibility to quality improvement and learning. Whilst it is acknowledged that the majority of incidents do not lead to harm, valuable lessons can be learnt from these and "near misses" – where an error was detected and stopped before it resulted in harm. Research has shown that the more incidents and near misses that are reported then the more information there is about what is going wrong and the more action that can be taken to make health and social care safer both locally and nationally[19].

It is essential that commitment from senior management within the organisation is evident and that clear lines of accountability and communication are defined. It is equally important to ensure that policies and procedures are not simply 'for show' and that staff experiences reflect the ethos agreed by senior management. For example, the ways in which the reporting, investigation and subsequent management of medication incidents have been handled to date, indicates that cultural change is possible and, as a consequence, staff are willing to report incidents. But for staff, the benefits of reporting are not always made clear, particularly when there is a fear of blame, no noticeable change and no feedback. In addition, reporting can seem time-consuming and complicated.

The benefits of reporting need to be cascaded throughout the HPSS. These include:

- improvement in care of patients, clients, service users and staff;
- resources targeted more effectively;
- increased responsiveness;
- pre-empting complaints; and
- reducing costs.

3.4 REGIONAL REPORTING SYSTEMS PROJECT

In order to promote consistency of approach to reporting, in January 2005, the DHSSPS commissioned a project to be carried out across the HPSS to standardise definitions, reporting forms and the coding of incidents. A summary of the first phase of this project is included in Appendix D. This work should help facilitate

[19] Seven Steps to Patient Safety – NPSA - 2004

the sharing of learning between HPSS organisations as data can be shared and analysed more easily across Trusts, Boards and relevant Agencies that comprise Northern Ireland's HPSS. This project's remit encompasses all adverse incidents, inclusive of clinical incidents, social care, staff incidents and any other adverse event that may affect the operation of the HPSS, including the family practitioner services. The work will further facilitate a future link with the National Patient Safety Agency's National Reporting and Learning System.

Whilst local reporting mechanisms will always be important, there is some potential duplication in current reporting systems at local, regional and national level. This is because reporting systems serve different purposes and may have different specialist audiences. In order to provide a greater understanding of where the links are at local, regional and national level will require the Department to work with the HPSS and the NPSA to promote a consistent approach. Of particular importance is the incorporation of all health (both clinical and non clinical) and social care incidents.

The Regional Reporting Systems Project is part of the work to provide greater consistency of approach locally. This Project is part of the phased implementation plan to join with the NPSA's National Reporting and Learning System (NRLS). Joining the NRLS will mean that the HPSS will receive comprehensive reports on patient safety incidents, tailored to the needs of Northern Ireland, but it will also facilitate comparisons with other regions in England and Wales on the frequency of reporting and type of incident. In addition, through the Patient Safety Observatory, the Department and HPSS will have access to the learning that will emerge from other reporting systems and sources, such as, MHRA for medicines and medical devices, professional bodies and National Confidential Enquiries. Use of computerised data analysis tools will help identify potential clusters, patterns and trends across these reporting systems.

Comparisons between regions are important; however, there remains a need within each HPSS organisation to ensure that a reporting culture is fostered and that tools such as the Heinrich ratio are used to regularly assess the "health" of the organisation's reporting system and, where appropriate, ask area/sections which are not reporting for a "nil return" to confirm that incidents have not occurred.

3.5 SHARING THE LESSONS ACROSS THE HPSS

Section 1 provided examples of the many and varied data sources from which learning on safety and quality issues can occur - for example, audits reports, incidents reporting systems, complaints procedures and claims and litigation. When an incident occurs, a fundamental principle of a systems approach to error management is the understanding of how and why an incident occurred[19]. It is only then that learning can be shared and the lessons learnt used to prevent its reoccurrence. The sharing of learning can and should take place at different levels, for example:

- multidisciplinary team discussion within HPSS organisations;
- participation in personal and team education, training and development e.g. development of guidelines and solutions;
- training and participation in and use of investigative tools such as Root Cause Analysis;
- formal data collection and analysis procedures e.g. outcome statistics discussed at team, clinical and social care governance and senior management levels;
- formal communications pathways and networks e.g. urgent communications, newsletters, IT-based systems and discussion fora; and
- production and cascade of annual/ quarterly reports on adverse events.

Further consideration will be given to developing a single information gateway to bring together all departmental publications and guidance in an accessible format and on a monthly basis. In addition, the DHSSPS and the HPSS will consider how the extranet could be used to disseminate the results of all root cause analysis between organisations.

The accountability for patient, service user and staff safety rests with the Chief Executive of an organisation. To facilitate discussion, analysis and feedback, an integrated governance approach should be encouraged within HPSS organisations. There is a need to ensure that there are clearly delineated relationships and communication pathways within the organisation. This is necessary so that front line staff and, in particular, clinical and social care governance leads and risk managers have access to up to date information and that there is a feedback loop to ensure that safety information is received and acted upon within an appropriate timeframe.

The Safety Alert Broadcast System (SABS) is an electronic system developed by the Department of Health in England, with the MHRA, NHS Estates and the NPSA. The aim of this system is to bring different types of alerts together into one electronic system thus ensuring that all urgent communications are received and implemented. Nominated leads in each Trust and Primary Care Trust are asked to disseminate it to those who need to take action. This role is similar to the current MHRA medical device liaison officer role but with the additional responsibility of providing feedback on action to implement the alert using a simple electronic form. The development of a Service Level Agreement with NPSA will provide an opportunity for the Department to explore with the Department of Health in England if appropriate links to the SABS system can be established.

3.6 INVESTIGATING SERIOUS INCIDENTS

Obtaining incident reporting data is just the first step towards a comprehensive approach to safety. Significant investment has been made locally and nationally in root cause analysis training to promote proper understanding of the cause(s) of an adverse incident. There should be a consistent approach to deciding which incidents need to be followed up and further investigated; these should follow best practice in the use of tools for root cause analysis. There are two main criteria, which the HPSS should use in determining further investigation of an incident:

- ***the level of severity/grade of the incident*** - e.g. an untoward death or permanent injury; and
- ***the potential for learning*** e.g. frequency of incident or near miss.

The Chief Executive of the organisation is responsible for investigating the cause of a serious incident as part of his/her commitment to quality of care, which is underpinned by the Duty of Quality. The immediate priority in this case should be to take all the necessary steps to secure the safety of services users, staff and other people involved. All HPSS organisations should have clear policies on incident reporting including a standard approach to investigation of each level of severity of incident. This will be facilitated by the Regional Reporting Systems Project (see Appendix D) and links with the NPSA.

Incidents involving unexpected death or serious harm and requiring investigation by the police and/or the Health & Safety Executive (HSENI) are rare but have increased in number in the

past few years. There is a statutory duty placed on individuals and organisations to report such incidents. When they happen, incidents need to be handled correctly for public safety reasons as well as the maintenance of confidence in the HPSS, Police, Coroner and Health and Safety Executive. To achieve this, it is important that these four arms of the public sector communicate and work with one another in a consistent and ordered manner. The DHSSPS has finalised a Memorandum of Understanding[20] between these four organisations in order to better facilitate these complex interactions. The Memorandum complements existing joint procedures in relation to the protection of children and vulnerable adults.

Special action must be taken in the event of a public health hazard such as a major incident, chemical contamination, or biological, radiological or nuclear emergency. Specific regional guidance governs arrangements for dealing with major incidents.

Regional guidance should be followed where incidents involve suicides or other serious events involving people who have a mental disorder, child protection issues or when an incident fitting the criteria of a National Confidential Enquiry has occurred.

Where an incident involving a medicine has occurred, which falls within the remit of the Medicines Act and the Pharmacy Inspectorate of the DHSSPS, organisations should comply with regional reporting arrangements and co-operate with the investigation.

3.7 ENHANCED ASSESSMENT OF CLINICAL AND SOCIAL CARE PRACTICE

In countries that have promoted safety and quality in healthcare, there is a link between institutional assessment, reviews, accreditation and safety and quality initiatives; the assumption being that quality and safety, to some extent, can be assured by a review, inspection or an accreditation process. All of these processes take account of recognised standards of care.

This inspection, review or accreditation can take place at different levels, for example at:

- national level – through professional bodies and national accreditation schemes;

[20] http://www.dhsspsni.gov.uk/mou_investigating_patient_or_client_safety_incidents.pdf

agenda and used to facilitate implementation of solutions, where appropriate.

The development of a Service Level Agreement with the NPSA opens up the possibility for the HPSS to be selected to pilot new approaches to the delivery of care/improvements in patient safety. This is particularly appropriate in areas where the HPSS has carried out innovative work e.g. Medicines Governance and in areas where the HPSS presents a unique challenge, for example, the large and complex area of social care. Participation in the development of innovative work will stimulate the further development of a safety culture across the HPSS and will engage both health and social care professionals.

Effective design of health and social care facilities remains an important aspect of quality of care. This is because effective design thinking can deliver products, services, processes and environments that are simple to understand, to use, comfortable and convenient, and consequently less likely to lead to accidental misuse, error and accidents. The report, *Design for Patient Safety* [22] identifies opportunities for improving patient and service user safety through the more effective use of design.

[22] Design for patient safety: A system-wide design-led approach to tackling patient safety in the NHS Department of Health and the Design Council. February 2004. Available at : http://www-edc.eng.cam.ac.uk/medical/reports.html

- regional level – though statutory inspection procedures and clinical and social care governance reviews;
- local level – through commissioning arrangements with providers of care; and
- individual level – through the organisational assessment of individual performance.

The RQIA will be reviewing clinical and social care governance within the HPSS using the five themes contained within the Quality Standards, with particular emphasis on Safe and Effective Care. This approach will assist RQIA and the HPSS in the future development of methodologies and the refinement of self-assessment processes.

RQIA will report on the quality of care provided by the HPSS following its governance reviews. This developmental approach will promote quality improvement across organisations.

In addition to RQIA's inspection and review functions, it also has the power to investigate serious incidents at the request of the Minister, Department or the public. It will report to the Department on the quality of care within all HPSS services. As the work of RQIA progresses, it will provide a rich source of learning for the HPSS, the DHSSPS and the public.

At national level, the impact of major inquiries such as Shipman, Kerr/Haslam and Climbié, will continue to have a major impact on organisational and professional practice locally. In addition, reviews[21], such as those currently being undertaken by Sir Liam Donaldson and Mr Andrew Foster will impact on clinical and social care governance arrangements locally, including how an individual practitioner's fitness to practise is assessed.

A formal link with the National Clinical Assessment Service has already been established to provide advice, support and, where appropriate, full assessment for HPSS organisations, where a doctor's or dentist's performance is called into question. In addition, annual appraisal of individuals is now a reality for many HPSS staff. Where performance of an individual is considered to put patients or service users at risk, then the organisation must have processes in place to facilitate action and prevent harm.

[21] CMO Review of Medical Revalidation: A Call for Ideas, 3 March 2005 – www.dh.gov.uk; Review of Non-Medical Regulation – Call for Ideas, 29 June 2005, Mr Andrew Foster – www.dh.gov.uk

New disciplinary procedures for HPSS-employed doctors and dentists have been introduced to promote the early and active assessment and resolution of concerns regarding clinical practice. In addition, primary legislation is being drafted for the family practitioners services, to further extend the function of the Health Service Tribunal and the powers of HSS Boards where there is a concern about professional or personal conduct or practice.

A local response to Shipman Inquiry recommendations will be produced, to cover:

- Shipman 3 – Recommendations on new death certification pathways and investigation;
- Shipman 4 – Recommendations on enhanced monitoring and inspection of controlled drugs; and
- Shipman 5 – Recommendations on complaints, whistle-blowing, appraisal and professional performance.

3.8 DESIGNING AND IMPLEMENTING SOLUTIONS

The HPSS does not, as yet, have good mechanisms to facilitate the sharing of solutions on quality and safety problems. There is often excellent work in progress across the HPSS but no clear forum for sharing this work to others in similar situations. This may lead to duplication and wasted resources and the reoccurrence of adverse incidents. The measures identified in paragraph 3.4 will facilitate the cascade of effective solutions. So too will links with national bodies specifically involved with solutions development such as the NPSA, MHRA and the NHS Purchasing and Supply Agency.

Whilst reporting systems are a pivotal part of the identification of trends and themes requiring solutions, they are not the only source of information at local or national level. There is a need, therefore, to promote partnership working within the HPSS and at national level to share resources in solutions development. However, where a solution needs to be developed and implemented locally, it should be specifically commissioned by the DHSSPS with the scope of the project clearly defined and resourced.

To facilitate implementation, where appropriate, a solution should be designed in toolkit format in order to promote consistency of approach across the HPSS. As identified in the Safety Alert Broadcast System (SABS), there should be a feedback loop to confirm that implementation is completed. New arrangements for regional audit should be linked to the wider quality and safety

agenda and used to facilitate implementation of solutions, where appropriate.

The development of a Service Level Agreement with the NPSA opens up the possibility for the HPSS to be selected to pilot new approaches to the delivery of care/improvements in patient safety. This is particularly appropriate in areas where the HPSS has carried out innovative work e.g. Medicines Governance and in areas where the HPSS presents a unique challenge, for example, the large and complex area of social care. Participation in the development of innovative work will stimulate the further development of a safety culture across the HPSS and will engage both health and social care professionals.

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[22] Design for patient safety: A system-wide design-led approach to tackling patient safety in the NHS Department of Health and the Design Council. February 2004. Available at : http://www-edc.eng.cam.ac.uk/medical/reports.html

KEY POINTS

- An **informed** organisational culture, that builds on many data sources, is necessary to promote safety and quality. This culture requires endorsement and agreement by senior management in order to promote a **reporting** culture, and one, which is seen to be **just**, **flexible** and has the capacity to **learn** from errors.
- A systematic approach to raising awareness of risk of the factors that contribute to human and organisational failures is essential for staff, especially new recruits.
- Promoting timely open reporting is a major challenge for all HPSS organisations; the benefits of reporting should be highlighted to staff with clear feedback mechanisms identified.
- The first step to a comprehensive approach to safety, is obtaining and analysing **all** incident data. Clear policies and procedures for the reporting and investigation of serious incidents are the responsibility of senior management.
- The NPSA's National Reporting and Learning System will facilitate a cohesive approach to data collection in Northern Ireland and will facilitate benchmarking against other regions.
- Links to the NPSA, through its "Seven Steps" Programme together with use of tools and guidance will promote reporting and investigation of serious incidents in secondary and primary care, and build on existing work.
- Designing and sharing the solution, should draw on national and local work; where appropriate, local organisations should lead in the piloting of such solutions.
- Enhanced assessment of clinical and social care practice through HPSS Regulation and Quality Improvement Authority will promote learning.
- Where individual performance is called into question, the National Clinical Assessment Service will provide advice and support to organisations, and formal assessment of the individual, if required.

SECTION 4 – INVOLVING AND COMMUNICATING WITH THE PUBLIC

4.1 INTRODUCTION

There is now good evidence that trusting and respecting the patient/user at a number of levels (e.g. individual and community) in the health and social care system improves health and well-being significantly[23]. Patients, service users and the public have a major part to play in the prevention and detection of errors in health and social care.

4.2 PUBLIC INVOLVEMENT IN PROMOTING HEALTH, WELL-BEING AND SAFETY

People are ultimately responsible for their own health and well-being, and that of their dependants. However, it is acknowledged that health and well-being are influenced by many factors, such as poverty, crime, violence, education and unemployment. HPSS service provision plays but one part in the overall health of the population. The HPSS needs to work in partnership with other agencies, communities and the media to seek to influence and improve the health, social well-being and safety of the public and their staff. In this regard the media have an important public health and safety role in tandem with their duty to responsibly hold public bodies to account.

The Quality Standards for Health and Social Care set out the values and principles which all HPSS organisations and staff should adopt when engaging with the public and service users. These include the need to involve people in all stages of care and to provide timely and appropriate information to assist in decision-making.

Integration of service users, carers and local communities into all stages of planning, development, evaluation and review of health and social care services is an important part of continuous quality improvement and the open culture which should be promoted throughout the HPSS.

Through proactive involvement of the public in safety matters, it is hoped that:

[23] www.pickereurope.org

- risks will be identified;
- concerns and ideas for improvement will be shared; and
- solutions will be generated in partnership with service users and the public which will be more realistic and achievable.

4.3 PUBLIC EXPECTATION OF A QUALITY SERVICE

Understanding the expectations of the public, staff, media and an organisation can sometimes be difficult. But proactive involvement of the public and staff will lead to a mutual understanding of needs and drivers for change; for example, why certain HPSS services require development to ensure safe and effective care and others do not. In addition, it will promote an understanding of the complexity of factors which determine why health and social care services will never be error free, but minimisation of the risk of error is important for service improvement and health and social care outcomes. But when things go wrong, people have a right to feel let down by the Service, to make a complaint and to seek redress if harm has been caused. Some organisations and staff have a tendency to think of these actions in a negative light because of fear of litigation, adverse media coverage and potential for destruction of reputation and career pathway. Both service users and staff need open and fair processes to investigate and determine the cause of what went wrong. For this to happen means that there are special responsibilities placed on the media, the public, service users and staff. A system that does not support an open and fair process is to no-one's advantage in Northern Ireland, as it will not encourage open reporting, communication or learning.

4.4 CHANGING LOCAL COMPLAINTS PROCEDUES

The reporting and handling of complaints are also part of a learning culture. The public has a right to complain when concerned about their treatment or care. Complaints tend to be seen in a negative light, but nonetheless are a significant source of learning for individuals and organisations.

The Department is currently undertaking a review of the HPSS complaints procedures, with the aim of making complaints systems more effective for the public, staff and organisations. It is anticipated that a public consultation on the new procedures will commence in early 2006. This consultation will also incorporate some of the recommendations contained in the 5th Shipman Inquiry Report.

In reviewing the HPSS complaints procedures, the aim is to:

- make procedures easier to access;
- be fair to all parties;
- respond to complaints in a timely way;
- emphasise early resolution;
- ensure the process is aimed at satisfying the complainant's concerns; and
- promote learning across the HPSS.

4.5 A SYSTEM OF REDRESS

Errors will happen and although most do not lead to harm, some will. But what happens when things go wrong and a service user is harmed? Not all service users and carers are content with the current system and sometimes find it hard to engage with HPSS organisations to find out what happened to themselves or to their loved one.

Openness is fundamental to the partnership between the service user and those who provide care. In support of that openness, people should be given an explanation of what has happened, an apology, reassurance, remedial treatment and compensation, where appropriate. A unified approach to redress should be developed. Effective redress will be part of the regional and local goal to promote a timely response for the service user. It will also set "error" in the context of learning in order to promote quality improvements within the HPSS.

4.6 COMMUNICATING SERIOUS INCIDENTS

All organisations should have a clear policy on how to communicate a serious incident to individuals, families and carers, staff and to the media, where appropriate. This policy should comply with best practice relating to the confidentiality of information, human rights, and privacy for service users and staff. The six major parts of this policy should include:

- a unified approach to redress (as identified above) for the individual, their family and carers;
- support for service users and carers during the course of an investigation and/or further treatment;
- support for individuals within the organisation to cope with the physical and psychological impact of what has happened;
- a timely inter-organisational communication system;

- designated and trained key people within the organisation with responsibility for communication; and
- how and by whom the incident should be investigated.

KEY POINTS

- Individuals have responsibility for their own health, and that of their dependants.
- The HPSS, public and media need to work in partnership to promote public health and social well-being, and to enhance safety for service users and staff.
- Provision of information, in accessible format, to support decision-making in treatment and care, and to enhance safety, is essential for service users and carers.
- The public has a pivotal role in the prevention and detection of error.
- The public has a right to complain when concerned about their treatment or care. Complaints are a significant source of learning for HPSS organisations.
- The public and media have important responsibilities regarding the promotion of an open and fair culture, in order to prevent reoccurrence of incidents.
- Service users and staff need open and fair processes when a serious adverse incident is being investigated.
- Redress means having systems in place to offer an apology, reassurance, speedy remedial treatment, and compensation, if appropriate, when harm has been caused to an individual.
- All HPSS organisations should have an effective communication policy in place.

SECTION 5 – ACTION PLAN AND STEPS TOWARDS SUSTAINABLE IMPROVEMENT

5.1 INTRODUCTION

In this section, the action plan and steps underpinning sustainable improvement in the HPSS are brought together in five key themes:

- implementing evidence–based best practice and learning from adverse events;
- agreeing common systems for collection, analysis and management of adverse events;
- sharing the learning;
- building public confidence; and
- promoting education, training and support for health and social care staff.

The audience for this action plan is HPSS managers, staff, educationalists and practitioners, including those working within the family practitioner services. The plan also includes action which will be undertaken by the DHSSPS as part of its commitment to safe and effective care. Given the broad nature of the safety and quality agenda, the plan does not aim to be all-encompassing but rather to focus on high level actions which need to take place in order to prevent adverse outcomes, and to improve service user, carer and staff experiences. It is seen as complementary to the many other initiatives which are ongoing in the HPSS primary, secondary and community sectors to improve health and social care outcomes.

The vision for the future is a safer service, where there is a systematic and co-ordinated approach to safety and quality. This requires staff, organisations and the public to work in partnership to promote a culture of learning, which is open and fair to service users, carers and staff, and one which minimises errors.

The following action plan will be reviewed and updated in 2007 to take account of progress and local and national developments.

5.1.1 Implementing evidence based practice and learning from adverse events			
Responsibility	**Action**	**Outcome**	**Completion date**
DHSSPS	Links to the National Patient Safety Agency will be agreed and guidance issued to the HPSS	Access to training, tool and guidance for the HPSS and the Department	April 2006
DHSSPS	A phased implementation plan to support joining the National Reporting and Learning System (NRLS) will be put in place	Triangulation of data sources, benchmarking and cascade of learning	June 2006
DHSSPS	All HPSS organisations will be part of NRLS	Triangulation of data sources, benchmarking and cascade of learning	December 2007
DHSSPS	Guidance on the nature of links to NICE and local pathways will be cascaded to the HPSS	Promotion of evidence based best practice	February 2006
DHSSPS	Following links with NICE, specific guidance on the introduction of new interventional procedures into the HPSS will be produced	Safer introduction of new diagnostic equipment and treatments.	April 2006
DHSSPS, CREST	CREST together with the Department will agree and publish the process for development of its annual work programme	Better linkage of regional priorities and audit programmes	June 2006
DHSSPS, CREST, RMAG	The Review of Regional Audit Arrangements will be implemented. Regional audit programmes will be linked to the wider safety and quality agenda	Better linkage to regional priorities and audit programmes	April 2006 Ongoing
RQIA	Will commence evaluation of HPSS quality of care	Assessment quality of care	From April 2006 ongoing

5.1.2 Agreeing common systems for data collection, analysis and management of adverse events			
Responsibility	**Action**	**Outcome**	**Completion date**
DHSSPS, HPSS	All organisations will adopt the definition of an adverse incident as identified in Section 1	Standardisation of definition and local data collection in adverse incidents	March - 2006 ongoing
DHSSPS, HPSS	All organisations will recognise the need for an informed safety culture	Supports timely reporting and an open, fair, flexible and learning culture	March 2006
DHSSPS	Better linkage on quality and safety agenda within Departmental structures	Integration of quality and safety issues	April 2006
DHSSPS, HPSS	Safety and quality will be a standing agenda item at board meetings	Senior management commitment to quality and safety	February 2006 and ongoing
HPSS	Organisations will have incident reporting levels reviewed at least quarterly by senior management	Regular analysis of adverse incidents and near misses	March 2006 ongoing
HPSS	All organisations will have a designated lead to determine when a serious incident investigation should be instigated	Clarity and consistency in handing investigation of major incidents	April 2006
DHSSPS, HPSS	Algorithms on common and specific reporting systems will be designed and cascaded for use in HPSS	Avoidance of duplication and clarity of reporting arrangements	September 2006
DHSSPS	Develop and publish policy guidance to clarify the role and function of Interim Arrangements for the Reporting of Serious Adverse Incidents	Clarity for the HPSS and the Department in the Reporting of Serious Adverse Incidents	February 2006
DHSSPS	Review local Interim Arrangements for the Reporting of Serious Adverse Incidents, in light of links with the NPSA's Patient Safety Observatory	Clarification of purpose and avoidance of duplication	April 2007
DHSSPS, HPSS	Regional Reporting Systems Project for primary and secondary care will be completed, and linked to joining with NRLS	Standardisation of definitions, reporting forms and coding of incidents	April 2007

5.1.2 Agreeing common systems for data collection, analysis and management of adverse events			
Responsibility	**Action**	**Outcome**	**Completion date**
DHSSPS	A centralised database of clinical negligence claims will be developed	Enhanced data analysis and sharing the learning	December 2006
DHSSPS, in collaboration with PSNI, HSE, and Coroner's service	A Memorandum of Understanding will be published on the investigation of unexpected death or serious harm, which will complement existing procedures and processes for protection of children and vulnerable adults	Promoting communication and shared working between the public sector	March 2006
DHSSPS	Further guidance will be issued on how and when to investigate a serious adverse incident	Clarity and consistency in handling investigations	September 2006

5.1.3 Sharing the learning			
Responsibility	**Action**	**Purpose**	**Completion date**
HPSS, including FPS	Each organisation will have a policy on incident management which will be endorsed by senior management and will be regularly reviewed	Consistency of approach in incident management and learning throughout the organisation	March 2006
DHSSPS, HPSS including FPS	Each organisation will demonstrate a multidisciplinary team approach to reducing risk and improving reporting	Engagement with staff. Consistency of approach in incident management and learning throughout the organisation	April 2006
HPSS including FPS	Each organisation will have a feedback mechanism in place when an incident is reported by an individual or team	Facilitation of action, learning and service change	March 2006
DHSSPS, HPSS	Where a major incident has been identified locally, local solutions will be designed by convening a panel of experts and/or building into existing programmes e.g. CREST, NPSA	Facilitation of action, learning and service change	Ongoing
DHSSPS	An annual report on local serious adverse events will be issued to the HPSS	Sharing the learning and implementing change	March 2006 and Ongoing
RQIA	Following investigation of specific serious adverse incidents, RQIA will produce and cascade a report	Cascade of learning and prevention of reoccurrence of adverse incident	April 2006 and ongoing
DHSSPS, HPSS	A review of communication channels will be undertaken by the Department to include; - consideration of links with SABS, a gateway approach to provision of information, revision of departmental website "governance" pages and extranet access on the results of root cause analysis in the HPSS	Enhanced communication, timely distribution of urgent communications and sharing of learning	December 2006

5.1.4 Building public confidence			
Responsibility	**Action**	**Outcome**	**Completion date**
DHSSPS, HPSS	Organisations will recognise that health and social care will never be error–free, but patients, clients, service users and carers have an important partnership role to play in identification and reduction of errors	Better information to service users and acknowledgement of their role as partners in care	February 2006 Ongoing
DHSSPS, HPSS	Organisations will have a policy on how to communicate a serious adverse incident to individuals/families/staff and the media	Better information and coordination of communication with stakeholders	April 2006
DHSSPS in collaboration with NISCC	A programme for roll-out of registration for the social care workforce will be agreed and commenced in April 2006	Enhanced regulation of the workforce	April 2006
DHSSPS	A public consultation will be undertaken on a new HPSS complaints system	Improved openness, transparency and learning	April 2006
DHSSPS, in collaboration with HPSS	Guidance on redress, where harm is caused to service users, will be developed and implemented in the HPSS	Supporting openness, an apology, an explanation, remedial treatment and compensation, where appropriate	December 2006
DHSSPS, in collaboration with HPSS	A composite set of safety/quality performance indicators will be developed encompassing clinical and non-clinical care, and social care	Enhanced accountability and performance management on safety and quality	July 2006
DHSSPS	New Primary Care legislation will be introduced to enhance the role and functions of the Health Service Tribunal and powers of the HSS Boards	Improved procedures for considering the conduct or performance of family practitioners	November 2006
DHSSPS, HPSS Boards and Trusts	A specific project will be convened to consider key elements to enhance safety and communication at the interface of primary and secondary care	Enhanced safety and quality of care at the interface of primary and secondary care	February 2007
DHSSPS, HPSS Boards, Primary care	Medicines Governance Team Programme will extend into primary care	Promotion of medicines risk management and improvement in quality of	January 2006 Ongoing

5.1.4 Building public confidence			
Responsibility	**Action**	**Outcome**	**Completion date**
practitioners Medicines Governance Team		care	
DHSSPS	A Northern Ireland response to Shipman Inquiry Report Recommendations will be consulted upon and published	Improved professional practice and public protection	July 2006
DHSSPS	A review of existing appraisal systems (medical) will be undertaken	Improved professional practice and public protection	January 2006
DHSSPS	Following the outcome of Donaldson & Foster reviews on professional regulation, implementation of national recommendations will be implemented	Improved professional practice and public protection	Date to be determined
DHSSPS	The Department will publish guidance on Protecting Personal Information	Supports confidentiality and implementation of professional practice and legislation	January 2006
DHSSPS	Guidance on a new disciplinary framework for employed doctors and dentists will be published and implemented in the HPSS	Improved procedures for considering the conduct or performance of doctors/dentists in the HPSS	February 2006
CREST, DHSSPS, HPSS	All organisations will implement CREST guidance on Inter-hospital transfer of medical records	Reduction of risk to service user, when transferred in or between HPSS establishments	April 2006
HPSS	HPSS will complete implementation of the Hine Review on endoscope decontamination	Consistent approach to disinfection and decontamination of endoscopes	July 2006
DHSSPS, HPSS	A response to the O' Hara Inquiry Recommendations will be published and implemented	Safer care for sick children who require intravenous fluid	Date to be determined
DHSSPS, HPSS, in collaboration with Universities, CREST RMAG NIPEC,	The recommendations from the RQIA report on *Review of the lessons arising from the death of Mrs Janine Murtagh* will be implemented	Consistent and improved approach to consent, pre and post operative care, leadership and communication, and the implementation of policies and procedures	March 2007

5.1.4 Building public confidence			
Responsibility	**Action**	**Outcome**	**Completion date**
NIMDTA			
DHSSPS	A Regional Procurement Strategy, incorporating safety, will be published for the HPSS	Safer health service procurement, design and practice	January 2006

5.1.5 Promoting education, training and support for all health and social care staff			
Responsibility	**Action**	**Outcome**	**Completion date**
HPSS	All HPSS organisations will include risk awareness within induction programmes to the organisation, and in specific areas of care	Awareness of risk and of organisational reporting policies and procedures	April 2006 Ongoing
DHSSPS, in collaboration with NIMDTA	A project will be convened to consider the generic contents of an induction programme for new doctors, building on recent learning from adverse events	Standardisation of induction, for new doctors	February 2006
DHSSPS, in collaboration with Universities, NIPEC, NICPPET, NIMDTA NISCC NPSA	Discussion will be held with key stakeholders to incorporate risk awareness, and adverse incident policies and procedures into basic training modules, including specific high risk areas such as medicines, medical devices and child protection issues	Promotion of safety and quality and cascade of learning	December 2006

5.2 CONCLUSION

Safety First: A Framework for Sustainable Improvement in the HPSS sets out a clear policy direction to improve quality of care. This policy and action plan is part of the modernisation and reform agenda and places safety and quality at the heart of good governance.

It recognises that major steps are needed to promote partnership working and enhance public confidence in the services provided. Support, training and education of staff are vital to its success.

The action plan will be reviewed in 2007 to assess progress on implementation. Quality and safety are part of good governance and will be reported on by the HPSS Regulation and Quality Improvement Authority. In addition, the action plan will form part of the ongoing accountability review processes for HPSS organisations, including primary care practitioners. A number of quality and safety performance indicators will be developed as part of implementation of the action plan.

GLOSSARY

ACCREDITATION

Formal recognition or approval of a service or training programme from a recognised authority e.g. a royal college.

ADVERSE EVENT OR INCIDENT

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

CARER

A carer is an individual who looks after someone who is unwell and/or who requires special assistance to manage their complex needs or situation.

CLINICAL AUDIT

A quality assessment and improvement mechanism in which healthcare professionals peer review their practice, compare it to best practice and introduce improvement in line with their findings.

Clinical and social care audit is interpreted as multi-disciplinary or multi-professional audit, involving a wide range of clinical and social care professions, with inputs from all its constituent groups working together or in single disciplines.

CLINICAL AND SOCIAL CARE GOVERNANCE

A framework through which local organisations are accountable for the quality of service they provide.

CLINICAL NEGLIGENCE

Failure to exercise a reasonable standard of care appropriate to the circumstances, resulting in unintended injury, loss or death to another party.

CULTURE

The general customs and beliefs, of a particular organisation at a particular time. 'How we do things around here.'

HEINRICH RATIO

A proactive check on a systems "vital signs"- The Heinrich ratio of one major injury to twenty nine minor injuries to three hundred no-injury incidents.

HOMICIDE

An act of murder.

HOSPITAL AND SOCIAL CARE EPISODE STATISTICS

Statistics on hospital and social care episodes of care, e.g. admissions, outpatients appointments, domiciliary care hours provided.

INTELLIGENCE MECHANISMS

The mechanisms for the collection and co-ordination of data.

MEDICINES GOVERNANCE

A focus on risk management involving the prescription, supply, dispensing administration and disposal of medicines. It aims to improve patient & client care through a programme of continuous improvement in medicines management.

NEAR MISS

An unexpected or unintended incident that was prevented, resulting in no harm.

RISK REGISTER

A record of residual risk which details the source, nature, existing controls, assessment of the consequences and likelihood of occurrence, action necessary to manage risk, person responsible for implementing action and timetable for completion.

SERVICE LEVEL AGREEMENT

A service level agreement is a document, which defines the relationship between two parties: the provider and the recipient.

SERVICE USER

Anyone who uses, requests, applies for, or benefits from health and social care services. They may also be referred to as clients, patients or consumers.

ABBREVIATIONS AND ACRONYMS

CEMACH

Confidential Enquiry on Maternal and Child Health.

CISH

Confidential Inquiry into Suicides and Homicides by people with mental illness.

CREST

Clinical Resource Efficiency Support Team.

CSCG

Clinical and Social Care Governance.

DHSSPS

Department of Health, Social Services and Public Safety (Northern Ireland).

DIS

Directorate of Information Systems (DHSSPS).

FPS

Family Practitioner Services- e.g. general medical practitioners, community pharmacists, general dental practitioners, and optometrists.

GB

Great Britain.

GDC

General Dental Council.

GMC

General Medical Council.

HPSS

Health and Personal Social Services commissioning and providing treatment and care in hospitals, communities and through family practitioner services.

HRD

Human Resources Directorate (DHSSPS).

HSENI

Health and Safety Executive Northern Ireland.

IHI

Institute for Healthcare Improvement in the United States of America.

MHRA

Medicines and Healthcare products Regulatory Agency.

MRSA

Methicillin-Resistant Staphylococcus Aureus.

NCAS

National Clinical Assessment Service now part of NPSA but previously the autonomous NCAA (National Clinical Assessment Authority)

NCEPOD

National Confidential Enquiry into Patient Outcome and Death.

NHS

National Health Service.

NI

Northern Ireland.

NIAIC

Northern Ireland Adverse Incident Centre.

NICE

National Institute for health and Clinical Excellence.

NIMDTA

Northern Ireland Medical and Dental Training Agency.

NIPEC

Northern Ireland Practice and Education Council for Nursing and Midwifery.

NICPPET

Northern Ireland Council for Pharmaceutical Postgraduate Education and Training.

NISCC

Northern Ireland Social Care Council.

NPSA

National Patient Safety Agency.

NRLS

National Reporting and Learning System.

PCD

Primary Care Directorate (DHSSPS).

PPMD

Planning and Performance Management Directorate (DHSSPS).

RMAG

Regional Multi-professional Audit Group.

RQIA

Health and Personal Social Services Regulation and Quality Improvement Authority.

SABS

Safety Alert Broadcast System.

SAI

Serious Adverse Incidents.

SCD

Secondary Care Directorate (DHSSPS).

SCIE

Social Care Institute for Excellence.

APPENDIX A - TERMS OF REFERENCE AND MEMBERSHIP OF GROUPS

The terms of reference for this project are as follows:

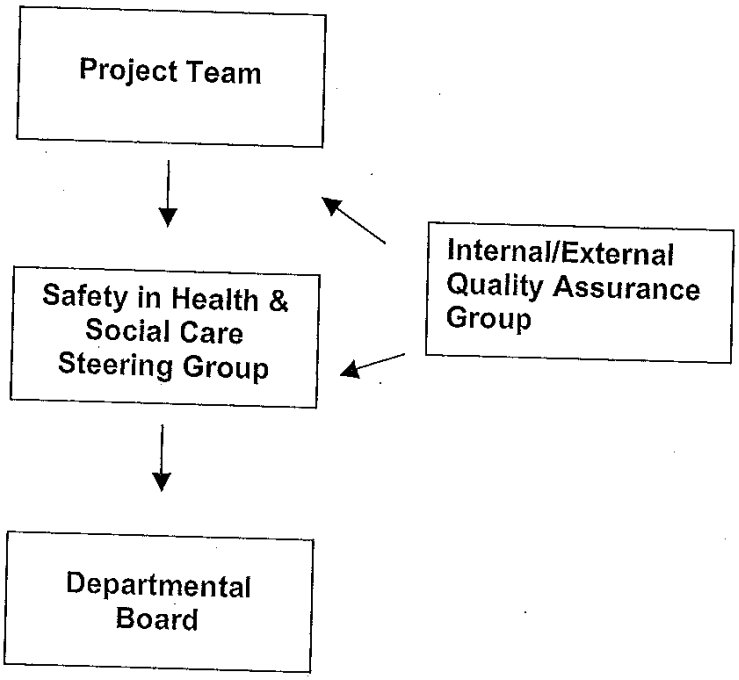
Service user and staff safety concerns everyone who uses or works in the HPSS. The safety policy framework will:

- identify the key components of a safety policy;
- consolidate good practice;
- promote and support an open and fair safety culture;
- link local objectives and priorities, with national developments;
- build capacity and capability at local level; and
- embed service user and staff safety in everyday practice, clinical and social care governance systems and health and social care environments.

The safety framework will be accompanied by an action plan, which will identify key tasks to be taken forward by the Department and the HPSS. This policy framework and action plan will be reviewed in early 2007.

Reporting arrangements

The Safety in Health and Social Care Steering Group will act as the steering group for this project. This Group will report to the Departmental Board by early September 2005.



Safety in Health and Social Care Steering Group

Chair: Dr Ian Carson – Deputy Chief Medical Officer, DHSSPS

Members: Mr Jonathan Bill, DHSSPS
Ms Tracey Boyce, RGH
Mr Brian Godfrey, DHSSPS
Dr Maura Briscoe, DHSSPS
Dr Glenda Mock, DHSSPS
Mr Don Hill, DHSSPS
Ms Irene Low, Ulster Community Hospitals Trust
Ms Nicola Kelly, Belfast City Hospital Trust
Ms Yvonne Kirkpatrick, Belfast City Hospital Trust
Mrs Nuala McArdle, DHSSPS
Dr Norman Morrow, DHSSPS
Mr Pat Newe, DHSSPS
Mrs Elizabeth Qua, DHSSPS
Mr Robert Sergeant, DHSSPS
Mrs Heather Shepherd, Regional Governance Adviser HPSS
Mrs Doreen Wilson, DHSSPS

The Project Team

The project team will comprise:

Mrs Heather Shepherd – Regional Governance Adviser, HPSS
Dr Maura Briscoe – Medical & Allied Group (lead), DHSSPS
Mr Jonathan Bill- Planning & Performance Management Directorate, DHSSPS
Ms Tracey Boyce – Medicines Governance Advisor, NI Medicine Governance Team, Royal Group Hospitals Trust
Mr Brian Godfrey – Health Estates Agency, DHSSPS
Mrs Liz Qua - Health Estates Agency, DHSSPS
Mr Pat Newe – Social Services Inspectorate, DHSSPS

Secretariat – Mr Jonathan Wright, Medical & Allied Group, DHSSPS

Quality Assurance Group

There will be a virtual QA Group comprising nominees from:

- Primary Care Directorate DHSSPS;
- Secondary Care Directorate DHSSPS;
- Community Care Directorate DHSSPS;
- Human Resources Directorate DHSSPS;
- Best Practice, Best Care Steering Group;
- Finance Management Directorate (Claims and Litigation) DHSSPS;
- Public Safety Unit DHSSPS;
- Planning and Performance Management Directorate DHSSPS;
- Professional Groups within the DHSSPS;
- Health and Personal Social Services Regulation and Quality Improvement Authority;
- Health Estates Agency DHSSPS;
- Northern Ireland Social Care Council;
- Mr Howard Arthur, CGST, Modernisation Agency
- HPSS Trusts & Boards; and
- HSS Councils.

APPENDIX B – EXAMPLES OF DATA SOURCES AND FINDINGS

Information Source	Examples of factors that will affect findings	Examples of findings
Incident reporting Systems	More likely to record near misses and errors which did not lead to harm. May be less likely to report known side effects and complications of treatment.	4.9 incidents reported for every 100 hospital admissions, and 1.2 incidents reported for every 100 bed days (England). 1.1 to 3.8 incidents for every 100 bed days (Regions, Pennsylvania, USA)[24]
Medical record review	The threshold that is used for including minor errors or deviations from standards of care. The threshold that is used for determining that harm to a patient was preventable.	Four to 17 adverse events in every 100 hospital admissions (studies in North America and Europe).
Routine data Collection	Recording of adverse events likely to be incomplete. Recording likely to improve with greater awareness of issues.	About two adverse events in every 100 hospital admissions in England[25]. 16 deaths from MRSA in every million men, and 8.5 deaths for every million women[26].
Surveys of patients and staff	Level of awareness of staff and patients. Patient's condition: for example, people with long-term conditions are more likely to be aware of errors than those receiving life-saving treatment.	35 in every 100 NHS staff reported seeing at least one error or near miss that could have harmed patients during the month before the survey[27]. 18 to 28 in every 100 patients with health problems from five countries believe a medical mistake or medication error affecting them had occurred in the two years before the survey[28].

Source:- ***Building a memory: preventing harm, reducing risk and improving patient safety.*** **National Patient Safety Agency, July 2005.**

[24] Department of Health. *Building a Safer NHS for Patients.* Available at www.doh.gov.uk/buildsafenhs (November 2003)
[25] Aylin P et al. How often are adverse events reported in English hospital statistics? *BMJ* 2004;329:369
[26] Office on National Statistics. *Health Statistics Quarterly.* Spring 2005:60-5
[27] Healthcare Commission. *NHS Staff Survey 2004: Summary Report.* March 2005
[28] Commonwealth Fund. *2002 International Health Policy Survey of Adults with Health Problems.* Available at: www.cmwf.org/surveys/surveys_show.htm?doc_id=228168

How to Classify Adverse Incidents and Risk

Guidance for Senior Managers Responsible for Adverse Incidents Reporting and Management

Summary Version

The full version of this document will be subject to review and up-to-date versions will be available on the governance website.

http://www.dhsspsni.gov.uk/index/hss/governance.htm

To improve patient and service user safety, the education and training of all HPSS staff must include risk awareness. Inclusion of "risk awareness" is an integral part of the risk management standard included in Controls Assurance Standards, the HPSS Quality Standards and the Care Standards.

Particular attention needs to be paid to the induction of temporary staff to ensure that key policies and procedures relevant to their level of competence are known prior to the commencement of practice.

Induction and in-service training programmes, should include:

- an overview on the organisation's safety culture, policies and procedures;
- basic awareness of the systems approach to patient and service user safety;
- awareness that health and social care is a high risk industry and the importance of being risk aware;
- awareness of their own personal responsibilities within their specific areas of work;
- the current incident statistics for health and social care within the organisation;
- examples of how things can go wrong;
- why incidents happen;
- how to report incidents;
- the importance of working within one's own ability; and,
- practical skills to practise safely.

Contents

1.0 Introduction

1.1 This is a shortened version of a document produced to assist Health and Personal Social Services organisations (HPSS) in developing or reviewing processes to assess incidents and their consequent risk implications. It has been written for senior managers responsible for reporting and overall management of adverse incidents and it is not intended as guidance for all staff. It does not provide detailed guidance for HPSS incident investigation, as this will be the subject of further work.

1.2 The following pages outline a tool to help managers classify incidents and risk, using the Australian / New Zealand Standard: Risk Management (AS/NZS 4360: 2004) and "Step 4 – Promote Reporting" from the National Patient Safety Agency (NPSA) publication "Seven Steps to Patient Safety" as primary sources.

1.3 The guidance should be used for all incidents not just those that involve patients / service users. This is in line with the current systems and processes that HPSS organisations use to manage incidents. The tool has been developed for use across the HPSS including the primary care sector and covers all incidents including clinical and social care incidents.

1.4 HPSS and primary care organisations should follow the principles of this guidance when developing, revising and implementing their own local policies and procedures. It is of key importance however that these principles are tailored to suit the objectives, nature and size of the particular organisation. The broad aim of this document is to facilitate better systems for sharing learning from adverse incidents across the HPSS and beyond. It provides a framework for appropriate and sufficient analysis of, and learning from events where there has been significant harm or potential harm to, and/or death of a patient, service user, staff member, visitor and/or significant damage to property or the environment.

1.5 One important principle is that all adverse incidents should be considered and recorded centrally within organisations so that any organisation-wide implications can be captured as early as possible. However, this must not negate the importance of local management responsibility for handling incidents in their area. All types of incidents should be included; for example; social care, clinical, health and safety, fire, infection control etc.

1.6 To help with capturing all incidents within similar processes an HPSS regional definition of an incident has been devised; an adverse incident within the HPSS context is therefore defined as;

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

1.7 Further associated work in this area will include a regional minimum dataset for recording incidents and a set of regional codes for the most prevalent types of incidents.

2.0 Stages of Adverse Incident Management (See Flowchart One)

Stage 1 – Incident occurs and is reported via the organisations' internal reporting mechanism to the organisations' central recording system. Incident details are communicated internally as necessary.

Stage 2 – Determine actual incident severity.

Stage 3 – Assess incident to determine immediate action required. Following initial assessment consider whether it is appropriate to report to external organisations (See flowchart for examples)

Stage 4 – Initiate incident investigation as appropriate. Consider whether it is appropriate to report to external organisations. (See examples of organisations requiring reports in Flowchart One)

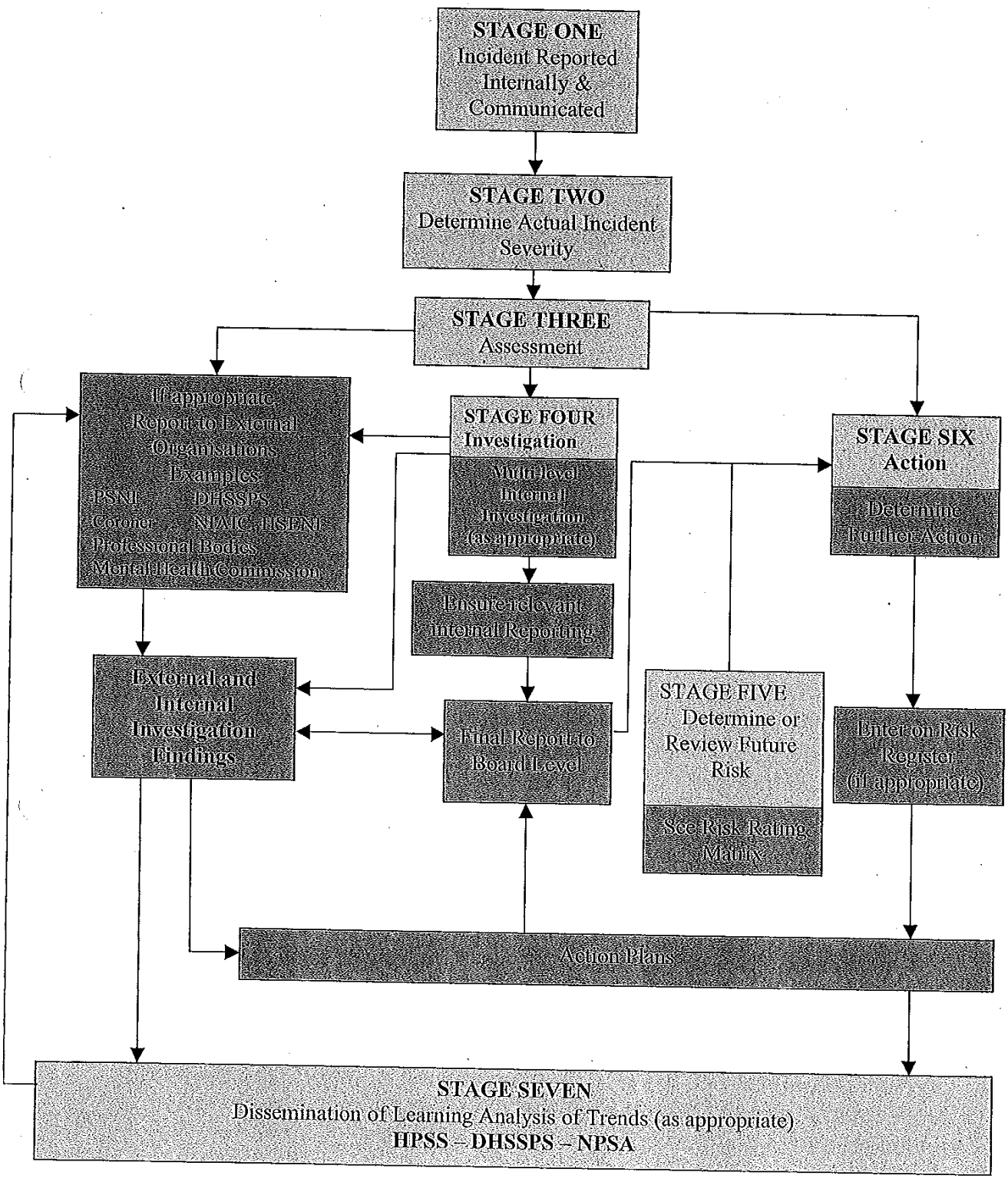
Stage 5 - This is a secondary classification mechanism for assessing ***potential future risks***. Use the following prompts:

(a) Think about the likely impact if the incident were to occur again without any intervening circumstances that made the incident less severe.
(b) Assess the likelihood of the incident occurring again.
(c) Use the Risk Rating Matrix (available in the full version of this document) to determine the risk severity.

Stage 6 – Use the Action Guidance to determine what further action should be taken. For example, consider whether this issue needs to be entered on the risk register.

Stage 7 – Determine any local and regional learning and communicate this within the organisation and with the appropriate regional / national bodies. Following the outcome and learning from investigations keep the future risk rating (Stage 5) under regular review.

STAGES OF ADVERSE INCIDENT MANAGEMENT FLOWCHART ONE



APPENDIX E

PROMOTING EQUALITY AND HUMAN RIGHTS

Section 75 of the Northern Ireland Act 1998 requires the Department, in carrying out its functions, powers and duties, to have due regard to the need to promote equality of opportunity:

- between persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation;
- between men and women generally;
- between persons with a disability and persons without; and
- between persons with dependants and persons without.

Members of the project team met to consider the equality and human rights implications of the safety framework and action plan. A screening exercise was undertaken, against four questions, which are identified below. The following text represents a summary of the discussion.

Is there any evidence of higher or lower participation or uptake by different groups?

The Group discussed the potential for greater integration of safety and quality policy development and action. It recognised that diminished standards on safety reflected a poor quality of treatment and care, for service users across the spectrum of care provided. Given the diverse nature of this framework, no one particular section 75 category would be disadvantaged. Indeed, the aim was to benefit all service users by promoting a safety culture, and a systematic approach to prevention, detection, reporting and management of adverse incidents. A part of this safety culture was the promotion of learning to prevent reoccurrence of incidents.

It was noted that whilst all people have the right to access HPSS services, greater use of these services are made by the very young, older people and those with complex needs and chronic conditions. The safety framework acknowledges the complexity of health and social care provision and environments. It advocates an open and fair culture which promotes involvement of all service users, particularly in relation to identification of risk and the part that service users, carers and the wider public have to play in the minimisation of that risk and in the development of solutions appropriate to their needs.

The safety framework links to the values and principles identified in the Quality Standards for the HPSS. These have been consulted upon;

these values include equality, diversity, choice, rights and respect for the individual.

Is there any evidence that different groups have different needs, experience, issues and priorities in relation to the particular policy?

No. It was considered that religion, political opinion, racial group, marital status, sexual orientation, gender or disability had no direct impact on this high level policy document or action plan. It was noted that there was a full section contained in the framework on involving and communicating with service users, carers and the public. This recognised that all people had a right to complain when concerned about their treatment or care, and that appropriate redress was an integral part of a quality system, when things go wrong. It was felt that the action plan was a relatively high level one which brought together many different strands of the quality and safety agenda. The action plan also attributed action to a number of organisations. In such circumstances, there would be a general need to consider equality and human rights implications when implementing specific actions.

Is there an opportunity to better promote equality of opportunity or good relations by altering policy or working with others in government or the community at large?

Equality of opportunity and good relations will be promoted through development of this policy. The policy and action plan recognise the need for:

- Enhanced promotion of health and safety for **all** service users, carers, staff, practitioners and visitors;
- Development of organisational communication policies and the training of staff to enhance engagement with service users and carers;
- Promotion of good relations through development and support of an informed safety culture;
- Increase in the reporting of adverse incidents and shared learning of experience;
- A more systematic approach to redress, when things go wrong;
- Enhanced communication across primary, secondary and community care, and with other agencies, for example, police, Health and Safety Executive and coroners;

- Increase in the availability of information and consultation on treatment and care with service users, carers and practitioners; and

- Enhanced education, training and development of staff.

How will this impact on complementary policy areas?

The safety framework and action plan complement other policy areas. It is part of the overall quality framework as set out in Best Practice Best Care (2001), which was subject to extensive consultation. Safety is an integral part of clinical and social care governance, care standards, controls assurance and quality standards. All of these developments are aimed at enhancing health and social care outcomes and the service user experience. The safety framework also supports other initiatives to promote continuous professional development, life-long learning and enhanced regulation of the workforce. The safety framework and action plan is underpinned by the Duty of Quality as outlined in the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003.

Conclusion

The safety framework is a high level document, which aims to bring together different strands of the wider safety and quality agenda. It draws on existing policy developments and identifies, in a single plan, actions which need to take place within the next two years to enhance safety within health and social care services. The project team concluded there was no adverse impact on equality or human rights arising from the safety framework. It was also noted that equality and human rights implications would be considered as part of the development and implementation of specific actions associated with the framework.

APPENDIX F

REFERENCES, CIRCULARS AND GUIDANCE

CIRCULARS

NIAIC Safety Notice MDEA (NI) 2004/01 Reporting Adverse Incidents and Disseminating Medical Device/Equipment Alerts. Health Estates, Northern Ireland Adverse Incident Centre.

Circular HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control (DHSSPS)
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS (PPM) 6/2002 – AS/NZS 4360:1999-Risk Management (DHSSPS) http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS (PPM) 8/2002 – Risk Management in the Health and Personal Social Services (DHSSPS)
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS (PPM)10/2002 – Governance in the HPSS: Clinical and Social Care Governance – Guidance on Implementation (DHSSPS)
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS(PPM)13/2002 – Governance in the HPSS – Risk Management (DHSSPS)
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS (F) 20/2002 – Clinical Negligence: Prevention of Claims and Claims Handling (DHSSPS)

Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance (DHSSPS)
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS (FAU) 19/2003 – Statement of Internal Control: Transitional Statement 2002/03(DHSSPS)
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS (PPM)6/2004 – Reporting and follow-up on serious adverse incidents: Interim Guidance (DHSSPS)
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS (PPM)8/2004 – Governance in the HPSS: Controls assurance standards – update
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS (F) 2/2004 – Statement on Internal Control – Full Implementation for 2003/04 (DHSSPS)
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS (PPM) 5/2005 – Reporting of Serious Adverse Incidents within the HPSS
www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS (PPM) 2/2006 – Reporting and Follow-up on Serious Adverse Incidents
www.dhsspsni.gov.uk/hss/governance/guidance.asp

STANDARDS

Quality Standards – Consumer Involvement in Community Care Services (DHSSPS) 1999

Quality Standards for Health and Social Care: supporting good governance and best practice in the HPSS
http://www.dhsspsni.gov.uk/qpi_quality_standards_for_health_social_care.pdf

GUIDANCE

Guidance on Implementation of the HPSS Complaints Procedure, (DHSSPS), March 1996

Guidance on Handling HPSS Complaints: Hospital, Community Health and Social Services, (DHSSPS) April 2000

Guidance to Trusts on reporting defective medicinal products (2001), DHSSPS

Codes of Practice for Social Care Workers and Employers of Social Care Workers, (Northern Ireland Social Care Council) September 2002
http://www.niscc.info/

Co-operating to Safeguarding Children, (DHSSPS) 2003
http://www.dhsspsni.gov.uk/publications/2003/safeguard/safeguard.asp

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http://www.dhsspsni.gov.uk/foi/Prof_advice.asp

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www.dhsspsni.gov.uk

March 2006

DHSSPS 333-117-080

Reporting Adverse Incidents and Disseminating Medical Device Alerts

Reference	Date of Issue	Description
MDEA(NI)2008/001- Medical devices; non-medical equipment, plant and buildings	04/01/2008	Under-reporting of medical device and estates related adverse incidents to the Northern Ireland Adverse Incident Centre.
MDA(NI)2009-001- Please Note the NEW format for NIAIC Medical Devices Alerts (MDA's)	07/01/2009	Medical Device Alerts in Northern Ireland are based on the format and content of the Medicines and Healthcare products Regulatory Agency's (MHRA) Alerts
DB2010(NI)-01- Reporting Adverse Incidents and Disseminating Medical Device Alerts	10/02/2010	Reporting Procedure 2010 This publication provides guidance on the NIAIC's voluntary adverse incident reporting system and encourages users to report adverse incidents involving medical devices. Topics covered include: • what an adverse incident is and when to report it • how to make reports • what to do with a device that has been involved in an adverse incident • the role of the medical device liaison officer in disseminating Medical Device Alerts.
MDA/2011/001(NI)- All medical devices.	04/01/2011	Growing levels of reporting of medical device related adverse incidents to the Medicines and Healthcare products Regulatory Agency's Adverse Incident Centre in a changing health and social care environment.
DB2010(NI)-01 (v.2.0)- Reporting adverse incidents and disseminating alerts Northern Ireland version of DB2010(01)	March 2013	Reporting adverse incidents and disseminating alerts Northern Ireland version of DB2010(01)
NIA/2014/001- Publication of the MHRA and NHS England Patient Safety Alert – Stage 3 Directive Improved Medical Device Reporting and Supporting Information. 20th March 2013.	10/04/2014	Publication of the MHRA and NHS England Patient Safety Alert – Stage 3 Directive Improved Medical Device Reporting and Supporting Information. 20th March 2013.
NIA/2015/001- Reporting of Medical Device Adverse Incidents & Near Misses and disseminating Alerts.	16/02/2015	*** The action relating to this alert is dissemination to all relevant staff. Please can you forward on to the appropriate staff under your remit *** Reporting of Medical Device Adverse Incidents & Near Misses and disseminating Alerts.
NIA/2015/002-	16/02/2015	*** The action relating to this alert is dissemination to all

Reporting of Estates and Facilities Adverse Incidents & Near Misses and disseminating Alerts		relevant staff. Please can you forward on to the appropriate staff under your remit *** Reporting of Estates and Facilities Adverse Incidents & Near Misses and disseminating Alerts
HEI-17-113361-Reporting Medical Device and Estates Adverse Incidents	13/10/2017	The Northern Ireland Adverse Incident Centre (NIAIC) operates as part of the Chief Medical Officers (CMO) Group within the Department of Health (DoH). The key aim of the NIAIC is to record and investigate reported adverse incidents involving medical devices, non-medical equipment, plant and buildings used within the healthcare environment across Northern Ireland and to issue warning notices and guidance to help prevent recurrence and avert patient, staff, client or user injury. To this end it is important that open reporting and balanced analysis of adverse incidents are encouraged in principle and by example. The attached revised guidance outlines the mechanisms and processes employed by NIAIC to promote and manage reporting of adverse incidents to them and how the lessons learned are disseminated back to healthcare organisations. We would therefore be grateful if you would distribute this to the appropriate individuals within your directorates who would need to be aware of this.
HE1/18/136232-Reporting Medical Device and Estates Adverse Incidents	03/10/2018	HE1/18/136232 - Reporting Medical Device and Estates Adverse Incidents The purpose of this document is to act as a reminder that: • In the interests of patients, staff and visitor safety all regulated healthcare providers have a requirement to report Adverse Incidents involving medical devices to the Department via the Northern Ireland Adverse Incident Centre (NIAIC). The aim of this reporting and any subsequent investigation is to identify learning that can be shared across all healthcare service providers and work towards reducing the chances of the incident reoccurring, thereby improving safety for all. • All adverse incidents or near misses involving any medical device must be reported to the NIAIC via the appropriate NIAIC Adverse Incident reporting form as is found in DatixWeb or on the Hub. NB this form has now been updated and this version (2018/01BT) should be used going forward. • All Medical Device Alerts issued via the Safety Alert Broadcast System (SABS) need to be disseminated to the key relevant people in your organisation, to ensure senior stakeholders are engaged and involved. This document provides guidance on: 1) What constitutes a Medical Device Adverse Incident 2) When to report an Adverse Incident

		3) Actions required by all providers of healthcare services. 4) How reporting should be carried out. 5) Other actions and responsibilities. 6) What should happen to an item involved in an Adverse Incident. 7) Safety Alerts from NIAIC (MDAs, EFAs, & NIAs) and manufacturers (FSNs & FSCAs).
NIA/2019/001- Reporting of Medical Device and Estates Adverse Incidents and disseminating Alerts	09/01/2019	Reporting of Medical Device and Estates Adverse Incidents and disseminating Alerts
NIA-2020-003 - Changes to MHRA alerts	24/09/2020	The Medicines and Healthcare products Regulatory Agency (MHRA) is now an accredited issuer of National Patient Safety Alerts. From now on, all safety-critical alerts for medicines and medical devices that require a response will be issued under the National Patient Safety Alert format. These alerts follow the criteria and template agreed by the National Patient Safety Alerting Committee (NaPSAC). This means there will be changes in what you receive from NICAS as set out below.
NIA-2021-001- Reporting of Medical Device and Estates Adverse Incidents and distribution of information	15/04/2021	The "Reporting Adverse Incidents and disseminating Safety Information" document has been updated to version 1.3 to reflect recent changes in the NIAIC operating procedures and changes in medical device safety information provided by the UK Competent Authority, the MHRA. Encourage staff to report all incidents that meet the NIAIC reporting criteria, using the new reporting form Healthcare organisation should make themselves familiar with changes in the latest version 1.3 and ensure older versions are removed from circulation.
NISN-2022-001 - Reporting of Medical Device and Estates Adverse Incidents	23/02/2022	The aim of reporting and any subsequent investigation is to identify learning that can be shared across other healthcare service providers and work towards reducing the risk of similar incidents reoccurring, thereby improving safety for all. Details on reporting adverse incidents to NIAIC can be found in document "Reporting Adverse Incidents and Disseminating Safety Information" updated APR 2021. An electronic copy of the NIAIC Adverse Incident Form can be downloaded at the following Trust address: https://tinyurl.com/NIAICFORM All incidents reported to NIAIC must first be reported on the Trust's DatixWEB incident reporting system

Health and Social Care Board

Procedure for the reporting and follow up of Serious Adverse Incidents

April 2010

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SECTION Page

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

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 users[1];
- 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 public

  occurring 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.

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[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 RQIA*[4]*)*

- 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 officer[5] 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 co-ordinated 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 Lead[6] 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.

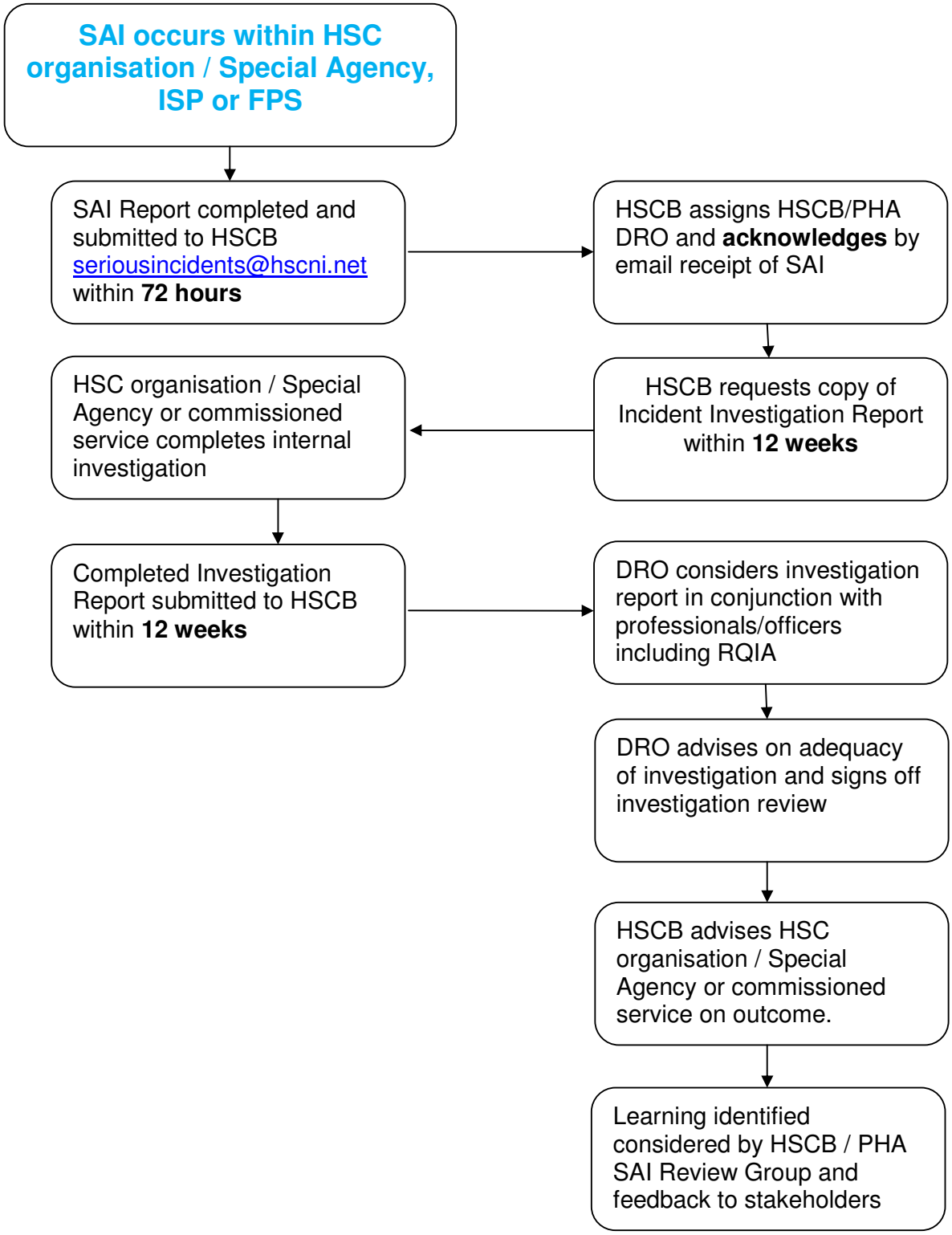
6.0 EQUALITY

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:** *(Name of lead officer to contact for further details)*

6. DESCRIPTION OF INCIDENT:

DOB: DD / MMM / YYYY **GENDER: M / F** **AGE: years**
(complete where relevant)

7. IMMEDIATE ACTION TAKEN:

HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? *(please select)*	**YES**	**NO**	**N/A**
HAVE ALL RECORDS / MEDICAL DEVICES / EQUIPMENT BEEN SECURED? *(please specify where relevant)*	**YES**	**NO**	**N/A**

8. WHY INCIDENT CONSIDERED SERIOUS: *(please select relevant criteria below)*

• serious injury to, or the unexpected/unexplained death, (*including suspected suicides or serious self harm*) of:	
– 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	
• unexpected serious risk to 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 public occurring 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 and data losses	

9. IS ANY <u>IMMEDIATE</u> REGIONAL ACTION RECOMMENDED? *(please select)*	**YES**	**NO**

if 'YES' (*full details should be submitted*):

10. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? *(e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HPC etc)* **if 'YES'** (*full details should be submitted*):	**YES**	**NO**
if 'YES' (*full details should be submitted*):		

11. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	**DATE INFORMED:**	**OTHER:**
DHSS&PS EARLY ALERT		
SERVICE USER / FAMILY		
HM Coroner		**Please specify:**
ICO		
NIAIC		
NIHSE		**Date informed:**
PSNI		
RQIA		

12. 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**

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

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**

HSCB USE ONLY			HSCB REF:
GOVERNANCE LEAD		GOVERNANCE OFFICE	
DATE NOTIFIED	DD / MMM /YYYY	DATE ACKNOWLEDGED	DD / MMM /YYYY
DESIGNATED REVIEW OFFICER ASSIGNED		DATE ASSIGNED	DD / MMM /YYYY
INVESTIGATION REPORT DUE		DD / MMM / YYYY	

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: *Include the details of the reporting organisation (Trust, FPS, ISP)*	**2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE** *Unique incident number / reference generated by the reporting organisation / practice*
3. DATE OF INCIDENT: DD / MMM / YYYY *Date incident occurred*	**4. CONTACT PERSON:** *(Name of lead officer to be contacted should the HSCB or PHA need to seek further information about the incident)*

5. DESCRIPTION OF INCIDENT:

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.*

In addition include the following:

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**
(complete where relevant)

6. IMMEDIATE ACTION TAKEN:
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

HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? *(please select)*	**YES**	**NO**	**N/A**
HAVE ALL RECORDS / MEDICAL DEVICES / EQUIPMENT BEEN SECURED? *(please specify where relevant)*	**YES**	**NO**	**N/A**

7. WHY INCIDENT CONSIDERED SERIOUS: *(please select relevant criteria below)*

• serious injury to, or the unexpected/unexplained death, (*including suspected suicides or serious self harm*) of: – 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	
• unexpected serious risk to 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 public occurring 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 and data losses	

8. IS ANY <u>IMMEDIATE</u> REGIONAL ACTION RECOMMENDED? *(please select)*	**YES**	**NO**
if 'YES' (*full details should be submitted*):		

9. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? *(please select)* *(e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HPC etc) where there appears to be a breach of professional code of conduct*	**YES**	**NO**
if 'YES' (*full details should be submitted*):		

10. OTHER ORGANISATION/PERSONS INFORMED: *(insert date informed)*	**DATE INFORMED:**	**OTHER:**
DHSS&PS EARLY ALERT		
FAMILY/CARER		
HM Coroner		**Please specify:**
ICO		
NIAIC		
NIHSE		**Date informed:**
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. (*delete as appropriate*)

Additional information submitted by: _____ **Designation:** _____

Email: **Telephone:** **Date: DD / MMM / YYYY**

14. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION

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 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.

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.

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 .

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

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
	complete 4	***complete 3b***

SECTION 3b: INVESTIGATION REPORT OVERDUE (not submitted within 12 weeks)		
HAS AN EXPLAINATION/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 *(where relevant)*	DD / MMM / YYYY
DRO COMMENTS ON ADEQUACY OF INVESTIGATION REPORT: *(in conjunction with other professionals and RQIA where relevant):*	

SECTION 5: CLOSURE OF SAI		
BASED ON INFORMATION PROVIDED IS DRO CONTENT TO CLOSE? *(confirm in conjunction with other professionals and RQIA where relevant):*	YES	NO *Continue to liaise with organisation/ practice*
DRO'S COMMENTS INCLUDING HOW IDENTIFIED RECOMMENDAITONS SHOULD BE MONITORED: *(in conjunction with other professionals and RQIA where relevant):*		
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: *(please specify)* *(learning identified will be submitted to HSCB/PHA SAI Review Group)*

Health and Social Care Board

Health & Social Care Board
12-22 Linenhall Street
BELFAST BT2 8BS

Tel : 0300 555 0115
Web Site : www.hscboard.hscni.net

Chief Executives HSC Trusts
Chief Executive Business Services Organisation
Chief Executive RQIA
Chief Executive Patient Client Council
Chief Executive NI Blood Transfusion Service
Chief Executive NI Medical Dental Training Agency
Chief Executive NI Practice & Education Council

8 June 2015

Dear Colleague

HSC PROCEDURE ON THE REPORTING AND FOLLOW-UP OF SERIOUS ADVERSE INCIDENTS

It is expected that the HSCB/PHA will review the 'Procedure for the Reporting and follow-up of SAIs' issued in October 2013, following the outcome of the Department's consultation on the Donaldson Report "The Right Time, The Right Place". In the meantime, there are a number of templates and Appendices within the current procedure which require immediate amendment, as follows:

- A revised SAI service user/family/carer engagement checklist which will enable easier data input and more meaningful information output, allowing a systematic approach to monitoring this information.

- Minor revisions to both the level 1 and level 2/3 review templates, incorporating the above checklist.

The revised forms have been shared with Trust Governance leads and relevant Family Practitioner Services staff, and reflect comments made. It is important the forms are implemented with immediate effect for all newly reported SAIs and for on-going SAIs for which investigations have not yet been completed.

I am also attaching three flowcharts which will assist reporting organisations and HSCB/PHA staff when managing the following:

- SAIs that are also being reviewed as adult or children's safeguarding incidents
- Interface incidents that have been reported via the SAI process
- Early Alerts that have reported in line with DHSSPS process

I can also advise that the panel of lay persons (already involved in the HSC Complaints Procedure), have recently received relevant SAI training and are now available to be invited to be a member of a SAI review team, particularly when a degree of independence to the team is required. Profiles and relevant contact details are attached for each individual and remuneration will be as per current HSC Complaints procedure arrangements.

I would ask you share this letter and attachments with all relevant staff, for immediate implementation.

If you require any further clarification, please contact Mrs Anne Kane, HSCB Governance Manager at [redacted]

Yours sincerely

pp

Valerie Watts
Chief Executive, HSCB

Encs

cc Trust Governance Leads
Michael Bloomfield, HSCB
Eddie Rooney, PHA
Carolyn Harper, PHA
Mary Hinds, PHA
Sloan Harper, HSCB
Brian Godfrey, DHSSPS
Conrad Kirkwood, DHSSPS

Health and Social Care Board

Procedure for the Reporting and Follow up of Serious Adverse Incidents

November 2016
Version 1.1

CONTENTS

SECTION TWO - APPENDICES

SECTION THREE - ADDENDUM

FOREWORD

Commissioners and Providers of health and social care want to ensure that when a serious event or incident occurs, there is a systematic process in place for safeguarding services users, staff, and members of the public, as well as property, resources and reputation.

One of the building blocks for doing this is a clear, regionally agreed approach to the reporting, management, follow-up and learning from serious adverse incidents (SAIs). Working in conjunction with other Health and Social Care (HSC) organisations, this procedure was developed to provide a system-wide perspective on serious incidents occurring within the HSC and Special Agencies and also takes account of the independent sector where it provides services on behalf of the HSC.

The procedure seeks to provide a consistent approach to:

- what constitutes a serious adverse incident;
- clarifying the roles, responsibilities and processes relating to the reporting, reviewing, dissemination and implementation of learning;
- fulfilling statutory and regulatory requirements;
- tools and resources that support good practice.

Our aim is to work toward clearer, consistent governance arrangements for reporting and learning from the most serious incidents; supporting preventative measures and reducing the risk of serious harm to service users.

The implementation of this procedure will support governance at a local level within individual organisations and will also improve existing regional governance and risk management arrangements by continuing to facilitate openness, trust, continuous learning and ultimately service improvement.

This procedure will remain under continuous review.

Valerie Watts
Chief Executive

SECTION ONE - PROCEDURE

1.0 BACKGROUND

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

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/hss(ppm)06-04.pdf

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

http://webarchive.proni.gov.uk/20120830142323/http://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.

http://webarchive.proni.gov.uk/20120830142323/http://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://webarchive.proni.gov.uk/20120830142323/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.health-ni.gov.uk/publications/quality-standards-health-and-social-care-documents

Circular HSC (SQS) 19/2007 advised of refinements to 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://webarchive.proni.gov.uk/20120830142323/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 Regulation & Quality Improvement Authority (RQIA) has a duty to make inquiry into any

case where it appears to the Authority that there may be amongst other things, ill treatment or deficiency in care or treatment. Guidance in relation to reporting requirements under the above Order previously issued in April 2000 was reviewed, updated and re-issued in August 2007. (Note: Functions of the previous Mental Health Commission transferred to RQIA on 1 April 2009).

http://webarchive.proni.gov.uk/20101215075727/http://www.dhsspsni.gov.uk/print/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.

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2022-09.pdf

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

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2008-10.pdf

Circular HSC (SQSD) 10/2010 advises on the operation of an Early Alert System, the arrangements to manage the transfer of Serious Adverse Incident (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).

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2010-10.pdf

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

In 2012 the HSCB issued the ‘Protocol for responding to SAIs involving an alleged homicide’. The 2013 revised HSCB ‘Protocol for responding to SAIs involving an alleged homicide’ is contained in Appendix 14.

Circular HSS (MD) 8/2013 replaces HSS (MD) 06/2006 and advises of a revised Memorandum of Understanding (MOU) when investigating patient or client safety incidents. This revised MOU is designed to improve appropriate information sharing and co-ordination when joint or simultaneous investigations/reviews are required when a serious incident occurs.

www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-8-2013.pdf

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

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/002%20%20HSCB-PHA%20Protocol%20for%20Safety%20Alerts.pdf

Circular HSC (SQSD) 56/16 (21 October 2016) from the Deputy Chief Medical Officer advises of the intention to introduce a Never Events process and that information relating to these events will be captured as part of the Serious Adverse Incident Process. The circular indicates the Never Events process will be based on the adoption of Never Event List with immediate effect.

https://www.health-ni.gov.uk/sites/default/files/publications/health/HSC-SQSD-56-16.pdf

2.0 INTRODUCTION

The purpose of this procedure is to provide guidance to Health and Social Care (HSC) Organisations, and Special Agencies (SA) in relation to the reporting and follow up of Serious Adverse Incidents (SAIs) arising during the course of their business or commissioned service.

The requirement on HSC organisations to routinely report SAIs to the Department of Health (DoH) {formerly known as the DHSSPS} ceased on 1 May 2010. From this date, the revised arrangements for the reporting and follow up of SAIs, transferred to the Health and Social Care Board (HSCB) working both jointly with the Public Health Agency (PHA) and collaboratively with the Regulation and Quality Improvement Authority (RQIA).

This process aims to:

- Provide a mechanism to effectively share learning in a meaningful way; with a focus on safety and quality; ultimately leading to service improvement for service users;

- Provide a coherent approach to what constitutes a SAI; to ensure consistency in reporting across the HSC and Special Agencies;

- Clarify the roles, responsibilities and processes relating to the reporting, reviewing, dissemination and implementation of learning arising from SAIs which occur during the course of the business of a HSC organisation / Special Agency or commissioned/funded service;

- Ensure the process works simultaneously with all other statutory and regulatory organisations that may require to be notified of the incident or be involved the review;

- Keep the process for the reporting and review of SAIs under review to ensure it is fit for purpose and minimises unnecessary duplication;

- Recognise the responsibilities of individual organisations and support them in ensuring compliance; by providing a culture of openness and transparency that encourages the reporting of SAIs;

- Ensure trends, best practice and learning is identified, disseminated and implemented in a timely manner, in order to prevent recurrence;

- Maintain a high quality of information and documentation within a time bound process.

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 in Department of Health (DoH) Arm's Length Bodies (ALBs) i.e.

- ***HSC organisations (HSC)***
  - Health and Social Care Board
  - Public Health Agency
  - Business Services Organisation
  - Belfast Health and Social Care Trust
  - Northern Health and Social Care Trust
  - Southern Health and Social Care Trust
  - South Eastern Health and Social Care Trust
  - Western Health and Social Care Trust
  - Northern Ireland Ambulance Service
  - Regulation and Quality Improvement Authority

- ***Special Agencies (SA)***
  - Northern Ireland Blood Transfusion Service
  - Patient Client Council
  - Northern Ireland Medical and Dental Training Agency
  - Northern Ireland Practice and Education Council

The principles for SAI management set out in this procedure are relevant to all the above organisations. Each organisation should therefore ensure that its incident policies are consistent with this guidance while being relevant to its own local arrangements.

3.2 Incidents reported by Family Practitioner Services (FPS)

Adverse incidents occurring within services provided by independent practitioners within: General Medical Services, Pharmacy, Dental or Optometry, are routinely forwarded to the HSCB Integrated Care Directorate in line with the HSCB Adverse Incident Process within the Directorate of Integrated Care (September 2016). On receipt of reported adverse incidents the HSCB Integrated Care Directorate will decide if the incident meets the criteria of a SAI and if so will be the organisation responsible to report the SAI.

3.3 Incidents that occur within the Independent /Community and Voluntary Sectors (ICVS)

SAIs that occur within ICVS, where the service has been commissioned/funded by a HSC organisation must be reported. For example: service users placed/funded by HSC Trusts in independent sector accommodation, including private hospital, nursing or residential care homes, supported housing, day care facilities or availing of HSC funded voluntary/community services. These SAIs must be reported and reviewed by the HSC organisation who has:

- referred the service user (this includes Extra Contractual Referrals) to the ICVS;

or, if this cannot be determined;

- the HSC organisation who holds the contract with the IVCS.

HSC organisations that refer service users to ICVS should ensure all contracts, held with ICVS, include adequate arrangements for the reporting of adverse incidents in order to ensure SAIs are routinely identified.

All relevant events occurring within ICVS which fall within the relevant notification arrangements under legislation should continue to be notified to RQIA.

3.4 Reporting of HSC 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 review 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.

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.

Some of these incidents will subsequently be reported as SAIs and may require other organisations to jointly input into the review. In these instances refer to Appendix 13 – Guidance on Joint Reviews.

3.5 Incidents reported and Investigated/ reviewed by Organisations external to HSC and Special Agencies

The reporting of SAIs to the HSCB will work in conjunction with and in some circumstances inform the reporting requirements of other statutory agencies and external bodies. In that regard, all existing local or national reporting arrangements, where there are statutory or mandatory reporting obligations, will continue to operate in tandem with this procedure.

3.5.1 Memorandum of Understanding (MOU)

In February 2006, the DoH issued circular HSS (MD) 06/2006 − a Memorandum of Understanding − which was developed to improve appropriate information sharing and co-ordination when joint or simultaneous investigations/reviews are required into a serious incident.

Circular HSS (MD) 8/2013 replaces the above circular and advises of a revised MOU Investigating patient or client safety incidents which can be found on the Departmental website:

www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-8-2013.pdf

The MOU has been agreed between the DoH, on behalf of the Health and Social Care Service (HSCS), the Police Service of Northern Ireland (PSNI), the Northern Ireland Courts and Tribunals Service (Coroners Service for NI) and the Health and Safety Executive for Northern Ireland (HSENI). It will apply to people receiving care and treatment from HSC in Northern Ireland. The principles and practices promoted in the document apply to other locations, where health and social care is provided e.g. it could be applied when considering an incident in a family doctor or dental practice, or for a person receiving private health or social care provided by the HSCS.

It sets out the general principles for the HSCS, PSNI, Coroners Service for NI and HSENI to observe when liaising with one another.

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

The MOU is intended to help:

- Identify which organisations should be involved and the lead investigating body.

- Prompt early decisions about the actions and investigations/reviews thought to be necessary by all organisations and a dialogue about the implications of these.

- Provide an understanding of the roles and responsibilities of the other organisations involved in the memorandum before high level decisions are taken.

- Ensure strategic decisions are taken early in the process and prevent unnecessary duplication of effort and resources of all the organisations concerned.

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

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

3.6 Reporting of SAIs to RQIA

RQIA have a statutory obligation to investigate some incidents that are also reported under the SAI procedure. In order to avoid duplication of incident notification and review, RQIA will work in conjunction with the HSCB/PHA with regard to the review of certain categories of SAI. In this regard the following SAIs should be notified to RQIA at the same time of notification to the HSCB:

- All mental health and learning disability SAIs reportable to RQIA under Article 86.2 of the Mental Health (NI) Order 1986.

- Any SAI that occurs within the regulated sector (whether statutory or independent) for a service that has been commissioned/funded by a HSC organisation.

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

- The HSCB/PHA Designated Review Officer (DRO) will lead and co-ordinate the SAI management, and follow up, with the reporting organisation; however for these SAIs this will be carried out in

conjunction with RQIA professionals. A separate administrative protocol between the HSCB and RQIA can be accessed at Appendix 15.

3.7 Reporting of SAIs to the Safeguarding Board for Northern Ireland

There is a statutory duty for the HSC to notify the Safeguarding Board for Northern Ireland of child deaths where:

- a child has died or been significantly harmed (Regulation 17(2)(a)

AND

- abuse/neglect suspected **or** child or sibling on child protection register **or** child or sibling is/has been looked after Regulation (2)(b) (see Appendix 17)

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'[1] arising during the course of the business of a 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

4.2.1 serious injury to, or the unexpected/unexplained death of:

- a service user, (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit)
- a staff member in the course of their work
- a member of the public whilst visiting a HSC facility;

4.2.2 unexpected serious risk to a service user and/or staff member and/or member of the public;

4.2.3 unexpected or significant threat to provide service and/or maintain business continuity;

[1] Source: DoH - How to classify adverse incidents and risk guidance 2006
http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/ph_how_to_classify_adverse__incidents_and_risk_-_guidance.pdf

4.2.4 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;

4.2.5 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;

4.2.6 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;

4.2.7 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 A SAI.

Note: The HSC Regional Risk Matrix may assist organisations in determining the level of 'seriousness' refer to Appendix 16.

5.0 SAI REVIEWS

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

Whilst most SAIs will be subject to a Level 1 review, for some more complex SAIs, reporting organisations may instigate a Level 2 or 3 review immediately following the incident occurring. The level of review should be noted on the SAI notification form.

The HSC Regional Risk Matrix (refer to Appendix 16) may assist organisations in determining the level of 'seriousness' and subsequently the level of review to be

undertaken. SAIs which meet the criteria in 4.2 above will be reviewed by the reporting organisation using one or more of the following:

5.1 Level 1 Review – Significant Event Audit (SEA)

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

- assess what has happened;
- assess why did it happened;
  - what went wrong and what went well;
- assess what has been changed or agree what will change;
- identify local and regional learning.

(refer to Appendix 5 – Guidance Notes for Level 1 – SEA & Learning Summary Report; Appendix 9 – Guidance on Incident Debrief); and Appendix 10 – Level 1 Review - Guidance on review team membership)

The possible outcomes from the review may include:

- closed – no new learning;
- closed – with learning;
- requires Level 2 or 3 review.

A SEA report will be completed **which should be retained by the reporting organisation** (see Appendices 4 and 5).

The reporting organisation will then complete a **SEA Learning Summary Report** (see Appendices 4 and 5 – Sections 1, 3-6), which should be signed off by the relevant professional or operational director and submitted to the HSCB within **8 weeks** of the SAI being notified.

The HSCB will not routinely receive SEA reports unless specifically requested by the DRO. This process assigns reporting organisations the responsibility for Quality Assuring Level 1 SEA Reviews. This will entail engaging directly with relevant staff within their organisation to ensure the robustness of the report and identification of learning prior to submission to the HSCB.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review, the review will move to either a Level 2 or 3 RCA review. In this instance the SEA Learning Report Summary will be forwarded to the HSCB within the timescales outlined above, with additional sections being completed to outline membership and Terms of Reference of the team completing the Level 2 or 3 RCA review and proposed timescales.

5.2 Level 2 – Root Cause Analysis (RCA)

As stated above, some SAIs will enter at Level 2 review following a SEA.

When a Level 2 or 3 review is instigated immediately following notification of a SAI, the reporting organisation will inform the HSCB within 4 weeks, of the Terms of Reference (TOR) and Membership of the Review Team for

consideration by the HSCB/PHA DRO. This will be achieved by submitting sections two and three of the review report to the HSCB. (Refer to Appendix 6 – template for Level 2 and 3 review reports).

The review must be conducted to a high level of detail (see Appendix 7 – template for Level 2 and 3 review reports). The review should include use of appropriate analytical tools and will normally be conducted by a multidisciplinary team (not directly involved in the incident), and chaired by someone independent to the incident but who can be within the same organisation. (Refer to Appendix 9 – Guidance on Incident Debrief); and Appendix 11 – Level 2 Review - Guidance on review team membership).

Level 2 RCA reviews may involve two or more organisations. In these instances, it is important a lead organisation is identified but also that all organisations contribute to, and approve the final review report (Refer to Appendix 13 Guidance on joint reviews/investigations).

On completion of Level 2 reviews, the final report must be submitted to the HSCB within 12 weeks from the date the incident was notified.

5.3 Level 3 – Independent Reviews

Level 3 reviews will be considered for SAIs that:

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

In some instances the whole team may be independent to the organisation/s where the incident/s has occurred.

The timescales for reporting Chair and Membership of the review team will be agreed by the HSCB/PHA Designated Review Officer (DRO) at the outset (see Appendix 9 – Guidance on Incident Debrief); and Appendix 12 – Level 3 Review - Guidance on Review Team Membership).

The format for Level 3 review reports will be the same as for Level 2 reviews (see Appendix 7 – guidance notes on template for Level 2 and 3 reviews).

For any SAI which involves an alleged homicide by 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, the Protocol for Responding to SAIs in the Event of a Homicide, issued in 2012 and revised in 2013 should be followed (see Appendix 14).

5.4 Involvement of Service Users/Family/Carers in Reviews

- Following a SAI it is important, in the spirit of honesty and openness to ensure a consistent approach is afforded to the level of service user / family engagement across the region. When engaging with Service Users/Family/Carers, organisations should refer to addendum 1 – *A Guide for Health and Social Care Staff Engagement/Communication with Service User/Family/Cares following a SAI.*

- In addition a 'Checklist for Engagement/Communication with the Service User/Family/Carers following a SAI' must be completed for each SAI regardless of the review level, and where relevant, if the SAI was also a Never Event (refer to section 12.2).

- The checklist also includes a section to indicate if the reporting organisation had a statutory requirement to report the death to the Coroners office and that this is also communicated to the Family/Carer.

6.0 TIMESCALES

6.1 Notification

Any adverse incident that meets the criteria indicated in section 4.2 should be reported within **72 hours** of the incident being discovered using the SAI Notification Form (see Appendix 1).

6.2 Review Reports

LEVEL 1 – SEA

SEA reports must be completed using the SEA template which will be retained by the reporting organisation (see Appendices 4 and 5). A SEA Learning Summary Report (see Appendices 4 and 5 – Sections 1, 3-6) must be completed and submitted to the HSCB within **8 weeks** of the SAI being reported for all Level 1 SAIs whether learning has been identified or not. The Checklist for Engagement/Communication with Service User/Family/Carer following a SAI' must also accompany the Learning Summary Report.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review, timescales for completion of the RCA will be indicated by Trusts via the Learning Summary Report to the HSCB.

LEVEL 2 – RCA

For those SAIs where a full RCA is instigated immediately, sections 2 and 3 of the RCA Report, outlining TOR and membership of the review team, must be submitted **no later** than **within 4 weeks** of the SAI being notified to the HSCB.

RCA review reports must be fully completed using the RCA report template and submitted together with comprehensive action plans for each recommendation identified to the HSCB **12 weeks** following the date the incident was notified. (see Appendix 6 – Level 2 & 3 RCA Review Reports and Appendix 8 – Guidance on Minimum Standards for Action Plans).

LEVEL 3 – INDEPENDENT REVIEWS

Timescales for completion of Level 3 reviews and comprehensive action plans for each recommendation identified will be agreed between the reporting organisation and the HSCB/PHA DRO as soon as it is determined that the SAI requires a Level 3 review.

Note: Checklist for Engagement/Communication with Service User/Family/Carer following a SAI must accompany all SAI Review/Learning Summary Reports which are included within the report templates.

6.3 Exceptions to Timescales

In most circumstances, all timescales for submission of reports **must be** adhered to. However, it is acknowledged, by exception, there may be occasions where a review is particularly complex, perhaps involving two or more organisations or where other external organisations such as PSNI, HSENI etc.; are involved in the same review. In these instances the reporting organisation must provide the HSCB with regular updates.

6.4 Responding to additional information requests

Once the review / learning summary report has been received, the DRO, with appropriate clinical or other support, will review the report to ensure that the necessary documentation relevant to the level of review is adequate.

If the DRO is not satisfied with the information provided additional information may be requested and must be provided in a timely manner. Requests for additional information should be provided as follows:

- Level 1 review within **2 week**
- Level 2 or 3 review within **6 weeks**

7.0 OTHER INVESTIGATIVE/REVIEW PROCESSES

The reporting of SAIs to the HSCB will work in conjunction with all other HSC investigation/review processes, statutory agencies and external bodies. In that regard, all existing reporting arrangements, where there are statutory or mandatory reporting obligations, will continue to operate in tandem with this procedure.

In that regard, there may be occasions when a reporting organisation will have reported an incident via another process before or after it has been reported as a SAI.

7.1 Complaints in the HSC

Complaints in HSC Standards and Guidelines for Resolution and Learning (The Guidance) outlines how HSC organisations should deal with complaints raised by persons who use/have used, or are waiting to use HSC services. While it is a separate process to the management and follow-up of SAIs, there will be occasions when an SAI has been reported by a HSC organisation, and subsequently a complaint is received relating to the same incident or issues, or alternatively, a complaint may generate the reporting of an SAI.

In these instances, the relevant HSC organisation must be clear as to how the issues of complaint will be investigated. For example, there may be elements of the complaint that will be solely reliant on the outcome of the SAI review and there may be aspects of the complaint which will not be part of the SAI review and can only be investigated under the Complaints Procedure.

It is therefore important that complaints handling staff and staff who deal with SAIs communicate effectively and regularly when a complaint is linked to a SAI review. This will ensure that all aspects of the complaint are responded to effectively, via the most appropriate means and in a timely manner. Fundamental to this, will obviously be the need for the organisation investigating the complaint to communicate effectively with the complainant in respect of how their complaint will be investigated, and when and how they can expect to receive a response from the HSC organisation.

7.2 HSCB Social Care Untoward Events Procedure

The above procedure provides guidance on the reporting of incidents relating to statutory functions under the Children (NI) Order 1995.

If, during the review of an incident reported under the HSCB Untoward Events procedure, it becomes apparent the incident meets the criteria of a SAI, the incident should immediately be notified to the HSCB as a SAI. Board officers within the HSCB will close the Untoward Events incident and the incident will continue to be managed via the SAI process.

7.3 Child and Adult Safeguarding

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 review 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 to the SAI process with the relevant findings from these investigations/reviews informing the SAI review (see appendix 17).

On occasion the incident under review may be considered so serious as 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.

7.4 Reporting of Falls

Reporting organisations will no longer be required to routinely report falls as SAIs which have resulted in harm in all Trust facilities, (as defined in the impact levels 3 – 5 of the regional risk matrix - see appendix 16). Instead a new process has been developed with phased implementation, which requires HSC Trusts to do a timely post fall review debrief to ensure local application of learning. See links below to Shared Learning Form and Minimum Data Set for Post Falls Review:

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/033%20Falls_Shared%20Learning%20Template_%20V2_June%202016.rtf

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/032%20Regional%20Falls%20Minimum%20Dataset%202016_V2_June%202016.pdf

Local learning will be shared with the Regional Falls Group where trends and themes will be identified to ensure regional learning.

Reporting organisations will therefore manage falls resulting in moderate to severe harm as adverse incidents, unless there are particular issues or the subsequent internal review identifies contributory issues/concerns in treatment and/or care or service issues, or any identified learning that needs to be reviewed through the serious adverse incident process.

7.5 Transferring SAIs to other Investigatory Processes

Following notification and initial review of a SAI, more information may emerge that determines the need for a specialist investigation.

This type of investigation includes:

- Case Management Reviews
- Serious Case Reviews

Once a DRO has been informed a SAI has transferred to one of the above investigation s/he will close the SAI.

7.6 De-escalating a SAI

It is recognised that organisations report SAIs based on limited information and the situation may change when more information has been gathered; which may result in the incident no longer meeting the SAI criteria.

Where a reporting organisation has determined the incident reported no longer meets the criteria of a SAI, a request to de-escalate the SAI should be submitted immediately to the HSCB by completing section 21 of the SAI notification form (Additional Information following initial Notification).

The DRO will review the request to de-escalate and will inform the reporting organisation and RQIA (where relevant) of the decision as soon as possible and at least within **10 working days** from the request was submitted.

If the DRO agrees, the SAI will be de-escalated and no further SAI review will be required. The reporting organisation may however continue to review as an adverse incident or in line with other HSC investigation/review processes (as highlighted above). If the DRO makes a decision that the SAI should not be de-escalated the review report should be submitted in line with previous timescales.

It is important to protect the integrity of the SAI review process from situations where there is the probability of disciplinary action, or criminal charges. The SAI review team must be aware of the clear distinction between the aims and boundaries of SAI reviews, which are solely for the identification and reporting learning points, compared with disciplinary, regulatory or criminal processes.

HSC organisations have a duty to secure the safety and well-being of patients/service users, the review to determine root causes and learning points should still be progressed **in parallel** with other reviews/investigations, ensuring remedial actions are put in place as necessary and to reduce the likelihood of recurrence.

8.0 LEARNING FROM SAIs

The key aim of this procedure is to improve services and reduce the risk of incident recurrence, both within the reporting organisation and across the HSC as a whole. The dissemination of learning following a SAI is therefore core to achieving this and to ensure shared lessons are embedded in practice and the safety and quality of care provided.

HSCB in conjunction with the PHA will:

- ensure that themes and learning from SAIs are identified and disseminated for implementation in a timely manner; this may be done via:
  - learning letters / reminder of best practice letters;
  - learning newsletter;
  - thematic reviews.

- provide an assurance mechanism that learning from SAIs has been disseminated and appropriate action taken by all relevant organisations;

- review and consider learning from external/independent reports relating to quality/safety.

It is acknowledged HSC organisations will already have in place mechanisms for cascading local learning from adverse incidents and SAIs internally within their own organisations. The management of dissemination and associated assurance of any regional learning is the responsibility of the HSCB/PHA.

9.0 TRAINING AND SUPPORT

9.1 Training

Training will be provided to ensure that those involved in SAI reviews have the correct knowledge and skills to carry out their role, i.e:

- Chair and/or member of an SAI review team
- HSCB/PHA DRO.

This will be achieved through an educational process in collaboration with all organisations involved, and will include training on review processes, policy distribution and communication updates.

9.2 Support

9.2.1 Laypersons

The panel of lay persons, (already involved in the HSC Complaints Procedure), have availed of relevant SAI training including Root Cause Analysis. They are now available to be called upon to be a member of a SAI review team; particularly when a degree of independence to the team is required.

Profiles and relevant contact details for all available laypersons can be obtained by contacting seriousincidents@hscni.net

9.2.2 Clinical/Professional Advice

If a DRO requires a particular clinical view on the SAI review, the HSCB Governance Team will secure that input, under the direction of the DRO.

10.0 INFORMATION GOVERNANCE

The SAI process deals with a considerable amount of sensitive personal information. Appropriate measures must be put in place to ensure the safe and secure transfer of this information. All reporting organisations should adhere to their own Information Governance Policies and Procedures. However, as a minimum the HSCB would recommend the following measures be adopted when

transferring patient/client identifiable information via e-mail or by standard hard copy mail:

- E-Mail - At present there is not a requirement to apply encryption to sensitive information transferred across the HSC network to other HSC organisations within Northern Ireland. Information transferred between the HSCB, Trusts and Northern Ireland Department of Health is not sent across the internet. If you are transferring information to any address that does not end in one of those listed below, it is essential that electronic measures to secure the data in transit, are employed, and it is advised that encryption is therefore applied at all times to transfers of sensitive / personal information.

  List of email addresses **within the Northern Ireland secure network:**
  '.hscni.net',
  'n-i.nhs.uk'
  'ni.gov.uk' or
  '.ni.gov.net'

  No sensitive or patient/service user data must be emailed to an address other than those listed above unless they have been protected by encryption mechanisms that have been approved by the BSO-ITS.

  Further advice on employing encryption software can be sought from the BSO ICT Security Team.

  Note: Although there is a degree of protection afforded to email traffic that contains sensitive information when transmitting within the Northern Ireland HSC network it is important that the information is sent to the correct recipient. With the amalgamation of many email systems, the chances of a name being the same or similar to the intended recipient has increased. It is therefore recommended that the following simple mechanism is employed when transmitting information to a new contact or to an officer you haven't emailed previously.

  Step 1 Contact the recipient and ask for their email address.
  Step 2 Send a test email to the address provided to ensure that you have inserted the correct email address.
  Step 3 Ask the recipient on receiving the test email to reply confirming receipt.
  Step 4 Attach the information to be sent with a subject line 'Private and Confidential, Addressee Only' to the confirmation receipt email and send.

- Standard Mail – It is recommended that any mail which is deemed valuable, confidential or sensitive in nature (such as patient/service user level information) should be sent using 'Special Delivery' Mail.

Further guidance is available from the HSCB Information Governance Team on: Tel 028 95 362912

11.0 ROLE OF DESIGNATED REVIEW OFFICER (DRO)

A DRO is a senior professional/officer within the HSCB / PHA and has a key role in the implementation of the SAI process namely:

- liaising with reporting organisations:
  - on any immediate action to be taken following notification of a SAI
  - where a DRO believes the SAI review is not being undertaken at the appropriate level

- agreeing the Terms of Reference for Level 2 and 3 RCA reviews;

- reviewing completed SEA Learning Summary Reports for Level 1 SEA Reviews and full RCA reports for level 2 and 3 RCA Reviews; liaising with other professionals (where relevant);

- liaising with reporting organisations where there may be concerns regarding the robustness of the level 2 and 3 RCA reviews and providing assurance that an associated action plan has been developed and implemented;

- identification of regional learning, where relevant;

- surveillance of SAIs to identify patterns/clusters/trends.

Whilst the HSCB will not routinely receive Level 1 SEA reports these can be requested, on occasion, by a DRO.

An internal HSCB/PHA protocol provides further guidance for DROs regarding the nomination and role of a DRO.

12.0 PROCESS

12.1 Reporting Serious Adverse Incidents

Any adverse incident that meets the criteria of a SAI as indicated in section 4.2 should be reported within 72 hours of the incident being discovered using the SAI Notification Form (Appendix 1) and forwarded to seriousincidents@hscni.net

HSC Trusts to copy RQIA at seriousincidents@rqia.org.uk in line with notifications relevant to the functions, powers and duties of RQIA as detailed in section 3.6 of this procedure.

Any SAI reported by FPS or ICVS must be reported in line with 3.2 and 3.3 of this procedure.

Reporting managers must comply with the principles of confidentiality when reporting SAIs and must not refer to service users or staff by name or by any other identifiable information. A unique Incident Reference/Number should be utilised on all forms/reports and associated

correspondence submitted to the HSCB and this should NOT be the patients H &C Number or their initials. (See section 10 – Information Governance)

12.2 Never Events

Never Events are SAIs that are wholly preventable, as guidance or safety recommendations that provide strong systemic protective barriers are already available at a national level and should have been implemented by all health care providers.

Each Never Event type has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a Never Event.

It is important, in the spirit of honesty and openness, that when staff are engaging with Service Users, Families, Carers as part of the SAI process, that in addition to advising an individual of the SAI, they should also be told if the SAI is a Never Event. However it will be for HSC organisations to determine when to communicate this information to Service Users, Families, Carers.

All categories included in the current NHS Never Events list (see associated DoH link below) should now be identified to the HSCB when notifying a SAI.

A separate section within the SAI notification form is to be completed to specify if the SAI is listed on the Never Events list. The SAI will continue to be reviewed in line with the current SAI procedure.

https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

12.3 Reporting Interface Incidents

In line with section 3.4 of this procedure, any organisation alerted to an incident which it feels has the potential to be a SAI should report the incident to the HSCB using the Interface Incident Notification form (Appendix 3) to seriousincidents@hscni.net.

An organisation who has been contacted by the HSCB Governance Team re: an interface incident being reported; will consider the incident in line with section 4.2 of the procedure, and if deemed it meets the criteria of a SAI, will report to the HSCB in line with 12.1 of this procedure.

12.4 Acknowledging SAI Notification

On receipt of the SAI notification the HSCB Governance Team will record the SAI on the DATIX risk management system and electronically acknowledge receipt of SAI notification to reporting organisation; advising

of the HSCB/PHA DRO, HSCB unique identification number, and requesting the completion of:

- SEA Learning Summary Report for Level 1 SAIs within 8 weeks from the date the incident is reported;
- RCA Report for Level 2 SAIs within 12 weeks from the date the incident is reported;
- RCA Report for Level 3 SAIs within the timescale as agreed at the outset by the DRO;

Where relevant, RQIA will be copied into this receipt.

12.5 Designated Review Officer (DRO)

Following receipt of a SAI the Governance Team will circulate the SAI Notification Form to the relevant Lead Officers within the HSCB/PHA to assign a DRO.

Once assigned the DRO will consider the SAI notification and if necessary, will contact the reporting organisation to confirm all immediate actions following the incident have been implemented.

12.6 Review/Learning Summary Reports

Note: Appendices 5 and 7 provide guidance notes to assist in the completion of Level 1, 2 & 3 review reports.

Timescales for submission of review/learning summary reports and associated engagement checklists will be in line with section 6.0 of this procedure.

On receipt of a review/learning summary report, the Governance Team will forward to the relevant DRO and where relevant RQIA.

The DRO will consider the adequacy of the review/learning summary report and liaise with relevant professionals/officers including RQIA (*where relevant*) to ensure that the reporting organisation has taken reasonable action to reduce the risk of recurrence and determine if the SAI can be closed. The DRO will also consider the referral of any learning identified for regional dissemination. In some instances the DRO may require further clarification and may also request sight of the full SEA review report.

If the DRO is not satisfied that a report reflects a robust and timely review s/he will continue to liaise with the reporting organisation and/or other professionals /officers, including RQIA (*where relevant*) until a satisfactory response is received. When the DRO has received all relevant and necessary information the timescale for closure of the SAI will be within 12 weeks, unless in exceptional circumstances which will have been agreed between the Reporting Organisation and the DRO.

12.7 Closure of SAI

Following agreement to close a SAI, the Governance Team will submit an email to the reporting organisation to advise the SAI has been closed, copied to RQIA (where relevant). The email will also indicate, if further information is made available to the reporting organisation (for example, Coroners Reports), which impacts on the outcome of the initial review, that it should be communicated to the HSCB/PHA DRO via the serious incidents mailbox.

This will indicate that based on the review / learning summary report received and any other information provided that the DRO is satisfied to close the SAI. It will acknowledge that any recommendations and further actions required will be monitored through the reporting organisation's internal governance arrangements in order to reassure the public that lessons learned, where appropriate have been embedded in practice.

On occasion and in particular when dealing with level 2 and 3 SAIs, a DRO may close a SAI but request the reporting organisation provides an additional assurance mechanism by advising within a stipulated period of time, that action following a SAI has been implemented. In these instances, monitoring will be followed up via the Governance team.

12.8 Regional Learning from SAIs

It is acknowledged HSC organisations will already have in place mechanisms for cascading local learning from adverse incidents and SAIs internally within their own organisations. However, the management of regional learning and associated assurance is the responsibility of the HSCB/PHA.

Therefore, where regional learning is identified following the review of an SAI, the DRO will refer this for consideration via HSCB/PHA Quality and Safety Structures and where relevant, will be disseminated as outlined in section 8.0.

12.9 Communication

All communication between HSCB/PHA and reporting organisation must be conveyed between the HSCB Governance department and Governance departments in respective reporting organisations. This will ensure all communication both written and verbal relating to the SAI, is recorded on the HSCB DATIX risk management system.

13 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.

SECTION TWO APPENDICES

APPENDICES

APPENDIX 1

Revised November 2016 (Version 1.1)

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

1. ORGANISATION:	**2.** UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE
3. HOSPITAL / FACILTY / COMMUNITY LOCATION *(where incident occurred)*	**4.** DATE OF INCIDENT: DD / MM / YYYY
5. DEPARTMENT / WARD / LOCATION EXACT *(where incident occurred)*	
6. CONTACT PERSON:	**7.** PROGRAMME OF CARE: *(refer to Guidance Notes)*

8. DESCRIPTION OF INCIDENT:

DOB: DD / MM / YYYY *(complete where relevant)* GENDER: M / F AGE: years

9. IS THIS INCIDENT A NEVER EVENT?				If 'YES' *provide further detail on which never event - refer to DoH link below* https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars
YES		NO		

DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING

STAGE OF CARE: *(refer to Guidance Notes)*	DETAIL: *(refer to Guidance Notes)*	ADVERSE EVENT: *(refer to Guidance Notes)*

10. IMMEDIATE ACTION TAKEN TO PREVENT RECURRENCE:

11. CURRENT CONDITION OF SERVICE USER: *(complete where relevant)*

12. HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? *(please select)*	YES	NO	N/A
13. HAVE ALL RECORDS / MEDICAL DEVICES / EQUIPMENT BEEN SECURED? *(please specify where relevant)*	YES	NO	N/A

14. WHY IS THIS INCIDENT CONSIDERED SERIOUS?: *(please select relevant criteria below)*

serious injury to, or the unexpected/unexplained death of: - a service user (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit) - a staff member in the course of their work - a member of the public whilst visiting a HSC facility.	
unexpected serious risk to a service user and/or staff member and/or member of the public	
unexpected or significant threat to provide service and/or maintain business continuity	
serious self-harm or serious assault *(including attempted suicide, homicide and sexual assaults)* by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service	
serious self-harm or serious assault *(including homicide and sexual assaults*) - on other service users, - on staff or - on members of the public by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the	

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

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	

15. IS ANY IMMEDIATE REGIONAL ACTION RECOMMENDED: *(please select)*	YES	NO
if 'YES' (*full details should be submitted*):		

16. HAS THE SERVICE USER / FAMILY BEEN ADVISED THE INCIDENT IS BEING REVIEWED AS A SAI?	YES	DATE INFORMED: DD/MM/YY
	NO	*specify reason:*

17. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? *(refer to guidance notes e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HCPC etc.) please specify where relevant*	YES	NO
if 'YES' (*full details should be submitted including the date notified*):		

18. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	DATE INFORMED:	OTHERS: *(please specify where relevant, including date notified)*
DoH EARLY ALERT		
HM CORONER		
INFORMATION COMMISSIONER OFFICE (ICO)		
NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)		
HEALTH AND SAFETY EXECUTIVE NORTHERN IRELAND (HSENI)		
POLICE SERVICE FOR NORTHERN IRELAND (PSNI)		
REGULATION QUALITY IMPROVEMENT AUTHORITY (RQIA)		
SAFEGUARDING BOARD FOR NORTHERN IRELAND (SBNI)		
NORTHERN IRELAND ADULT SAFEGUARDING PARTNERSHIP (NIASP)		

19. LEVEL OF REVIEW REQUIRED: *(please select)*	LEVEL 1	LEVEL 2*	LEVEL 3*

* FOR ALL LEVEL 2 OR LEVEL 3 REVIEWS PLEASE COMPLETE AND SUBMIT SECTIONS 2 AND 3 OF THE RCA REPORT TEMPLATE WITHIN 4 WEEKS OF THIS NOTIFICATION REFER APPENDIX 6

20. 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 / MM / YYYY

21. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION: *(refer to Guidance Notes)*

Additional information submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

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

APPENDIX 2

Revised November 2016 (Version 1.1)

Guidance Notes
SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

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

1. ORGANISATION: *Insert the details of the reporting organisation (HSC Organisation /Trust or Family Practitioner Service)*	**2.** UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE *Insert the unique incident number / reference generated by the reporting organisation.*
3. HOSPITAL / FACILTY / COMMUNITY LOCATION *(where incident occurred)* *Insert the details of the hospital/facility/specialty/department/ directorate/place where the incident occurred*	**4.** DATE OF INCIDENT: DD / MM / YYYY *Insert the date incident occurred*
5. DEPARTMENT / WARD / LOCATION EXACT *(where incident occurred)*	
6. CONTACT PERSON: *Insert the name of lead officer to be contacted should the HSCB or PHA need to seek further information about the incident*	**7.** PROGRAMME OF CARE: *Insert the Programme of Care from the following: Acute Services/ Maternity and Child Health / Family and Childcare / Elderly Services / Mental Health / Learning Disability / Physical Disability and Sensory Impairment / Primary Health and Adult Community (includes GP's) / Corporate Business(Other)*

8. DESCRIPTION OF INCIDENT:

*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 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.*

In addition include the following:

***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 Safeguarding Board has been advised.*

***Mental Health** - when reporting a serious injury to, or the unexpected/unexplained death (including suspected suicide, attempted suicide in an in-patient setting 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;*
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 / MM / YYYY GENDER: M / F AGE: years
(complete where relevant)

9. IS THIS INCIDENT A NEVER EVENT? Yes/No *(please select)*	If 'YES' *provide further detail on which never event - refer to DoH link below* https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING		
STAGE OF CARE: *(refer to Guidance Notes)* *Insert CCS Stage of Care Code description*	DETAIL: *(refer to Guidance Notes)* *Insert CCS Detail Code description*	ADVERSE EVENT: *(refer to Guidance Notes)* *Insert CCS Adverse Event Code description*

10. IMMEDIATE ACTION TAKEN TO PREVENT RECURRENCE:
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.

11. CURRENT CONDITION OF SERVICE USER: *(complete where relevant)*
Where relevant *please provide details on the current condition of the service user the incident relates to.*

12. HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? *(please select)*	YES	NO	N/A
13. HAVE ALL RECORDS / MEDICAL DEVICES / EQUIPMENT BEEN SECURED *(please select and specify **where relevant**)*	YES	NO	N/A

14. WHY INCIDENT CONSIDERED SERIOUS: *(please select relevant criteria from below)*

serious injury to, or the unexpected/unexplained death of: - a service user (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit) - a staff member in the course of their work - a member of the public whilst visiting a HSC facility.	
unexpected serious risk to a service user and/or staff member and/or member of the public	
unexpected or significant threat to provide service and/or maintain business continuity	
serious self-harm or serious assault *(including attempted suicide, homicide and sexual assaults)* by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service	
serious self-harm or serious assault *(including homicide and sexual assaults*) - on other service users, - on staff or - on members of the public by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including 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	

15. IS ANY IMMEDIATE REGIONAL ACTION RECOMMENDED: *(please select)*	YES	NO

if 'YES' *(full details should be submitted):*

16. HAS THE SERVICE USER / FAMILY BEEN ADVISED THE INCIDENT IS BEING REVIEWED AS A SAI? *(please select)*	YES	DATE INFORMED: DD/MM/YY *Insert the date informed*
	NO	*Specify reason:*

17. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? *(refer to guidance notes e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HCPC etc.) please specify where relevant*	YES	NO

if 'YES' (*full details should be submitted including the date notified*):

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 CARE PROFESSIONAL COUNCIL **(HCPC)**
REGULATION AND QUALITY IMPROVEMENT AUTHORTIY**(RQIA)**
SAFEGUARDING BOARD FOR NORTHERN IRELAND **(SBNI)**

OTHER – PLEASE SPECIFY BELOW

18. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	DATE INFORMED:	OTHERS: *(please specify where relevant, including date notified)*
DoH EARLY ALERT		
HM CORONER		
INFORMATION COMMISSIONER OFFICE (ICO)		
NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)		
HEALTH AND SAFETY EXECUTIVE NORTHERN IRELAND (HSENI)		
POLICE SERVICE FOR NORTHERN IRELAND (PSNI)		
REGULATION QUALITY IMPROVEMENT AUTHORITY (RQIA)		
SAFEGUARDING BOARD FOR NORTHERN IRELAND (SBNI)		
NORTHERN IRELAND ADULT SAFEGUARDING PARTNERSHIP (NIASP)		

19. LEVEL OF REVIEW REQUIRED: *(please select)*	LEVEL 1	LEVEL 2*	LEVEL 3*

* FOR ALL LEVEL 2 OR LEVEL 3 REVIEWS PLEASE COMPLETE AND SUBMIT SECTIONS 2 AND 3 OF THE RCA REPORT TEMPLATE WITHIN 4 WEEKS OF THIS NOTIFICATION REFER APPENDIX 6

20. 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 / MM / YYYY

21. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION:

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 review may not meet the criteria of a SAI. Use this section to rrequest that a 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 review under the SAI process.

The HSCB/PHA DRO 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 review report is required.

PLEASE NOTE PROGRESS IN RELATION TO TIMELINESS OF COMPLETED REVIEW REPORTS WILL BE REGULARLY REPORTED TO THE HSCB/PHA REGIONALGROUP. THEY WILL BE MONITORED ACCORDING TO AGREED 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 / MM / YYYY

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

APPENDIX 3
Revised November 2016 (Version 1.1)

HSC INTERFACE INCIDENT NOTIFICATION FORM

1. REPORTING ORGANISATION:	**2. DATE OF INCIDENT: DD / MM / YYYY**
3. CONTACT PERSON AND TEL NO:	**4. UNIQUE REFERENCE NUMBER:**

5. DESCRIPTION OF INCIDENT:

DOB: DD / MM / YYYY **GENDER: M / F** **AGE: years**
(complete where relevant)

6. ARE OTHER PROVIDERS INVOLVED? (e.g. *HSC TRUSTS / FPS / OOH / ISP / VOLUNTARY / COMMUNITY ORG'S*)	**YES**	**NO**
	if 'YES' (*full details should be submitted in section 7 below*)	

7. PROVIDE DETAIL ON ISSUES/AREAS OF CONCERN:

8. <u>IMMEDIATE</u> 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 REVIEW AND FOLLOW UP OF THIS INCIDENT?

10. OTHER COMMENTS:

REPORT SUBMITTED BY: _____ **DESIGNATION:** _____

Email: **Telephone:** **Date: DD / MM / YYYY**

Completed proforma should be sent to: seriousincidents@hscni.net

APPENDIX 4

Revised November 2016 (Version 1.1)

LEVEL 1 – SIGNIFICANT EVENT AUDIT INCLUDING LEARNING SUMMARY REPORT AND SERVICE USER/FAMILY/CARER ENGAGEMENT CHECKLIST

SECTION 1

1. ORGANISATION:	2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE:
3. HSCB UNIQUE IDENTIFICATION NO. / REFERENCE:	4. DATE OF INCIDENT/EVENT: DD / MM / YYYY
5. PLEASE INDICATE IF THIS SAI IS INTERFACE RELATED WITH OTHER EXTERNAL ORGANISATIONS: YES / NO ***Please select as appropriate***	6. IF 'YES' TO 5. PLEASE PROVDE DETAILS:
7. DATE OF SEA MEETING / INCIDENT DEBRIEF: DD / MM / YYYY	
8. SUMMARY OF EVENT:	

SECTION 2	
9. SEA FACILITATOR / LEAD OFFICER:	10. TEAM MEMBERS PRESENT:
11. SERVICE USER DETAILS: ***Complete where applicable***	
12. WHAT HAPPENED?	
13. WHY DID IT HAPPEN?	

SECTION 3 - LEARNING SUMMARY

14. WHAT HAS BEEN LEARNED:

15. WHAT HAS BEEN CHANGED or WHAT WILL CHANGE?

16. RECOMMENDATIONS (please state by whom and timescale)

17. INDICATE ANY PROPOSED TRANSFERRABLE REGIONAL LEARNING POINTS FOR CONSIDERATION BY HSCB/PHA:

18. FURTHER REVIEW REQUIRED? YES / NO
Please select as appropriate

If 'YES' complete SECTIONS 4, 5 and 6. If 'NO' complete SECTION 5 and 6.

SECTION 4 (COMPLETE THIS SECTION ONLY WHERE A FURTHER REVIEW IS REQUIRED)

19. PLEASE INDICATE LEVEL OF REVIEW: LEVEL 2 / LEVEL 3 **Please select as appropriate**	20. PROPOSED TIMESCALE FOR COMPLETION: DD / MM / YYYY

21. REVIEW TEAM MEMBERSHIP *(If known or submit asap)*:

22. TERMS OF REFERENCE *(If known or submit asap)*:

SECTION 5

APPROVAL BY RELEVANT PROFESSIONAL DIRECTOR AND/OR OPERATIONAL DIRECTOR

23. NAME:	24. DATE APPROVED:

25. DESIGANTION:

SECTION 6

26. DISTRIBUTION LIST:

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	
	Comment: ***If multiple service users are involved please indicate the number involved***			
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed 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 reviewed 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:			
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**	
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY		
	NO	If **NO**, provide details:		
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

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

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**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 engagement planned			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	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 CORONERS 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 on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**					
	If **YES**, insert **date informed**:							
	If **NO**, please provide details:							
2) If you have selected 'YES' to question 1, 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:							
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**		**Not Known**	
	If **YES**, insert **date informed**:							
	If **NO**, please provide details:							

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 5

Revised November 2016 (Version 1.1)

GUIDANCE NOTES
LEVEL 1 – SIGNIFICANT EVENT AUDIT INCLUDING SUMMARY REPORT AND SERVICE USER/FAMILY/CARER ENGAGEMENT CHECKLIST

SECTION 1 (To be submitted to the HSCB)

1. ORGANISATION: *Insert unique identifier number*	2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE: *Self- explanatory*
3. HSCB UNIQUE IDENTIFICATION NO. / REFERENCE: *Self- explanatory*	4. DATE OF INCIDENT/EVENT: DD / MM / YYYY *Self- explanatory*
5. PLEASE INDICATE IF THIS SAI IS INTERFACE RELATED WITH OTHER EXTERNAL ORGANISATIONS: YES / NO ***Please select as appropriate***	6. IF 'YES' TO 5. PLEASE PROVDE DETAILS: *Self- explanatory*
7. DATE OF SEA MEETING / INCIDENT DEBRIEF: DD / MM / YYYY *Self- explanatory*	
8. SUMMARY OF EVENT: ***As per notification form. (If the notification form does not fully reflect the incident please provide further detail.)***	

SECTION 2	
9. SEA FACILITATOR / LEAD OFFICER: *Refer to guidance on Level 1 review team membership for significant event analysis – Appendix 10*	10. TEAM MEMBERS PRESENT: *NAMES AND DESIGNATIONS*
11. SERVICE USER DETAILS: ***Complete where applicable*** *DOB / GENDER / AGE*	
12.WHAT HAPPENED? *(Describe in detailed chronological order what actually happened. Consider, for instance, how it happened, where it happened, who was involved and what the impact was on the patient/service user[1], the team, organisation and/or others).*	
13.WHY DID IT HAPPEN? *(Describe the main and underlying reasons contributing to why the event happened. Consider for instance, the professionalism of the team, the lack of a system or failing in a system, the lack of knowledge or the complexity and uncertainty associated with the event)*	

[1] *ensure sensitivity to the needs of the patient/ service user/ carer/ family member is in line with Regional Guidance on Engagement with Service Users, Families and Carers issued February 2015 (Revised November 2016)*

All sections below be submitted to the HSCB

SECTION 3 - LEARNING SUMMARY

14. WHAT HAS BEEN LEARNED: *(Based on the reason established as to why the event happened, outline the learning identified. Demonstrate that reflection and learning have taken place on an individual or team basis and that relevant team members have been involved in the analysis of the event. Consider, for instance: a lack of education and training; the need to follow systems or procedures; the vital importance of team working or effective communication)*

15. WHAT HAS BEEN CHANGED or WHAT WILL CHANGE? *Based on the understanding of why the event happened and the identification of learning, outline the action(s) agreed and implemented, where this is relevant or feasible. Consider, for instance: if a protocol has been amended, updated or introduced; how was this done and who was involved; how will this change be monitored. It is also good practice to attach any documentary evidence of change e.g. a new procedure or protocol.*

NOTE: Action plans should also be developed and set out how learning will be implemented, with named leads responsible for each action point (Refer to Appendix 7 Minimum Standards for Action Plans).

Action plans for this level of review will be retained by the reporting organisation.

16. RECOMMENDATIONS (please state by whom and timescale) *It should be noted that it is the responsibility of the HSCB/PHA to consider and review all recommendations, of suggested /proposed learning relevant to other organisations, arising from the review of a SAI. In addition, it is the responsibility if the HSCB/PHA to subsequently identify any related learning to be communicated across the HSC and where relevant with other organisations regionally and/or nationally.*

It is the responsibility of the reporting organisation to communicate to service users, families and carer's that learning identified relevant to other organisations (arising from the review of a SAI) and submitted to the HSCB/PHA, to consider and review, may not on every occasion result in regional learning.

17. INDICATE ANY PROPOSED TRANSFERRABLE REGIONAL LEARNING POINTS FOR CONSIDERATION BY HSCB/PHA:

Self- explanatory

18. FURTHER REVIEW REQUIRED? YES / NO

Please select as appropriate

If 'YES' complete SECTIONS 4, 5 and 6. If 'NO' complete SECTION 5 and 6.

SECTION 4 (COMPLETE THIS SECTION ONLY WHERE A FURTHER REVIEW IS REQUIRED)

19. PLEASE INDICATE LEVEL OF REVIEW: LEVEL 2 / LEVEL 3 **Please select as appropriate**	20. PROPOSED TIMESCALE FOR COMPLETION: DD / MM / YYYY

21. REVIEW TEAM MEMBERSHIP(If known or submit ASAP):

Refer to section 2 of appendix 7.

22. TERMS OF REFERENCE(If known or submit ASAP):

Refer to section 3 of appendix 7.

SECTION 5 - (COMPLETE THIS SECTION FOR ALL LEVELS OF REVIEW)

APPROVAL BY RELEVANT PROFESSIONAL DIRECTOR AND/OR OPERATIONAL DIRECTOR

23. NAME: *Self- explanatory*	24. DATE APPROVED: *Self- explanatory*

25. DESIGANTION: *Self- explanatory*

SECTION 6

26. DISTRIBUTION LIST:

List of the individuals, groups or organisations the final report has been shared with.

APPENDIX 5

To be submitted to the HSCB

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1					
INFORMING THE SERVICE USER[1] / FAMILY / CARER					
1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		
	Comment: ***If multiple service users are involved please indicate the number involved***				
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed 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 reviewed 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:				
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**		
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY			
	NO	If **NO**, provide details:			
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**					
Content with rationale?	**YES**		**NO**		

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER ***(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)***				
5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**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:			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	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 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 CORONERS 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 on the circumstances of the death? **Please select as appropriate (✓)**	**YES**				**NO**			
	If **YES**, insert **date informed**:							
	If **NO**, please provide details:							
2) If you have selected 'YES' to question 1, 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:							
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**		**Not Known**	
	If **YES**, insert **date informed**:							
	If **NO**, please provide details:							

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 6

Revised November 2016 (Version 1.1)

Insert organisation Logo

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier:

Date of Incident/Event:

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: (M/F) Age: (yrs)

Responsible Lead Officer:

Designation:

Report Author:

Date report signed off:

1.0 EXECUTIVE SUMMARY

2.0 THE REVIEW TEAM

3.0 SAI REVIEW TERMS OF REFERENCE

4.0 REVIEW METHODOLOGY

5.0 DESCRIPTION OF INCIDENT/CASE

6.0 FINDINGS

7.0 CONCLUSIONS

8.0 LESSONS LEARNED

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		HSCB Ref Number:	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	
	Comment: ***If multiple service users are involved please indicate the number involved***			
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed 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 reviewed 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:			
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**	
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY		
	NO	If **NO**, provide details:		
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

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

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**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 engagement planned			
	c) Report not shared but contents discussed **(*if you select this option please also complete 'I' below*)**			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER ***(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)***		
	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 CORONERS 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 on the circumstances of the death? **Please select as appropriate (✓)**	**YES**				**NO**			
	If **YES**, insert **date informed**:							
	If **NO**, please provide details:							
2) If you have selected 'YES' to question 1, 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:							
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**		**Not Known**	
	If **YES**, insert **date informed**:							
	If **NO**, please provide details:							

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 7
Revised November 2016 (Version 1.1)

Health and Social Care Regional Guidance

for

Level 2 and 3 RCA Incident Review Reports

INTRODUCTION

This document is a revision of the template developed by the DoH Safety in Health and Social Care Steering Group in 2007 as part of the action plan contained within "*Safety First: A Framework for Sustainable Improvement in the HPSS.*"

The purpose of this template and guide is to provide practical help and support to those writing review reports and should be used, in as far as possible, for drafting all **HSC Level 2 and Level 3** incident review reports. It is intended as a guide in order to standardise all such reports across the HSC including both internal and external reports.

The review report presents the work of the review team and provides all the necessary information about the incident, the review process and outcome of the review. The purpose of the report is to provide a formal record of the review process and a means of sharing the learning. The report should be clear and logical, and demonstrate that an open and fair approach has taken place.

This guide 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.

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

Insert organisation Logo

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier:

Date of Incident/Event:

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: (M/F) Age: (yrs)

Responsible Lead Officer:

Designation:

Report Author:

Date report signed off:

1.0 EXECUTIVE SUMMARY

Summarise the main report: provide a brief overview of the incident and consequences, background information, level of review, concise analysis and main conclusions, lessons learned, recommendations and arrangements for sharing and learning lessons.

2.0 THE REVIEW TEAM

Refer to Guidance on Review Team Membership

The level of review undertaken will determine the degree of leadership, overview and strategic review required.

- *List names, designation and review team role of the members of the Review Team. The Review Team 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 and the level of review to be undertaken. However, best practice would indicate that 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.*

3.0 SAI REVIEW TERMS OF REFERENCE

Describe the plan and scope for conducting the review. State the level of review, aims, objectives, outputs and who commissioned the review.

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

- To undertake a review of the incident to identify specific problems or issues to be addressed;
- To consider any other relevant factors raised by the incident;
- To identify and engage appropriately with all relevant services or other agencies associated with the care of those involved in the incident;
- To determine actual or potential involvement of the Police, Health and Safety Executive, Regulation and Quality Improvement Authority and Coroners Service for Northern Ireland[2] [3]
- To agree the remit of the review - the scope and boundaries beyond which the review should not go (e.g. disciplinary process) – state how far back the review will go (what point does the review start and stop e.g. episode of care) and the level of review;
- To consider the outcome of the review, agreeing recommendations, actions to be taken and lessons learned for the improvement of future services;
- To ensure sensitivity to the needs of the patient/ service user/ carer/ family member, where appropriate. The level of involvement clearly depends on the nature of the incident and the service user's or family's wishes or carer's wishes to be involved and must be in line with Regional Guidance on Engagement with Service Users, Families and Carers issued November 2016;

[2] *Memorandum of understanding: Investigating patient or client safety incidents (Unexpected death or serious untoward harm)- http://www.dhsspsni.gov.uk/ph_mou_investigating_patient_or_client_safety_incidents.pdf*

[3] *Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults 2009*

3.0 SAI REVIEW TERMS OF REFERENCE

- To agree the timescales for completing and submitting the review report, including the SAI engagement checklist, distribution of the report and timescales for reviewing actions on the action plan;

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

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

This list is not exhaustive

4.0 REVIEW METHODOLOGY

This section should provide an outline of the type of review and the methods used to gather information within the review process. The NPSA's "Seven Steps to Patient Safety[4]" and "Root Cause Analysis Review Guidance[5]" provide useful guides for deciding on methodology.

- Review of patient/ service user records and compile a timeline (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
- Outline engagement with patients/service users / carers / family members / voluntary organisations/ private providers
- Review of local, regional and national policies and procedures, including professional codes of conduct in operation at the time of the incident
- Review of documentation e.g. consent form(s), risk assessments, care plan(s), photographs, diagrams or drawings, training records, service/maintenance records, including specific reports requested from and provided by staff etc.

This list is not exhaustive

5.0 DESCRIPTION OF INCIDENT/CASE

Provide an account of the incident including consequences and detail what makes this incident a SAI. The following can provide a useful focus but please note this section is not solely a chronology of events

- Concise factual description of the serious adverse incident include the incident date and

[4] *http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787*

[5] *http://www.nrls.npsa.nhs.uk/resources/?entryid45=75355*

5.0 DESCRIPTION OF INCIDENT/CASE

type, the healthcare specialty involved and the actual effect of the incident on the service user and/or service and others;

- People, equipment and circumstances involved;
- Any intervention / immediate action taken to reduce consequences;
- Chronology of events leading up to the incident;
- Relevant past history – a brief description of the care and/or treatment/service provided;
- Outcome / consequences / action taken;
- Relevance of local, regional or national policy / guidance / alerts including professional codes of conduct in place at the time of the incident

This list is not exhaustive

6.0 FINDINGS

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/service provided. This section needs to clearly identify the care and service delivery problems and analysis to identify the causal factors.

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 (include employment status i.e. substantive, agency, locum voluntary etc.)
- 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 reviewed and recorded the table in the NPSA's "Seven Steps to Patient Safety" document (and associated Root Cause Analysis Toolkit) is useful. *http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/*

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

7.0 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 on-going engagement / contact with family members or carers.

This section should summarise the key findings and should answer the questions posed in the terms of reference.

8.0 LESSONS LEARNED

Lessons learned from the incident and the review should be identified and addressed by the recommendations and relate to the findings. Indicate to whom learning should be communicated and this should be copied to the Committee with responsibility for governance.

9.0 RECOMMENDATIONS AND ACTION PLANNING

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

- Recommendations for the reviewing organisation
- Suggested /proposed learning that is relevant to other organisations

Action plans should be developed and should set out how each recommendation will be implemented, with named leads responsible for each action point (Refer to Appendix 8 Guidance on Minimum Standards for Action Plans). This section should clearly demonstrate the arrangements in place to successfully deliver the action plan.

It should be noted that it is the responsibility of the HSCB/PHA to consider and review all recommendations, of suggested /proposed learning relevant to other organisations, arising from the review of a SAI. In addition, it is the responsibility if the HSCB/PHA to subsequently identify any related learning to be communicated across the HSC and where relevant with other organisations regionally and/or nationally.

It is the responsibility of the reporting organisation to communicate to service users/families/carers that regional learning identified and submitted to the HSCB/PHA for consideration may not on every occasion result in regional learning.

10.0 DISTRIBUTION LIST

List the individuals, groups or organisations the final report has been shared with. This should have been agreed within the terms of reference.

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	
	Comment: ***If multiple service users are involved please indicate the number involved***			
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed 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 reviewed 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:			
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**	
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY		
	NO	If **NO**, provide details:		
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

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

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**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 engagement planned			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER ***(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)***		
	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 CORONERS 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 on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						
2) If you have selected 'YES' to question 1, 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:						
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**		**Not Known**
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 8

GUIDANCE ON MINIMUM STANDARDS FOR ACTION PLANS

The action plan must define:

- Who has agreed the action plan
- Who will monitor the implementation of the action plan
- How often the action plan will be reviewed
- Who will sign off the action plan when all actions have been completed

The action plan **MUST** contain the following

1. Recommendations based on the contributing factors	The recommendations from the report - these should be the analysis and findings of the review
2. Action agreed	This should be the actions the organisation needs to take to resolve the contributory factors.
3. By who	Who in the organisation will ensure the action is completed
4. Action start date	Date particular action is to commence
5. Action end date	Target date for completion of action
6. Evidence of completion	Evidence available to demonstrate that action has been completed. This should include any intended action plan reviews or audits
7. Sign off	Responsible office and date sign off as completed

APPENDIX 9

GUIDANCE ON INCIDENT DEBRIEF

- ## Level 1 - SEA Reviews

For level 1 reviews, the incident debrief can serve the purpose of the SEA review, (these can also be known as 'hot debriefs').

The review should:

- Collect and collate as much factual information on the event as possible, including all relevant records. Also gather the accounts of those directly and indirectly involved, including, where relevant, service user/relatives/carers or other health professionals.

- The incident debrief/significant event meeting should be held with all staff involved to provide an opportunity to:

    - support the staff involved[6]
    - assess what has happened;
    - assess why did it happened;
        - what went wrong and what went well;
    - assess what has been changed or agree what will change;
    - identify local and regional learning.

- The meeting/s should be conducted in an open, fair, honest, non-judgemental and supportive atmosphere and should be undertaken as soon as practical following the incident.

- Write it up – keep a written report of the analysis undertaken using the SEA Report template (see Appendix 4)

- Sharing SEA Report – SEA reports should be shared with all relevant staff, particularly those who have been involved in the incident.

- ## Level 2 and 3 RCA Reviews

An incident debrief can also be undertaken for level 2 and 3 reviews. This would be separate from the RCA review and should occur quickly after the incident to provide support to staff and to identify any immediate service actions.

[6] *Note: link to ongoing work in relation to Quality 2020 - Task 2 - Supporting Staff involved in SAIs and other Incidents*

APPENDIX 10

LEVEL 1 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

The level of review of an incident should be proportionate to its significance; this is a judgement to be made by the Review Team.

Membership of the team should include all relevant professionals but should be appropriate and proportionate to the type of incident and professional groups involved. Ultimately, for a Level 1 review, it is for each team to decide who is invited, there has to be a balance between those who can contribute to an honest discussion, and creating such a large group that discussion of sensitive issues is inhibited.

The review team should appoint an experienced facilitator or lead reviewing officer from within the team to co-ordinate the review. The role of the facilitator is as follows:

- Co-ordinate the information gathering process
- Arrange the review meeting
- Explain the aims and process of the review
- Chair the review meeting
- Co-ordinate the production of the Significant Event Audit report
- Ensure learning is shared in line with the Learning Summary Report

APPENDIX 11

LEVEL 2 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

The level of review undertaken will determine the degree of leadership, overview and strategic review required. The level of review of an incident should therefore be proportionate to its significance. This is a judgement to be made by the Review Team.

The core review team should comprise a minimum of three people of appropriate seniority and objectivity. Review teams should be multidisciplinary, (or involve experts/expert opinion/independent advice or specialist reviewers). The team shall have no conflicts of interest in the incident concerned and should have an Independent Chair. (*In the event of a suspected homicide HSC Trusts should follow the HSCB Protocol for responding to SAIs in the event of a Homicide – revised 2013*)

The Chair of the team shall be independent of the service area where the incident occurred and should have relevant experience of the service area and/or chairing investigations/reviews. He/she shall not have been involved in the direct care or treatment of the individual, or be responsible for the service area under review. The Chair may be sourced from the HSCB Lay People Panel *(a panel of 'lay people' with clinical or social care professional areas of expertise in health and social care, who could act as the chair of an independent review panel, or a member of a Trust RCA review panel*).

Where multiple (*two or more*) HSC providers of care are involved, an increased level of independence shall be required. In such instances, the Chair shall be completely independent of the main organisations involved.

Where the service area is specialised, the Chair may have to be appointed from another HSC Trust or from outside NI.

Membership of the team should include all relevant professionals, but should be appropriate and proportionate to the type of incident and professional groups involved.

Membership shall include an experienced representative who shall support the review team in the application of the root cause analysis methodologies and techniques, human error and effective solutions based development.

Members of the team shall be separate from those who provide information to the review team.

It may be helpful to appoint a review officer from within the review team to co-ordinate the review.

APPENDIX 12

LEVEL 3 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

The level of review shall be proportionate to the significance of the incident. The same principles shall apply, as for Level 2 reviews. The degree of independence of the review team will be dependent on the scale, complexity and type of the incident.

Team membership for Level 3 reviews will be agreed between the reporting organisation and the HSCB/PHA DRO prior to the Level 3 review commencing.

APPENDIX 13

GUIDANCE ON JOINT REVIEWS/INVESTIGATIONS

Where a SAI involves multiple (*two or more*) HSC providers of care (e.g. a patient/service user affected by system failures both in an acute hospital and in primary care), a decision must be taken regarding who will lead the review and reporting. This may not necessarily be the initial reporting organisation.

The general rule is for the provider organisation with greatest contact with the patient/service user to lead the review and action. There may, however, be good reason to vary this arrangement e.g. where a patient/service user has died on another organisation's premises. The decision should be made jointly by the organisations concerned, if necessary referring to the HSCB Designated Review Officer for advice. **The lead organisation must be agreed by all organisations involved.**

It will be the responsibility of the lead organisation to engage all organisations in the review as appropriate. This involves collaboration in terms of identifying the appropriate links with the other organisations concerned and in practice, separate meetings in different organisations may take place, but a single review report and action plan should be produced by the lead organisation and submitted to the HSCB in the agreed format.

Points to consider:

- If more than one service is being provided, then all services are required to provide information / involvement reports to the review team;
- All service areas should be represented in terms of professional makeup / expertise on the review team;
- If more than one Trust/Agency is involved in the care of an individual, that the review is conducted jointly with all Trusts/Agencies involved;
- Relevant service providers, particularly those under contract with HSC to provide some specific services, should also be enjoined;
- There should be a clearly articulated expectation that the service user (where possible) and family carers, perspective should be canvassed, as should the perspective of staff directly providing the service, to be given consideration by the panel;
- The perspective of the GP and other relevant independent practitioners providing service to the individual should be sought;
- Service users and carer representatives should be invited / facilitated to participate in the panel discussions with appropriate safeguards to protect the confidentiality of anyone directly involved in the case.

This guidance should be read in conjunction with:

- Guidance on Incident Debrief (Refer to Appendix 9)
- Guidance on Review Team Membership (Refer to Appendix 11 & 12)
- Guidance on completing HSC Review Report Level 2 and 3 (Refer to Appendix 7)

APPENDIX 14

PROTOCOL FOR RESPONDING TO SERIOUS ADVERSE INCIDENTS IN THE EVENT OF A HOMICIDE – 2013 (updated November 2016 in line with the HSCB Procedure for the Reporting and Follow up of SAIs)

1. INTRODUCTION AND PURPOSE

1.1. INTRODUCTION

The Health and Social Care Board (HSCB) Procedure for the Reporting and Follow up of Serious Adverse Incidents (SAIs) was issued in April 2010 and revised November 2016. This procedure provides guidance to Health and Social Care (HSC) Trusts and HSCB Integrated Care staff in relation to the reporting and follow up of SAIs arising during the course of business of a HSC organisation, Special Agency or commissioned service.

This paper is a revised protocol, developed from the above procedure, for the specific SAIs which involves an alleged homicide perpetrated by 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.

This paper should be read in conjunction with Promoting Quality Care – Good Practice Guidance on the Assessment and Management of Risk in Mental Health and Learning Disability Services (Sept 2009 & May 2010).

1.2. PURPOSE

The purpose of this protocol is to provide HSC Trusts with a standardised approach in managing and coordinating the response to a SAI involving homicide.

2. THE PROCESS

2.1. REPORTING SERIOUS ADVERSE INCIDENTS

Refer to the HSCB Procedure for the Reporting and Follow up of Serious Adverse Incidents revised in 2016.

2.2. MULTI-DISCIPLINARY REVIEW

As indicated in Promoting Quality Care (5.0) an internal multi-disciplinary review must be held as soon as practicable following an adverse incident. Where the SAI has resulted in homicide a more independent response is required.

An independent review team should be set up within twenty working days, of the notification of the incident, to the Trust.

2.3. ESTABLISHING AN INDEPENDENT REVIEW TEAM

2.3.1 CHAIR

The Chair of the Review Team should be independent from the HSC Trust, not a Trust employee or recently employed by the Trust. They should be at Assistant Director level or above with relevant professional expertise.

It is the role of the Chair to ensure engagement with families, that their views are sought, that support has been offered to them at an early stage and they have the opportunity to comment on the final draft of the report.

2.3.2 MEMBERSHIP

A review team should include all relevant professionals. The balance of the Team should include non-Trust staff and enable the review team to achieve impartiality, openness, independence, and thoroughness in the review of the incident. [ref: Case Management Review Chapter 10 Cooperating to Protect Children].

The individuals who become members of the Team must not have had any line management responsibility for the staff working with the service user under consideration. The review team must include members who are independent of HSC Trusts and other agencies concerned.

Members of the review team should be trained in the Procedure for the Reporting and Follow up of Serious Adverse Incidents 2016.

3. TERMS OF REFERENCE

The terms of reference for the review team should be drafted at the first meeting of the review team and should be agreed by the HSCB before the second meeting.

The Terms of Reference should include, as a minimum, the following:

- establish the facts of the incident;
- analyse the antecedents to the incident;
- consider any other relevant factors raised by the incident;
- establish whether there are failings in the process and systems;
- establish whether there are failings in the performance of individuals;
- identify lessons to be learned from the incident; and

- identify clearly what those lessons are, how they will be acted upon, what is expected to change as a result, and specify timescales and responsibility for implementation.

4. TIMESCALES

The notification to the Trust of a SAI, resulting in homicide, is the starting point of this process.

The Trust should notify the HSCB within 24hours and the Regulation and Quality Improvement Authority (RQIA) as appropriate.

An independent review team should be set up within twenty working days of the notification of the incident to the Trust.

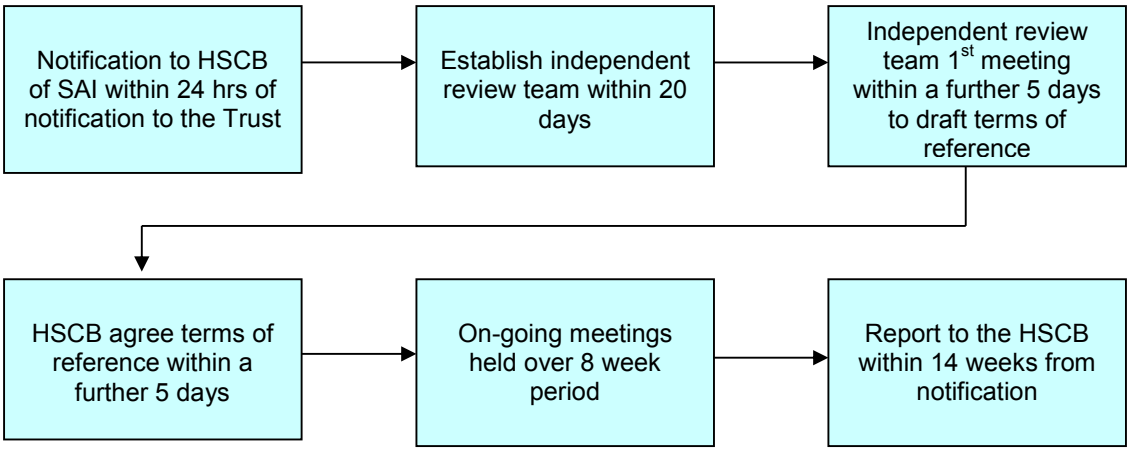
The team should meet to draft the terms of reference within a further five working days (i.e. twenty five days from notification of the incident to the Trust).

The HSCB should agree the terms of reference within a further five working days to enable work to begin at a second meeting.

The review team should complete their work and report to the HSCB within 14 weeks, this may be affected by PSNI investigations.

FLOWCHART OF PROCESS WITH TIMESCALES

NB Days refers to working days from the date of notification of the incident to the Trust



5. THE HEALTH AND SOCIAL CARE BOARD RESPONSIBILITY

On receipt of the completed Trust review report the HSCB will consider the findings and recommendations of the report and must form a view as to whether or not an Independent Inquiry is required.

The HSCB must advise the Department of Health, (DoH) as to whether or not an Independent Inquiry is required in this particular SAI.

APPENDIX 15

ADMINISTRATIVE PROTOCOL

REPORTING AND FOLLOW UP OF SAIs INVOLVING RQIA MENTAL HEALTH/LEARNING DISABILITY AND INDEPENDENT/REGULATED SECTOR

On receipt of a SAI notification and where a HSC Trust has also copied RQIA into the same notification, the following steps will be applied:

1. HSCB acknowledgement email to Trust advising on timescale for review report will also be copied to RQIA.

2. On receipt of the review/learning summary report from Trust, the HSCB Governance Team will forward to the HSCB/PHA Designated Review Officer (DRO).

3. At the same time, the HSCB Governance Team will also forward the review report/learning summary report[1] to RQIA, together with an email advising of a **3 week** timescale from receipt of review report/learning summary report, for RQIA to forward comments for consideration by the DRO.

4. The DRO will continue with his/her review liaising (where s/he feels relevant) with Trust, RQIA and other HSCB/PHA professionals until s/he is satisfied SAI can be closed.

5. If no comments are received from RQIA within the 3 week timescale, the DRO will assume RQIA have no comments.

6. When the SAI is closed by the DRO, an email advising the Trust that the SAI is closed will also be copied to RQIA.

All communications to be sent or copied via:

HSCB Governance Team: ***seriousincidents@hscni.net***
and RQIA: **seriousincidents@rqia.org.uk**

[1] **For Level 1 SAIs the HSCB only routinely receive the Learning Summary Report. If RQIA also wish to consider the full SEA Report this should be requested directly by RQIA from the relevant Reporting Organisation.**

APPENDIX 16

HSC Regional Impact Table – with effect from April 2013 (updated June 2016)

DOMAIN	IMPACT (CONSEQUENCE) LEVELS [can be used for both actual and potential]				
	INSIGNIFICANT (1)	**MINOR (2)**	**MODERATE (3)**	**MAJOR (4)**	**CATASTROPHIC (5)**
PEOPLE *(Impact on the Health/Safety/Welfare of any person affected: e.g. Patient/Service User, Staff, Visitor, Contractor)*	• Near miss, no injury or harm.	• Short-term injury/minor harm requiring first aid/medical treatment. • Any patient safety incident that required extra observation or minor treatment e.g. first aid • Non-permanent harm lasting less than one month • Admission to hospital for observation or extended stay (1-4 days duration) • Emotional distress (recovery expected within days or weeks).	• Semi-permanent harm/disability (physical/emotional injuries/trauma) (Recovery expected within one year). • Admission/readmission to hospital or extended length of hospital stay/care provision (5-14 days). • Any patient safety incident that resulted in a moderate increase in treatment e.g. surgery required	• Long-term permanent harm/disability (physical/emotional injuries/trauma). • Increase in length of hospital stay/care provision by >14 days.	• Permanent harm/disability (physical/ emotional trauma) to more than one person. • Incident leading to death.
QUALITY & PROFESSIONAL STANDARDS/ GUIDELINES *(Meeting quality/ professional standards/ statutory functions/ responsibilities and Audit Inspections)*	• Minor non-compliance with internal standards, professional standards, policy or protocol. • Audit / Inspection – small number of recommendations which focus on minor quality improvements issues.	• Single failure to meet internal professional standard or follow protocol. • Audit/Inspection – recommendations can be addressed by low level management action.	• Repeated failure to meet internal professional standards or follow protocols. • Audit / Inspection – challenging recommendations that can be addressed by action plan.	• Repeated failure to meet regional/ national standards. • Repeated failure to meet professional standards or failure to meet statutory functions/ responsibilities. • Audit / Inspection – Critical Report.	• Gross failure to meet external/national standards. • Gross failure to meet professional standards or statutory functions/ responsibilities. • Audit / Inspection – Severely Critical Report.
REPUTATION *(Adverse publicity, enquiries from public representatives/media Legal/Statutory Requirements)*	• Local public/political concern. • Local press < 1day coverage. • Informal contact / Potential intervention by Enforcing Authority (e.g. HSENI/NIFRS).	• Local public/political concern. • Extended local press < 7 day coverage with minor effect on public confidence. • Advisory letter from enforcing authority/increased inspection by regulatory authority.	• Regional public/political concern. • Regional/National press < 3 days coverage. Significant effect on public confidence. • Improvement notice/failure to comply notice.	• MLA concern (Questions in Assembly). • Regional / National Media interest >3 days < 7days. Public confidence in the organisation undermined. • Criminal Prosecution. • Prohibition Notice. • Executive Officer dismissed. • External Investigation or Independent Review (eg, Ombudsman). • Major Public Enquiry.	• Full Public Enquiry/Critical PAC Hearing. • Regional and National adverse media publicity > 7 days. • Criminal prosecution – Corporate Manslaughter Act. • Executive Officer fined or imprisoned. • Judicial Review/Public Enquiry.
FINANCE, INFORMATION & ASSETS *(Protect assets of the organisation and avoid loss)*	• Commissioning costs (£) <1m. • Loss of assets due to damage to premises/property. • Loss – £1K to £10K. • Minor loss of non-personal information.	• Commissioning costs (£) 1m – 2m. • Loss of assets due to minor damage to premises/ property. • Loss – £10K to £100K. • Loss of information. • Impact to service immediately containable, medium financial loss	• Commissioning costs (£) 2m – 5m. • Loss of assets due to moderate damage to premises/ property. • Loss – £100K to £250K. • Loss of or unauthorised access to sensitive / business critical information • Impact on service contained with assistance, high financial loss	• Commissioning costs (£) 5m – 10m. • Loss of assets due to major damage to premises/property. • Loss – £250K to £2m. • Loss of or corruption of sensitive / business critical information. • Loss of ability to provide services, major financial loss	• Commissioning costs (£) > 10m. • Loss of assets due to severe organisation wide damage to property/premises. • Loss – > £2m. • Permanent loss of or corruption of sensitive/business critical information. • Collapse of service, huge financial loss
RESOURCES *(Service and Business interruption, problems with service provision, including staffing (number and competence), premises and equipment)*	• Loss/ interruption < 8 hour resulting in insignificant damage or loss/impact on service. • No impact on public health social care. • Insignificant unmet need. • Minimal disruption to routine activities of staff and organisation.	• Loss/interruption or access to systems denied 8 – 24 hours resulting in minor damage or loss/ impact on service. • Short term impact on public health social care. • Minor unmet need. • Minor impact on staff, service delivery and organisation, rapidly absorbed.	• Loss/ interruption 1-7 days resulting in moderate damage or loss/impact on service. • Moderate impact on public health and social care. • Moderate unmet need. • Moderate impact on staff, service delivery and organisation absorbed with significant level of intervention. • Access to systems denied and incident expected to last more than 1 day.	• Loss/ interruption 8-31 days resulting in major damage or loss/impact on service. • Major impact on public health and social care. • Major unmet need. • Major impact on staff, service delivery and organisation - absorbed with some formal intervention with other organisations.	• Loss/ interruption >31 days resulting in catastrophic damage or loss/impact on service. • Catastrophic impact on public health and social care. • Catastrophic unmet need. • Catastrophic impact on staff, service delivery and organisation - absorbed with significant formal intervention with other organisations.
ENVIRONMENTAL *(Air, Land, Water, Waste management)*	• Nuisance release.	• On site release contained by organisation.	• Moderate on site release contained by organisation. • Moderate off site release contained by organisation.	• Major release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service etc).	• Toxic release affecting off-site with detrimental effect requiring outside assistance.

HSC Regional Risk Matrix – April 2013 (updated June 2016)

HSC REGIONAL RISK MATRIX – WITH EFFECT FROM APRIL 2013 (updated June 2016)

Risk Likelihood Scoring Table			
Likelihood Scoring Descriptors	**Score**	**Frequency (How often might it/does it happen?)**	**Time framed Descriptions of Frequency**
Almost certain	5	Will undoubtedly happen/recur on a frequent basis	Expected to occur at least daily
Likely	4	Will probably happen/recur, but it is not a persisting issue/circumstances	Expected to occur at least weekly
Possible	3	Might happen or recur occasionally	Expected to occur at least monthly
Unlikely	2	Do not expect it to happen/recur but it may do so	Expected to occur at least annually
Rare	1	This will probably never happen/recur	Not expected to occur for years

	Impact (Consequence) Levels				
Likelihood Scoring Descriptors	**Insignificant(1)**	**Minor (2)**	**Moderate (3)**	**Major (4)**	**Catastrophic (5)**
Almost Certain (5)	**Medium**	**Medium**	**High**	**Extreme**	**Extreme**
Likely (4)	**Low**	**Medium**	**Medium**	**High**	**Extreme**
Possible (3)	**Low**	**Low**	**Medium**	**High**	**Extreme**
Unlikely (2)	**Low**	**Low**	**Medium**	**High**	**High**
Rare (1)	**Low**	**Low**	**Medium**	**High**	**High**

APPENDIX 17

CHILD AND ADULT SAFEGUARDING AND SAI PROCESSES

The Procedure for the Reporting and Follow up of Serious Adverse Incidents (Revised November 2016) provides guidance to Health and Social Care organisations in relation to the reporting and follow up of Serious Adverse Incidents arising during the course of their business or commissioned service.

The guidance notes that the SAI review should be conducted at a level appropriate and proportionate to the complexity of the incident under review.

The guidance notes that there are three possible levels of review of an SAI and specifies the expected timescale for reporting on a review report as follows:

Level 1 Review – Significant Event Audit (SEA). To be completed and a Learning Summary Report sent to the HSCB within 8 weeks of the SAI being reported.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review timescales for completion of the RCA will be determined following submission of the Learning Summary Report to the HSCB.

Level 2 Review – Root Cause Analysis (RCA). The final report to be submitted to the HSCB within 12 weeks from the date the incident was notified.

Level 3 Review – Independent Review. Timescales for completion to be agreed by the DRO.

It should be noted that not every referral to child or adult safeguarding processes will proceed to the completion of an SAI report. Within Children's Services, the most complex cases and those that involve death or serious injury to a child, where concerns about how services worked together exist, will be notified to the HSCB as an SAI and may be assessed as meeting the criteria for a Case Management Review (CMR) in which case they will be managed out of the SAI system. The CMR report will highlight the learning from the case.

However, the timescales for the completion of SAI reviews at Level 2 and 3 have proved to be challenging for the cases that do not reach the threshold for a CMR or which result from allegations of abuse of an adult. These are more likely to be some of the more complex cases, and generally involve inter- and multi- agency partnership working.

In responding to allegations of the abuse, neglect or exploitation of a child or vulnerable adult where it is suspected that criminal offence may have been committed, the Health and Social Care Trusts operate under the principles for joint working with the PSNI and other agencies as set out in

- Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults (2009);

- Sharing to Safeguard (DoH Revised HSCC 3/96 and currently being revised by DoH);
- Co-operating to Safeguard Children (DoH 2003); and
- Protocol for joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse – Northern Ireland (2013)

The Memorandum of Understanding: Investigating patient or client safety incidents (2013) states that in cases where more than one organisation may/should have an involvement in investigating any particular incident, then:

"The HSC Organisation should continue to ensure patient or client safety, but not undertake any activity that might compromise any subsequent statutory investigations."

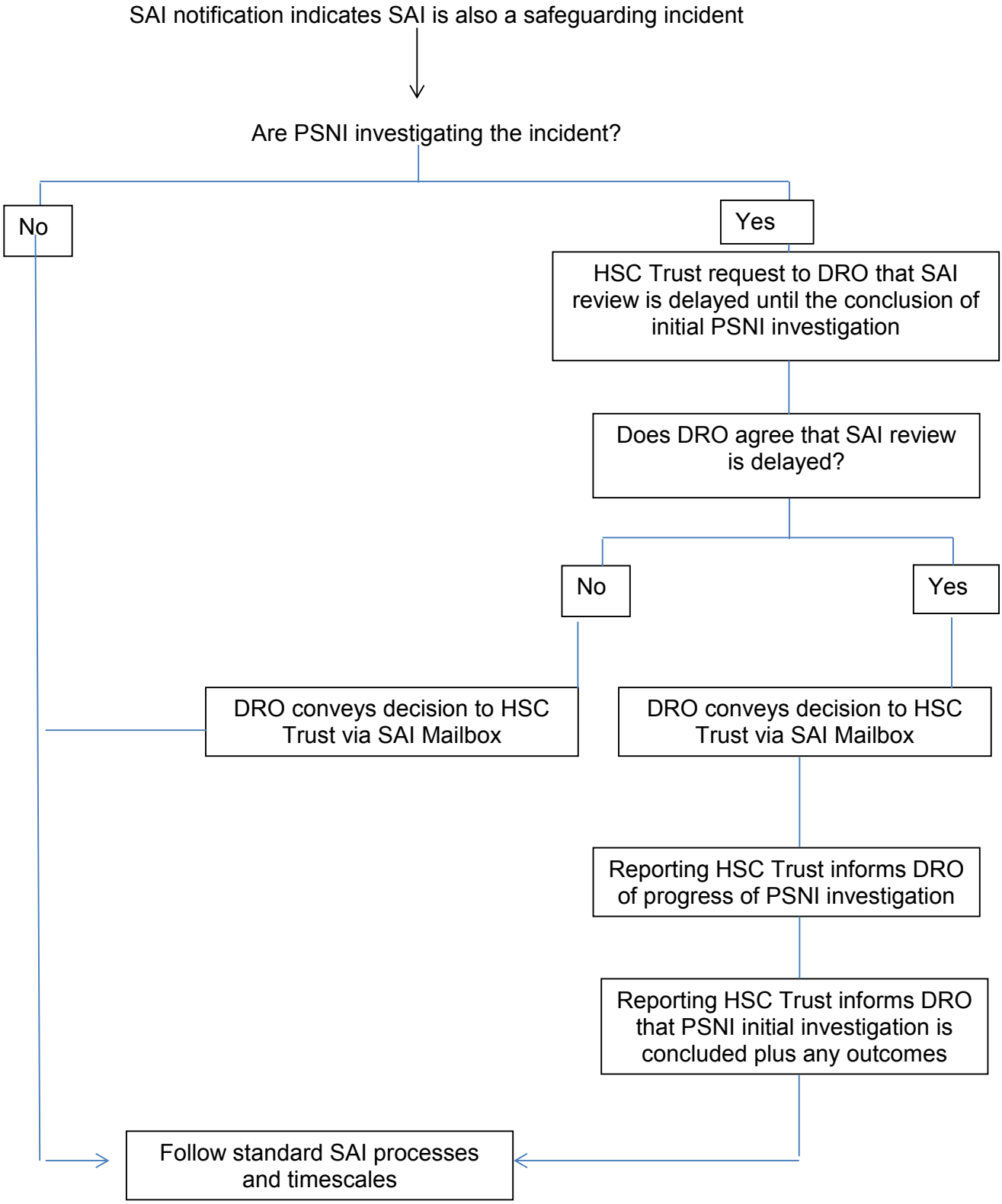
In addition "Achieving Best Evidence: Guidance on interviewing victims and witnesses, the use of special measures and the provision of pre-trial therapy" (revised in 2012), sets out clear protocols for interviewing vulnerable witnesses or victims, whether they are children or adults. This guidance ensures that interviews with vulnerable witnesses and victims are led by specially trained staff, conducted at the victims pace and take place in an environment that is conducive to the needs of the victim.

Clearly, there is an inter-dependency between PSNI and HSC investigations/reviews in complex cases involving multi-agency approaches and protocols. The identification and analysis of learning from these events is likely to be incomplete until both the PSNI and HSC have completed their separate and joint investigations/reviews using the protocols outlined above, and it is unlikely that this can be achieved within the timescales set out for both Level 1 and Level 2 reviews under the SAI procedure.

In such circumstances, the following process should be used:

- Trust report SAI to HSCB using the SAI Notification Form;
- The SAI Notification Form or section 22 of the notification form i.e. 'additional information following initial notification, should indicate the following:
  - The SAI is also a Safeguarding incident
  - PSNI are conducting an investigation of the circumstances surrounding the SAI
  - SAI evaluation will commence at the conclusion of the initial PSNI investigation;
  - Set out the arrangements for keeping the DRO informed of the progress of the PSNI initial investigation;
- If satisfied, the DRO will advise the Trust via the SAI Mailbox that he/she is in agreement with the proposal to delay the SAI review until the conclusion of the initial PSNI investigation;
- The reporting HSC Trust will inform the DRO as soon as the initial PSNI investigation has concluded, along with any outcomes and advise the SAI evaluation has commenced;
- The SAI will continue to be monitored by HSCB Governance team in line with timescales within the Procedure for the Reporting and Follow up of SAIs;
- If the DRO is **not** in agreement with the proposal to delay the SAI review, the reasons for this will be clearly conveyed to the Trust via the SAI Mailbox. Possible reasons for this may include, for example, situations where a criminal incident has occurred on HSC Trust premises but does not involve HSC Trust staff, or an incident involving a service user in their own home and a member of the public is reported to the PSNI by HSC Trust staff.

CHILD AND ADULT SAFEGUARDING AND SAI PROCESSES



SECTION THREE ADDENDUM

ADDENDUM

ADDENDUM 1

A Guide for Health and Social Care Staff

Engagement/Communication with the Service User/Family/Carers following a Serious Adverse Incident

November 2016
Version 1.1

Contents

Notes on the Development of this Guidance

This guidance has been compiled by the Health and Social Care Board (HSCB) and Public Health Agency (PHA) working in collaboration with the Regulation and Quality Improvement Authority (RQIA), the Patient Client Council (PCC) and Health and Social Care (HSC) Trusts.

This guidance has been informed by:

- National Patient Safety Agency (NPSA) Being Open Framework (2009)
- Health Service Executive (HSE) – Open Disclosure National Guidelines (2013)

Please note the following points:

- *The term 'service user' as used throughout this guidance includes patients and clients availing of Health and Social Care Services from HSC organisations and Family Practitioner Services (FPS) and/or services commissioned from the Independent Sector by HSC organisations.*

- *The phrase 'the service user / family' is used throughout this document in order to take account of all types of engagement scenarios, and also includes a carer(s) or the legal guardian of the service user, where appropriate. However, when the service user has capacity, communication should always (in the first instance) be with them (see appendix 1 for further guidance).*

A review / re-evaluation of this guidance will be undertaken one year following implementation.

1.0 Introduction

When an adverse outcome occurs for a service user it is important that the service user / family (as appropriate) receive timely information and are fully aware of the processes followed to review the incident.

The purpose of a Serious Adverse Incident (SAI) review is to understand what occurred and where possible improve care by learning from incidents. Being open about what happened and discussing the SAI promptly, fully and compassionately can help the service user / family cope better with the after-effects and reduce the likelihood of them pursuing other routes such as the complaints process or litigation to get answers to their questions.

It is therefore essential that there is:

- full disclosure of a SAI to the service user / family,
- an acknowledgement of responsibility,
- an understanding of what happened and a discussion of what is being done to prevent recurrence.

Communicating effectively with the service user / family is a vital part of the SAI process. If done well, it promotes person-centred care and a fair and open culture, ultimately leading to continuous improvement in the delivery of HSC services. It is human to make mistakes, but rather than blame individuals, the aim is for all of us to identify and address the factors that contributed to the incident. The service user / family can add valuable information to help identify the contributing factors, and should be integral to the review process, unless they wish otherwise.

2.0 Purpose

This is a guide for HSC staff to ensure effective communication with the service user / family, following a SAI, is undertaken in an open, transparent, informed, consistent and timely manner.

It is important this guidance is read in conjunction with the regional Procedure for Reporting and Follow up of SAIs (November 2016) and any subsequent revisions relating to the SAI process that have or may be issued in the future. This will ensure the engagement process is closely aligned to the required timescales, documentation, review levels etc. *To view the SAI Procedure please follow the link below* http://www.hscboard.hscni.net/download/PUBLICATIONS/policies-protocols-and-guidelines/Procedure-for-the-reporting-and-follow-up-of-SAIs-2016.pdf.

The HSCB Process works in conjunction with all other review processes, statutory agencies and external bodies. Consequently, there may be occasions when a reporting organisation will have reported an incident via another process before or after it has been reported as a SAI. It is therefore important that all existing processes continue to operate in tandem with the SAI procedure and should not be an obstacle to the engagement of the service user / family; nor should an interaction through another process replace engagement through the SAI process.

In that regard, whilst this guidance is specific to 'being open' when engaging with the service user / family following a SAI, it is important HSC organisations are also mindful of communicating effectively with the service user / family when investigating adverse incidents. In these circumstances, organisations should refer to the NPSABeingOpenFramework www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726 which will provide assistance for organisations to determine the level of service user / family engagement when investigating those adverse incidents that do not meet SAI criteria.

The Being Open Framework may also assist organisations with other investigative processes e.g. complaints, litigation, lookback exercises, and any other relevant human resource and/or risk management related policies and procedures.

3.0 Principles of Being Open with the Service User / Family

Being open and honest with the service user / family involves:

- Acknowledging, apologising and explaining that the organisation wishes to review the care and treatment of the service user;
- Explaining that the incident has been categorised as a SAI, and describing the review process to them, including timescales;
- Advising them how they can contribute to the review process, seeking their views on how they wish to be involved and providing them with a leaflet explaining the SAI process (see appendix 2);
- Conducting the correct level of SAI review into the incident and reassuring the service user / family that lessons learned should help prevent the incident recurring;
- Providing / facilitating support for those involved, including staff, acknowledging that there may be physical and psychological consequences of what happened;

- Ensuring the service user / family have details for a single point of contact within the organisation.

It is important to remember that saying sorry is not an admission of liability and is the right thing to do.

The following principles underpin being open with the service user / family following a SAI.

3.1 Acknowledgement

All SAIs should be acknowledged and reported as soon as they are identified. In cases where the service user / family inform HSC staff / family practitioner when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all professionals.

In certain circumstances e.g. cases of criminality, child protection, or SAIs involving theft, fraud, information breaches or data losses that do not directly affect service users; it may not be appropriate to communicate with the service user / family. When a lead professional / review team make a decision, based on a situation as outlined above, or based on a professional's opinion, not to disclose to the service user / family that a SAI has occurred, the rationale for this decision must be clearly documented in the SAI notification form / SAI review checklist that is submitted to the HSCB.

It is expected, the service user / family will be informed that a SAI has occurred, as soon as possible following the incident, for all levels of SAI reviews. In very exceptional circumstances, where a decision is made not to inform the service user / family, this decision must be reviewed and agreed by the review team, approved by an appropriate Director or relevant committee / group, and the decision kept under review as the review progresses. In these instances the HSCB must also be informed:

- **Level 1 reviews - on submission of Review Report and Checklist Proforma**
- **Level 2 and 3 reviews - on submission of the Terms of Reference and Membership of the review team.**

3.2 Truthfulness, timeliness and clarity of communication

Information about a SAI must be given to the service user / family in a truthful and open manner by an appropriately nominated person (see 4.2.2). The service user / family should be provided with an explanation of what happened in a way that considers their individual circumstances, and is delivered openly. Communication should also be timely, ensuring the service user / family is provided with information about what happened as soon as practicable without causing added distress. Note, where a number of service users are involved in one incident, they should all be informed at the same time where possible.

It is also essential that any information given is based solely on the facts known at the time. Staff should explain that new information may emerge as an incident review is undertaken, and that the service user / family will be kept informed, as the review progresses. The service user / family should receive clear information with a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff, and the use of jargon, should be avoided.

3.3 Apology / Expression of Regret

When it is clear, that the organisation / family practitioner is responsible for the harm / distress to the service user, it is imperative that there is an acknowledgement of the incident and an apology provided as soon as possible. Delays are likely to increase the service user / family sense of anxiety, anger or frustration. Relevant to the context of a SAI, the service user / family should receive a meaningful apology – one that is a sincere expression of sorrow or regret for the harm / distress that has occurred as a result of the SAI.

3.4 Recognising the expectations of the Service User / Family

The service user / family may reasonably expect to be fully informed of the facts, consequences and learning in relation to the SAI and to be treated with empathy and respect.

They should also be provided with support in a manner appropriate to their needs. Specific types of service users / families may require additional support (see appendix 1).

In circumstances where the service user / family request the presence of their legal advisor this request should be facilitated. However, HSC staff

should ensure that the legal advisor is aware that the purpose of the report / meeting is not to apportion liability or blame but to learn from the SAI. Further clarification in relation to this issue should be sought from Legal Services.

3.5 Professional Support

HSC organisations must create an environment in which all staff, whether directly employed or independent contractors, are encouraged to report SAIs. Staff should feel supported throughout the incident review process because they too may have been traumatised by being involved. There should be a culture of support and openness with a focus on learning rather than blame.

HSC organisations should encourage staff to seek support where required form relevant professional bodies such as the General Medical Council (GMC), Royal Colleges, the Medical Defence Union (MDU), the Medical Protection Society (MPS), the Nursing and Midwifery Council, the Northern Ireland Association for Social Work (NIASW) and the Northern Ireland Social Care Council (NISCC).

3.6 Confidentiality

Details of a SAI should at all times be considered confidential. It is good practice to inform the service user / family about those involved in the review and who the review report will be shared with.

3.7 Continuity of Care

In exceptional circumstances, the service user / family may request transfer of their care to another facility; this should be facilitated if possible to do so. A member of staff should be identified to act as a contact person for the service user / family to keep them informed of their on-going treatment and care.

4.0 Process

Being open with the service user / family is a process rather than a one-off event. There are 5 stages in the engagement process:

- Stage 1 – Recognition
- Stage 2 - Communication
- Stage 3 – Initial Meeting
- Stage 4 – Follow up Discussions

- Stage 5 – Process Completion

The duration of this process depends on the level of SAI review being undertaken and the associated timescales as set out in the Procedure for the Reporting and Follow up of SAIs (2013).

4.1 Stage 1 - Recognition

As soon as the SAI is identified, the priority is to prevent further harm / distress. The service user / family should be notified that the incident is being reviewed as a SAI.

4.1.1 Preliminary Discussion with the Service User / Family

On many occasions it will be at this stage when the lead professional / family practitioner responsible for the care of the service user will have a discussion with the service user / family, advising of the need to review the care and treatment. This preliminary discussion (which could be a telephone call) will be in addition to the formal initial meeting with the service user / family (see 4.3).

A Level 1 review may not require the same level of engagement as Levels 2 and 3 therefore the preliminary discussion may be the only engagement with service user / family prior to communicating findings of the review, provided they are content they have been provided with all information.

There may be occasions when the service user / family indicate they do not wish to engage in the process. In these instances the rationale for not engaging further must be clearly documented.

4.2 Stage 2 – Communication

4.2.1 Timing of Initial Communication with the Service User / Family

The initial discussion with the service user / family should occur as soon as possible after recognition of the SAI. Factors to consider when timing this discussion include:

- service user's health and wellbeing;
- service user / family circumstances, preference (in terms of when and where the meeting takes place) and availability of key staff *(appendix 1 provides guidance on how to manage different categories of service user / family circumstances);*

4.2.2 Choosing the individual to communicate

The person[7] nominated to lead any communications should:

- Be a senior member of staff with a comprehensive understanding of the facts relevant to the incident;
- Have the necessary experience and expertise in relation to the type of incident;
- Have excellent interpersonal skills, including being able to effectively engage in an honest, open and transparent manner, avoiding excessive use of jargon;
- Be willing and able to offer a meaningful apology / expression of regret, reassurance and feedback.

If required, the lead person communicating information about the SAI should also be able to nominate a colleague who may assist them with the meeting and should be someone with experience or training in communicating with the service user / family.

The person/s nominated to engage could also be a member/s of the review team (if already set up).

[7] *FPS SAIs involving FPS this will involve senior professionals/staff from the HSCB Integrated Care Directorate.*

4.3 Stage 3 - Initial Meeting with the Service User / Family

The initial discussion is the first part of an on-going communication process. Many of the points raised here should be expanded on in subsequent meetings with the service user / family.

4.3.1 Preparation Prior to the Initial Meeting

- The service user / family should be given the leaflet - What I Need to Know About a SAI (see appendix 2);
- Share with the service user / family what is going to be discussed at the meeting and who will be in attendance.

4.3.2 During the Initial Meeting

The content of the initial meeting with the service user / family should cover the following:

- Welcome and introductions to all present;
- An expression of genuine sympathy or a meaningful apology for the event that has occurred;
- The facts that are known to the multidisciplinary team;
- Where a service user has died, advising the family that the coroner has been informed (where there is a requirement to do so) and any other relevant organisation/body;
- The service user / family are informed that a SAI review is being carried out;
- Listening to the service user's / families understanding of what happened;
- Consideration and formal noting of the service user's / family's views and concerns;
- An explanation about what will happen next in terms of the SAI review, findings, recommendations and learning and timescales;
- An offer of practical and emotional support for the service user / family. This may involve getting help from third parties such as charities and voluntary organisations, providing details of support from other organisations, as well as offering more direct assistance;
- Advising who will be involved in the review before it takes place and who the review report will be shared with;
- Advising that all SAI information will be treated as confidential.

If for any reason it becomes clear during the initial discussion that the service user / family would prefer to speak to a different health / social

care professional, these wishes should be respected, and the appropriate actions taken.

It is important during the initial meeting to try to avoid any of the following:

- Speculation;
- Attribution of blame;
- Denial of responsibility;
- Provision of conflicting information from different health and social care individuals.

It should be recognised that the service user / family may be anxious, angry and frustrated, even when the meeting is conducted appropriately. It may therefore be difficult for organisations to ascertain if the service user / family have understood fully everything that has been discussed at the meeting. It is essential however that, at the very least, organisations are assured that the service user / family leave the meeting fully aware that the incident is being reviewed as a SAI, and knowing the organisation will continue to engage with them as the review progresses, so long as the service user / family wish to engage.

Appendix 3 provides examples of words / language which can be used during the initial discussion with the service user / family.

4.4 Stage 4 – Follow-up Discussions

Follow-up discussions are dependent on the needs and wishes of the service user / family.

The following guidelines will assist in making the communication effective:

- The service user / family should be updated if there are any delays and the reasons for the delays explained;
- Advise the service user / family if the incident has been referred to any other relevant organisation / body;
- Consideration is given to the timing of the meetings, based on both the service users / families health, personal circumstances and preference on the location of the meeting, e.g. the service users / families home;
- Feedback on progress to date, including informing the service user / family of the Terms of Reference of the review and membership of the review panel (for level 2 and 3 SAI reviews);
- There should be no speculation or attribution of blame. Similarly, the health or social care professional / senior manager communicating the SAI must not criticise or comment on matters outside their own experience;
- A written record of the discussion is kept and shared with the service user / family;
- All queries are responded to appropriately and in a timely way.

4.5 Stage 5 – Process Completion

4.5.1 Communicating findings of review / sharing review report

Feedback should take the form most acceptable to the service user / family. Communication should include:

- a repeated apology / expression of regret for the harm / distress suffered;
- the chronology of clinical and other relevant factors that contributed to the incident;
- details of the service users / families concerns;
- information on learning and outcomes from the review
- Service user / family should be assured that lines of communication will be kept open should further questions arise at a later stage and a single point of contact is identified.

It is expected that in most cases there will be a complete discussion of the findings of the review and that the final review report will be shared with

the service user / family. In some cases however, information may be withheld or restricted, for example:

- Where communicating information will adversely affect the health of the service user / family;
- Where specific legal/coroner requirements preclude disclosure for specific purposes;
- If the deceased service users health record includes a note at their request that he/she did not wish access to be given to his/her family.

Clarification on the above issues should be sought form Legal Services.

There may also be instances where the service user / family does not agree with the information provided, in these instances Appendix 1 (section 1.8) will provide additional assistance.

In order to respond to the timescales as set out in the Procedure for the Reporting and Follow up of SAIs (November 2016) organisations may not have completed stage 5 of the engagement process prior to submission of the review report to HSCB. In these instances, organisations must indicate on the SAI review checklist, submitted with the final review report to the HSCB, the scheduled date to meet with the service user / family to communicate findings of review / share review report.

4.5.2 Communicating Changes to Staff

It is important that outcomes / learning is communicated to all staff involved and to the wider organisation as appropriate.

4.6 Documentation

Throughout the above stages it is important that discussions with the service user / family are documented and should be shared with the individuals involved.

Documenting the process is essential to ensure continuity and consistency in relation to the information that has been relayed to the service user / family.

Documentation which has been produced in response to a SAI may have to be disclosed later in legal proceedings or in response to a freedom of information application. It is important that care is taken in all communications and documents stating fact only.

Appendix 4 provides a checklist which organisations may find useful as an aide memoire to ensure a professional and standardised approach.

5.0 Supporting Information and Tools

In addition to this guidance, supporting tools have been developed to assist HSC organisations with implementing the actions of the NPSA's Being Open Patient Safety Alert.

Training on being open is freely available through an e-learning tool for all HSC organisations.

Information on all these supporting tools can be found at: www.**npsa**.nhs.uk/**beingopen** and www.nrls.**npsa**.nhs.uk/**beingopen**/.

Guidance on sudden death and the role of bereavement co-ordinators in Trusts can be found at:
http://webarchive.proni.gov.uk/20120830110704/http://www.dhsspsni.gov.uk/sudden-death-guidance.pdf

List of Acronyms and Abbreviations

FPS	-	Family Practitioner Services
GMC	-	General Medical Council
HSC	-	Health and Social Care
HSCB	-	Health and Social Care Board
HSE	-	Health Service Executive
MDU	-	Medical Defence Union
MPS	-	Medical Protection Society
NIASW	-	Northern Ireland Association for Social Work
NISCC	-	Northern Ireland Social Care Council
NMC	-	Nursing and Midwifery Council
NPSA	-	National Patient Safety Agency
PCC	-	Patient Client Council
PHA	-	Public Health Agency
RC	-	Royal colleges
RCA	-	Root Cause Analysis
RQIA	-	Regulation and Quality Improvement Authority
SAI	-	Serious Adverse Incident
SEA	-	Significant Event Audit

Appendix 1

Particular Service user Circumstances

The approach to how an organisation communicates with a service user / family may need to be modified according to the service user's personal circumstances.

The following gives guidance on how to manage different categories of service user circumstances.

1.1 When a service user dies

When a SAI has resulted in a service users death, the communication should be sensitive, empathetic and open. It is important to consider the emotional state of bereaved relatives or carers and to involve them in deciding when it is appropriate to discuss what has happened.

1.2 Children

The legal age of maturity for giving consent to treatment is 16 years old. However, it is still considered good practice to encourage young people of this age to involve their families in decision making.

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the communication process after a SAI.

The opportunity for parents / guardians to be involved should still be provided unless the child expresses a wish for them not to be present. Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents / guardians alone or in the presence of the child. In these instances the parents' / guardians' views on the issue should be sought.

1.3 Service users with mental health issues

Communication with service users with mental health issues should follow normal procedures unless the service user also has cognitive impairment (see1.4 Service users with cognitive impairments).

The only circumstances in which it is appropriate to withhold SAI information from a service user with mental health issues is when advised to do so by a senior clinician who feels it would cause adverse psychological harm to the service user. However, such circumstances are rare and a second opinion may be required to justify withholding information from the service user.

In most circumstances, it is not appropriate to discuss SAI information with a carer or relative without the permission of the service user, unless in the public interest and / or for the protection of third parties.

1.4 Service users with cognitive impairment

Some individuals have conditions that limit their ability to understand what is happening to them.

In these cases communication would be conducted with the carer / family as appropriate. Where there is no such person, the clinicians may act in the service users best interest in deciding who the appropriate person is to discuss the SAI with.

1.5 Service users with learning disabilities

Where a service user / family has difficulties in expressing their opinion verbally, every effort should be made to ensure they can use or be facilitated to use a communication method of their choice. An advocate / supporter, agreed on in consultation with the service user, should also be identified. Appropriate advocates / supporters may include carer/s, family or friends of the service user or a representative from the Patient Client Council (PCC).

1.6 Service users with different language or cultural considerations

The need for translation and advocacy services and consideration of special cultural needs must be taken into account when planning to discuss SAI information. Avoid using 'unofficial translators' and / or the service users family or friends as they may distort information by editing what is communicated.

1.7 Service users with different communication needs

Service users who have communication needs such as hearing impaired, reduced vision may need additional support.

1.8 Service users who do not agree with the information provided

Sometimes, despite the best efforts the service user/family/carer may remain dissatisfied with the information provided. In these circumstances, the following strategies may assist:

- Facilitate discussion as soon as possible;
- Write a comprehensive list of the points that the service user / family disagree with and where appropriate reassure them you will follow up these issues.
- Ensure the service user / family has access to support services;
- Offer the service user / family another contact person with whom they may feel more comfortable.
- Use an acceptable service user advocate e.g. PCC or HSC layperson to help identify the issues between the HSC organisation and the service user / family and to achieve a mutually agreeable solution;

There may be occasions despite the above efforts the service user/family/carer remain dissatisfied with the HSC organisation's attempts to resolve their concerns. In these exceptional circumstances, the service user/family/carer through the agreed contact person, should be advised of their right to approach the Northern Ireland Public Services Ombudsman (NIPSO). In doing so, the service user/family requires to be advised by the HSC organisation that the internal procedure has concluded (within two weeks of this process having been concluded), and that the service user/family should approach the NIPSO within six months of this notification.

The contact details for the NIPSO are: Freephone 0800 34 34 34 or Progressive House, 33 Wellington Place, Belfast, BT1 6HN.

1.9 Service Users who do not wish to participate in the engagement process

It should be documented if the service user does not wish to participate in the engagement process.

Appendix 2

Health and Social Care Board

Public Health Agency

What I need to know about a Serious Adverse Incident

Information for Service Users, Family Members and Carers

Insert Name of Organisation

This leaflet is written for people who use Health and Social Care (HSC) services and their families.

**The phrase service user / family member and carer is used throughout this document in order to take account of all types of engagement scenarios. However, when a service user has capacity, communication should always (in the first instance) be with them.*

Introduction

Events which are reported as Serious Adverse Incidents (SAIs) help identify learning even when it is not clear something went wrong with treatment or care provided.

When things do go wrong in health and social care it is important that we identify this, explain what has happened to those affected and learn lessons to ensure the same thing does not happen again. SAIs are an important means to do this. Areas of good practice may also be highlighted and shared, where appropriate.

What is a Serious Adverse Incident?

A SAI is an incident or event that must be reported to the Health and Social Care Board (HSCB) by the organisation where the SAI has occurred. It may be:

- an incident resulting in serious harm;
- an unexpected or unexplained death;
- a suspected suicide of a service user who has a mental illness or disorder;
- an unexpected serious risk to wellbeing or safety, for example an outbreak of infection in hospital;

A SAI may affect services users, members of the public or staff.

Never events are serious patient safety incidents that should not occur if the appropriate preventative measures have been implemented by healthcare providers. A small number of SAIs may be categorised as never events based on the Department of Health Never Events list.

SAIs, including never events, occurring within the HSC system are reported to the HSCB. You, as a service user / family member / carer, will be informed where a SAI and/or never event has occurred relating to treatment and care provided to you by the HSC.

Can a complaint become a SAI?

Yes, if during the follow up of a complaint the (**insert name of organisation)** identifies that a SAI has occurred it will be reported to the HSCB. You, as a service user / family member and carer will be informed of this and updated on progress regularly.

How is a SAI reviewed?

Depending on the circumstance of the SAI a review will be undertaken. This will take between 8 to 12 weeks depending on the complexity of the case. If more time is required you will be kept informed of the reasons.

The (**insert name of organisation**) will discuss with you how the SAI will be reviewed and who will be involved. The (**insert name of organisation**) will welcome your involvement if you wish to contribute.

Our goal is to find out what happened, why it happened and what can be done to prevent it from happening again and to explain this to those involved.

How is the service user or their family/carer involved in the review?

An individual will be identified to act as your link person throughout the review process. This person will ensure as soon as possible that you:

- Are made aware of the incident, the review process through meetings / telephone calls;
- Have the opportunity to express any concerns;
- Know how you can contribute to the review, for example share your experiences;
- Are updated and advised if there are any delays so that you are always aware of the status of the review;
- Are offered the opportunity to meet and discuss the review findings;
- Are offered a copy of the review report;

- Are offered advice in the event that the media make contact.

What happens once the review is complete?

The findings of the review will be shared with you. This will be done in a way that meets your needs and can include a meeting facilitated by **(insert name of organisation)** staff that is acceptable to you.

How will learning be used to improve safety?

By reviewing a SAI we aim to find out what happened, how and why. By doing this we aim to identify appropriate actions which will prevent similar circumstances occurring again.

We believe that this process will help to restore the confidence of those affected by a SAI.

For each completed review:

- Recommendations may be identified and included within an action plan;
- Any action plan will be reviewed to ensure real improvement and learning.

We will always preserve your confidentiality while also ensuring that opportunities to do things better are shared throughout our organisation and the wider health and social care system. Therefore as part of our process to improve quality and share learning, we may share the anonymised content of the SAI report with other HSC organisations'

Do families get a copy of the report?

Yes, a copy of the review report will be shared with service users and/or families with the service user's consent.

If the service user has died, families/carers will be provided with a copy of the report and invited to meet with senior staff.

Who else gets a copy of the report?

The report is shared with the Health and Social Care Board (HSCB) and Public Health Agency (PHA). Where appropriate it is also shared with the Coroner.

The Regulation and Quality Improvement Authority (RQIA) have a statutory obligation to review some incidents that are also reported under the SAI procedure. In order to avoid duplication of incident notification and review, RQIA work in conjunction with the HSCB / PHA with regard to the review of certain categories of SAI including the following:

- All mental health and learning disability SAIs reportable to RQIA under Article 86.2 of the Mental Health (NI) Order 1986.

- Any SAI that occurs within the regulated sector for example a nursing, residential or children's home (whether statutory or independent) for a service that has been commissioned / funded by a HSC organisation.

In both instances the names and personal details that might identify the individual are removed from the report. The relevant organisations monitor the (**insert name of organisation)** to ensure that the recommendations have been implemented. The family may wish to have follow up / briefing after implementation and if they do this can be arranged by their link person within the (**insert name of organisation**).

All those who attended the review meeting are given a copy of the anonymised report. Any learning from the review will be shared as appropriate with relevant staff/groups within the wider HSC organisations.

Further Information

If you require further information or have comments regarding this process you should contact the nominated link person - name and contact details below:

Your link person is ……..…….

Your link person's job title is……..…..

Contact number …….

Hours of work……..……

Prior to any meetings or telephone call you may wish to consider the following:

Think about what questions and fears/concerns you have in relation to:

(a) What has happened?
(b) Your condition / family member condition
(c) On-going care

You could also:

- Write down any questions or concerns you have;
- Think about who you would like to have present with you at the meeting as a support person;
- Think about what things may assist you going forward;
- Think about which healthcare staff you feel should be in attendance at the meeting.

Patient and Client Council

The Patient Client Council offers independent, confidential advice and support to people who have a concern about a HSC Service. This may include help with writing letters, making telephone calls or supporting you at meetings, or if you are unhappy with recommendations / outcomes of the reviews.

Contact details:
Free phone number: 0800 917 0222

Appendix 3

Examples of communication which enhances the effectiveness of being open	
Stage of Process	**Sample Phrases**
Acknowledgement	"We are here to discuss the harm that you have experienced/the complications with your surgery/treatment" "I realise that this has caused you great pain/distress/anxiety/worry" "I can only imagine how upset you must be" "I appreciate that you are anxious and upset about what happened during your surgery – this must have come as a big shock for you" "I understand that you are angry/disappointed about what has happened" "I think I would feel the same way too"
Sorry	"I am so sorry this has happened to you" "I am very sorry that the procedure was not as straightforward as we expected and that you will have to stay in hospital an extra few days for observation" "I truly regret that you have suffered xxx which is a recognised complication associated with the x procedure/treatment." "I am so sorry about the anxiety this has caused you" "A review of your case has indicated that an error occurred – we are truly sorry about this"
Story	**Their Story** "Tell me about your understanding of your condition" "Can you tell me what has been happening to you" "What is your understanding of what has been happening to you" **Your understanding of their Story: (Summarising)** "I understand from what you said that" xxx "and you are very upset and angry about this"

	Is this correct? (i.e. summarise their story and acknowledge any emotions/concerns demonstrated.) "Am I right in saying that you……." **Your Story** "Is it ok for me to explain to you the facts known to us at this stage in relation to what has happened and hopefully address some of the concerns you have mentioned? "Do you mind if I tell you what we have been able to establish at this stage?" "We have been able/unable to determine at this stage that……." "We are not sure at this stage about exactly what happened but we have established that ……. We will remain in contact with you as information unfolds" "You may at a later stage experience xx if this happens you should ……"
Inquire	"Do you have any questions about what we just discussed?" "How do you feel about this?" "Is there anything we talked about that is not clear to you?"
Solutions	"What do you think should happen now?" "Do you mind if I tell you what I think we should do?" "I have reviewed your case and this is what I think we need to do next" "What do you think about that?" "These are your options now in relation to managing your condition, do you want to have a think about it and I will come back and see you later?" "I have discussed your condition with my colleague Dr x we both think that you would benefit from xx. What do you think about that?"
Progress	"Our service takes this very seriously and we have already started a review into the incident to see if we can find out what caused it to happen" "We will be taking steps to learn from this event so that we can

	try to prevent it happening again in the future” “I will be with you every step of the way as we get through this and this is what I think we need to do now” “We will keep you up to date in relation to our progress with the review and you will receive a report in relation to the findings and recommendations of the review team” “Would you like us to contact you to set up another meeting to discuss our progress with the review?” “I will be seeing you regularly and will see you next in….days/weeks. “You will see me at each appointment” “Please do not hesitate to contact me at any time if you have any questions or if there are further concerns – you can contact me by……” “If you think of any questions write them down and bring them with you to your next appointment.” “Here are some information leaflets regarding the support services we discussed – we can assist you if you wish to access any of these services”

Appendix 4

Organisations may find this checklist useful an aide memoire to ensure a professional and standardised approach

Before, During and After Communication / Engagement Documentation Checklist

BEFORE	***Note taking***
Service users full name	
Healthcare record number	
Date of birth	
Date of admission	
Diagnosis	
Key HSC professional(s) involved in service user's care	
Date of discharge (if applicable)	
Date of SAI	
Description of SAI	
Outcome of SAI	
Agreed plan for management of SAI	
Agreed professional to act as contact person with the service user / family	

Service user / family informed incident is being reviewed as a SAI: • Date • By Whom • By what means (telephone call / letter / in person)	
Date of first meeting with the service user / family	
Location of first meeting (other details such as room booking, arrangements to ensure confidentiality if shared ward etc)	
Person to be responsible for note taking identified	
Person Nominated to lead communications identified	
Colleague/s to assist nominated lead	
Other staff identified to attend the disclosure meeting	
Anticipated service user / family concerns queries	
Meeting agenda agreed and circulated	
Additional support required by the service user / family, if any?	
The service user / family has been advised to bring a support person to the meeting?	
The service user consented to the sharing of information with others such as designated family members / support person?	

It has been established that the service user / family requires an interpreter? If yes, provide details of language and arrangements that have been or to be made.	

Signature: _____

***Date*:** _____

DURING ***Note taking***

There has been an acknowledgment of the SAI in relation to the service user / family experience.	
An apology / expression of regret provided	
The service user / family was provided with factual information regarding the adverse event	
The service user / family understanding of the SAI was established	
The service user / family was provided with the opportunity to: - Tell their story - Voice their concerns and - Ask questions	
The next steps in relation to the service user's on-going care were agreed and the service user was involved in the decisions made.	
The service user / family was provided with information in relation to the supports available to them.	
Reassurance was provided to the service user / family in relation to the on-going communication of facts when the information has been established and available – continuity provided.	
Next meeting date and location agreed	

Signature: _____

***Date*:** _____

AFTER

Circulate minutes of the meeting to all relevant parties for timely verification.
Follow through on action points agreed.
Continue with the incident review.
Keep the service user included and informed on any progress made – organise further meetings.
Draft report to be provided to the service user in advance of the final report (if agreed within review Terms of Reference that the draft report is to be shared with the service user prior to submission to HSCB/PHA).
Offer a meeting with the service user to discuss the review report and allow for amendments if required.
Follow through on any recommendations made by the incident review team.
Closure of the process is mutually agreed.
When closure / reconciliation was not reached the service user was advised of the alternative courses of action which are open to them i.e the complaints process.

Signature: _____

***Date*:** _____

From the Head of Safety Strategy Unit
Brian Godfrey

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Reinstatement of HSC (SQSD) 24/19 Regional Operational Policy Templates

For Action:
Chief Executives HSC Trusts
Chief Executive HSCB/PHA
Chief Executive RQIA
Chief Executive, NIMDTA
Chief Executive, NIAS

Implementation
30th June 2020

Date of Issue: 21st January 2020

Dear Colleagues

Circular HSC (SQSD) 24/19 was issued on 27th August 2019 covering the availability of a suite of regional operational policy templates developed by HSC governance leads for regional adoption by HSC Trusts.

In September 2019 the circular was suspended to allow further refinement of the MOU Investigating Patient Safety Incidents and ensure clarity in respect to the status of the Being Open template in respect to the Duty of Candour IHRD workstream.

This work has now been completed and clarification provided therefore the suspension of the circular has been lifted.

I have attached the following policies and we would recommend that HSC Trusts should work towards adoption of these templates to match local circumstances by 30th June 2020.

- Adverse Incident Policy;
- Policy on Early Alerts (updated to include recent DoH circular);
- Policy on Being Open;
- Policy on RIDDOR Incidents;
- Supporting Staff involved in Incidents, Claims and Complaints;
- Policy on MOU investigating Patient Safety Incidents

Any enquiries about the content of this circular should be addressed to me at:

Safety Strategy Unit
Department of Health
Room D2.4, Castle Buildings
BELFAST, BT4 3SQ
Tel: [redacted]
[redacted]

Yours sincerely

Brian Godfrey

From the Deputy Chief Medical Officer
Dr Lourda Geoghegan

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Reference: HSC (SQSD) 7/21

Date of Issue: 20 August 2021

HSC REVISED NEVER EVENTS LIST

For Action:

Chief Executives of HSC Trusts
Chief Executives HSCB and PHA
Chief Executive RQIA

For Information:
Distribution as listed at the end of this circular.

Related documents
https://www.england.nhs.uk/publication/never-events/

Superseded documents
HSC (SQSD) 56/16
HSC (SQSD) 36/18

Implementation
Immediate

DoH Safety and Quality Circulars including Patient Safety Alerts can be accessed on:
https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

Dear Colleagues

SUMMARY

The purpose of this circular is to advise you of the revised HSC 'Never Events' List.

ACTION

Chief Executives of HSC Trusts should:

- Disseminate this circular to all relevant Trust staff for information.
- Ensure that any Never Events are reported to the HSCB/PHA in line with Serious Adverse Incident (S) guidance.

Chief Executives, HSCB and PHA should:

- Disseminate this circular to all relevant HSCB/PHA staff for consideration through the normal HSCB/PHA processes for assuring implementation of safety and quality alerts.
- Monitor the reporting of Never Events via the SAI process.
- Include information on Never Events (including numbers) in the six-monthly SAI Learning Reports published in the HSCB/PHA internet site

Chief Executive, NIMDTA and NIPEC should:

- Disseminate this circular to doctors and dentists in training in all relevant specialities.

Chief Executive RQIA should:

- Disseminate this circular to all relevant independent providers.

BACKGROUND

Sir Liam Donaldson in his report "The Right Time, the Right Place" made a number of recommendations aimed at improving the safety, quality and effectiveness of the delivery of health and social care services in Northern Ireland. Recommendation 6 of the Donaldson Report advises that the system for serious adverse incident and adverse incident reporting should be retained but modified through the creation of a limited list of Never Events.

This recommendation has been implemented through the adoption of a HSC Never Events list containing all current categories listed in the NHS England & Improvement (E&I) Never Event List that applies in England.

The NHS E&I list was amended in England in February 2021 with the updating of the category relating to 'wrong site surgery' - to exclude the removal of wrong teeth. The rational for this change being that the systemic barriers to prevent the removal of wrong teeth are considered not to be strong enough to prevent these events from occurring e.g. lack of standardisation in types of tooth notation and difficulties with site marking.

The revised List of Never Events List for the HSC in Northern Ireland, including details of existing guidance to prevent each Never Event, is attached at **Annex 1**.

It is important, in the spirit of transparency and candour, that when staff are engaging with service users, families and carers as part of the SAI process, that in addition to advising an individual of an SAI (as it has occurred), they should also be told if the SAI is a Never Event.

Any enquiries about the content of this circular should be addressed to:

David Wilson
Safety Strategy Unit
Department of Health
Room D2.4
Castle Buildings
Stormont
BELFAST
BT4 3SQ

[redacted]

Yours sincerely

Dr Lourda Geoghegan
Deputy Chief Medical Officer

Distributed for Information to:

Executive Medical Director/Director of Public Health, PHA
Director of Nursing and Allied Health Professions, PHA
Director of Performance Management & Service Improvement, HSCB
Chief Executive, BSO
Safety and Quality Alerts Team, HSC Board
Prof Donna Fitzsimons, Head of Nursing & Midwifery, QUB
Prof Pascal McKeown, Head of Medical School, QUB
Dr Neil Kennedy, Acting Director of Centre for Medical Education, QUB
Prof Carmel Hughes, Head of School of Pharmacy QUB
Prof Sonja McIlfatrick, Head of School of Nursing, UU
Prof Paul McCarron, Head of Pharmacy School, UU
Chief Executive, NIPEC
Staff Tutor of Nursing, Open University
Director, Safety Forum
NI Centre for Pharmacy Learning and Development
Clinical Education Centre
NI Royal College of Nursing

Annex 1

HSC NEVER EVENTS LIST MAY 2021

NEVER EVENT	RELATED INFORMATION	RELATED NHS/NRLS GUIDANCE	RELATED SAFETY, NICE & NIAIC GUIDANCE
1. Wrong site surgery	An invasive procedure[1] performed on the wrong patient or at the wrong site (e.g. wrong knee, eye, and limb). The incident is detected at any time after the start of the procedure. **Includes:** Interventions that are considered to be surgical but may be done outside a surgical environment – for example, wrong site block (including blocks for pain relief), biopsy, interventional radiology procedure, cardiology procedure, drain insertion and line insertion (e.g. peripherally inserted central catheter (PICC)/ Hickman lines). **Excludes:** • removal of wrong teeth • local anaesthetic blocks for dental procedures (exclusion added May 2019 • interventions where the wrong site is selected because the patient has	Safer Practice Notice – Standardising Wristbands improves patient safety, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824 Patient Safety Alert – WHO Surgical Safety Checklist, 2009, available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/ -Standards for providing a 24 hour interventional radiology service, 2008, The Royal College of Radiologists. Available at http://www.rcr.ac.uk/docs/radiology/pdf/Stand_24hr_IR_provision.pdf National safety standards for invasive procedures (NatSSIPs) (2015).	HSC (SQSD) 16/08 National Patient Safety Agency: Safer Practice Notice 24: Standardising Wristbands improves patient safety Learning Communication 5/09 Risk to patient safety of not using the H+C Number as the regional identifier for all patients and clients HSS (MD) 18/09 Safer Surgery Saves Lives

[1] The start of an invasive procedure is when a patient's anatomy begins to be permanently altered. For example, this is when the first incision is made that will scar the patient and take time to heal and recover from.

	unknown/unexpected anatomical abnormalities; these should be documented in the patient's notes • wrong level spinal surgery* • wrong site surgery due to incorrect laboratory reports/results or incorrect referral letters • Contraceptive hormone implant in the wrong arm. *Excluded from the current list while NHS Improvement works with the relevant professional organisations to ensure development of robust national barriers to prevent this incident. **Setting:** All patients receiving HSC funded care.	• Patient Safety Alert – Supporting the introduction of the national safety standards for invasive procedures (2015).	
2. Wrong implant/prosthesis	Placement of an implant/prosthesis different from that specified in the procedural plan, either before or during the procedure. The incident is detected any time after the implant/prosthesis is placed in the patient. **Excludes:** • placed implant/prosthesis is intentionally different from that specified in the surgical plan,	Safer Practice Notice – Standardising Wristbands improves patient safety, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824 Patient Safety Alert – WHO Surgical Safety Checklist, 2009, available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/	HSC (SQSD) 16/08 National Patient Safety Agency: Safer Practice Notice 24: Standardising Wristbands improves patient safety Learning Communication 5/09 Risk to patient safety of not using the H+C Number as the regional identifier for all patients and clients

	based on clinical judgement at the time of the procedure • specified implant/prosthesis is placed as planned but later found to be suboptimal • implant/prosthesis is different from the one specified due to incorrect preprocedural measurements or incorrect interpretation of the preprocedural data – for example, wrong intraocular lens placed due to wrong biometry or using wrong dataset from correct biometry. **Includes:** ·implantation of an intrauterine contraceptive device different from the one in the procedural plan **Setting:** All healthcare premises.	National safety standards for invasive procedures (NatSSIPs) (2015). Patient Safety Alert – Supporting the introduction of the national safety standards for invasive procedures (2015).	HSS (MD) 18/09 Safer Surgery Saves Lives
3. Retained foreign object post-procedure	Retention of a foreign object in a patient after a surgical/invasive procedure. 'Surgical/invasive procedure' includes interventional radiology, cardiology, interventions related to vaginal birth and interventions performed outside of the surgical environment e.g. central line placement in ward areas	Reducing the risk of retained swabs after vaginal birth and perineal suturing, 2010 available at http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=74113 Reducing the risk of retained throat packs after surgery, 2009, available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59853	HSC (SQSD) 16/08 National Patient Safety Agency: Safer Practice Notice 24: Standardising Wristbands improves patient safety Learning Communication 5/09 Risk to patient safety of not using the H+C Number as the regional identifier for all patients and clients

	‘Foreign object’ includes any items that should be subject to a formal counting /checking process at the commencement of the procedure and a counting /checking process before the procedure is completed (such as swabs, needles, instruments and guide wires) **except where:** Items are inserted any time before the procedure that are not subject to the formal counting/checking process, with the intention of removing them during the procedure Items are inserted during the procedure that are subject to the counting/ checking process, but are intentionally retained after completion of the procedure, with removal planned for a later time or date and clearly recorded in the patients notes Items are known to be missing prior to the completion of the procedure and may be within the patient (e.g. screw fragments, drill bits) but where further action to locate and/or retrieve would be impossible or be more damaging than retention	National safety standards for invasive procedures (NatSSIPs) (2015). • Patient Safety Alert – Supporting the introduction of the national safety standards for invasive procedures (2015).	HSS (MD) 18/09 Safer Surgery Saves Lives NICE CG190: Intrapartum care http://www.nice.org.uk/guidance/cg190

4. Mis – selection of a strong potassium containing solution	Mis - selection refers to: • When a patient intravenously receives a strong potassium solution rather than an intended different medication **Setting:** All patients receiving HSC funded care.	Patient safety alert – Potassium chloride concentrate solutions, 2002 (updated 2003), available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59882	HSC (SQSD) 34/14 Risk of death or serious harm from accidental ingestion of potassium permanganate preparations NICE CG174: Intravenous Fluid Therapy in Adults in Hospital (**NOTE NI Caveats**)http://www.nice.org.uk/guidance/cg174 NICE Quality Standard 66: IV Fluid Therapy in Adults http://www.nice.org.uk/guidance/qs66 NICE CG130: Hyperglycaemia in acute coronary syndromes https://www.nice.org.uk/guidance/cg130 NICE CG84: Diarrhoea and vomiting in children http://www.nice.org.uk/guidance/cg84

			NICE CG99: Constipation in children and young people http://www.nice.org.uk/guidance/cg99 NICE CG32: Nutritional support in adults http://www.nice.org.uk/guidance/cg32
5. Wrong route administration of medication	The patient receives one of the following: • Intravenous chemotherapy administered via the intrathecal route • Oral/enteral medication or feed/flush administered by any parenteral route • Intravenous administration of a medicine intended to be administered via the epidural route * During the transition period for the introduction of NRFit™ devices, the 'intravenous administration of a medicine intended to be administered by the epidural route' cannot be considered a Never Event. An update will be provided when this period ends.	Patient Safety Alert NPSA/2007/19 - Promoting safer measurement and administration of liquid medicines via oral and other enteral routes, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59808 Patient Safety Alert NPSA/2007/21, Safer practice with epidural injections and infusions, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59807	HSC (SQSD) 61/08 Using Vinca Alkaloid Minibags HSC (SQSD) 85/09 Minimising risks of mismatching spinal, epidural and regional devices HSC (SQSD) 85/09 Addendum 1 HSC (SQSD) 6/11Minimising risks of mismatching spinal, epidural and regional devices with incompatible connectors HSC (SQSD) 50/08 Promoting safer measurement and

	Setting: All patients receiving NHS funded care.		administration of liquid medicines via oral and other enteral routes HSC (SQSD) 28/07 Safer practice with epidural injections and infusions HSC (SQSD)28/17 Resources to support safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures, and delivery of regional blocks NICE CG55: Intrapartum Care https://www.nice.org.uk/guidance/cg55 NICE Interventional Procedure 249: Ultrasound-guided catheterisation of the epidural space http://www.nice.org.uk/guidance/ipg249
6. Overdose of Insulin due to abbreviations	Overdose refers to when: • a patient is given a 10-fold or greater overdose of insulin because the words	Rapid response report – Safer administration of insulin, 2010, available at http://www.nrls.npsa.nhs.uk/alerts/?entryid45=74287 Diabetes: insulin, use it safely Patient	HSC (SQSD) 12/10 Safer administration of insulin

or incorrect device	'unit' or 'international units' are abbreviated; such an overdose was given in a care setting with an electronic prescribing system. **This definition of a Never Event has been temporarily suspended in the HSC Never Event List pending implementation of electronic prescribing system barriers in HSC care settings.** • a healthcare professional fails to use a specific insulin administration device – that is, an insulin syringe or pen is not used to measure the insulin • A healthcare professional withdraws insulin from an insulin pen or pen refill and then administers this using a syringe and needle. **Setting:** All patients receiving NHS funded care.	information booklet 03 January 2011 - NHS Diabetes and Kidney Care Patient Safety Alert – Risk of severe harm and death due to withdrawing insulin from pen devices (2016).	HSC (SQSD) 3/11 The adult patient's passport to safer use of insulin HSC (SQSD) 54/16 Ensuring the safe administration of insulin HSC (SQSD) 55/16 Minimising the risk of medication errors with high strength, fixed combination and biosimilar insulin products
7. Overdose of methotrexate for non-cancer treatment **s Never Event has been**	patient is given a dose of methotrexate, by any route, for non-cancer treatment that is more than the intended weekly dose; such an overdose was given in a care setting with an electronic prescribing system[2].	Patient safety alert - Improving compliance with oral methotrexate guidelines, 2006, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59800	http://www.dhsspsni.gov.uk/hsc__sqsd__07_08__policy_guidance_oral_methotrexate_guidance_.pdf

[2] Electronic prescribing, dispensing and administration systems are an evidence-based method to reduce patient harm from medicines. All NHS organisations should introduce them as soon as possible. When the definitions for the insulin and methotrexate overdose Never Events were revised in 2015, it was agreed that those for insulin

temporarily suspended in the HSC Never Event List pending implementation of electronic prescribing system barriers in HSC care settings.	**Setting**: All patients receiving NHS funded care.		

given in overdose because of the use of abbreviations for 'unit' and for all methotrexate overdose incidents would only apply to care settings with electronic prescribing systems as indicated. The systemic protective barriers for these two types of Never Event were found not to be strong enough in care settings where electronic barriers do not exist. For example, even though most acute hospitals do use a pre-printed insulin prescription to try and prevent prescribers using the abbreviations 'iu' or 'u', this is not the case in all care settings. Also, pre-printed prescriptions on its own are not a reliably strong enough barrier to prevent a potential 10-fold dosing error as prescribers can still prescribe insulin on general prescriptions.

8. Mis-selection of high strength of midazolam during conscious sedation	Mis - selection refers to • When a patient receives an overdose due to the selection of a high strength midazolam preparation (5mg/ml or 2mg/ml) rather than the 1mg/ml preparation, in a clinical area performing conscious sedation. • Excludes clinical areas where the use of high strength midazolam is appropriate. These are generally only in general anaesthesia, intensive care, palliative care, or where its use has been formally risk assessed within an organisation. **Setting**: All healthcare premises.	Rapid Response Report - Reducing risk of overdose with midazolam injection in adults, 2008, available at http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=59896&p=2	Rapid Response Report - Reducing risk of overdose with midazolam injection in adults (issued via SABS)
9. Failure to install functional collapsible shower or curtain rails	Involves either; • Failure of collapsible curtain or shower rails to collapse when an inpatient suicide is attempted/ successful. • failure to install collapsible rails and an inpatient suicide is attempted/successful using these non-collapsible rails **Setting:** All mental health inpatient premises.	Safety Notice- archived document NHSE SN (2002) 01: Cubicle rail suspension system with load release support systems, 2002, http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Estatesalerts/DH_4122863?PageOperation=email Safety Notice – archived document NHSE (2004) 10: Bed cubicle rails, shower curtain rails and curtain rails in psychiatric in-patients settings, 2004, www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh_4119476	**EFA/2010/009 - Flush fitting anti-ligature curtain rails: ensuring correct installation.(PDF 28KB)** **EFA/2010/003 - Anti-ligature curtain rails (including shower curtains): risks from incorrect installation or modification (PDF 27 KB)** MDEA(NI)2007/61 - Cubical curtain track rails (anti ligature): Installation issues with anti-

		Health building note 03-01 – Adult acute mental health units (2013). • Health building note 03-02 – Facilities for child and adolescent mental health services (CAMHS) (2017). NHS Improvement 03 – G-rail 2301, window curtain tracking system (2004). • NHS Improvement 08 – Cubicle rail tracking and PVC dustcovers (2004). • Department of Health 08 – Cubicle curtain track rail (2007).	ligature cubical curtain track rails (PDF 164 KB) MDEA(NI)2007/83 - Curtain tracks and other fixed fittings in Emergency Admission Units - used as points of ligature (PDF 120 KB)
10. Falls from poorly restricted windows	A patient falling from a poorly restricted window. • Applies to windows "within reach" of patients. This means windows (including the window sill) that are within reach of someone standing at floor level and that can be exited/fallen from without needing to move furniture or use tools to assist in climbing out of the window. • Includes windows located in facilities/areas where healthcare	*Health Building Note (HBN) 00-10 Part D: Windows and associated hardware*, available via https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/273867/20131223_HBN_00-10_PartD_FINAL_published_version.pdf *DH(2014)/003 – Window restrictors of cable and socket design, 2014, available at https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102246*	EFA/2013/002 - Window restrictors. Window restrictors may be inadequate in preventing a determined effort to force a window open beyond the 100mm restriction. (PDF 40KB) EFA/2012/001 - restrictors incorporate a plastic spacer (PDF 94 KB) MDEA(NI)2007/100 - Window restrictors (PDF 5 KB)

	is provided and where patients can and do access. • Includes where patients deliberately or accidentally fall from a window where a restrictor has been fitted but previously damaged or disabled, but does not include events where a patient deliberately disables a restrictor or breaks the window immediately before the fall. • Includes where patients are able to deliberately overcome a window restrictor by hand or using commonly available flat bladed instruments as well as the 'key' provided. **Setting:** All patients receiving NHS funded care.		Health Building Note 00-10Part D: Windows and associated hardware- http://www.dhsspsni.gov.uk/hbn00-01-partd.pdf NICE PH29 – Strategies to prevent unintended injuries among the under-15s http://www.nice.org.uk/guidance/ph29
11. Chest or neck entrapment in bedrails	Entrapment of a patient's chest or neck within bedrails, or between bedrails, bedframe or mattress, where the bedrail dimensions or the combined bedrail, bedframe and mattress dimensions do not comply with Medicines and Healthcare products Regulatory Agency (MHRA) guidance[3]	*DB 2006(06) v 2.1 Safe use of bed rails,* Dec 2013, available at http://www.mhra.gov.uk/home/groups/dts-bs/documents/publication/con2025397.pdf	HSC (SQSD) 22/07 Using bedrails safely and effectively

[3] This includes windows where the provider has not put a restrictor in place in accordance with guidance.

	Setting: All settings providing NHS funded healthcare, including NHS funded patients in care home settings, and equipment provided by the NHS for use in patients' own homes.		
12. Transfusion or transplantation of ABO-incompatible blood components or organs	Unintentional transfusion of ABO-incompatible blood components. Excludes where ABO-incompatible blood components are deliberately transfused with appropriate management. Unintentional ABO mismatched solid organ transplantation. Excluded are scenarios in which clinically appropriate ABO incompatible solid organs are transplanted deliberately In this context, 'incompatible' antibodies must be clinically significant. If the recipient has donor specific anti-ABO antibodies and is therefore, likely to have an immune reaction to a specific ABO compatible organ then it would be a never event	Department of Health CEM/CMO/2017/005 – Safe transfusion practice: use a bedside checklist (2017). • British Society for Histocompatibility and Immunogenetics and British Transplantation Society – Guidelines for the detection and characterisation of clinically relevant antibodies in allotransplantation (2014). • British Transplantation Society – Guidelines for antibody incompatible transplant (2015). Safer Practice Notice – Standardising Wristbands improves patient safety, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824	HSC (SQSD) 30/07 Right Patient, Right Blood QIPP – Electronic Blood Transfusion – Improving safety & efficiency of transfusion systems https://www.nice.org.uk/savingsAndProductivityAndLocalPracticeResource?ci=http%3a%2f%2farms.evidence.nhs.uk%2fresources%2fQIPP%2f29453%3fniceorg%3dtrue NICE TA156: Routine antenatal anti-D prophylaxis is recommended as a treatment option for all pregnant women who are RhD negative https://www.nice.org.uk/guidance/ta156

	to transplant that organ inadvertently and without appropriate management. **Setting:** All patients receiving NHS funded care.		
13. Misplaced naso - or oro-gastric tubes	Misplacement and use of a naso- or oro-gastric tube in the pleura or respiratory tract where the misplacement of the tube is not detected prior to commencement of feeding, flush or medication administration. **Setting:** All patients receiving NHS funded care.	• Patient Safety Alert – Nasogastric tube misplacement: continuing risk of death and severe harm (2016). • NHS Improvement – Initial placement checks for nasogastric and orogastric tubes: resource set (2016).	HSC (SQSD) 02/11 Reducing the harm caused by misplaced nasogastric feeding tubes in adults, children and infants HSC (SQSD) 02/12 Harm from flushing of nasogastric tubes before confirmation of placement Learning Communication 2/09 Reducing Harm caused by the Misplacement of Nasogastric Feeding Tubes HSC (SQS) 47/16 Nasogastric tube misplacement: continuing risk of death and severe harm
14. Scalding of patients	Patient being scalded by water used for washing/bathing • Excludes scalds from water being used for purposes other than washing/bathing (e.g. from kettles)	- Health Technical Memorandum 04-01 - The control of Legionella, hygiene, “safe” hot water, cold water and drinking water systems, 2006, available via http://www.whtlimited.com/doc/lib/98/htm-04-01-part-b-20061009113435.pdf	See **Scottish Hospital Technical Note** 6The Safe Operation and Maintenance of Thermostatic Mixing Valves http://www.hfs.scot.nhs.uk/publications/SHTN%206%20The%20S

	Settings: All patients receiving NHS funded care.	- Scalding risks from hot water in health and social care LAC: 79/5, 2007, available at http://www.hse.gov.uk/lau/lacs/79-5.htm - Scalding and burning, available at http://www.hse.gov.uk/healthservices/scalding-burning.htm	afe%20Operation%20and%20Maintenance%20of%20Thermostatic%20Mixing%20Valves.pdf Health Technical Memorandum 04-01 - The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems, 2006, applicable to NI HBN 00-10 part C Sanitary Assemblies http://www.dhsspsni.gov.uk/hbn_00-10_part_c_l.pdf issued in NI
15. Unintentional connection of a patient requiring oxygen to an air flowmeter	This applies when a patient who requires oxygen is connected to an air flowmeter when the intention was to connect them to an oxygen flowmeter. **Excludes:** • Unintentional connection to an air cylinder instead of an oxygen cylinder as robust barriers to prevent this have not yet been identified. **Setting:** All settings providing HSC-funded care.	**National safety requirement:** • Patient Safety Alert – Reducing the risk of oxygen tubing being connected to air flowmeters (2016).	HSC (SQSD) 57/16 Reducing the Risk of Oxygen Tubing being connected to air flow meters

NORTH & WEST BELFAST HEALTH & SOCIAL SERVICES TRUST

Adverse Events/Incidents

- New Report Forms
- Guidance Notes
- Management Policy

Human Resources
&
Corporate Affairs

Contents

1.0 Introduction

This policy is an integral element of the North and West Belfast Health and Social Services Trust, Risk Management Strategy and supports the Trusts commitment to providing high quality patient and client services and ensuring high standards of Health and Safety.

The Trust will therefore implement a single adverse event/incident and near miss recording system to cover all areas of Trust business including professional (clinical and social care) operational and environmental issues.

Robust and clearly understood systems must be in place to identify, record, manage and report events that have caused, or have the potential to cause, harm to a patient, client, member of staff, visitor or contractor.

The Trust recognises that the recording of incidents is a vital part of managing and controlling risks. Incident reporting provides valuable information to the Trust on the underlying factors that contribute to incidents and can serve as a key indicator of the effectiveness of risk management and health and safety performance. This requires the commitment, involvement and acceptance of staff at all levels. This will be achieved by ensuring that the policy is readily available to all staff and providing the necessary education training and support to ensure that staff are aware of their individual responsibilities,

The Trust recognises that on occasions things will go wrong and as a result a patient, client and/or member of staff or visitor may suffer harm. The Trust is committed to the concept that in such circumstances the response will be one of learning from the event with a drive to reduce future similar risk events, and concern for staff who may be affected as a consequence.

The response will not be one of blame.

2.0 Policy Statement for Adverse event/Incident and near miss recording

The incident reporting policy statement outlined below represents the Trusts corporate philosophy in relation to incident recording.

The purpose of this policy statement is to ensure that all staff are aware of their ongoing responsibilities for recording incidents.

North and West Belfast Health and Social Services Trust
INCIDENT REPORTING POLICY STATEMENT

The Trust believe that the systematic identification, analysis and control of risk will be facilitated by effective incident recording, which will be afforded a high priority within the Trust.

An educational process and the establishment of a supportive, open and learning culture that encourages staff to report mistakes, incidents and near misses through the appropriate channels will underpin this.

The Trust supports a 'fair blame' culture that means:

'Staff who make a prompt and honest report in relation to an incident, near miss or mistake will not be disciplined except under the following circumstances':-

- Where the member of staff acted in a criminal deliberate or malicious manner;

- Where the member of staff is guilty of wilful or gross carelessness or neglect contravening the Trust policies and procedures and/or professional codes of conduct and could reasonably be expected to appreciate the direct consequences of his/her behaviour.

- Where an incident follows other similar incidents of a similar nature and the Trust, has provided all necessary training counselling and supervision to prevent a reoccurrence.

3.0 Definitions

3.1 Individuals

For the purpose of this policy the definition of individuals directly or indirectly involved in patient/client treatment and/or care includes employees, bank, locum or agency staff, contractors and volunteers. All grades of Trust staff are covered by this definition.

3.2 Adverse event/incident

Any event that has given or may give rise to actual or possible personal injury, to patient/client dissatisfaction or to property loss or damage. This definition includes accidents, ill heath and dangerous occurrences.

3.3 Serious Professional Event/Incident

An incident will be classified as a serious professional event/incident when one or more patients/clients suffers severe unexpected impairment of health/injury/death or disability during the course of their treatment and/or care within the Trust.

The responsibility for determining when an incident becomes so classified shall rest within the appropriate Director in conjunction with the relevant professional staff and any other staff deemed appropriate.

(Please refer to the Serious Professional event/incident policy/guidelines on managing these incidents).

3.4 Near Miss

Any event that did not lead to personal harm but could have, are referred to as 'near misses' an occurrence which, but for luck or good management, would in all probability have become a fully blown incident.

3.5 Hazard

A hazard is defined as something identified, with the potential to cause harm. (Hazards should be reported through the maintenance Faults office MAH 94 463333 ext 2470

3.6 Harm

Harm is defined as "injury, either physical or psychological, disease, suffering, disability or death".

4.0 Staff responsibilities

4.1 Directors/senior managers have a responsibility to ensure that:

- Designated Line Managers for adverse event/incidents are identified to cover all areas of their programme/service area responsibilities.
- Designated individuals are trained in adverse event/incident investigation and/or root cause analysis.
- Local guidance is produced for processing of adverse event/incident forms.
- Where appropriate, an investigation, and if required a root cause analysis is conducted into the circumstances of the adverse event/incident with recommendations and actions co-ordinated and fully documented.
- Staff have the appropriate support, training and supervision in relation to adverse event/incident reporting and management.
- Report forms are readily available in all work areas.
- Witness statements are taken as appropriate, with copies attached to the respective report form.
- All new employees are made aware of the Trust policy on adverse event/incident reporting and are made aware of the location of incident report forms.
- Processes are in place to regularly monitor and review adverse event/incident reports and the information is used as a foundation for improvement strategies.
- Encourage the reporting of adverse events/incidents including near misses.
- Serious professional events/incidents are managed in line with the 'serious professional event/incident policy.

4.2 All Trust Staff

All Trust Staff have a responsibility to:

- Report to the appropriate line manager any adverse event/incident and near miss they witness or are involved in.
- Record all factual information (and not opinion) on the Trusts adverse event/incident report form in conjunction with the appropriate line manager.

- Record any appropriate details in the patient/clients records.
- Co-operate with any subsequent investigation whether initiated internally or externally.
- Retain any equipment or material evidence securely for any subsequent inspection.
- Attend education and training sessions in relation to incident reporting and management.

5.0 Adverse Event/Incident reporting

- The routine reporting of adverse events/incidents is an essential requirement of the Trust Risk Management strategy. The Trust is mindful that 'near misses' represent free lessons to the organisation and provide the ideal opportunity to implement risk control measures in a pro-active manner.
- As soon as an adverse event/incident occurs or is discovered, the appropriate line supervisor/manager should be informed in order that any actions to contain the situation or prevent a re-occurrence of the incident can be initiated.
- As soon as possible afterwards, but within twenty four hours of the incident, an adverse event/incident report form should be completed. The form should be completed by the appropriate line supervisor/manager in conjunction with the person who was involved in, witnessed or discovered the incident.
- If the incident is classified by the relevant Director, as serious or results in death of a patient/client the Chief Executives Office must be notified immediately.
- If the serious incident occurs out of working hours the Trust on-call officers should be informed immediately. The Trust on-call officer will liaise with the Director Human Resources and Corporate Affairs to provide advice on how the incident should be managed.
- All parts of the Trusts Adverse event incident report form should be completed (Refer Guidance notes on incident report books).
- The completed form should not become part of the patient/client records.
- The member of staff involved in the incident should document in the patient/client records the actual facts relating to the incident. This entry should be clearly dated, timed and signed.

- The Trust recognise that different Directorates, programmes and service areas will require specific distribution of incident forms. The relevant Director is responsible for ensuring appropriate distribution mechanisms are in place.

- The Trust requires that the following documentation flows are incorporated into local arrangements.

		Community	Muckamore Abbey Hospital
White Copy Form A	to	Chief Executive's Office	Medical Records
		Datix	Datix
White Copy Form B Blue Copy A & B	to	Designated Manager Incident/Accidents	Designated Manager Incident/Accidents
White Copy Form B	to	Chief Executive's Office	Medical Records
		Datix	Datix
Pink Form	to	Fast Copy Book	Fast Copy Book

- Patient/Client Related → copy to → Consultant/Professional Head
- Staff Injury or Sickness → copy to → Occupational Health Manager; Health and Safety Manager
- Security Related → copy to → Hotel Services Manager → Community; Muckamore
- Fire Related → copy to → Health & Safety Manager
- Harassment/ Abuse/ Threats → copy to → Director of Human Resources & Corporate Affairs

6.0 Adverse Event/Incident Grading

Grading incidents according to the actual severity (consequence) and the potential future risk (likelihood) to patients, clients, staff and the organisation will establish:

- The immediate actions that should be considered as a result of an incident.
- The level of local investigation and root cause analysis that should be carried out.
- The reporting requirements in relation to external bodies.

6.1 Actual Severity/Consequence rating of event

An immediate assessment of the actual severity/consequence of the incident should be undertaken. It is acknowledged that the designated line manager (incidents) may not be in possession of all the facts at the time of grading the incident. However the incident grading should be re-visited on completion of the investigation and/or as the facts emerge.

The incident should be graded using the following table.

Severity (Consequence rating of risk)

Score	*Descriptor*	Impact on Individual(s)	Impact on Trust	Number of Persons Affected at one time	Financial Loss/ Complaint/ Litigation
1	*Insignificant*	• No injury or adverse outcome	• No risk to Trust	None – one	• Remote litigation risk • Complaint unlikely • Damage/ theft/ loss of equipment/ property < £100
2	*Minor*	• First aid • Minor injury • Minor illness	• Minimal risk to Trust • Staff absence < 3 days	Two	• Litigation unlikely • Complaint possible • Damage/ theft/ loss of equipment/ property > £100 < £1,000
3	*Moderate*	• Injury/ illness requiring 3 days or more absence • Temporary incapacity • Prolonged/ additional treatment and/or care	• Riddor reportable • MDA reportable • Needs careful PR • Staff absence < 4 weeks	3 – 10	• Litigation possible • Complaint expected • Damage/ theft/ loss of equipment/ property > £1,000 < £10,000
4	*Major*	• Major/ serious injury • Major clinical/ professional intervention required • Permanent incapacity	• Service reductions • Service closures • Staff absence > 4 weeks • Local adverse publicity	10 – 20	• Litigation expected • Damage/ theft/ loss of equipment/ property > £10,000 < £50,000
5	*Catastrophic*	• Death	• Regional/ national adverse publicity • Subject to external investigations	> 30	• Serious litigation expected • Damage/ theft/ loss of equipment/ property £50,000 +

The incident should be assessed across all four impact categories (individual, Trust, No of persons, Loss) and the grading designated as the highest recorded.

6.2 Future Risk (Frequency/Likelihood)

The designated line manager (incidents) should make an assessment on the likelihood of a similar type of incident re-occurring within their working area/environment. It is accepted that this may be a subjective assessment, but it enables a future risk rating to be determined.

The following table should be used:

Frequency – (An assessment of likelihood of risk occurring)

Score	Descriptor	Description
5	Almost Certain	Likely to re-occur on many occasions, a persistent issue
4	Likely	Will probably re-occur but is not a persistent issue
3	Possible	May re-occur occasionally
2	Unlikely	Do not expect it to happen again but it is possible
1	Rare	Do not believe that this will ever happen again

6.3 Risk Matrix

Using the Risk matrix below the incident should be plotted to determine the Risk Score/Colour Category Rating.

Risk Matrix

Frequency	Severity				
	1 Insignificant	2 Minor	3 Moderate	4 Major	5 Catastrophic
5 Almost Certain					
4 Likely					
3 Possible					
2 Unlikely					
1 Rare					

6.4 Risk Control

The designated line manager (incidents) should provide recommendations or suggestions to prevent a recurrence and record details on the incident report form (Part B).

7.0 Level and Nature of Investigation

The designated Line Manger (incidents) will determine the level of investigation required for each incident. The grading of the incident and the risk rating determined by the matrix will assist in the process and the following guidance is given:

High Risk	Red	➢ These incidents will always be the subject of al full investigation, the results of which will be subject to a root cause analysis to determine the underlying issues that require addressing.
Significant Risk	Orange	➢ Although a lesser degree of investigation may be required for this category of incident a root cause analysis should be undertaken at the conclusion of the investigation.
Moderate Risk	Yellow	➢ These represent lower risk situations and the designated Line Manager (incidents) should decide on the appropriate level of investigation.
Low Risk	Green	➢ These incidents should be subject to aggregate review at Directorate/programme/ service area level.

7.1 Purpose of Investigation

The purpose of any investigation is to:

- Learn from incidents and make recommendations for improvement.
- Identify reasons for substandard performance.
- Identify underlying failures in management systems.
- Implement improvement strategies to help prevent/reduce future risk of harm.
- Satisfy mandatory external reporting requirements.

7.2 Principles of Investigation

The following principles will apply to the process of investigation:

- The investigation will be lead by a designated person within the Directorate/programme/service area with support as necessary from the corporate risk team.
- The investigation should commence as soon as possible after the incident, and should be completed as promptly as possible.
- The investigation should be carried out according to the principles of the 'fair blame' statement.
- In some instances it may be necessary for the relevant Director to nominate the lead in investigating/managing a particular incident.
- Any equipment involved may need to be segregated for the period of investigation. It may also require to be professionally inspected/tested.
- On completion of the investigation the initial risk rating of the incident should be reviewed and revised as necessary.

8.0 Root Cause Analysis

- Root Cause Analysis is a structured examination that aims to identify the true cause (s) of a problem and the necessary actions to eliminate it.
- The process of root cause analysis involves identifying causal factors that if corrected, would prevent a re-occurrence of the same incident.
- Without addressing the root causes of incidents it will be difficult if not impossible to take pro-active risk management action to prevent a future occurrence.

- In Health and Social Care, the true cause (s) of many adverse patient/client incidents lie in the systems that support professionals in the delivery of treatment and/or care. Consequently, root cause analysis seeks to identify the system issues that contributed to the incident.

- The Trust recognise that the process of root cause analysis requires particular skills and are committed to training a wide range of relevant staff in the process.

9.0 Communicating with Patients/clients and relatives

The professional staff responsible for the treatment and/or care of the patient/client will retain the responsibility for communicating with them and their relatives about the incident. The following points should be noted:

- Following an assessment, patients/clients and relatives (bearing in mind issues of patient/client confidentiality) are provided with explanations of what has happened, why it happened, how it will be investigated and how lessons will be learned from the incident.

- If the professional head/consultant considers there are compelling professional reasons not to discuss the incident with the patient/clients relative (s) a clear record should be made of this in the patient/client records. In such circumstances further advice may be sought from the relevant Director.

- If deemed appropriate, an apology should be given acknowledging that an apology is not an admission of liability.

- If appropriate, following the investigation, a meeting should be offered to patient/client relative (s) with the relevant Trust personnel. A summary of the points discussed and any agreements made should form part of the overall investigative paper work and a copy provided to the patient/client relative (s).

- The patient/client relative (s) will be informed of any external body the incident is being reported to and why.

10.0 Education and Training

- The Trust recognises that measures need to be implemented to further encourage all staff to report adverse events/incidents including near misses.

  This will be achieved through an educational process, including awareness sessions, policy distribution, leaflets and communication updates.

- The Trust are committed to the skills training key staff in the following areas:

11.0 Relationship between Incident Reporting and Disciplinary Action

Fear of disciplinary action may deter staff from reporting an incident. The view of the Trust Board is that disciplinary action should not normally result from incident reporting where individuals reporting the incident are subsequently found to be at fault.

There are however circumstances in which disciplinary action should be considered and these include:

- Where the member of staff acted in a criminal deliberate or malicious manner;

- Where the member of staff is guilty of wilful or gross carelessness or neglect contravening the Trust policies and procedures and/or professional codes of conduct and could reasonably be expected to appreciate the direct consequences of his/her behaviour.

- Where an incident follows other similar incidents of a similar nature and the Trust, has provided all necessary training counselling and supervision to prevent a reoccurrence.

12.0 External Reporting

Depending on the nature of the incident the Trust are required to report details of the incident to a number of external bodies.

These are:

- Health and Safety Executive (RIDDOR) — Criteria Appendix 1
- Commissions Boards — Criteria Appendix 2
- Registration and Inspection — Criteria Appendix 3
- Market Health Commission — Criteria Appendix 4
- Northern Ireland Adverse Incident Centre (Medical Devices) — Criteria Appendix 5
- Health and Social Services Executive (Fire) — Criteria Appendix 6
- Medicines related incidents should be reported to the pharmaceutical branch DHSS&PS
- Food related incidents should be reported to the local environmental Health Officer/Department who are responsible for notifying the Food Standards Agency as necessary

- Estates Services Department will report incidents involving Medical Devices and Fire.

- All other reporting to External Bodies will be actioned by the Chief Executives office.

Appendix 1

RIDDOR

Criteria for Reporting:

- Death or major injury
- Over three day injury (If accident at work results in an employee being off work for over 3 days. Also applies to self employed persons working on Trust premises).
- Disease
- Dangerous occurrence

Incidents meeting the above criteria are normally notified to the Health and Safety Executive as soon as possible by telephone and then followed up by completing form NI2508.

Address: Health and Safety Executive for NI
83 Ladas Drive
Belfast
BT6 9FR

Tel: 028 9024 3249

Appendix 2

COMMISSIONING BOARDS

Criteria for Reporting:

EHSSB

There is no written criteria therefore the Trust applies that criteria required by the other 3 Boards and the Mental Health Commission.

Contact: Mr. Michael Cruickshanks
Eastern Health and Social Services Board
Administration Department
12/22 Linenhall Street
Belfast

Tel: 028 9032 1313

WHSSB

- Death of a patient
- Suicide of a patient
- Sexual assault of a patient
- Allegations of professional misconduct against a patient
- Patient absent without leave

Contact: Mr. J Simpson
Service Planner
Western Health and Social Services Board
15 Gransha Park
Clooney Road
Londonderry BT47 1TG

Tel: 028 7186 0086

SHSSB

- Death, suicide or para-suicide of a patient
- Patient/client missing more than 24 hours
- Allegations of professional misconduct
- Allegations of harm or injury, neglect or abuse to patient or client
- Assault by a patient

Contact: Mr. T Smith
Assistant Director of Social Services
Southern Health and Social Services Board
Tower Hill
Armagh
BT61 9DR

Tel: 028 3741 4550

NHSSB

- Suspicious death, suicide or suspected suicide involving a patient or client
- Alleged or confirmed harm, injury, neglect or abuse to patient or client
- Patient/client missing for more than 24 hours
- Allegations of professional misconduct
- Serious deficiencies in standards of patient/client care

Contact: Mr. J C Crutchley
Head of Corporate Services
Northern Health and Social Services Board
County Hall
182 Galgorm Road
Ballymena
Co. Antrim
BT42 1QB

Tel: 028 2565 3333

When there is an incident involving a patient/client from the Republic of Ireland the Trust would use the criteria required by our own Commissioning Boards and report to the relevant Board.

Contact: Ms Christine Tanner
Child Care Manager
Southern Health Board
Abbeycourt House
Georges Quay
Cork

Ms T Cunningham
Acting Area Manager
Disability Service
19 Mill Street
Monaghan

Mr. F McDonald
Principal Social Worker
Midland Health Board
Social Work Department
Community Care Offices
O'Carroll Street
Tullamore
Co Offaly

Appendix 3

REGISTRATION AND INSPECTION UNIT

Criteria for Reporting:

- The death of any resident not resulting from natural causes
- Suspected suicides
- Sexual assaults
- Actual or alleged physical assaults by members of staff
- Serious outbreak of infectious disease
- Serious injury to or serious illness of any person residing in the home
- Absence of a resident from a home where the person may be a danger to himself/herself or others
- An outbreak of fire
- Any theft, burglary or accident in the home

Untoward incidents should be reported to the Registration and Inspection Unit by telephone as soon as possible after the event or by completing the appropriate form within 24 hours of the event.

Contact: Ms K Greer
Registration and Inspection Unit
Eastern Health and Social Services Board
12/22 Linenhall Street
Belfast
BT2

Tel: 028 9032 1313

Appendix 4

MENTAL HEALTH COMMISSION

Criteria for Reporting:

The Commission requires to be advised of incidents involving those suffering from a mental disorder as and when they occur as soon as possible after the event.

- The death of any resident not resulting from natural causes
- Suspected suicides
- Sexual assaults
- Actual or alleged physical assaults by members of staff

Contact: Mrs A McLoughlin
Mental Health Commission for NI
Elizabeth House
118 Holywood Road
Belfast
BT4 1NY

Tel: 028 9065 1157

Appendix 5

NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)

Criteria for Reporting:

Where there is an adverse incident relating to medical devices, non-medical equipment, buildings and plant, resulting in the following:

- Death, life-threatening illness or injury
- Deterioration in health
- The necessity for medical or surgical intervention
- Unreliable test results leading to inappropriate diagnosis or therapy

Contact:

Mr. B Godfrey
NIAIC Manager
N. Ireland Adverse Incident Centre (NIAIC)
Room A7
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald

Tel: 028 9052 3714

Incidents are reported to NIAIC by Estates Department staff.

Appendix 6

FIRE REPORTING PROCEDURES TO HPSS/ME

Criteria for Reporting:

- Details of all outbreaks of fire to which the fire brigade is called occurring in any premises under the control of, or contracted to, a HSS Board, HSS Trust or Agency must be reported promptly (within 48 hours) by the Nominated Officer (Fire) to HPSS/ME. In addition, fires involving death, major injury of damage on a very large scale must be notified immediately by telephone/fax to:

  Estates Services Directorate HPSS/ME
  Tel: 028 9052 3701
  Fax: 028 9048 3299

  Outside normal office hours the Department's Duty Officer should be contacted at Stormont:
  Tel: 028 9052 7095

NORTH AND WEST BELFAST HEALTH AND SOCIAL SERVICES TRUST

Guidance Notes for completing Adverse event/Incident Report Form

Definitions

A reportable adverse event/incident may be described as:

- Any event that has given or may give rise to actual or possible personal injury, to patient/client dissatisfaction or to property loss or damage. This definition includes accidents, ill health and dangerous occurrences.

A near miss may be described as:

- Any event that did not lead to personal harm but could have, are referred to as 'near misses' an occurrence which, but for luck or good management, would in all probability have become a fully blown incident.

General

- Use the adverse event/incident report form to record **ALL** incidents/accidents and any near misses.
- Record only known facts – not opinions.
- Please complete a separate form for each person directly affected by the incident i.e. any person who suffers or potentially suffered injury, ill health or loss.
- Completing the adverse event/incident report form does not constitute an admission of liability of any kind on any person.
- Any equipment involved in the incident should be retained untouched and in safe keeping for examination.
- The adverse/incident report form should be completed, where the incident occurred, by the member of staff in charge, or line manager for incident relating to the member of staff in charge. Copy distribution as follows:

		Community	Muckamore Abbey Hospital
White Copy Form A	to	Chief Executive's Office	Medical Records
		↓	↓
		Datix	Datix
White Copy Form B Blue Copy A & B	to	Designated Manager Incident/Accidents	Designated Manager Incident/Accidents
White Copy Form B	to	Chief Executive's Office	Medical Records
		↓	↓
		Datix	Datix
Pink Form	to	Fast Copy Book	Fast Copy Book

Copies of Form should be further distributed according to local requirements/ arrangements, however the following guide should be adhered to:

- ❖ Patient/Client Related → copy to → Consultant/Professional Head
- ❖ Staff Injury or Sickness → copy to → Occupational Health Manager; Health and Safety Manager
- ❖ Community Security Related → copy to → Hotel Services Manager; Muckamore
- ❖ Fire Related → copy to → Health & Safety Manager
- ❖ Harassment/ Abuse/ Threats → copy to → Director of Human Resources & Corporate Affairs

- Please use a **black ball point pen** to write clearly, using **block capitals** where possible
- Please take care always to ensure that the correct boxes are ticked and all sections relevantly completed. Where a text entry is required please refer to the section guidance notes.
- **WHERE DEATH OR SERIOUS INJURY HAS OCCURRED THIS MUST BE REPORTED IMMEDIATELY TO TRUST HEADQUARTERS – CHIEF EXECUTIVE'S OFFICE**
- **Estates Services Department will report incidents involving Medical Devices and Fire.**
- **All reporting to External Bodies will be actioned by the Chief Executives office.**

Section A **Incident Details**

- **Programme/Directorate e.g.**

Learning Disability	Primary Care
Elderly	Human Resources/Corporate Affairs
Mental Health	Finance
Physical Disability	Planning, Contracts & Information
Family and Child Care	Other – please specify

- **Facility** – please refer to Trust Facilities directory

  * *If adverse event/incident occurred in domiciliary setting please register the Trust facility used as base.*

- **Department/Ward**

  Examples for the completion of this section are as follows:

Community	**Muckamore**
Physiotherapy	Movilla A
Occupational Therapy etc	Erne
	Administration
	Pharmacy etc.

* If adverse event/incident occurred in domiciliary setting please register the name of Team.

- **Date of Incident**

  Please record the date the actual incident occurred.

- **Time**

  Please record the time of incident using the 24 hour clock e.g.
  08:30 or 21:40

- **Location (Exact)**

  Please record the detail of the actual room/area of facility that the incident occurred.

  Eg:

Community	**Muckamore**
Reception	Day Room
Residents Bedroom	Residents Bedroom
Kitchen	Bathroom
Bathroom	Kitchen
Treatment Room etc.	

- If adverse event/incident occurred in domiciliary setting please register the client`s address

- Near Miss – Please refer to definition in guidance note

Description of Incident including apparent contributory factors

Apparent circumstances of incident including possible contributory factors. Give brief, clear, factual details of the circumstances of the incident. If the form is being completed by someone other than the person directly involved state clearly if you:

- actually **SAW** the incident
- saw the **RESULT** of the incident
- or that it was reported/stated by the employees, patient/client etc that the following happened.

Details of the incident should include:

- Indicate the events leading up to the incident and the part played by any person (s) in the sequence of events.
- If any equipment is involved in the incident, give details including serial numbers as applicable.
- For incidents involving patients/clients give relevant details regarding their condition.
- Indicate if the incident was a near miss.
- If the incident involves theft, give full details including estimate of financial value.
- In the case of personal injury or ill health, indicate what the person was doing at the time and whether environmental factors (e.g. temperature, lighting etc) might be involved. Specify the name of any substance (s) involved. It should be noted that speculation about contributory factors should be avoided unless they are **actually known**.

Section B

The individual affected by the incident is the person who suffers or potentially suffers injury, ill health, or loss, including theft and any other property damage or loss. If this is the case please tick yes and complete the details as requested. If no proceed to **Section G**.

Section C **Details of Injury**

Please provide text entry in the spaces provided ensuring the correct choice is made by carefully choosing from the pick lists detailed below. No deviation from the pick lists should be made.

Pick List 1
Part of body affected

Part	Part	Side
Abdomen	Hand	Left
Ankle	Head	
Arm/elbow	Hip	Right
Back	Jaw	
Breast	Knee	
Buttock	Leg	Both
Cheek	Mouth	Not applicable
Chest	Neck	
Chin	Nose	
Ear	Penis	
Eyebrow	Shin	
Eye	Shoulder	
Face	Scrotum	
Finger (s) / Thumb	Tooth	
Foot / ankle	Thigh	
Forehead	Thumb	
Groin	Wrist	
Hair loss	Other (please specify)	

Be clear about part of body affected. State left or right side or both e.g. left hand, right foot, both eyes etc and if fingers or toes are injured, specify which one (s).

Pick List 2 **Apparent Nature of Injury/Ill Health or Adverse Effect**	
Abrasion	Nausea
Amputation	Nipped
Bite Skin Not Broken	Other injury
Breathing Difficulties	Old wound re-opened
Bruise/swelling	Pain General
Burn/scald	Pressure ulcers/sores
Concussion	Redness
Dislocation	Scratch/scrape/nail marks
Distressed	Sharps injury
Fracture	Skin Irritation
Laceration	Sprain/strain
Loss of body part	Injury unknown at this time
Muscular injury	Visual Disturbance
No Apparent Injury	

Section D **Apparent Cause of Injury**

Please provide text entry in the space provided ensuring the current choice is made by careful choosing from the pick list detailed below. No deviation from the pick list should be made.

Pick List 3 Apparent Cause of Injury	
Absconding	Actual fire
Alcohol, drug or solvent abuse	General clinical incident
Allegations	Alleged harassment of staff by staff
Animal attack	Hijacking
Arson	Infection
Assault on patient/client by others	Infestation
Assault on patient/client by staff	Intimidation
Assault by patient on another patient	Lifting and handling
Assault on staff by non-patient/client	Medication dosage mistakes
Assault on staff by patient/client	Medication errors
Assault on Visitor by patient/client	Loss of medication
Attitude	Medication not given
Back injury	Refusal of medication
Bomb, bomb scare	Wrong medication given
Break-in or attempted break-in	Near miss
Breathing difficulties	Other incident (please specify)
Burn or scald	Patient lifting and handling
Car crime	Failure/misuse of personal protective equipment
Challenging behaviour	Punishment beating
Choking or swallowing difficulties	Road traffic accident
Civil disturbance or rioting	Seizure or epiletic fit
Communications failure	Self harm minor (cut/bruise)
Theft of controlled drugs	Self harm hanging
Control/restraint	Self harm other
Other crime	Sexually inappropriate behaviour
Cut by sharp object	Sharps injury
Death of patient (cause unknown)	Dermatological problems
Death of patient (natural causes)	Shooting
Diagnosis	Struck by a moving object
Discharge of fire equipment	Struck by a stationary object
Displacement	Theft or attempted theft
Equipment failure	Threats or threatening behaviour
Failure of medical equipment	Injury sustained during training
Exposure of hazardous substance	Body part trapped
Exposure to non-hazardous substance	Treatment error
Fall from a height	Unexplained injury
Fall on the same level/slip/trip	Vandalism
	Verbal abuse

Where equipment has been involved in an adverse event/incident it should be removed from use and stored in a safe place for inspection by the Trust Health and Safety Manager and/or relevant supplier/contractor as appropriate.

Section J

Potential Frequency of re-occurrence

An assessment on the likelihood of a similar type of event (not necessarily involving the same individual (s)) re-occurring within the working area/environment should be made using the following table:

Score	Descriptor	Description
5	Almost Certain	Likely to re-occur on many occasions, a persistent issue
4	Likely	Will probably re-occur but is not a persistent issue
3	Possible	May re-occur occasionally
2	Unlikely	Do not expect it to happen again but it is possible
1	Rare	Do not believe that this will ever happen again

Severity (ACTUAL consequences rating of incident)

An assessment of the actual severity/consequence of the incident (to the individual (s) actually involved or the Trust) should be made using the following table:

Severity (Consequence rating of risk)

Score	*Descriptor*	Potential Impact on Individual(s)	Potential Impact on Trust	Number of Persons Affected at one time	Potential Financial Loss/ Complaint/ Litigation
1	*Insignificant*	• No injury or adverse outcome	• No risk to Trust	None – one	• Remote litigation risk • Complaint unlikely • Damage/ theft/ loss of equipment/ property < £100
2	*Minor*	• First aid • Minor injury • Minor illness	• Minimal risk to Trust • Staff absence < 3 days	Two	• Litigation unlikely • Complaint possible • Damage/ theft/ loss of equipment/ property > £100 < £1,000
3	*Moderate*	• Injury/ illness requiring 3 days or more absence • Temporary incapacity • Prolonged/ additional treatment and/or care	• Riddor reportable • MDA reportable • Needs careful PR • Staff absence < 4 weeks	3 – 10	• Litigation possible • Complaint expected • Damage/ theft/ loss of equipment/ property > £1,000 < £10,000
4	*Major*	• Major/ serious injury • Major clinical/ professional intervention required • Permanent incapacity	• Service reductions • Service closures • Staff absence > 4 weeks • Local adverse publicity	10 – 20	• Litigation expected • Damage/ theft/ loss of equipment/ property > £10,000 < £50,000
5	*Catastrophic*	• Death	• Regional/ national adverse publicity • Subject to external investigations	> 30	• Serious litigation expected • Damage/ theft/ loss of equipment/ property £50,000 +

The incident should be assessed across all four impact categories (individual, Trust, No of persons, Loss) and the grading designated as the highest recorded.

4. Risk Score/Category

Using the assessments of frequency and severity the Risk score is obtained by:

Risk Score = Frequency x Severity

The Risk Category is obtained by plotting the frequency and severity gradings on the following risk matrix.

Risk Matrix

	Severity				
Frequency	**1 Insignificant**	**2 Minor**	**3 Moderate**	**4 Major**	**5 Catastrophic**
5 Almost Certain					
4 Likely					
3 Possible					
2 Unlikely					
1 Rare					

Section K **Absence From Work**

The designated line manager (Adverse events/incidents) should enter the actual absence at the time of completing the form.

Section L **Proposed Further Action**

This section should be completed by the designated line manager (adverse events /incidents) and detail any proposed action to be taken.

Further Investigation

This section should also be completed by the designated line manager (adverse events/incidents) and should further investigation be deemed necessary a nominated investigation officer and root cause analysis lead officer should be detailed as appropriate.

Section M **Troubles Related**

Incidents relating to the troubles are those incidents in which staff or service users are threatened, harmed or attacked, physically or verbally, during politically motivated incidents or civil unrest. Incidents where staff are delayed or prevented delivering services and service users are unable to avail of Trust services should also be included.

Section N **Signatory**

This section should also be completed by the designated line manager (adverse events/incidents)

Please Remember

Part A should be completed within 24 hrs of the incident.

Part B to be completed within 10 working days.

NORTH & WEST BELFAST HEALTH & SOCIAL SERVICES TRUST

DATIX CHANGE REQUEST FORM

Change Request *To be used to request an addition, deletion or amendment to the Datix system fields and reports, or where an error or failure is detected.* *One form to be completed for each request and sent to: Gillian Moore, Glendinning House*		
From (Name):		**Ward/Department:**
Facility:	**Tel. Extn:**	**Date:**

Module *(please tick as appropriate)*:	**INCIDENT** ☐	**CLAIMS** ☐	**COMPLAINTS** ☐
	RFI ☐	**OTHER** ☐	*specify -*
DETAILS OF ADDITION OR AMENDMENT REQUESTED			
Field / report / document / record name and Datix ID No: *(as shown on screen)*			
Addition:			
Amendment:			
Deletion: *(please give record or document number and date created)*			
Error: *(please give full error message details where appropriate)*			
Reason for change and additional comments:			

For Risk Management use only

Impact Analysis: *(please tick)*	Field Update – No Impact	**Field Update – impact on existing data**	**Duplicate/s to be removed**	**Application error to be reported to Datix**	**P.C./ Network error**	**Conflict identified**
	☐	☐	☐	☐	☐	☐
Recommendation:	Accept & Implement	**Report to Datix**	**Report to I.T**	**Defer**	**Reject**	
	☐	☐	☐	☐	☐	
Action Required:						
Authorisation: (Name & signature)	Date:	**Date Actioned:**				
		Initials:				

NORTH & WEST BELFAST HEALTH AND SOCIAL SERVICES TRUST

ADVERSE INCIDENT INVESTIGATION

EVENT CHRONOLOGY

Full name:	
Address:	
Date of Birth	
Ward / Dept:	
GP (if relevant):	
Patient / client / staff no:	
Date of incident:	
Notification by:	
Compiled by:	

*The following is a tabulation of relevant events concerning this case presented in chronological order and interspersed with observations in **bold italic**.*

Date	Event	Source of Information

PRIVATE AND CONFIDENTIAL

NORTH & WEST BELFAST HEALTH AND SOCIAL SERVICES TRUST

ADVERSE INCIDENT INVESTIGATION

STATEMENT

Statement relating to Incident concerning [name of patient, client, relative, member of staff, etc.], Hospital No / Ref No: [number] on the [date] at [location, including ward / department, hospital site].

Statement prepared by	
Full name:	
Designation:	
Facility	
Ward / Dept:	
Date of preparation:	

STATEMENT

Signed:	
Date of signing:	

NORTH & WEST BELFAST HEALTH AND SOCIAL SERVICES TRUST

SERIOUS ADVERSE INCIDENT REPORT

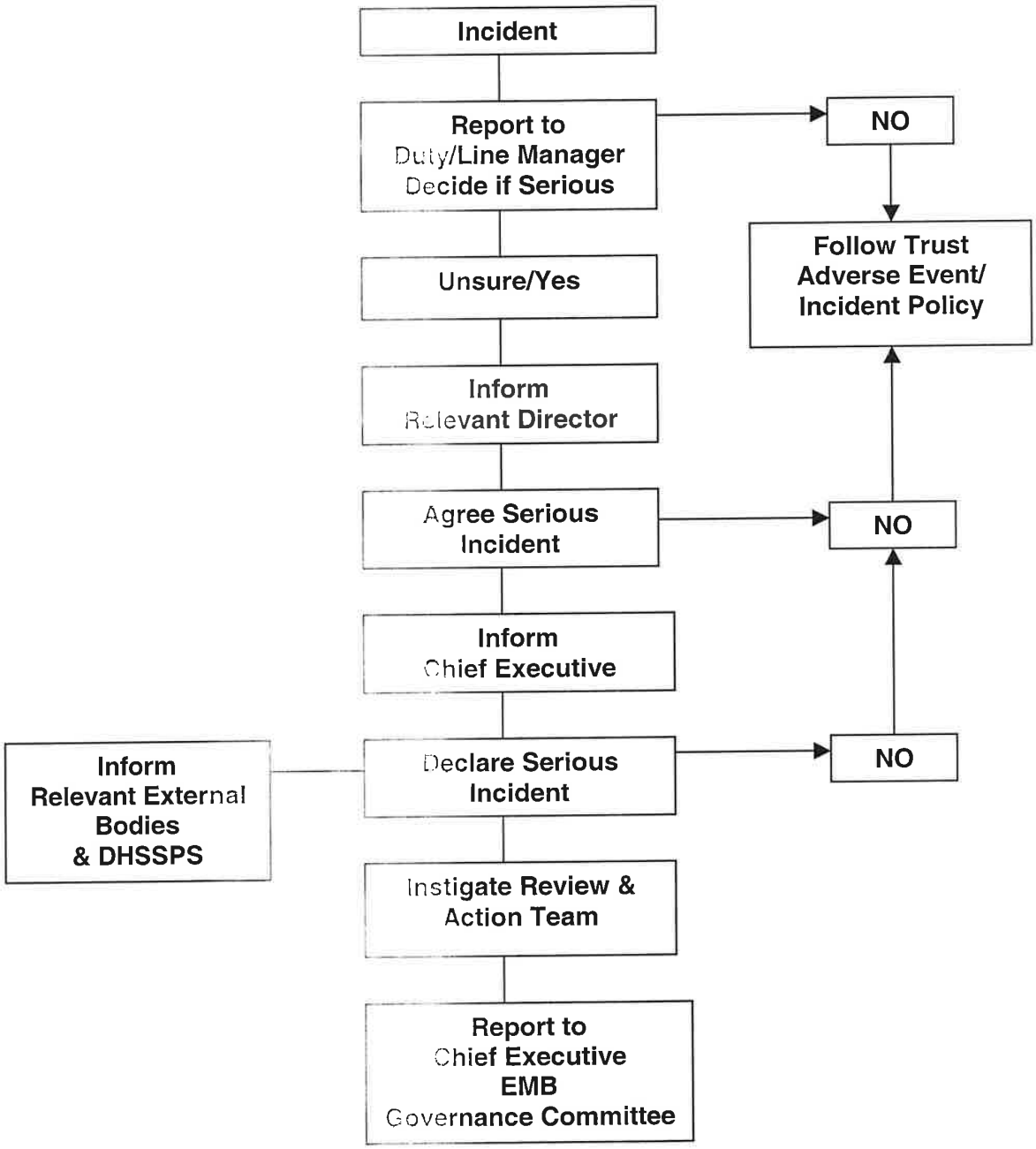
1 Organisation
2 Brief Summary (And Date) Of Incident
3 Why Incident Considered Serious
4 Action Taken
5 Is Any Regional Action Recommended? *If yes, full details should be submitted*
Yes / No
6 Is An Independent Review Being Considered? *If yes, full details should be submitted*
Yes / No
7 Other Organisations Informed
HSS Board: Yes / No PSNI: Yes / No Coroner: Yes / No NIHSE: Yes / No Other:
8 Report Submitted By *Name and contact details of nominated senior manager or chief executive*

Completed proforma should be sent, by email, to:
adverse.incidents@dhsspsni.gov.uk

If email cannot be used, fax to 028 528126

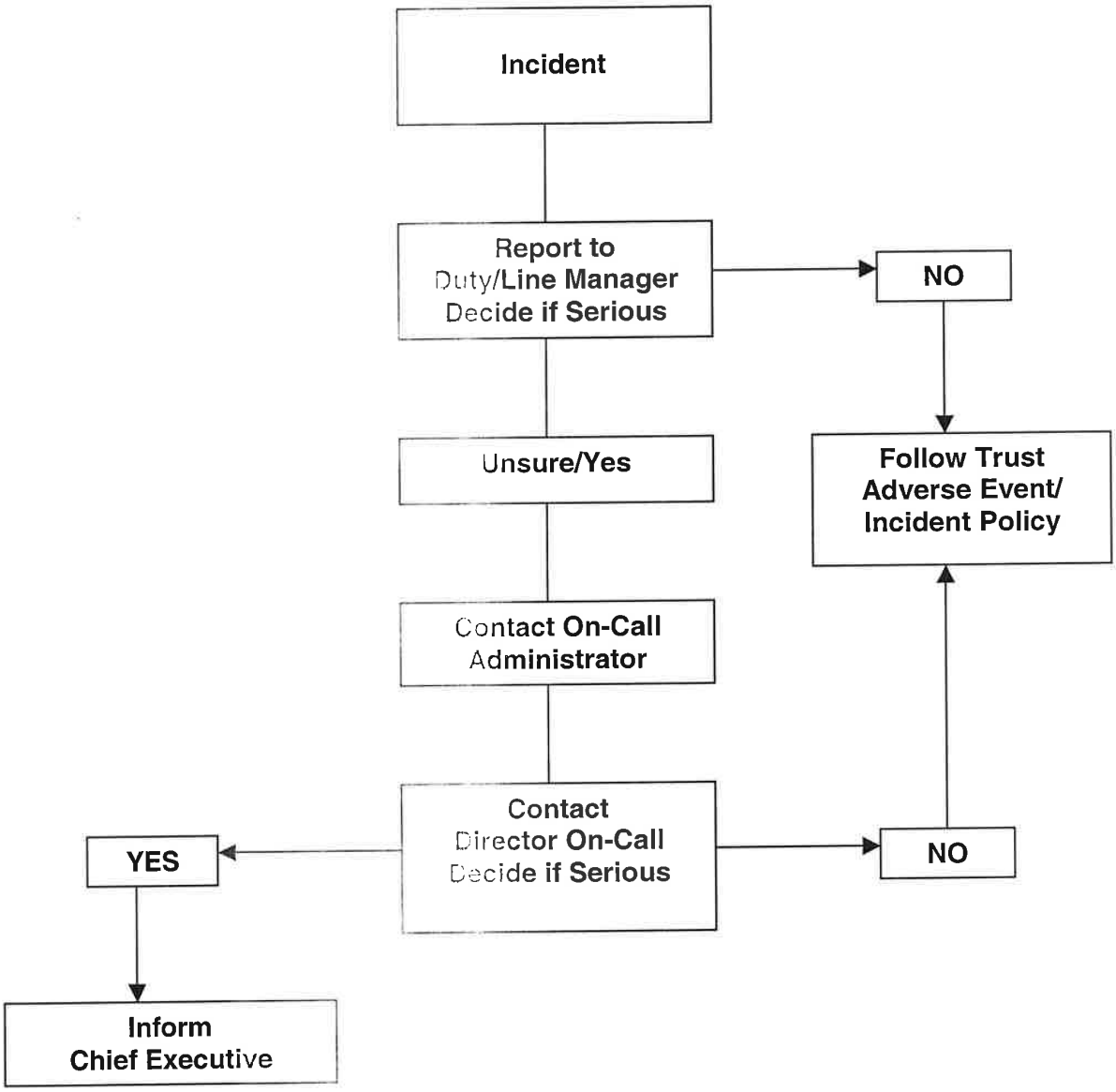
SERIOUS ADVERSE INCIDENT REPORTING FLOWCHART

DURING OFFICE HOURS



SERIOUS ADVERSE INCIDENT REPORTING FLOWCHART

OUT OF HOURS



NORTH & WEST BELFASTHEALTH AND SOCIAL SERVICES TRUST

ADVERSE INCIDENT INVESTIGATION

TIMELINE

Date	Time	Date	Time	Date	Time	Date	Time	Date	Time
Event →		Event →		Event →		Event →		Event →	
Supplementary Info		Supplementary Info		Supplementary Info		Supplementary Info		Supplementary Info	
Person(s) Present		**Person(s) Present**		**Person(s) Present**		**Person(s) Present**		**Person(s) Present**	
Source of Information		**Source of Information**		**Source of Information**		**Source of Information**		**Source of Information**	
Positive Points		**Positive Points**		**Positive Points**		**Positive Points**		**Positive Points**	
Problems		**Problems**		**Problems**		**Problems**		**Problems**	
Further Info Required		**Further Info Required**		**Further Info Required**		**Further Info Required**		**Further Info Required**	

Belfast Health and Social Care Trust

Title:	**Adverse Incident Reporting Policy and Procedure including Adverse incident Investigation Procedure**	**Ratified by Policy Committee: YES**	
Ownership:	**Belfast Health and Social Care Trust**	**Status:**	**Current:**
Publication Date:		**Review due: January 2009**	
Author(s) **Marie Bardgett, (Senior Manager for Patient/Client Safety Services)**			
Versions: **V1.0**	**Ref. TP008/08**		

CONTENTS

PART A

Adverse Incident Reporting Policy

1.0 Policy Statement

The Belfast Health and Social Care Trust is committed to providing the best possible services for patients, clients, visitors and staff. The Trust recognises that incidents will occur and that it is important to identify causes to ensure lessons are learned to prevent reoccurrence.

It is therefore essential that a responsive and effective adverse incident reporting and analysis system is in place to achieve this aim.

This policy and its linked procedures will ensure that staff have access to a comprehensive, clear and user-friendly adverse incident reporting system that will encourage the reporting of adverse incidents so that real opportunities for improvement and risk reduction are taken. Where learning from such incidents is identified the necessary changes will be put in place to improve practice.

Learning and sharing from incidents can only take place when they are reported and investigated in a positive, open and structured way. Crucial to the effectiveness of adverse incident reporting is the Trust's wish to promote an open, honest, just culture where all staff can participate in reporting incidents. Ultimately the Trust wants to encourage staff to report areas of concern and to foster a positive ethos around reporting.

All staff must report adverse incidents as outlined in the Trust procedure for adverse incident reporting. Staff who make a prompt and honest report in relation to an incident or near miss will not be disciplined except under the following circumstances:

- A breach of law
- Wilful or gross carelessness or professional misconduct
- Repeated breaches of Trust policy and procedure
- Where, in the view of the Trust, and/or any professional registration body, the action causing the incident is far removed from acceptable practice
- Where there is failure to report a serious incident in which a member of staff was involved or about which they were aware.

Mere completion of an Adverse Incident Reporting form or web form does not discharge staff of the duty of care and their risk management responsibility.

Service Group Leads eg Governance and Risk Managers should ensure timely and appropriate follow-up of adverse incidents and to identify contributing factors to these events.

Investigation officers should ensure preventative measures or procedural changes are identified to minimise risk.

Appropriate training and guidance will be provided to ensure that all Trust employees understand their responsibilities under this policy and are able to effectively fulfil their obligations to report identified risks and adverse incidents.

2.0 Definition

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 April 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*)

A **near miss** is a situation in which an event or omission, or a sequence of events or omissions, arising during clinical care fails to develop further, whether or not as the result of compensatory action, thus preventing injury to a patient.
(Organisation with a memory, Department of Health, 2000)

Incidents that did not lead to harm but could have are referred to as **near misses**.
(*Doing Less Harm. NHS. National Patient Safety Agency 2001*)

3.0 Responsibilities

3.1 Trust Board

The Trust Board is responsible for the implementation of the Trust Adverse Incident reporting Policy. It will:

- Ensure that the organisational arrangements contained within the policy and its associated procedures are implemented;
- Monitor and review the overall reporting performance and receive regular reports from the Chief Executive;
- Set corporate objectives for adverse incident management and decide on the appropriate performance indicators
- Ensure adverse incident management is integrated within the Trust's performance management and Assurance Framework.

3.2 Chief Executive

As Accountable Officer, the Chief Executive is responsible for ensuring the Trust meets it's statutory and legal requirements and adheres to the guidance issued by the Department of Health, Social Services and Public Safety for Northern Ireland (DHSSPSNI) to the Trust Board for the management of adverse incidents.

The chief executive will:

- Report at regular intervals to Trust Board on the management of adverse incidents;
- Set targets for safety and quality management.
- The Chief Executive has delegated these executive functions to the Medical Director.

3.3 Medical Director

The Medical Director or his/her deputy has responsibility for the management of adverse incidents throughout the Belfast Health and Social Care Trust. The Medical Director will report to the Senior Trust Board Team and Assurance Committee in all matters relating to adverse incidents. The Medical Director has a shared responsibility with the Director of Nursing and Patient Experience for clinical quality.

The Medical Director will ensure:

- The development of suitable organisational arrangements for the management of adverse incidents;
- The development and maintenance of systems to monitor and disseminate learning from adverse incidents across the organisation and when necessary externally;
- Systems are in place to ensure reporting of incidents to external agencies as required e.g. DHSSPSNI, Mental Health Commissioner, RQIA, etc.
- Oversee the prioritisation of action to prevent adverse incidents / risks.

3.4 Co-Director Risk & Governance

The Co-Director will support the Medical Director in meeting his/ her responsibility for health and safety management of patients, clients, staff and public, and patient safety. The Co-Director has Trust-wide lead for the co-ordination, implementation and evaluation of risk management systems and the Trust Risk Management Strategy, ensuring the Trust's approach to risk management is compliant with regional and national legislation.

The Co-Director will:

- Promote an open, honest and just culture for adverse incident reporting;
- Maintain systems for the reporting, recording and analysing of adverse incidents;
- Make arrangements for the investigation of adverse incidents
- Ensure that subsequent learning from adverse incidents is shared across the Trust, through appropriate management structures
- Take account of relevant adverse incidents when reviewing service group risk registers and ensure appropriate linkage to the corporate risk register
- Ensure that the Trust has an appropriate risk management training programme which is accessible to relevant staff.

3.5 Senior Manager for Patient / Client Safety Services

It is the responsibility of the Senior Manager for Patient / Client Safety Services, on behalf of the Medical Director, to ensure:

- All serious adverse incidents are reported to the DHSSPSNI according to circular HSS(PPM) 02/2006

3.6 Directors

It is the responsibility of directors to:

- Disseminate and promote this policy and procedures within their responsibility and ensure its implementation by providing support and advice to managers and staff
- Ensure reported adverse incidents are investigated appropriately
- Ensure that adverse incidents are monitored and reviewed within their Service Group and ensure any recommendations made as a result of investigations are implemented and monitored
- Ensure that subsequent learning from adverse incidents is shared across Service Groups, through appropriate management structures
- Take account of relevant adverse incidents when reviewing their Risk Register and ensure that this is linked appropriately to the Corporate Risk Register
- Ensure staff have access to advice and training on adverse incident reporting and management and, where appropriate, investigation and review.

3.7 Service Group Managers

Service Group Managers are responsible and accountable to their service group directors for ensuring that this policy and its procedures are effectively implemented across their area of responsibility. They must promote an open, honest and just reporting culture and ensure that appropriate investigation is carried out within their area of responsibility.

3.8 Service Group Governance and Quality Manager

It is the responsibility of the Service Group Governance and Quality Manager, on behalf of the Director, to ensure:

- All serious adverse incidents are reported the Senior Manager for Patient / Client Safety Services.

3.9 Supervisory staff

Supervisory staff have a responsibility for ensuring adverse incidents are reported and appropriate investigation is carried out.

3.10 All Staff

All Trust employees have a responsibility to:

- Report to their line manager any adverse incident they witness or are involved in
- Cooperate with any appropriate investigation process.

4.0 Reporting Adverse Incidents

4.1 When to report:

http://intranet.belfasttrust.local/Policies%20and%20Procedures/Adverse%20Incident%20-SAI%20Annex%20A%20and%20Procedure.doc

- Reporting of an adverse incident, either an event or near miss should be immediate, if this is impracticable then up to 24 hours after the incident
- A serious adverse incident ie SAI. It must be reported immediately, i.e.
  - serious enough to warrant regional action to improve safety or care,
  - be of public concern (such as serious media interest); or
  - require an independent review.

4.2 What to report:

- **Patient / Client Safety Incident** – an incident (event or near miss) in which a patient is involved that had a potential or actual adverse clinical outcome, which would not be expected to occur in the routine course of events.
  This includes medication incidents such as prescribing, dispensing, administration errors and incidents involving medical devices.
  (Examples of reportable clinical incidents are listed in Appendix A).
  All Service Groups will have agreed trigger lists of incidents they wish to report and monitor under this system.

- **Personal Incident** - Any incident which affected an individual not directly related to clinical treatment.

- **Violence, abuse or harassment** - Any incident involving verbal abuse, anti-social behaviour, racial, religious or sexual harassment or physical assault whether or not injury results.

- **Fire Incident** - Any incident, no matter how small, involving fire or fire warning systems (including false alarms).

- **Security Incident** - Any untoward incident involving theft, loss, or damage to personal or the organisations' property, intrusions, false alarms (not fire alarms), absconded patients and other security incidents.

- **Vehicle Incident** - Any incident involving a vehicle e.g. road traffic accident, excluding vandalism or theft which would be considered as a security incident.

- **Property incident** - loss or damage: whether accidental or not.

- **Any incident** - which may lead to publicity, litigation or loss of public confidence

- **Other incidents** - which might include environmental incidents (e.g. accidental discharge to drains or the atmosphere), food hygiene/safety incidents, radiation, sharps, equipment and medical devices. (This list is not exhaustive).

NB: The adverse incident reporting system does not replace other reporting systems; e.g. works and maintenance requests.

4.3 How to report:

Incidents should be reported on the Trusts incident reporting forms. Web based reporting is being rolled out across the Trust.

5.0 Procedure for managing incidents

See Flow Chart Part A, Appendix A.

- The injured person or damaged property should be assessed immediately, to ascertain extent of injuries/damages and identify emergency or urgent treatment/action required. The situation must be made safe

- Appropriate treatment/ actions should be taken to minimise the extent of injury or damage. For patient / client errors, contact the relevant medical team to assess. Refer as appropriate for medical/other opinion

- The patient/client and/or their relatives should be informed, as soon as possible of the incident and any treatment that may be necessary and before the media are involved if there is a likelihood of media interest

- Any equipment involved in the incident should be removed from use and clearly labelled, “Do not use”, until appropriate checks can be carried out

- An incident form or web based form should be completed as soon as possible, preferably by the staff member involved in the incident, and passed to the relevant line manager

- Where appropriate, witness names and contact addresses should be recorded; witness statements may be required

- Any other agencies involved in the incident should be recorded i.e. police or fire brigade

- The incident form should be completed accurately and fully stating facts not opinions

- In the case of an incident involving patients, the incident should be recorded in the patient/client’s medical notes.

- All incidents should be appropriately investigated by the person in-charge of the department/team and graded accordingly

- The level of investigation will be determined by the grading of the incident. **The relevant level of investigation should be carried out following the guidance in the Trusts Procedure for the Investigation and Root Cause Analysis of Incidents, Complaints and Claims (see Part B)**

- Management actions and preventative measures taken must be recorded.

5.1 Links with the Trust Complaints Procedure;

If an incident is being investigated under the incident reporting procedure and a complaint is received, the investigation will cease in its current form and be dealt with under the Trusts' complaints procedure.

6.0 Staff Support directly following an incident

6.1 The Trust recognises that it has a responsibility to all staff to support them, following incidents.

All staff ie. doctors, nurses, social care workers and any other staff who are involved in an incident (particularly a serious adverse incident) will need support from their peers, colleagues and managers. It is the line manager's responsibility to ensure that individuals are supported appropriately. Support can be provided by Occupational Health and the staff counselling service. Staff involved must be kept informed of the progress of an investigation at all stages. Individuals who have been absent from work may require additional support and supervision to aid confidence when returning to work.

7.0 Incident Review

All incidents along with complaints and claims will be recorded on the Datix Risk Management System managed by the Medical Directors Office. This will allow the Trust to monitor and analyse the types of incidents, complaints and claims occurring. From this clear identification of areas of success and those requiring further action can be made. The relevant committees e.g. Assurance Committee, Clinical Negligence and Incident Review committee, Health and Safety Committee, will receive regular reports to agreed timescales.

N.B. Each site will continue to use their existing incident reporting form until the new Belfast Health and Social Care Trust Incident Report Form is introduced.

8.0 Learning lessons, implementing and monitoring improvement strategies

The Trust aims to learn lessons from individual patient/client incidents, from local aggregate reviews and from wider experiences, including feedback and benchmarking. Improvement strategies aimed at reducing risk to future patients/clients will be implemented, monitored by the Trust and where appropriate, practice will be changed to improve the safety and quality of care for patients/clients.

9.0 Training

Training will be provided for all staff to ensure that each member of staff is aware of their responsibilities regarding the reporting of incidents and follow-up as required.

Records of training will be maintained within Service Groups and updated as necessary.

10.0 External Reporting

Depending on the nature of the incident the Trust is required to report details to a number of external bodies, for example:

- **Health and Safety Executive NI (RIDDOR)**
- **Northern Ireland Adverse Incident Centre (NIAIC)**
- **Health and Social Services Executive (Fire)**
- **DHSSPSNI**:
  Where a serious adverse event occurs it should be reported immediately to the Medical Director through the Senior Manager for Patient / Client Safety Services and the Directors of the Service Groups.

  If the Senior Manager for Patient / Client Safety Services considers that the incident is likely to be:

  - Serious enough to warrant regional action to improve safety or care within the broader HPSS;
  - Be of public concern; or
  - Require an Independent Review.

  He/ she will provide the Department with a brief report using the pro-forma provided in ***DHSSPSNI Circular HSS (PPM) 02/2006***

11.0 Access to Policy

http://intranet.belfasttrust.local/Policies%20and%20Procedures/Adverse%20Incident%20-SAI%20Annex%20A%20and%20Procedure.doc

12.0 This policy will be made available on the Trust's intranet site.

13.0 Review

This policy has been developed in the light of information currently available and will be reviewed annually or sooner to ensure it meets the needs of the Trust.

Appendix A

Flow chart following an incident

Adverse Event or Near Miss Occurs

↓

Carry out actions necessary to minimise harm

↓

Inform medical staff if appropriate

↓

Use facts not opinion

↓

Record incident details on Trust Incident Report Form, as soon as possible

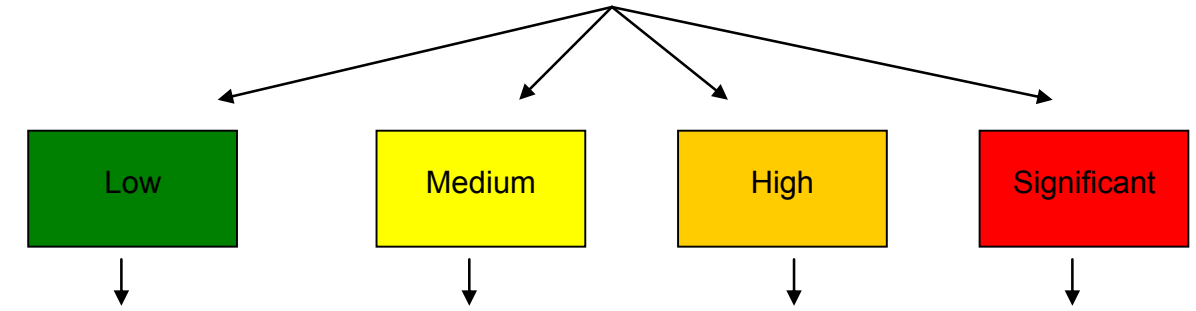
↓

SEND TO LINE MANAGER

↓

Line Manager: assess severity and likelihood of recurrence of the incident and grade appropriately
Forward to Datix Central Office(s)* on your site

If graded **orange** or **red** inform the Quality and Governance Services Manager for your Service Group, as soon as possible on day of incident



Communicate information as appropriate with patients and staff (All relatives with patient consent

↓

Investigation as per Trust Procedures for Investigation Procedure for the Investigation of Adverse Incidents, Complaints and Claims

*(1) Royal Hospitals – Musgrave & Clarke Building, (2) North & West, Glendinning House, (3) South & East - Administration Building, Knockbracken, (4) Belfast City Hospital - Finance Building, (5) Mater Hospital - Fairview House, (6) Greenpark – McKinney House

PART B

Procedure for the Investigation of Adverse Incidents, Complaints and Claims

1. Introduction

1.1 This procedure can be applied to clinical and non-clinical adverse events and complaints, it details how to decide the level of investigation required and the action to be taken by the investigation team or individual investigating. The process aims to identify and record the direct, contributory and root causes of the incident. The information obtained can then be analysed and common causes and trends highlighted. Appropriate preventative action can then be taken to avoid a recurrence.

1.2 For ease of reference adverse events, will all be referred to as “incidents” for the remainder of this procedure document.

2. Definitions

2.1 Direct cause is defined as the immediate cause which triggered the incident.

2.2 Contributory cause is defined as a cause which contributes to the incident but which by itself would not have caused the incident.

2.3 Root causes are defined as the underlying causes to which the incident can be ultimately attributed and which if corrected will prevent a recurrence.

3. Undertaking an investigation

3.1 The primary purpose of investigating an incident is to ascertain:

- What happened?
- How did it happen?
- Why did it happen?

So that appropriate action can be taken to prevent future occurrences.

3.2 While it is recognised that human error is frequently seen as the direct cause or a contributory cause of incidents, the root cause is often a more complex series of factors which have been lying dormant or have been tolerated and have come together to allow the event to occur.

3.3 Unless incidents are investigated to identify the underlying, tolerated or dormant factors, and these are addressed, any improvement strategy aimed solely at individual practice is unlikely to be successful in preventing a recurrence of that type of event.

3.4 All staff must feel safe to report incidents and safety issues and to this end the Trust operates a fair and just culture with regard to incidents in the Trust .The information they provide will be used to improve the safety and quality of health services for patients and the working environment for staff and visitors.

3.5 The incident investigation process must be:
- Fair and equitable
- Focused on learning and change
- Focused on identifying contributory and root causes

3.6 This should mean that:
- It will be a rare occurrence for a reported incident to lead to disciplinary action being taken
- The disciplinary process will only be used where it is clear that the actions of those involved included an intention to harm, a criminal act, serious professional misconduct or continued professional misconduct.

4 Deciding what to investigate

4.1 It is unrealistic to suggest that all incidents should be investigated to the same degree, or at the same level within the Trust. Furthermore the outcome of an incident, including a "near miss", is often a poor indicator of the level of investigation required.

4.2 The following risk assessment process should be applied to all incidents at the time of occurrence in order to decide what level of investigation is required and at what level within the Trust the investigation should be conducted.

5 Step One – What was the outcome of the event?

5.1 The person reporting the incident or their manager should normally undertake this stage of the assessment. Based on the perceived outcome of the incident at the time of occurrence (taking into account psychological as well as physical harm) a judgement is made as to the incident's severity based on the table below.

Insignificant No obvious injury or adverse outcome	Minor harm or Damage	Moderate Harm or Damage	Major harm or Damage	Significant harm Or damage

5.2 Incidents assessed as causing major or significant harm should be given immediate consideration for a full root cause analysis. Further investigation of these events is necessary.

5.3 For incidents causing lesser levels of harm the following stages of the assessment process should be followed to decide on the level of investigation required.

6 Step Two – What might the outcome be if the event occurs again?

(This stage of the process would apply to non-harming to moderate harming events only).

6.1 To answer this you need to think about the event and the circumstances in which it occurred. Was the outcome a chance happening? Could the outcome realistically

6.2 have been a lot worse? How many people might be hurt if it happened again? How seriously might someone be hurt if it happened again?

6.3 The Impact table,(table 1) can be used to map the answers to these questions.

Table 1: Impact Descriptors and Scores

	1	2	3	4	5
Descriptors	**Insignificant**	**Minor**	**Moderate**	**Major**	**Significant**
A Objectives/ Projects	Insignificant cost Increase/schedule slippage. Barely Noticeable reduction in scope or quality	Less than 5% over budget/ Schedule slippage. Minor reduction in scope/ quality/	5-10% over budget/ Schedule slippage. Reduction in scope or quality.	10-20% over budget/schedule slippage. Doesn't meet secondary objectives.	More than 25% over budget/schedule slippage. Does not meet primary objectives
B Injury	Minor injury not requiring first aid	Minor injury or illness first aid/intervention required. Requiring first aid	RIDDOR reportable. Semi permanent physical/emotional injury/trauma/harm. (Recovery expected within 1 year).	Permanent physical/emotional injuries/trauma/harm (Recovery expected within 1 year).	Incident that lead to one or more deaths.
C Numbers Affected	None	Very few 1 - 2	Small numbers 3 - 5	18 -50	50+
D Patient/Client Experience	Unsatisfactory patient/client experience not directly related to care	Unsatisfactory patient/client experience – readily resolvable	Mismanagement of patient/client care	Serious mismanagement of patient/client care	Totally unsatisfactory patient outcome or experience
E Complaints/ Claims	Locally resolved complaint	Justified complaint peripheral to care	Below excess claim. Justified complaint involving lack of appropriate care.	Claim above excess limit. Multiple justified complaints.	Multiple claims or single major claim.
F Service/ Business Interruption	Loss or interruption between I and 8 hours	Loss/interruption between 8 and 24 hours	Loss/interruption between 1 and 7 days	Loss/interruption more than 1 week	Permanent loss of service or facility
G Staffing and Competence	Short term low staffing, level temporarily reduces service quality (less than 1 day)	Ongoing low staffing level reduces service quality	Late delivery of key objectives/service due to lack of staff. Minor error due to poor training. Ongoing unsafe	Uncertain delivery of key objective/service due to lack of staff. Serious error due to poor training	Non delivery of key objective/service due to lack of staff. Loss of key staff. Critical error due to insufficient training.
H Financial	Small Loss	Loss of more than 0.1% of budget	Loss of more than 0.2% of budget	Loss of more than 0.5% of budget	Loss of more than 1% of budget
I Inspection/ Audit	Minor recommendations Minor non compliance with standards. Recommendations given. Non-compliance with standards	Reduced rating. Challenging recommendations. Non compliance with standards.	Reduced rating. Challenging recommendations. Non compliance with core standards	Criminal prosecution/prohibition notice. Low rating. Critical report. Major non-compliance with core standards.	Prosecution. Zero rating. Severely critical report.
J Adverse publicity/ reputation	Rumours	Local media – short term interest. Minor effect on staff morale.	Local media – Long term. Significant effect on staff morale.	Regional media less than 3 days. Independent review.	Regional media more than 3 days. MLA concern.DHSSPS executive investigation following incident or complaint.

7 Step Three – What are the chances of the event occurring again?

7.1 In order to obtain a realistic assessment of the event you need to consider how likely it is that the event will occur again under similar circumstances. This can be done using the likelihood table, see Table 2.

Table 2: Likelihood Scores

	1	2	3	4	5
Descriptor	Rare	Unlikely	Possible	Likely	Almost Certain
Frequency	Not expected to Occur for years	Expected to occur at least annually	Expected to occur at least monthly	Expected to occur at least weekly	Expected to occur at least daily
Probability	< 10% Will only occur In exceptional circumstances	10-24% Unlikely to occur	25-49% Reasonable chance of occurring	50-74% Likely to occur	75% + More likely to occur than not

8 Step Four – What is the overall risk score for this event?

8.1 Take the answers you obtained in Step Two and Step Three and plot them. See table 3 below. The colour category assigned determines the level of investigation required and the level at which the investigation should be conducted.

8.1.1 The colour category will influence who is responsible for remedial action and the timescales for any subsequent investigations. See Table 3:

Table 3: Risk Rating Matrix

LIKELIHOOD	CONSEQUENCE (Potential Impact)				
	Insignificant 1	Minor 2	Moderate 3	Major 4	Significant 5
5 - Almost certain (will undoubtedly recur, a persistent issue)					
4 - Likely (will probably recur, not a persistent issue)					
3 - Possible (may recur occasionally)					
2 - Unlikely (do not expect it to happen again)					
1 - Rare (can't believe it will ever happen again)					

Risk Rating

Low	Moderate	High	Significant

8.2 Green Incidents – Insignificant harm or Low Risk

Investigated and reviewed locally in the ward/facility or in which the event occurred. The investigation lead will normally be the ward or department manager. It is likely that nothing further can be done to eliminate/reduce/control risk further. The local team should identify learning points or safety improvements and implement control measures. Any controls identified which are not within the local team's control should be communicated to more senior managers for consideration.

8.3 Yellow Incidents – Medium Risk

Investigated and managed locally, as for green incidents, but reviewed by the Co-Director / Service Improvement Manager / lead for risk and governance for that area.

8.4 Orange Incidents – Moderate harm to High Risk

Investigated and managed locally and may be subject to a root cause analysis investigation led by a suitably trained person within the Service Groups in which the event occurred. The Risk & Governance Manager in conjunction with the relevant Director should decide on the appropriate person to lead the investigation. It is the responsibility of the relevant management team to ensure that all learning points and safety improvements are appropriately identified and those not within the control of the local management team are communicated to the Risk Management/Governance Committee or the Health and Safety Committee. It is recommended that high risks are recorded on the Service Group Risk Register.

8.5 Red Incidents – Major/Significant Risks

8.5.1 Where major (i.e. permanent injury) or catastrophic harm (avoidable death or significant shortening of life expectancy) has occurred the Medical Director with the support and advice of relevant Directors and Governance Leads should appoint an investigative team led by a trained facilitator in root cause analysis. All of the resulting reports and improvement strategies should be monitored by the Trust Assurance Committee. Where the risk is not immediately reducable the risk will be added to the Service Group/Corporate Risk Register via the Assurance Group.

8.5.2 Where the incident is coded "Red" because of its potential consequences and likelihood of recurrence it is the responsibility of the relevant Co- Director to ensure the incident is managed in line with "Orange" incidents and appropriately reviewed in line with root cause analysis principles.

8.5.3 It is recognised that not all events resulting in major or significant harm are as a result of any human or system failure. In these cases the manager notified of the event should satisfy themselves that there is no need to progress to a full root cause analysis by considering the information available about the event and asking some simple questions to ascertain if there were any factors present that deserve closer inspection.

8.5.4 Ask yourself if any of the following contributed to the outcome of the event:

- Was there anything about the task / procedures involved?
- Was there anything about the way the team works together or perceives each other's role?
- Was there anything about the equipment involved?
- Was there anything related to the working environment or conditions of work?
- Was there anything about the training and education of the staff in relation to their competence to a) provide the care / service required and b) manage the event when it occurred?
- Was there anything relating to communication systems, between individual staff, departments, or electronic communications (e.g. test results via computer)?
- Was there anything about the availability, or quality, of any guidance notes, policies or procedures?
- Was there anything about the Trust's strategy, its strategic objectives and priorities?

If you answer "No" to all of these questions it is acceptable not to investigate further. If you have answered "Yes" to any of these questions some degree of root cause analysis of the incident is recommended, even if a decision is taken not to review the whole event.

9 The Investigation Team

9.1 For all moderate to very high risk events (orange – red) and events causing moderate to significant harm it is good practice for the investigation to be undertaken by more than one person. The lead facilitator should ideally have been trained in root cause analysis.

9.2 Authority to investigate an incident or to set up an investigation.

	Ward/ Department Manager	Operational Manager/ Specialty Leads	Service Group Co-director	Chief Executive/ Executive Director
Significant	X	X	X	✓
Major	X	X	✓	□
Moderate	X	✓	✓	□
Minor	✓	□	□	□
Insignificant	✓	□	□	□

9.3 Incident investigation will normally comprise of the following processes:

- Identify the incident to be investigated
- Form the investigation team
- Preserve direct evidence from the scene
- Photographs taken when possible
- Chart the event with current knowledge
- Gather documentary and other evidence
- Revise the event chart
- Arrange and carry out interviews
- Revise the event chart
- Identify casual factors
- Analyse casual factors
- Decide on option for improvement and obtain costs
- Produce an incident report
- Ensure implementation of improvement plans.

9.4 Good practice indicates that Incident investigation should normally be completed within the following timescales:

Significant event	within 45 working days
Major event or high risk/very high risk	within 30 working days
Moderate event or moderate risk	within 10-20 working days
Minor event or low risk	within 5 working days
Insignificant event or very low risk	within 1 working day

In exceptional circumstances the period of investigation may take longer.

10 Investigating the Incident

Step One: Identify the scope of the incident and collect complete information

10.1 Information Gathering

All material facts relating to the incident must be gathered as soon as possible after the event. In determining what information to collect you must consider the lead up to, as well as the incident itself. For complex events it is only by starting at the point the incident occurred and working backwards that the “start point” for the incident can be identified. For some incidents the start point will be identified as the patient’s admission to hospital (or even before).

Investigators will find it helpful to consider information from a range of sources including:

- The people involved in or witnessing the event
- The place or environment in which the event took place
- The equipment or objects involved in the event
- The paper work related to the event
- The widely held beliefs about the normal work processes, team relationships and adequacy of leadership in the workplace.

10.2 From Persons involved in the event

All staff/patients/visitors/contractors involved in the event must be identified and informed an incident investigation is taking place. They must be informed that their assistance in investigating the incident would be appreciated and that the purpose of the investigation is to identify areas where systems failed rather than to focus on human error.
All witnesses to the event should be interviewed if possible along with the “affected” person (if circumstances allow).

All staff involved in tragic or significant incidents must be advised of the availability of confidential support and counselling during what will be a stressful period, and told they can have a friend or staff side representative with them during interviews.

All staff involved in, or witness to the event must be asked to make a full record of the incident (including events leading up to and following the incident) as soon as possible after the event. Guidelines for writing a statement are included as Appendix 1.

10.3 From the Place (environment) in which the event occurred

Investigators should visit the environment where the incident took place preferably before any changes are made and note the layout. A sketch of the area and its layout may be useful particularly if annotated with the location of persons involved in the incident, and other witnesses to the incident. Photographic evidence of the environment can be invaluable.

10.4 From the Equipment or objects involved in the event

Any piece of equipment involved in the incident should be removed and preserved as evidence.

10.5 From any Paper evidence

For example:

- Guidelines, policies and procedures
- Clinical records
- Incident reports
- Risk assessments
- Maintenance records
- Clinical audits

10.6 From Working Practices

It is important to elicit custom and practice in the workplace in which the incident occurred. The information obtained can help you shape the context in which factors which leave an area vulnerable to incidents have come to pass.

11 Investigating the Incident

Step Two: Sort and Map the Data

The chronology of events is of utmost importance in your investigation and must be mapped out to allow identification of problem areas and areas of good practice in the sequence of events. Two common methods of doing this are shown below.

This consists of a timed record of events as they took place in chronological order. Dates and times should be recorded on the left of the page with a narrative stating what happened.

11.1 **Diagrammatic Timelines**

This provides a much greater degree of clarity about the key stages of the event and allows the recording of supporting information. It also allows mapping of the interface between involved agencies on a single document. The timeline will assist investigators to identify the primary issues or concerns which require a causal analysis.

When mapping the event timeline you can start at the point from which the chain of events leading to the incident occurred or work backwards from the incident until you reach what you believe to be the start point.

Each happening, plus the date and time of its occurrence are placed in a rectangular or square box in chronological order. Arrows indicating the flow of time connect the boxes. Supporting information that assists in building up the picture can be attached at relevant points on the time line. An example time line is included as Appendix 2.

12 Investigating the Incident

Step Three: Problem Identification and Prioritisation

As you map the chronology of events you will generate questions to which you will need answers. Some of these will be issues relating to the chain of events and issues of clarification, others will be “Why” questions as you try to understand how the event happened.

The fact based questions can be answered with relative ease by going back to the people involved in the incident. The “Why” questions are harder to answer and may require the involved parties to get together with the support of the investigation team to explore the unanswered questions.

Having gathered all relevant information about the incident you are now ready to perform a root cause analysis.

12.1 **Option 1 : Investigation Team Analysis**

Using the information collected during the investigation the investigation team can independently undertake the causal analysis using brain storming techniques.

12.2 Option 2 : Critical Incident Meeting

Call a critical incident meeting and invite all relevant staff. The purpose of such a meeting is to:

- Present a full chronology of events
- Involve them in identifying and prioritising the critical issues that need to be explored further
- Explore the critical issues for contributory / influencing factors and root causes
- Generate a series of recommendations
- Acknowledge and commend identified good practice and action taken in mitigating the seriousness of the incident

13 Investigating the Incident

Steps Four and Five: Problem Exploration and Identification of Quality Improvements

The problem should be explored using Root Cause Analysis tools. Some easy to use root cause analysis tools have been detailed below.

13.1 Brainstorming

This is a familiar technique that can be used to assist the group to identify the issues that need further exploration. There are no right or wrong answers and the trick is not to allow any in-depth exploration during the brainstorm. The facilitator must record the ideas as they are spoken.

13.2 The Five Why's

This is used to delve deeper into a problem asking "why?" for each primary cause identified, then asking "why" again in response to each answer until there are no more causes forthcoming. It is best suited for exploring simple non-complex problems. As a brief rule of thumb it usually takes about five rounds of asking "why?" to identify the root cause of a problem, but you may need to ask why more or less than five times.

You can only investigate one cause at a time using this method and it is better to follow each identified cause to its end before investigating another.

13.3 Fishbone Diagrams

Draw a long horizontal arrow on a sheet of paper. At the head of the arrow write the problem to be explored. Spines are then added to the arrow and each spine is given a classification label representing the main areas under which you want to explore the contributory factors to the identified problem. It is suggested that the following classifications be used to explore the problem.

- Patient factors
- Individual (staff member)
- Team and social factors
- Equipment
- Work conditions

- Task / process
- Communications
- Education and training
- Strategic management

You should then consider each classification in turn and consider if there were any issues of influence that map under it. Not all influencing factors are negative. You could also identify positive factors that reduced the impact the identified problem had on the incident. This is particularly true of “near miss” incidents. These should be recorded as swell as they can make a valuable contribution to safety improvement strategies. An example fishbone diagram is included as Appendix 3.

13.4 Cause and Effect Charting

This is extremely useful if you wish to view the incident as a whole. It builds on the timeline discussed in section 12 (above). It allows you to chart the chronology of events and add conditions, changes, barriers and influencing and causal factors. The cause and effect chart is constructed using defined features denoted by symbols and lines as depicted in Appendix 4.

Step 1

Define the scope of the chart:
- Initiating event (i.e. the start of the incident’s journey)
- Terminal event (the incident being investigated)

Step 2

Assess information and documentation for completeness
- What happened
- When did it happen
- How did it happen
- What were the consequences

Step 3

Construct a timeline (as in section 12.2) then at the appropriate places along the timeline:
- Insert secondary events (supporting information and other happenings not part of the direct sequence of events)
- Insert conditions (e.g. working conditions, availability of equipment, skill mix)

Step 4

Gather new facts and add these to the chart
- Insert new information
- Identify and add underlying conditions

Step 5

Identify and add causal factors and failed barriers
- Decide what actions were inappropriate
- Verify that the facts support your conclusions

Step 6

Identify corrective actions taken and needed
- Based upon failed barriers and causal factors
- Corrective actions must be supported by facts and feasible

14 Investigating the Incident

Step six – Generating the Incident Investigation Report, Recommendations and an Action Plan

The incident report must be easy to follow and clearly present the salient points. It is recommended that the report should follow the structure outline in Appendix 5 (Health and Social Care Regional Guidance for Incident Investigation / Review Report, DHSSPSNI, September 2007).

Recommendations must be focused on addressing the root causes or fundamental issues associated with the incident i.e those things that once addressed will prevent the problem from recurring. Recommendations should make explicit where you think responsibility lies for considering or acting on the recommendations. Recommendations can include supervisory and training issues. Recommendations should also include some indication of the risk of doing nothing.

Key points for formulating action plans:
- All action planned must be within the control of the person / team making the plan
- The person / team must agree and own the content of the plan
- The person responsible for implementing each point of the plan must be identified and instructed
- Time scales for the delivery of completed action points must be agreed
- Monitoring and review processes must be agreed.

15 Review

This procedure has been developed in the light of currently available information and will be reviewed annually or sooner if needs arise.

Policy Links

Links to other Belfast Health and Social Care Trust policies / procedures

- Whistle blowing policy
- Health and Safety Policy
- Fire Safety Policy
- Medical Devices Policy
- Disciplinary Procedures
- Major Incident Plan
- Infection Control Policy and Procedures
- Claims Management Policy/Procedure
- Medication Policy
- Violence and Aggression Policy

Policies can be found on the Belfast Health and Social Care Trust Intranet

Acknowledgements

The above policy and procedures has been developed from the policies and procedures, which were in place in the legacy acute and community Trusts.

The Belfast HSC Trust would like to acknowledge and thank the staff in the Governance and Risk Management departments who have devised, maintained and updated their policies and procedures to reflect regional and national best practice.

Legacy Trusts

Belfast City Hospital
Greenpark Hospital
Mater Hospital
North and West Belfast Health and Social Services
Royal Group of Hospitals
South and East Belfast Health and Social Services

Appendix 1

Guidelines for Writing a Statement

1. There are many circumstances in which you may be called upon to provide a written statement. This may be as a result of being asked to give an opinion as a health care professional, or as part of an investigation into an incident, complaint or claim. Reports may be of a factual nature, such as a description of the events surrounding an incident, or an opinion, which is an interpretation of facts such as an evaluation of a patient's prognosis. The report should be directed to the purpose for which it is required, it is therefore important that you recognise what type of statement you are being required to give.

2. These guidelines aim to provide you with some simple advice on preparing a statement of fact, which has been requested for an investigation into an untoward event that has occurred during the course of your employment.

3. You must assume that the reader of your statement knows nothing of the facts of the case, of the patient's medical history or of hospital routines. The statement will thus form a story which will tell an intelligent lay person (the coroner in the case of a death) the circumstances of the incident as you remember them.

4. Use good quality A4 paper. Do not use scraps of paper, pages from notepads, medical records sheets, or the backs of documents designed for other purposes.

5. Statements should be typed using only one side of each page. Wide margins and double line spacing are recommended. If it is not possible to have your statement typed you must write neatly using black ink.

6. Each page should be numbered consecutively in the right hand corner and all of the pages should be securely fastened together.

7. Each page should be headed with the incident, complaint or claim reference number.

8. Begin the statement with your name, professional qualifications, length of service and what post you hold within the Trust.

9. Be clear about the times you were on and off duty on the days in question and about what you saw and heard. Put events in the order in which they happened giving precise dates and times (using am or pm or the 24 hour clock).

10. State your location at the time of the incident and name any other witnesses who were present. When referring to other people in your statement give their full names and job titles.

11. Stick to facts and avoid expressing opinions. Only include facts or conversations you have actually witnessed or taken part in. Do not include things that other people told you happened or conversations reported to you.

Appendix 1

12. Write your statement in simple terms and avoid using jargon or abbreviations. Be as brief as possible while covering all essential points.

13. All numbers, including dates, should be expressed in figures, not words.

14. If you include in your statement any information you have read in professional records, documents, papers or notes you should include references as to where it can be found e.g.: "It is recorded on 23/9/2002 on Mrs Smith's communication sheet that a request for a CT scan had been sent to Radiology."

15. Your statement should be written in the first person i.e.: "I was asked by Staff Nurse Jane Smith to record Mr Green's blood pressure."

16. Any alterations to your statement should be made by drawing a single line through the words you wish to change. This should then be initialled.

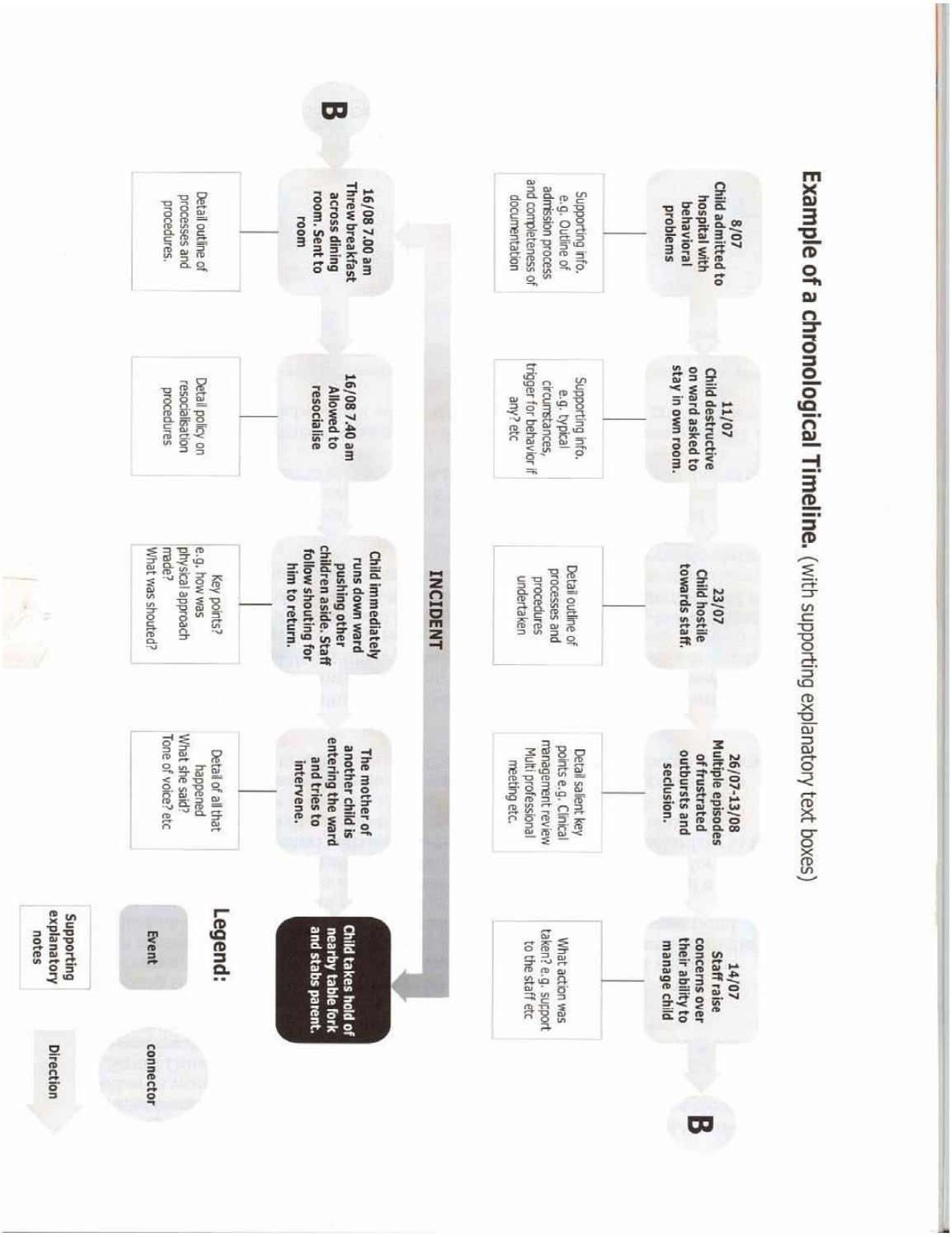
17. The final paragraph of your statement should read: "This statement is true to the best of my knowledge and belief."

18. Your statement should be signed and dated. You should also print your full name and job title.

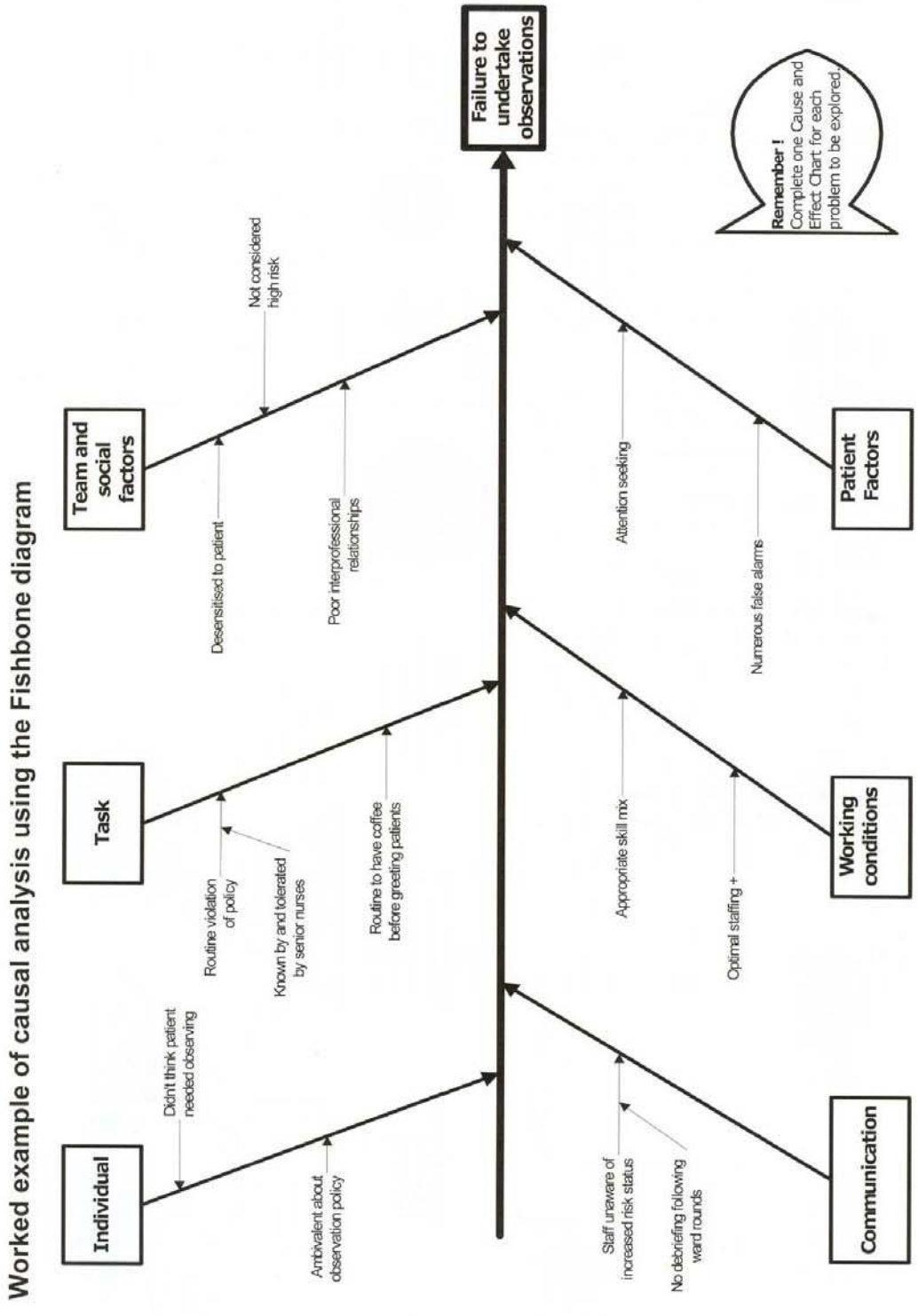
19. Double check your statement before signing it. It is recommended that you keep a copy of your statement for your own records.

20. Remember that unless your statement has been prepared for a legal claim it will be disclosable. You should therefore make sure that you are happy for others to read it. If you need help of advice in writing a statement ask your manager.

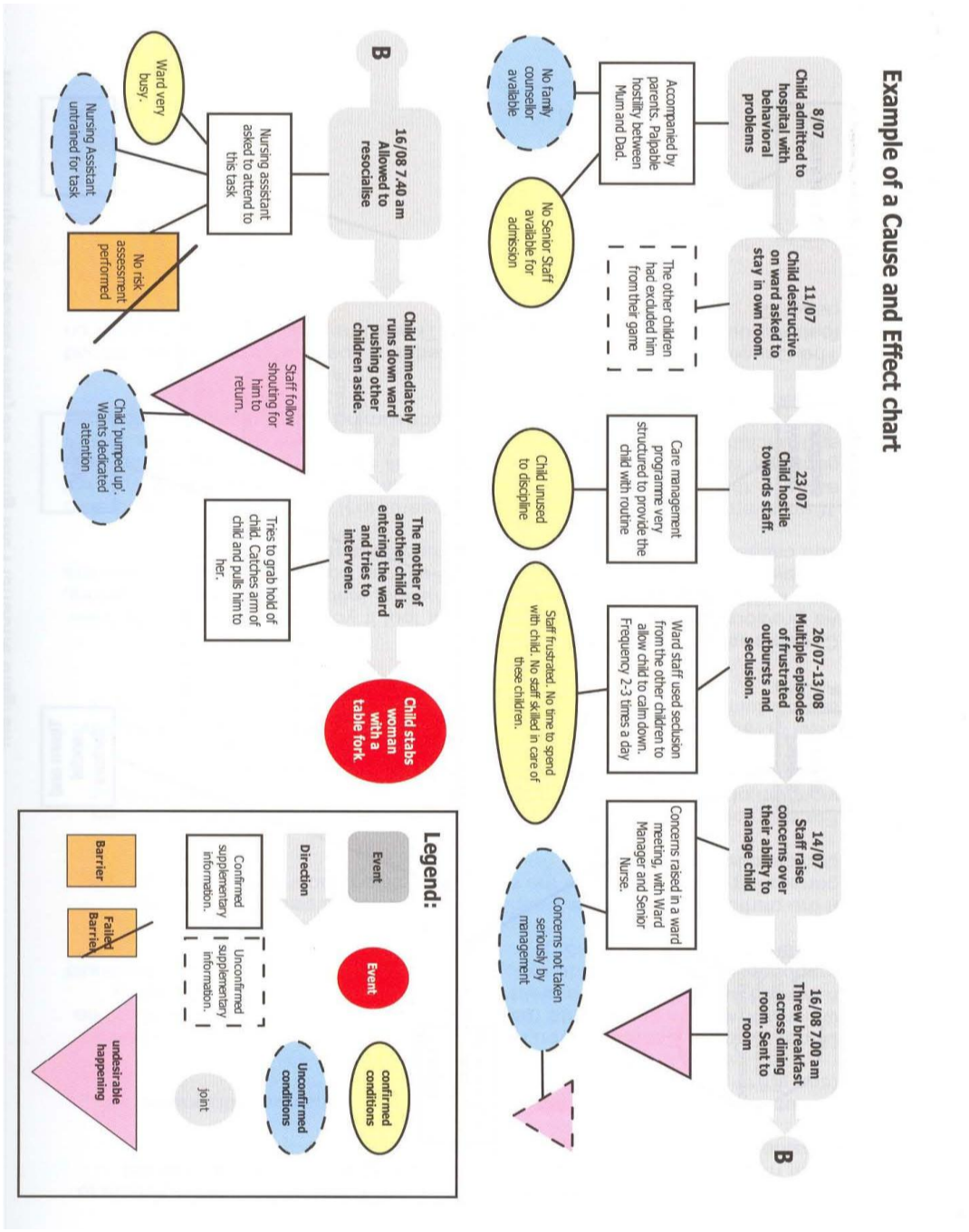
Appendix 2


Example of a chronological Timeline. (with supporting explanatory text boxes)
8/07
Child admitted to hospital with behavioral problems
Supporting info. e.g. Outline of admission process and completeness of documentation
11/07
Child destructive on ward asked to stay in own room.
Supporting info. e.g. typical circumstances, trigger for behavior if any? etc
23/07
Child hostile towards staff.
Detail outline of processes and procedures undertaken
26/07-13/08
Multiple episodes of frustrated outbursts and seclusion.
Detail salient key points e.g. Clinical management review Multi professional meeting etc.
14/07
Staff raise concerns over their ability to manage child
What action was taken? e.g. support to the staff etc
B
INCIDENT
Child takes hold of nearby table fork and stabs parent.
The mother of another child is entering the ward and tries to intervene.
Detail of all that happened What she said? Tone of voice? etc
Child immediately runs down ward pushing other children aside. Staff follow shouting for him to return.
Key points? e.g. how was physical approach made? What was shouted?
16/08 7.40 am
Allowed to resocialise
Detail policy on resocialisation procedures
16/08 7.00 am
Threw breakfast across dining room. Sent to room
Detail outline of processes and procedures.
B
Legend:
Event
connector
Direction
Supporting explanatory notes

Appendix 3


Worked example of causal analysis using the Fishbone diagram
Failure to undertake observations
Remember !
Complete one Cause and Effect Chart for each problem to be explored.
Team and social factors
Task
Individual
Working conditions
Patient Factors
Communication
Not considered high risk
Desensitised to patient
Poor interprofessional relationships
Routine violation of policy
Known by and tolerated by senior nurses
Routine to have coffee before greeting patients
Didn't think patient needed observing
Ambivalent about observation policy
Appropriate skill mix
Optimal staffing +
Staff unaware of increased risk status
No debriefing following ward rounds
Attention seeking
Numerous false alarms

Appendix 4


Example of a Cause and Effect chart
8/07 Child admitted to hospital with behavioral problems
Accompanied by parents. Palpable hostility between Mum and Dad.
No family counsellor available
No Senior Staff available for admission
11/07 Child destructive on ward asked to stay in own room.
The other children had excluded him from their game
23/07 Child hostile towards staff.
Care management programme very structured to provide the child with routine
Child unused to discipline
26/07-13/08 Multiple episodes of frustrated outbursts and seclusion.
Ward staff used seclusion from the other children to allow child to calm down. Frequency 2-3 times a day
Staff frustrated. No time to spend with child. No staff skilled in care of these children.
14/07 Staff raise concerns over their ability to manage child
Concerns raised in a ward meeting, with Ward Manager and Senior Nurse.
Concerns not taken seriously by management
16/08 7.00 am Threw breakfast across dining room. Sent to room
B
B
16/08 7.40 am Allowed to resocialise
Nursing assistant asked to attend to this task
Ward very busy.
Nursing Assistant untrained for task
No risk assessment performed
Child immediately runs down ward pushing other children aside.
Staff follow shouting for him to return.
Child 'pumped up'. Wants dedicated attention
The mother of another child is entering the ward and tries to intervene.
Tries to grab hold of child. Catches arm of child and pulls him to her.
Child stabs woman with a table fork
Legend:
Event
Direction
Confirmed supplementary information.
Barrier
Event
Unconfirmed conditions
Unconfirmed supplementary information.
Failed Barrier
confirmed conditions
joint
undesirable happening

Appendix 5

Health and Social Care Regional Template and Guidance for Incident Investigation / Review Report, DHSSPSNI, September 2007.

Appendix 5

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

Appendix 5

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.

Appendix 5

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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

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/7

Appendix 5

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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.

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References, circulars and guidance

Being Open. Communicating patient safety incidents with patients and their carers. The National Patient Safety Agency, 2005 www.npsa.nhs.uk

Doing Less Harm; Improving the Safety and Quality of Care through Reporting, Analysing and Learning from Adverse Incidents, Department of Health and The National Patient Safety Agency, 2001

Organisation with a memory; Report of an expert group on learning from adverse events on the NHS, Department of Health, 2000

Seven Steps to Patient Safety A guide for NHS staff SSG/2003/01 - The National Patient Safety Agency www.npsa.nhs.uk/health/resources/7steps

Decision making tool to reduce unnecessary suspensions and support a safety culture – The National Patient Safety Agency www.npsa.NHS.uk/idt

Confidentiality: Protecting and Providing Information. General Medical Council 2004

Circular HSS (PPM) 06/04 Reporting and follow-up on serious adverse incidents: Interim Guidance, DHSSPS
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

Circular HSS (PPM) 02/06 Reporting and follow-up of Serious Adverse Incidents
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

NIAIC Safety Notice MDEA (NI) 2004/01 Reporting Adverse Incidents and Disseminating Medical Device/Equipment Alerts. Health Estates, Northern Ireland Adverse Incident Centre.

Mental Health Commission for Northern Ireland: Monitoring of Untoward Events by the Mental Health Commission (Revised Guidance) S6/2006 April 2006.

Taylor-Adams S.E (2002) Long version of the CRU/ALARM protocol: Successful Systems Event Analysis (in print).

Safety First: A Framework for Sustainable Improvement in the HPSS, DHSSPS, March 2006

Establishing an Assurance Framework: A Practical Guide for management boards of HPSS organisations DHSSPS January 2006

Memorandum of Understanding Investigating patient or client safety incidents (Unexpected death or serious untoward harm) DHSSPS, PSNI, Coroners Service and HSENI, February 2006

The Quality Standards for Health and Social Care, Supporting Good Governance and Best Practice in the HPSS, DHSSPS, March 2006

Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults DHSSPS & PSNI 2003

Co-operating to Safeguard Children DHSSPS 2003
http://www.dhsspsni.gov.uk/publications/2003/safeguard/safeguard.asp

Choosing to Protect – A Guide to Using the Protection of Children, Northern Ireland [POC (NI)] Service. DHSSPS 2005
http://www.dhsspsni.gov.uk/foi/Prof_advice.asp

Choosing to Protect – A Guide to Using the Protection of Vulnerable Adults, Northern Ireland [POC (NI)] Service. DHSSPS 2005
http://www.dhsspsni.gov.uk/foi/Prof_advice.asp

Protocol for Joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse – NI September 2004

A Guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 ISBN 0 337 11259 2

Northumbria Healthcare NHS Trust

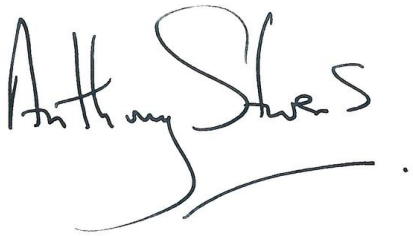
'Six steps to Root Cause Analysis', Maria Dineen

Section 16: Signature and Authorisation

Template Completed By:

Name: Marie Bardgett, Senior Manager for Patient/Client Safety Services

Directorate: Medical Director Corporate Service Group & Human Resources



Signature: …… Date: 20 February 2008
Dr. A B Stevens, Medical Director

Approved by: Policy Committee **Date:** 25 February 2008

Chief Executive: …….. Date: 27 February 2008

2013

Belfast Health and Social Care Trust

TYPE OF DOCUMENT Trust Policy for approval by **Trust Policy Committee**

REFERENCE NUMBER	To be assigned by Trust committee
TITLE	Adverse Incident Reporting and Management Policy
Summary	This policy provides the framework for reporting and managing all adverse incidents and near misses, which affect patients/clients, employees, contractors, visitors to premises, or have an impact on the BHSCT, its reputation, or its legal duty of care. The Trust is committed to an open and just culture and reporting of adverse incidents is encouraged so that the organisation can learn from mistakes and take actions to reduce the risk of reoccurrence
Supercedes	*BHSCT Adverse Incident Reporting Policy*
Operational date	*01.04.2010*
Review date	*01.04.2013*
Version Number	*2.0 Revised Adverse Incident Policy*
Director Responsible	*Dr AB Stevens*
Lead Author	Claire Cairns
Lead Author, Position	Senior Manager, Corporate Governance Services
Department / Service Group	Risk & Governance Department Medical Directors Group
Contact details	*Claire Cairns, 028 90565648*
Additional Author(s)	*Ann Johnston, 028 90631086*

Version Record

Date	Version	Author	Comments
25/2/08	1.0	M Bardgett	Adverse Incident Reporting and Management Policy
19/4/10	2.0	CRCairns	Revised Adverse Incident Reporting and Management Policy

Policy Record

		Date	Version
Author - CR Cairns/ A Johnston	Approval	19/4/10	2.0
Director Responsible – Dr AB Stevens	Approval	19/4/10	2.0

Approval Process – Trust Policies

Policy Committee	Approval		
Executive Team	Authorise		
Chief Executive	Sign Off		

Approval Process – Clinical Standards and Guidelines

Standards and Guidelines Committee	Approval		
Policy Committee	Ratify		
Executive Team	Authorise		
Appropriate Director	Sign Off		

Local Approval Process

	Approval		

Dissemination

Areas :	

Title:
Adverse Incident Reporting and Management Policy

1.0 Purpose

1.1 The aim of adverse incident management is to ensure that systems are in place to secure patient/client, staff and visitor safety, ensure internal accountability and safeguard the BHSCT assets and reputation. Learning from adverse incidents and near misses enables the Trust to reduce risk and improve services proactively.

1.2 The purpose of this policy is to enable a robust and systematic approach to be consistently applied to the management of all adverse incidents in the BHSCT. In so doing, ensure that the BHSCT meets all relevant statutory responsibilities and reporting requirements; and that the BHSCT safeguards the wellbeing of its patients/clients, staff and visitors.

2.0 Objectives

- To provide a safe environment for patients/clients, staff and visitors.
- To provide staff with an opportunity to participate in and effect changes in practice and patient/client care
- To provide information to allow effective evaluation and monitoring of patient/client care, services and procedures
- To provide formal documentation to assist in the management of complaints, claims and investigations by statutory bodies
- To facilitate organisational learning to reduce subsequent/similar risk

3.0 The Scope:

This policy applies to all staff in the Belfast Health & Social Care Trust. This includes contractors, students, bank, volunteers and agency staff. The policy should be read in conjunction with the Risk Management Strategy, the Health & Safety Policy, the Claims Management Policy, the Complaints policy and the Management of Medical Devices policy and the Whistle Blowing Policy.

4.0 Policy Statement(s):

4.1 The Belfast Health and Social Care Trust is committed to providing the best possible services for patients, clients, visitors and staff. The Trust recognises that adverse incidents will occur and that it is important to identify causes to ensure lessons are learned to prevent reoccurrence.

4.2 It is therefore essential that a responsive and effective adverse incident reporting and analysis system is in place to achieve this aim.

4.3 This policy and its linked procedures will ensure that staff have access to a comprehensive, clear and user-friendly adverse incident reporting system that

will encourage the reporting of adverse incidents so that real opportunities for improvement and risk reduction are taken.

4.4 Where learning from such adverse incidents is identified the necessary changes will be put in place to improve practice. Learning and sharing from adverse incidents can only take place when they are reported and investigated in a positive, open and structured way.

4.5 Crucial to the effectiveness of adverse incident reporting is the Trusts wish to promote an open, honest and just culture where all staff can participate in reporting adverse incidents. Ultimately the Trust wants to encourage staff to report areas of concern and to foster a positive ethos around reporting.

4.6 All staff must report and manage adverse incidents according to this policy and related procedures for adverse incident reporting (see page 9). Staff who make a prompt and honest report in relation to an adverse incident or near miss will not be disciplined except under the following circumstances:

- A breach of law
- Wilful or gross carelessness or professional misconduct
- Repeated breaches of Trust policy and procedure
- Where, in the view of the Trust, and/or any professional registration body, the action causing the adverse incident is far removed from acceptable practice
- Where there is failure to report a major or catastrophic adverse incident in which a member of staff was involved or about which they were aware.

4.7 Mere completion of an Adverse Incident Reporting form or web form does not discharge staff of the duty of care and their risk management responsibility. Service Group Managers should ensure timely and appropriate follow-up of adverse incidents and to identify contributing factors to these events. Investigation officers should ensure preventative measures or procedural changes are identified to minimise risk.

4.8 Appropriate training and guidance will be provided to ensure that all Trust employees understand their responsibilities under this policy and are able to effectively fulfil their obligations to report identified risks and adverse incidents.

5.0 Definitions:

5.1 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 April 2006*)

5.2 **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*)

5.3 A **near miss** is a situation in which an event or omission, or a sequence of events or omissions, arising during clinical care fails to develop further, whether or not as the result of compensatory action, thus preventing injury to a patient.
(Organisation with a memory, Department of Health, 2000)

'Incidents that did not lead to harm but could have are referred to as **near misses'**.
(*Doing Less Harm. NHS. National Patient Safety Agency 2001*)

6.0 Roles and Responsibilities:

6.1 Trust Board

The Trust Board is responsible for the implementation of the Trust Policy for Reporting and Management of Adverse Incidents. It will:

- Ensure that the organisational arrangements contained within the policy and its associated procedures are implemented;
- Monitor and review the overall reporting performance and receive regular reports from the Chief Executive ;
- Set corporate objectives for adverse incident management and decide on the appropriate performance indicators
- Ensure adverse incident management is integrated within the Trust's performance management and Assurance Framework.

6.2 Chief Executive

As Accountable Officer, the Chief Executive is responsible for ensuring the Trust meets its statutory and legal requirements and adheres to the guidance issued by the Department of Health, Social Services and Public Safety for Northern Ireland (DHSSPSNI) to the Trust Board for the management of adverse incidents.
The Chief Executive will:

- Report at regular intervals to Trust Board on the management of adverse incidents;
- Set targets for safety and quality management.

The Chief Executive has delegated these executive functions to the Medical Director.

6.3 Medical Director

The Medical Director or his/her deputy has responsibility for the management of adverse incidents throughout the Belfast Health and Social Care Trust. The Medical Director will report to the Senior Trust Board Team and Assurance Committee in all matters relating to adverse incidents.
The Medical Director will:

- ensure development of suitable organisational arrangements for the management of adverse incidents;
- ensure development and maintenance of systems to monitor and disseminate learning from adverse incidents across the organisation and when necessary externally;
- ensure systems are in place to ensure reporting of adverse incidents to external agencies as required e.g. DHSSPSNI, Health and Social Care Board (HSCB), Public Health Agency (PHA) RQIA, PSNI etc.
- Oversee the prioritisation of action to prevent adverse incidents / risks.

6.4 Co-Director Risk & Governance

The Co-Director will support the Medical Director in meeting his/ her responsibility for the management of adverse incident throughout the BHSCT. The Co-Director will:

- Promote an open, honest and just culture for adverse incident reporting;
- Maintain systems for the reporting, recording and analysing of adverse incidents;
- Make arrangements for the investigation of significant adverse incidents
- Ensure that subsequent learning from adverse incidents is shared across the Trust, through appropriate management structures
- Ensure that the Trust has an appropriate risk management training programme which is accessible to relevant staff.

6.5 Senior Manager for Corporate Governance Services

The Senior Manager for Corporate Governance Services will support the Co Director in meeting his/her responsibility of adverse incident management. It is the responsibility of for the Senior Manager Corporate Governance Services, on behalf of the Medical Director, to ensure:

- All serious adverse incidents (SAI's), as defined by the HSCB according to Procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAI's), April 2010[1]

6.6 Senior Manager for Corporate Risk Services

It is the responsibility of the Senior Manager for Corporate Risk Services to:

- Review all adverse incidents highlighted as RIDDOR reportable
- If necessary, liaise with Service Groups to ensure the accuracy of information
- Sign off the RIDDOR form before it is reported to HSENI

6.7 Directors

It is the responsibility of directors to:

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1 http://www.hscboard.hscni.net/consult/Policies/HSCB%20Procedure%20for%20the%20reporting%20and%20followup%20of%20SAI%20-%20April%202010.pdf Procedure for the reporting and followup of SAI – April 2010.pdf

- Disseminate and promote this policy and procedures within their responsibility and ensure its implementation by providing support and advice to managers and staff
- Ensure reported adverse incidents are investigated appropriately
- Ensure that adverse incidents are monitored and reviewed within their Service and Corporate Groups and ensure any recommendations made as a result of investigations are implemented and monitored
- Ensure that subsequent learning from adverse incidents is shared across Service Groups, through appropriate management structures
- Take account of relevant adverse incidents when reviewing their Risk Register and ensure that this is linked appropriately to the Corporate Risk Register
- Ensure staff have access to advice and training on adverse incident reporting and management and, where appropriate, investigation and review.
- Ensure all serious adverse incidents (SAI's), as defined by the HSCB according to Procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAI's), April 2010 are reported

6.8 Co Directors, Managers and Senior Clinicians

Co Directors, Managers and clinicians are responsible and accountable to their directors for ensuring that this policy and its procedures are effectively implemented across their area of responsibility. They must promote an open, honest and just reporting culture and ensure that appropriate investigation is carried out within their area of responsibility.

6.9 Service Group Governance and Quality Manager

It is the responsibility of the Service Group Governance and Quality Manager, on behalf of the Director, to ensure:

- All serious adverse incidents (SAI's), as defined by the HSCB according to Procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAI's), April 2010 are forwarded to Corporate Governance Services in a timely manner.

6.10 Line Managers

Line Managers have responsibility to:

- ensure adverse incidents are reported
- check adverse incident report forms for accuracy and completeness
- complete the appropriate section of the adverse incident report form
- forward the completed form and any associated documentation to the Corporate Governance Dept.
- ensure appropriate local investigation is carried out, in conjunction with other relevant departments if required. (See Procedure for Investigating an Adverse Incident for further guidance)

- ensure that copies of incident forms are retained in line with the Data Protection Act and Freedom of Information Act, and are not placed in the patient/client file
- ensure that their staff are aware of and adhere to this policy and associated procedures.
- Ensure staff are appropriately trained in adverse incident reporting training
- Promote a open, honest and just culture of reporting
- Ensure reporting to other external bodies as appropriate
- Ensure the Governance & Quality Manager for the Service Group is informed of a Serious Adverse Incident (SAI).
- Ensure all relevant evidence including materials, equipment, samples, records, witness details etc are not compromised until appropriate investigate is complete – refer to the Medical Devices Policy and Procedures for further guidance with regard to medical devices.
- Ensure that for adverse incidents where a death or a major injury has occurred, the security of the location and/or equipment is maintained for inspection purposes by senior managers and/or statutory authorities.
- Ensure that all possible remedial action is taken immediately following an adverse incident to prevent reoccurrence without compromising the investigation processes
- Ensure staff are given appropriate support following an adverse incident
- Communicate with the patient/client and their relatives/carers as appropriate following an adverse incident.

6.11 All Staff

All Trust employees have a responsibility to:

- ensure individuals involved (patients, clients, visitors or staff) and the environment / equipment, are made safe
- avoid putting themselves and others in situations of danger
- ensure the appropriate line manager/supervisor/ person in charge is informed
- Report adverse incidents by completing the Trust adverse incident report form (electronic or paper) and forward to their line manager / supervisor / person in charge
- co-operate with the adverse incident investigation process including the provision of witness statements

7.0 Education and Training

Training will be provided for all staff to ensure that each member of staff is aware of their responsibilities regarding the reporting of adverse incidents and follow-up as required. Records of training will be maintained within Service Groups and updated as necessary.

8.0 Consultation Process:

Workshop with Service Managers for Governance & Quality

Working in partnership with wider Risk & Governance teams

9.0 Equality and Human Rights screening carried out:

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, the Belfast Trust has carried out an initial screening exercise to ascertain if this policy should be subject to a full impact assessment.

[x] Screening completed No action required.

[ ] Full impact assessment to be carried out.

10. This policy should be read in conjunction with the following key procedures and guidelines:

Procedure for Reporting and Managing Adverse Incidents
Procedure for Grading an Adverse Incident
Procedure for Investigating an Adverse Incident
SAI Reporting protocol
Guidelines for Writing a Statement
HCAI RCA procedure to be confirmed

Director

Date: June 2010

Chief Exectutive
(For Trust Policies Only)

June 2010

References, including relevant external guidelines:

Being Open. Communicating patient safety incidents with patients and their carers. The National Patient Safety Agency, 2005
www.npsa.nhs.uk
http://www.npsa.nhs.uk/site/media/documents/1456_Beingopenpolicy1_11.pdf

Doing Less Harm; Improving the Safety and Quality of Care through Reporting, Analysing and Learning from Adverse Incidents, Department of Health and The National Patient Safety Agency, 2001

Organisation with a memory; Report of an expert group on learning from adverse events on the NHS, Department of Health, 2000

Seven Steps to Patient Safety A guide for NHS staff SSG/2003/01 – The National Patient Safety Agency
www.npsa.nhs.uk/health/resources/7steps

Decision making tool to reduce unnecessary suspensions and support a safety culture – The National Patient Safety Agency
ww.npsa.NHS.uk/idt

Confidentiality: Protecting and Providing Information. General Medical Council 2004

Circular HSS (MD) 12/2006 Guidance Document – "How to classify Incidents and Risk"
http://www.dhsspsni.gove.uk/index/hss/governance/htm

NIAIC Safety Notice MDEA (NI) 2004/01 Reporting Adverse Incidents and Disseminating Medical Device/Equipment Alerts. Health Estates, Northern Ireland Adverse Incident Centre.

Mental Health Commission for Northern Ireland: Monitoring of Untoward Events by the Mental Health Commission (Revised Guidance) S6/2006 April 2006.

UTEC Committee Guidance Note, Mental Health Commission for Northern Ireland, 2007

Long version of the CRU/ALARM protocol. Successful Systems Event Analysis (in print). Taylor-Adams S.E (2002)

Systems Analysis of Clinical Incidents The London Protocol. Taylor-Adams, S.E. & Vincent, C Clinical Safety Research Unit, Imperial College London, 2004
http://www.patientensicherheit.ch/de/projekte/londonprotocol

Safety First: A Framework for Sustainable Improvement in the HPSS,

DHSSPS, March 2006

An Assurance Framework: *a Practical Guide for Boards of DHSSPS Arm's Length Bodies March 2009*

Memorandum of Understanding Investigating patient or client safety incidents(Unexpected death or serious untoward harm) DHSSPS, PSNI, Coroners Service and HSENI, February 2006

The Quality Standards for Health and Social Care, Supporting Good Governance and Best Practice in the HPSS, DHSSPS, March 2006

Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults DHSSPS & PSNI 2003

Co-operating to Safeguard Children DHSSPS 2003
http://www.dhsspsni.gov.uk/publications/2003/safeguard/safeguard.asp

Choosing to Protect – A Guide to Using the Protection of Children, NorthernIreland [POC (NI)] Service. DHSSPS 2005
http://www.dhsspsni.gov.uk/foi/Prof_advice.asp

Choosing to Protect – A Guide to Using the Protection of Vulnerable Adults,Northern Ireland [POC (NI)] Service. DHSSPS 2005
http://www.dhsspsni.gov.uk/foi/Prof_advice.asp

Protocol for Joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse – NI September 2004

A Guide to the Reporting of Injuries, Diseases and Dangerous OccurrencesRegulations (NI) 1997 ISBN 0 337 11259 2
Northumbria Healthcare NHS Trust

'Six steps to Root Cause Analysis', Maria Dineen

A Risk Matrix for Risk Managers, National Patient Safety Agency, 2008
www.npsa.nhs.uk

2.014

Belfast Health and Social Care Trust

Reference No. TP08/08

Title:	**Adverse Incident Reporting and Management Policy**		
Author(s)	Claire Cairns, Adrienne Mc Kimm		
Ownership:	Medical Director		
Approval by:	Trust Policy Committee Executive Team	**Approval date:**	7 April 2014 9 April 2014
Operational Date:	April 2014	**Next Review:**	March 2017
Version No.	3.0 **Supercedes** Version 2.0		
Links to other policies	- Being Open Policy - Claims Management Policy & Procedural Arrangements - General Health and Safety Policy - Management of Medical Devices Procedures and Guidelines - Whistle Blowing Policy - Management of Complaints & Compliments Policy - Policy on the Data Protection Act 1998 and Protection of Personal Information - Risk Management Strategy - Protocol for Root Cause Analysis (RCA) of MRSA bacteraemias, Clostridium difficile clusters and where MRSA or C difficile is listed on Part 1 of a death certificate July 2010.BHSCT Medicines Code February 2011 - Procedure for Reporting and Managing Incidents - Procedure for Grading an Incident - Procedure for Investigating an Incident - Procedure on Memorandum of Understanding Procedure for Reporting and Managing Serious Adverse Incidents - Guidance on RIDDOR reporting - Guidance on Writing a Witness Statement		

Date	Version	Author	Comments
25/2/08	1.0	M Bardgett	Adverse Incident Reporting and Management Policy
19/4/10	2.0	CRCairns	Revised Adverse Incident Reporting and Management Policy
06/01/2012	2.1	S McCaul	Comments from H&S colleagues
11/06/12	2.2	A McKimm	Comments from Risk & Governance
20/07/12	2.3	AMcKimm	Comments from H&S re Radiation Protection & Licensing & Regulations
01/08/12	2.4	A McKimm	Further comments from Corporate Governance colleagues
4/12/13	2.5	G Moore	Comments from Corporate Governance Review Team

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11/12/13	2.6	G Moore	Comments from Corporate Governance Review Team
3/3/14	2.7	G Moore	Comments from June Champion

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CONTENTS

Belfast Health and Social Care Trust

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

This policy provides the framework for reporting and managing all adverse incidents which affect service users[1], staff and visitors to its premises or have an impact on the Belfast Health and Social Care Trust[2] (BHSCT), its reputation or its legal duty of care.

The Trust is committed to an open and fair culture and reporting of adverse incidents is encouraged so that the organisation can learn from incidents and take actions to reduce the risk of reoccurrence.

1.2 Purpose

The purpose of this policy is to enable a robust and systematic approach to the management of adverse incidents that will be consistently applied across the Trust. This will contribute to ensuring that the Trust meets all relevant statutory or mandatory responsibilities and reporting requirements and safeguards the wellbeing of service users, staff and visitors.

The aim of adverse incident management is to ensure that systems are in place to secure service user, staff and visitor safety; ensure internal accountability and safeguard the Trust's assets and reputation. Learning from adverse incidents enables the Trust to proactively reduce risk and improve services.

2.0 DEFINITIONS/SCOPE OF THE POLICY

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

2.2 **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*)

2.3 **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*)

2.4 **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[3] . The Trust will be responsible for the

[1] The term service user also refers to patients, clients, children and young people under 18 years and carers
[2] "the Trust"
[3] http://www.hscboard.hscni.net/publications/Policies/102%20Procedure_for_the_reporting_and_followup_of_Serious_Adverse_Incidents-Oct2013.pdf

Belfast Health and Social Care Trust

onward reporting of SAIs relevant internally, and to their Independent Service Providers (ISPs) and contractors, and will ensure the appropriate investigation, learning and sharing of lessons regarding same.

2.5 **Memorandum of Understanding (MoU)**[4]. Incidents involving unexpected death or serious harm and requiring investigation by the police and/or Health and Safety Executive (HSENI) are rare and there is a statutory duty placed on individuals and organisations to report such incidents. Such incidents 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 is to better facilitate these complex interactions. The MoU compliments existing joint procedures in relation to the protection of children and vulnerable adults. (See Evidence procedure)

2.6 **Service User.** The term also refers to patients, clients (including children and young people under 18 years) and carers.

3.0 ROLES/RESPONSIBILITIES

3.1 Trust Board

The Trust Board is responsible for the implementation of the Trust Policy for Reporting and Management of Adverse Incidents (and related procedures). It will:

- Ensure that the organisational arrangements contained within the policy and its associated procedures are implemented;
- Monitor and review the overall reporting performance and receive regular reports from the Chief Executive ;
- Set corporate objectives for adverse incident management and decide on the appropriate performance indicators;
- Ensure adverse incident management is integrated within the Trust's performance management arrangements and the Assurance Framework.

3.2 Chief Executive

As Accountable Officer, the Chief Executive is responsible to the Trust Board for the management of adverse incidents for ensuring the Trust meets its statutory and mandatory requirements and adheres to the guidance issued by external bodies

The Chief Executive will:

- Report at regular intervals to Trust Board on the management of adverse incidents;
- Set targets for safety and quality management.

[4] Memorandum of Understanding Investigating patient or client safety incidents (Unexpected death or serious untoward harm) DHSSPS, PSNI, Coroners Service and HSENI, March 2013 http://www.dhsspsni.gov.uk/ph_mou_investigating_patient_or_client_safety_incidents.pdf

The Chief Executive has delegated these executive functions to the Medical Director.

3.3 Medical Director

The Medical Director (or his/her deputy) has responsibility for the management of adverse incidents throughout the Belfast Health and Social Care Trust. The Medical Director will report to the Senior Trust Board Team and Assurance Committee in all matters relating to adverse incidents.

The Medical Director will:

- ensure the promotion of an open and fair culture for adverse incident reporting;
- ensure the development of suitable organisational arrangements for the management of adverse incidents;
- ensure the development and maintenance of systems to monitor and disseminate learning from adverse incidents across the organisation and when necessary externally;
- ensure that systems are in place for the reporting of adverse incidents to relevant regulatory and external agencies as required
- ensure that systems are in place for the reporting of adverse incidents relevant to professional bodies;
- oversee the prioritisation of action to prevent adverse incidents / risks.

3.4 Co-Director Risk and Governance

The Co-Director will support the Medical Director in meeting his/ her responsibility for the management of adverse incidents throughout the BHSCT and will:

- ensure the promotion of an open and fair culture for adverse incident reporting;
- ensure that systems are in place for the reporting of adverse incidents to relevant regulatory and external agencies as required;
- ensure that systems are in place for the reporting of adverse incidents to relevant professional bodies;
- ensure appropriate arrangements are in place for the investigation of serious adverse incidents (SAIs);
- ensure that subsequent learning from adverse incidents is shared across the Trust through appropriate management structures;
- ensure that the Trust has an appropriate risk management training programme which is accessible to relevant staff.

3.5 Senior Manager, Corporate Governance Services

The Senior Manager for Corporate Governance Services will support the Co Director Risk and Governance in meeting his/her responsibility for adverse incident management and will:

- ensure that systems are in place for the reporting, recording and analysing of adverse incidents;

Belfast Health and Social Care Trust

- ensure that the Trust has an appropriate adverse incident reporting and investigating training programme which is accessible to relevant staff;
- fulfil the role of NIAIC (Northern Ireland Adverse Incident Centre) Liaison Officer
- ensure that serious adverse incidents (SAI's) and Early Alerts (EAs) are reported and followed up in accordance with HSCB procedures;

3.6 Senior Manager responsible for RIDDOR

The Senior Manager responsible for RIDDOR will support the Co Director Risk and Governance in meeting his/her responsibility for adverse incident management and will ensure that systems are in place for the appropriate management and reporting of Health and Safety adverse incidents including the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 (RIDDOR). (See Guidance on RIDDOR reporting).

3.7 Head of Pharmacy and Medicines Management

All adverse incidents or concerns involving the safe use and management of Controlled Drugs must be reported directly to the Trust Accountable Officer through one of the Designated Officers.

The Accountable Office for the Trust is the Head of Pharmacy and Medicines Management and the Deputy Heads of Pharmacy are the Designated Officers.

For further guidance see:
http://intranet.belfasttrust.local/policies/Documents/Dealing%20with%20discrepancies%20or%20concerns%20involving%20Controlled%20Drugs.pdf

3.8 Directors

It is the responsibility of Directors to:

- ensure the promotion of an open and fair culture for adverse incident reporting
- disseminate and promote this policy (and related procedures and guidelines) within their area of responsibility and ensure its implementation by providing support and advice to managers and staff;
- ensure reported adverse incidents are investigated appropriately;
- ensure that adverse incidents are monitored and reviewed within their area of responsibility and that any recommendations made as a result of investigations are implemented and monitored;
- ensure that subsequent learning from adverse incidents is shared within their Directorate through appropriate assurance structures;
- ensure learning relevant to other areas is escalated through the Trust Assurance Framework.
- take account of relevant adverse incidents when reviewing their Risk Register and ensure that this is linked appropriately to the Corporate Risk Register and/or Principle Risk Document;
- ensure staff have access to advice and training on adverse incident reporting and management and, where appropriate, investigation and review;

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- ensure all serious adverse incidents (SAI's) as defined by the HSCB are managed in line with Trust procedure and are reported to the Corporate Governance Department in a timely manner.

3.9 Co Directors and Senior Clinicians

Co Directors and Senior Clinicians are responsible for supporting their Directors with the responsibilities outlined in section 3.8 of this policy, and in doing so they will ensure that this policy (and related procedures and guidelines) are effectively implemented across their area of responsibility.

3.10 Directorate Governance and Quality Managers

It is the responsibility of the Directorate Governance and Quality Manager on behalf of their Director to ensure that:

- all adverse incidents (including SAI's) within their Directorate are monitored and managed appropriately.

3.11 Line Managers

Line Managers have responsibility within their area to:

- promote a open and fair culture of reporting;
- ensure that their staff are aware of and adhere to this policy (and related procedures and guidelines);
- ensure that their staff are trained in adverse incident reporting and in the appropriate level of adverse incident investigation, including appropriate escalation as required;
- ensure that adverse incidents are reported as per Trust policies (and related procedures and guidelines);
- ensure the onward reporting of adverse incidents both internally and, where appropriate, externally and that their staff are aware of these particular local arrangements;
- ensure that copies of adverse incident forms are retained in line with the Data Protection Act and Freedom of Information Act and are not placed in the service user's file;
- secure all relevant evidence including materials, equipment, consumables, samples, records, witness details etc and ensure that these are not compromised until appropriate investigation is complete. (See Investigation and Evidence procedures);
- ensure that where a death or a major injury has occurred, the security of the location and/or equipment/consumables, is maintained for inspection purposes by senior managers and/or statutory authorities (See Investigation and Evidence procedures);
- ensure that all possible remedial action is taken immediately following an adverse incident to prevent reoccurrence without compromising the investigation processes;
- ensure appropriate local investigation is carried out in conjunction with other relevant departments if required. (See Investigation Procedure);
- ensure staff are given appropriate support following an adverse incident;

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- communicate with the service user and/or their relatives/carers as appropriate. (See "Being Open" Policy for guidance);
- provide feedback and share learning with staff and ensure that risk assessments and training needs are reviewed where relevant following adverse incident reviews.

3.12 All Staff

All Trust employees have a responsibility to:

- ensure individuals involved (service users, visitors or staff) and the environment / equipment are made safe;
- avoid putting themselves and others in situations of danger;
- report adverse incidents by completing the Trust incident report form (electronic or paper) and forwarding to their line manager / approving manager;
- be aware of any particular local service arrangements/requirements for the onward reporting both internally and externally; depending on the initial grading of the adverse incident, you may also have to telephone to allow for the prompt escalation of these adverse incidents;
- co-operate with the adverse incident investigation process including the provision of witness statements (see Guidance for Writing a Witness Statement).

4.0 KEY POLICY PRINCIPLES

Key Policy Statement
The Trust recognises its duty to provide a safe environment for service users, staff and visitors and to report incidents in accordance with mandatory and statutory reporting requirements. This will also include cooperation with statutory agencies with regard to the response to, and investigation of, incidents of suspicious / unexpected death and serious untoward harm.

4.1 Policy Principles

4.1.1 The Belfast Health and Social Care Trust is committed to providing and safeguarding the highest standards of care for service users, staff and visitors. The Trust recognises that adverse incidents will occur and that it is important to identify causes to ensure lessons are learned to reduce the likelihood of reoccurrence.

4.1.2 It is therefore essential that a responsive and effective adverse incident reporting and analysis system is in place to achieve this aim.

4.1.3 This policy (and its related procedures and guidelines) will ensure that staff have access to a comprehensive, clear and user-friendly adverse incident reporting system that will encourage the reporting of adverse incidents so that real opportunities for improvement and risk reduction are taken.

4.1.4 Learning from adverse incidents can only take place when they are reported and investigated in a positive, open and structured way. Where learning from such

adverse incidents is identified the necessary changes will be put in place to improve practice.

4.1.5 Where learning from incidents will be relevant to other areas across the Trust, and externally, the learning should be shared using as per the Procedure for Investigating an Incident.

4.1.6 All staff must report and manage adverse incidents according to this policy (and related procedures) for adverse incident reporting.

4.1.7 Crucial to the effectiveness of adverse incident reporting is the Trust commitment to the promotion of an open and fair culture where all staff can participate in reporting adverse incidents. Ultimately the Trust wants to encourage staff to report areas of concern and to foster a positive ethos around reporting.

4.1.8. Staff who make a prompt and honest report in relation to an adverse incident will not be disciplined except under the following circumstances:
- A breach of law
- Wilful or gross carelessness or professional misconduct
- Repeated breaches of Trust policy and procedure
- Where, in the view of the Trust, and/or any professional registration body, the action causing the incident is far removed from acceptable practice
- Where there is failure to report a serious incident in which a member of staff was involved or about which they were aware.

4.1.9 Mere completion of an Incident Report form does not discharge staff of their duty of care and their risk management responsibility.

4.1.10 There should be timely and appropriate follow-up of adverse incidents. Where preventative measures and/or procedural changes are identified these should be put in place to minimise the risk of the adverse incident reoccurring.

4.1.11 All Trust employees must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty of openness, transparency and candour.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

5.1.1 All staff employed by the Trust, including agency staff and contractors, should be provided with access to this policy.

5.1.2. The latest version of this policy (and its related procedures and guidelines) will be available on the Trust intranet.

5.2 Resources

5.2.1 Adverse Incident training is mandatory for all staff and appropriate training and guidance will be provided by the Corporate Governance Department to ensure that

Belfast Health and Social Care Trust

all Trust employees understand their responsibilities under this policy and are able to effectively fulfil their obligations to report adverse incidents and identified risks.

5.2.2 Managers must maintain their own records of training for staff members and ensure Trust training administration systems are appropriately utilised.

5.2.3 Managers must ensure availability of the Datixweb electronic incident reporting system where possible and should ensure that a hard copy incident book is retained as back-up.

5.3 Exceptions

5.3.1 Independent Service Providers (ISPs) and contractors will be required under their contractual arrangements to maintain a system of reporting and recording adverse incidents related to service users referred to them by the Trust for assessment and treatment and care.

5.3.2 ISPs are required to submit monitoring information as required. Adverse incidents and SAIs are discussed at contract monitoring meetings held with ISPs.

5.3.3 The Trust will decide whether an ISP adverse incident meets the criteria for reporting as a Serious Adverse Incident and is responsible for reporting the SAI to the Health & Social Care Board.

5.3.4 This policy does not provide for the DHSSPS Early Alert System which is the subject of separate DHSSPS guidance.

6.0 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

7.0 EVIDENCE BASE / REFERENCES

A Guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 ISBN 0 337 11259 2 Updated 2013 version: A brief guide .Published by the Health and Safety Executive 10/13 INDG453(rev1).

A Protocol for the Investigation and Analysis of Clinical Incidents Clinical Risk Unit (CRU) and Alarm 1999 http://www.patientsafety.ucl.ac.uk/CRU-ALARMprotocol.pdf

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An Assurance Framework: a Practical Guide for Boards of DHSSPS Arm's Length Bodies. 2009

An organisation with a memory; Report of an expert group on learning from adverse events on the NHS. Department of Health 2000
http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4065086.pdf

Being Open when Patients are Harmed, NPSA, NHS Commissioning Board Special Health Authority

Code of Practice on Protecting the Confidentiality of Service User Information C22 DHSSPS 2012

Confidentiality; NHS Code of Practice, Department of Health 2003

Confidentiality: Guidance for Doctors. General Medical Council 2009

Health and Social Care Regional Template and Guidance for Incident Investigation/Review Reports. DHSSPS, 2007

How to classify adverse incidents and risk guidance 2006 DHSSPS Circular HSS(MD) 12/2006
http://www.dhsspsni.gov.uk/ph_how_to_classify_adverse__incidents_and_risk_-_guidance.pdf

HSC (SQSD) 33/07 – HSC Regional Template and Guidance for Incident Review Reports (DHSSPS, 2007)

HSE Information sheet No.1 (revised): Reporting of Injuries, Diseases and Dangerous Occurrences in Health and Social Care: Guidance for employers 2013

Human Rights Act 1998

Incident Decision Tree National Patient Safety Agency - currently being redeveloped for re-launch in early 2014
www.npsa.nhs.uk/idt

Investigating accidents and incidents A workbook for employers, unions, safety representatives and safety professionals Health and Safety Executive, 2005
ISBN 978 0 7176 2827 8

Memorandum of Understanding Investigating patient or client safety incidents (Unexpected death or serious untoward harm) DHSSPS, PSNI, Coroners Service and HSENI. March 2013
http://www.dhsspsni.gov.uk/ph_mou_investigating_patient_or_client_safety_incidents.pdf

Mental Health Commission for Northern Ireland: Monitoring of Untoward Events by the Mental Health Commission (Revised Guidance) S6/2006 2006.
http://www.dhsspsni.gov.uk/mhc_guidance_on_monitoring_untoward_events.pdf

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NIAIC DB2010(NI)-01 (v.2.0) Reporting Adverse Incidents and Disseminating Medical Device/Equipment Alerts. Health Estates Northern Ireland Adverse Incident Centre, March 2013 (revision)

NIAIC MDA(NI)2011/001 All Medical Devices Health Estates Northern Ireland Adverse Incident Centre.

NISCC Code of Practice for Social Care Workers 2002

Procedure for the reporting and follow up of Serious Adverse Incidents, Oct 2013
http://www.hscboard.hscni.net/publications/Policies/102%20Procedure_for_the_reporting_and_followup_of_Serious_Adverse_Incidents-Oct2013.pdf

Promoting Quality Care – Good Practice Guidance on the Assessment and Management of Risk in Mental Health and Learning Disability Services (revised May 2010) DHSSPS
http://www.dhsspsni.gov.uk/mhld-good-practice-guidance-2010.pdf

Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults NI 2009
http://www.hscboard.hscni.net/publications/Policies/261%20Joint%20Investigation%20of%20Alleged%20and%20Suspected%20Cases%20of%20Abuse%20of%20Vulnerable%20Adults%20-%20July%202009.pdf

Protocol for Joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse NI 2004
http://www.rcpc.hscni.net/Publications/ProtocolVideoEvidence.pdf

Public Interest Disclosure (Northern Ireland) Order 1998

Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Feb 2013

Root Cause Analysis (RCA) Report-Writing Tools and Templates NPSA
http://www.nrls.npsa.nhs.uk/resources/?entryid45=59847

Safeguarding Vulnerable Adults Regional Adult Protection and Procedural Guidance DHSSPS 2006

Safety First: A Framework for Sustainable Improvement in the HPSS DHSSPS 2006

Seven Steps to Patient Safety A guide for NHS staff SSG/2003/01 National Patient Safety Agency
http://www.nrls.npsa.nhs.uk/resources/?entryid45=59787

The Northern Ireland Regional Infection Control Manual DHSSPS 2008
http://www.infectioncontrolmanual.co.ni/

UTEC Committee Guidance Note, Mental Health Commission for Northern Ireland 2007

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8.0 CONSULTATION PROCESS

Clinical Directors
Associate Medical Directors
Corporate Governance Managers
Governance and Quality Managers
Health and Safety Managers
Licensing and Regulations Manager
Performance and Service Delivery Managers
Pharmacy Managers

9.0 APPENDICES / ATTACHMENTS

None.

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 policy should be subject to a full impact assessment has been carried out.
The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact. [x]

SIGNATORIES

Anthony Stevens

Name Dr Tony Stevens
Title Medical Director

Date: 9 April 2014

Colm Donaghy

Name Colm Donaghy
Title Chief Executive

Date: 9 April 2014

2.040

Belfast Health and Social Care Trust

Reference No: PT094/14

Title:	**Procedure for Reporting and Managing Adverse Incidents**		
Author(s)	Claire Cairns Gillian Moore		
Ownership:	Medical Directorate		
Approval by:	Policy Committee Executive Team	**Approval date:**	7 April 2014 9 April 2014
Operational Date:	June 2014	**Next Review:**	June 2017
Version No.	V1	**Supercedes**	
Links to other policies/ procedures	**Adverse Incident Reporting and Management Policy** Procedure for Reporting and Managing Serious Adverse Incidents Procedure for Grading an Incident Procedure for Investigating an Incident Guidance on RIDDOR reporting Guidelines for Writing a Statement following an Incident Being Open Policy Whistleblowing Policy		

Date	Version	Author	Comments
24/04/2013	0.1	G Moore	Initial Draft
03/06/2013	0.2	G Moore	Comments from Corporate Governance team
09/09/2013	0.3	G Moore	Comments from Corporate Governance team
15/11/2013	0.4	G Moore	Comments from Corporate Governance team
20/11/2013	0.5	G Moore	Comments from Corporate Governance team
25/11/2013	0.6	G Moore	Comments from Corporate Governance team
04/12/2013	0.7	G Moore	Comments from Directorate Governance colleagues

1.0 INTRODUCTION

1.1 Background

This procedure provides guidance on reporting and managing all adverse incidents which affect service users[1], staff and visitors to its premises or have an impact on the Belfast Health and Social Care Trust[2] (BHSCT), its reputation or its legal duty of care.

The Trust is committed to an open and fair culture and reporting of adverse incidents is encouraged so that the organisation can learn from incidents and take actions to reduce the risk of reoccurrence.

1.2 Purpose

This procedure is one of a number of procedures directly associated with the Adverse Incident Reporting and Management Policy.

The purpose of this procedure is to enable a robust and systematic approach to the reporting and management of adverse incidents that will be consistently applied across the Trust. This will contribute to ensuring that the Trust meets all relevant statutory or mandatory responsibilities and reporting requirements and safeguards the wellbeing of service users, staff and visitors.

2.0 WHEN AN ADVERSE INCIDENT OCCURS

The injured person or damaged property should be assessed immediately, to ascertain extent of injuries / damage and identify emergency or urgent treatment / action required. The situation must be made safe.

Communicate with the service user and their relatives / carers as appropriate following an adverse incident. Ensure appropriate discussion with the service user and/or relatives/carers and give consideration to any additional support which may be required. See 'Being Open Policy' for guidance.

Any equipment involved in the adverse incident, even if not directly implicated, should be removed from use and:

- clearly labelled **"Do not use"** including a short description of the nature of the fault if possible;
- retain any related evidence such as packaging (for batch or serial numbers) or consumables/accessories (e.g. giving sets for pumps, etc.);
- decontaminate any device that can be decontaminated without destroying evidence and attach a decontamination certificate to that effect.

See the Trust Management of Medical Devices Policy and Procedures and Guidelines for further details

[1] The term service user also refers to patients, clients, children and young people under 18 years and carers
[2] "the Trust"

3.0 WHO SHOULD REPORT

Any member of staff can report an adverse incident. It is the responsibility of **ALL** staff who are involved, witness to, or become aware of an adverse incident, to ensure it is reported. If the incident involves another area within the Trust, this area must be communicated with (see Investigation procedure for further guidance).

4.0 WHEN TO REPORT

It is important that all adverse incidents are reported as soon as possible and ideally within 24 hours of occurrence or becoming aware of the adverse incident.
This supports effective investigation and timely learning, and ensures compliance with our responsibilities for external reporting.

5.0 WHAT TO REPORT

5.1 All adverse incidents must be reported. The definition of an adverse incident is as follows:

"Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation"[3].

5.2 Broad categories of possible adverse incidents are shown below and may assist reporters. This list is not comprehensive but gives a broad indication of what should be reported.

- Abusive, violent, disruptive, challenging or self harming behaviour
- Delays or difficulties during appointments, admissions, transfers or discharges
- Accidents e.g. falls, needlestick injuries, manual handling, exposure to hazardous substance, burn or scalds
- Cardiac arrests involving CPR and/or Defib
- Issues with clinical investigations, scans, x-rays, lab tests etc.
- Communication breakdowns between staff and/or with service users, issues with consent and confidentiality
- Diagnosis, missed or delayed
- Financial loss to the Trust
- Infrastructure or Resources (staffing, facilities, environment) – for example, unsafe environment, waste issues, misuse, failure or theft of IT equipment or systems, lack of facilities, equipment or supplies, inadequate staffing levels
- Infection control issues, pressure sores, fluid maintenance, pain management, any other issues relating to implementation of care or ongoing monitoring / review
- Labour or delivery adverse incidents
- Medical devices/equipment/non-medical device problems

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

- Medication adverse incidents
- Patient Information issue e.g. records, documents, test results, scans
- Treatment, procedure – any adverse incident immediately before, during or immediately after
- Security – for example, fires and fire risks, theft or damage to personal property, premises or vehicles, intruders or break-ins

5.3 External Reporting

5.3.1 Depending on the nature of the adverse incident the Trust is required to report details to other statutory agencies and external bodies. Staff should ensure that they are aware of their local reporting requirements to other statutory agencies and external bodies.

Please remember that a Trust Incident Report form (Datixweb or paper) must always be completed in the first instance.

5.3.2 It is not practicable to list all relevant agencies/external bodies; however, the table and list below indicate the most common.

External Organisation	Incidents to report	Who reports	Form to use
Health & Social Care Board (HSCB)	Incidents meeting SAI (Serious Adverse Incident) criteria	Corporate Governance Department	HSC Serious Adverse Incident Report Form
Health and Safety Executive Northern Ireland (HSENI)	Accidents and some diseases that arise out of or in connection with work	Health & Safety / Occupational Health/ Estates Dept	RIDDOR form
Northern Ireland Adverse Incident Centre (NIAIC)	Incidents relating to medical devices, non-medical equipment, plant and building items	Trust staff	NIAIC Adverse Incident Report Form
Regulation & Quality Improvement Authority (RQIA)	Various incidents depending on the service. (See RQIA guidance for further details)	Trust staff	RQIA Statutory Notification of Events

Others:

- Counter Fraud and Security Management Service (CFSMS)
- Department of Justice (NI)
- DHSSPSNI ("the Department")
- DHSSPSNI Health Estates
- DHSSPS Northern Ireland Head of Inspection and Enforcement (Pharmaceutical Branch)
- General Medical Council (GMC)
- Her Majesty Coroner (HMC) (NI)
- Human Fertilisation and Embryology Authority (HFEA)
- Human Tissue Authority (HTA)
- Information Commissioner Office (ICO) NI office
- Medicines and Healthcare Regulatory Agency (MHRA)

- Northern Ireland Environment Agency (NIEA)
- Nursing & Midwifery Council (NMC)
- Pharmaceutical Society of Northern Ireland (PSNI)
- Police Service of Northern Ireland (PSNI)
- Public Health Agency (PHA)
- Serious Hazards of Transfusion (SHOT)

6.0 HOW TO REPORT

6.1 All adverse incidents must be recorded on an electronic Trust incident form (Datixweb). (Paper incident forms may be used in areas which do not yet have access to Datixweb, or in the rare event that Datixweb is unavailable for a prolonged period of time.) See Section 3.0 Roles and Responsibilities.

6.2 **In respect of incidents involving patients/clients, please note that incident report forms are not health records and copies should not be filed in patients' notes.**

6.3 Other Reporting Systems – Some departments have additional error and incident monitoring arrangements (e.g. Laboratories) as part of specific legal, accreditation or quality assurance framework requirements for these services. Staff using these systems must ensure that incidents which meet the Trust definition in 4.1 of this procedure are also reported on a Trust incident form.

6.4 Responsibilities of the Reporter

- Gather the relevant facts to enable a Trust incident Report Form to be completed.
- Complete a Trust Incident Report Form, documenting fact only, not opinion. The electronic incident form is accessed via the Hub home page under '**I Want To…..**Report an Incident (Datixweb)'. Guidance on completion of forms is available on the electronic (Datixweb) form itself, or in the paper incident book.
- Send the incident form for approval, by either clicking 'Submit' on the electronic form or passing the white and green copy of the paper form, along with any attachments, to the approving / line manager for your area.
- Report the incident to your line manager as soon as possible after it has occurred. The line manager may well have already received notification via Datixweb however it is important that staff do not rely solely on this for communication.
- Inform any other relevant bodies / persons as appropriate.

6.5 Responsibilities of the Approving Manager / Line Manager

As soon as possible after receipt of the incident form, or becoming aware of the incident:

- Ensure section 2.0 of this procedure has been actioned as appropriate.
- Review the incident form to ensure that all relevant sections are complete and accurate and make amendments if required. It is good practice to discuss any amendments with the incident reporter.
- Complete the investigation and approval sections. Note: the mandatory fields should be completed as soon as possible and no later than 7 days after the reported date. Any investigation information can be added to the record at a later date (see Grading and Investigation procedures for further guidance).
- Click 'Save' on the electronic form, or forward the white copy of the paper form to Corporate Governance, 6th floor, McKinney House, Musgrave Park Hospital, Belfast, BT9 7JB.
- Inform any other relevant bodies / persons as appropriate.
- Ensure that appropriate feedback is given to the reporter of the incident.

Review and approval of incident forms should take place in a timely manner in accordance with the Escalation Protocol (Appendix 1).

7.0 STAFF SUPPORT DIRECTLY FOLLOWING AN ADVERSE INCIDENT

7.1 The Trust recognises that it has a responsibility to support all staff following adverse incidents.

7.2 All staff who are involved in an adverse incident will need the appropriate level of support. It is the line manager's responsibility to ensure that individuals are supported appropriately.

7.3 Support can be provided by Occupational Health and the Staffcare Service.

7.4 Staff involved must be kept informed of the progress of an investigation at all stages.

7.5 Individuals who have been absent from work may require additional support and supervision to aid confidence when returning to work.

See the Investigation procedure for further guidance.

Appendix 1

Escalation Protocol for Datixweb Incident Reporting

Timely reporting of incidents is vital in ensuring that incident data is as robust and accurate as possible. Incidents that remain unapproved for excessive periods of time do not appear in reports used throughout the Trust, or those requested by external bodies, such as the DHSSPS, the Assembly, FOI requests etc.
Furthermore it is easier and less time consuming to investigate incidents as near to the time of occurrence as possible.
The following action will therefore be taken regarding incidents overdue for approval.

1. Any incident remaining unapproved after 7 calendar days (excluding day reported) is deemed to be overdue. For overdue incidents, the manager responsible for DIF2 approval (the handler) will be sent a reminder email from the Risk & Governance Department.
   This email will be sent on a weekly basis until the incidents are approved.

2. If the incident remains overdue for a further 7 calendar days an email will be sent to the appropriate Service Manager.

3. If after a further 7 calendar days the incident/s still remain overdue, an email will be sent to the appropriate Service Manager and Senior Manager for Governance and Quality.

It would be expected that the managers copied into reminder emails would take the appropriate action to ensure outstanding incidents are approved.
The above process is summarised in the table below:

Incident remains unapproved after being reported (number of days)	Reminder sent to applicable		
	Approving Manager	Service Manager	Senior Manager for Governance & Quality
7 days	x		
14 days	x	x	
21 days	x	x	x

All managers responsible for approving incidents should ensure that there is a deputy identified to take over this role in their absence.

SIGNATORIES

Name Dr Tony Stevens
Title Medical Director

Date: 9 April 2014

Name Colm Donaghy
Title Chief Executive

Date: 9 April 2014

Belfast Health and Social Care Trust
caring supporting improving together

Reference No: TP094/14

Title:	**Procedure for Reporting and Managing Adverse Incidents**			
Author(s)	Claire Cairns, Senior Manager Corporate Governance Gillian Moore, Admin & Datix Manager			
Ownership:	Medical Directorate			
Approval by:	Policy Committee Executive Team		**Approval date:**	11th January 2018 24 January 2018
Operational Date:	January 2018		**Next Review:**	January 2023
Version No.	V2	**Supercedes**	V1 – 2014-2017	
Links to other policies/ procedures	**Adverse Incident Reporting and Management Policy** Procedure for Reporting and Managing Serious Adverse Incidents Procedure for Grading an Incident Procedure for Investigating an Incident The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 (RIDDOR) Procedural Arrangements Guidelines for Writing a Statement following an Incident Being Open Policy Whistleblowing Policy			

Date	Version	Author	Comments
24/04/2013	0.1	G Moore	Initial Draft
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25/11/2013	0.6	G Moore	Comments from Corporate Governance team
04/12/2013	0.7	G Moore	Comments from Directorate Governance colleagues
December 2013	0.8	Claire Cairns Gillian Moore	Revised version
June 2014	1.1	Claire Cairns Gillian Moore	Revised version
29th November 2017	1.2	Gillian Moore	Interim update pending regional policy / procedures

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See the Trust Management of Medical Devices Policy and Procedures and Guidelines for further details

[1] The term service user also refers to patients, clients, children and young people under 18 years and carers
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- Communication breakdowns between staff and/or with service users, issues with consent and confidentiality
- Diagnosis, missed or delayed
- Financial loss to the Trust
- Infrastructure or Resources (staffing, facilities, environment) – for example, unsafe environment, waste issues, misuse, failure or theft of IT equipment or systems, lack of facilities, equipment or supplies, inadequate staffing levels
- Infection control issues, pressure sores, fluid maintenance, pain management, any other issues relating to implementation of care or ongoing monitoring / review
- Labour or delivery adverse incidents
- Medical devices/equipment/non-medical device problems

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

- Medication adverse incidents
- Patient Information issues e.g. records, documents, test results, scans. This may also include any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed.
- Treatment, procedure – any adverse incident immediately before, during or immediately after
- Security – for example, fires and fire risks, theft or damage to personal property, premises or vehicles, intruders or break-ins

5.3 External Reporting

5.3.1 Depending on the nature of the adverse incident the Trust is required to report details to other statutory agencies and external bodies. Staff should ensure that they are aware of their local reporting requirements to other statutory agencies and external bodies.

Please remember that a Trust Incident Report form must always be completed in the first instance.

5.3.2 It is not practicable to list all relevant agencies/external bodies; however, the table and list below indicate the most common.

External Organisation	Incidents to report	Who reports	Form to use
Health & Social Care Board (HSCB)	Incidents meeting SAI (Serious Adverse Incident) criteria	Corporate Governance Department	HSC Serious Adverse Incident Report Form
Health and Safety Executive Northern Ireland (HSENI)	Injuries, diseases, conditions and dangerous occurrences that arise out of or in connection with work	Health & Safety / Occupational Health/ Estates Dept only. Trust staff / service users should not report directly to HSENI.	On-line RIDDOR report
Northern Ireland Adverse Incident Centre (NIAIC)	Incidents relating to medical devices, non-medical equipment, plant and building items	Trust staff	NIAIC Adverse Incident Report Form
Regulation & Quality Improvement Authority (RQIA)	Various incidents depending on the service. (See RQIA guidance for further details)	Trust staff	RQIA Statutory Notification of Events

Others:

- Counter Fraud and Security Management Service (CFSMS)
- Department of Justice (NI)
- DoH ("the Department")
- DoH Health Estates
- DoH Northern Ireland Head of Inspection and Enforcement (Pharmaceutical Branch)

- General Medical Council (GMC)
- Her Majesty Coroner (HMC) (NI)
- Human Fertilisation and Embryology Authority (HFEA)
- Human Tissue Authority (HTA)
- Information Commissioner Office (ICO) NI office
- Medicines and Healthcare Regulatory Agency (MHRA)
- Northern Ireland Environment Agency (NIEA)
- Nursing & Midwifery Council (NMC)
- Pharmaceutical Society of Northern Ireland (PSNI)
- Police Service of Northern Ireland (PSNI)
- Public Health Agency (PHA)
- Serious Hazards of Transfusion (SHOT)

6.0 HOW TO REPORT

6.1 All adverse incidents must be recorded on an electronic Trust incident form (Datixweb). (Paper incident forms may be used in areas which do not yet have access to Datixweb, or in the rare event that Datixweb is unavailable for a prolonged period of time.)

6.2 **In respect of incidents involving patients/service users, please note that incident report forms are not health records and copies should not be filed in patients'/service users notes.**

6.3 Other Reporting Systems – Some departments have additional error and incident monitoring arrangements (e.g. Laboratories) as part of specific legal, accreditation or quality assurance framework requirements for these services. Staff using these systems must ensure that incidents which meet the Trust definition in 5.1 of this procedure are also reported on a Trust incident form.

6.4 Responsibilities of the Reporter

- Gather the relevant facts to enable a Trust incident Report Form to be completed.
- Complete a Trust Incident Report Form, documenting fact only, not opinion. The electronic incident form is accessed via the Hub home page under '**I Want To…..**Report an Incident (Datixweb)'. Guidance on completion of forms is available on the electronic (Datixweb) form itself, or in the paper incident book.
- Send the incident form for approval, by either clicking 'Submit' on the electronic form or passing the white and green copy of the paper form, along with any attachments, to the approving / line manager for your area.
- Report the incident to your line manager as soon as possible after it has occurred. The line manager may well have already received

notification via Datixweb however it is important that staff do not rely solely on this for communication.
- Inform any other relevant bodies / persons as appropriate.

6.5 Responsibilities of the Approving Manager / Line Manager

As soon as possible after receipt of the incident form, or becoming aware of the incident:

- Ensure section 2.0 of this procedure has been actioned as appropriate.
- Review the incident form to ensure that all relevant sections are complete and accurate and make amendments if required. It is good practice to discuss any amendments with the incident reporter.
- Complete the investigation and approval sections. Note: the mandatory fields should be completed as soon as possible and no later than 7 days after the reported date. Any review / investigation information, and/or updates to current information, can be added to the record at a later date (see Grading and Investigation procedures for further guidance).
- Click 'Save' on the electronic form, or forward the white copy of the paper form to Corporate Governance, 6th floor, McKinney House, Musgrave Park Hospital, Belfast, BT9 7JB.
- Inform any other relevant bodies / persons as appropriate.
- Ensure that appropriate feedback is given to the reporter of the incident and the wider staff team as appropriate.
- Consider whether a hot debrief is required. A hot debrief is a review carried out as soon as possible after the incident. This is to identify any immediate learning that could influence future events as well as supporting staff involved.

Review and approval of incident forms should take place in a timely manner in accordance with the Escalation Protocol (Appendix 1).

7.0 STAFF SUPPORT DIRECTLY FOLLOWING AN ADVERSE INCIDENT

7.1 The Trust recognises that it has a responsibility to support all staff following adverse incidents.

7.2 All staff who are involved in an adverse incident will need the appropriate level of support. It is the line manager's responsibility to ensure that individuals are supported appropriately.

7.3 Support can be provided by Occupational Health and the Staffcare Service.

7.4 Staff involved must be kept informed of the progress of an investigation at all stages.

7.5 Individuals who have been absent from work may require additional support and supervision to aid confidence when returning to work.

See the Investigation procedure for further guidance.

SIGNATORIES

24 January 2018

_____ **Date:**

Name Dr Cathy Jack
Title Deputy Chief Executive/ Medical Director

24 January 2018

_____ **Date:**

Name Martin Dillon
Title Chief Executive

Appendix 1

Escalation Protocol for Datixweb Incident Reporting

Timely reporting of incidents is vital in ensuring that incident data is as robust and accurate as possible. Incidents that remain unapproved for excessive periods of time do not appear in reports used throughout the Trust, or those requested by external bodies, such as the DHSSPS, the Assembly, FOI requests etc.
Furthermore it is easier and less time consuming to investigate incidents as near to the time of occurrence as possible.
The following action will therefore be taken regarding incidents overdue for approval.

1. Any incident remaining unapproved after 7 calendar days (excluding day reported) is deemed to be overdue. For overdue incidents, the manager responsible for DIF2 approval (the handler) will be sent a reminder email from the Risk & Governance Department.
   This email will be sent on a weekly basis until the incidents are approved.

2. If the incident remains overdue for a further 7 calendar days an email will be sent to the appropriate Service Manager.

3. If after a further 7 calendar days the incident/s still remain overdue, an email will be sent to the appropriate Service Manager and Senior Manager for Governance and Quality.

It would be expected that the managers copied into reminder emails would take the appropriate action to ensure outstanding incidents are approved.
The above process is summarised in the table below:

Incident remains unapproved after being reported (number of days)	Reminder sent to applicable		
	Approving Manager	Service Manager	Senior Manager for Governance & Quality
7 days	x		
14 days	x	x	
21 days	x	x	x

All managers responsible for approving incidents should ensure that there is a deputy identified to take over this role in their absence.

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Ref No TP008/08

Title:	Adverse Incident Reporting and Management Policy		
Author(s)	Claire Cairns, Senior Manager Corporate Governance Adrienne McKimm, Patient & Client Safety Services Gillian Moore, Admin & Datix Manager		
Ownership:	Dr Cathy Jack, Medical Director		
Approval by:	Trust Policy Committee Executive Team	**Approval date:**	11th January 2018 24th January 2018
Operational Date:	January 2018	**Next Review:**	January 2023
Version No.	4.0 **Supercedes** Version 3.0		
Links to other policies	- Being Open Policy - Claims Management & Engagement of Legal Services Policy - General Health and Safety Policy - Management of Medical Devices Procedures and Guidelines - Whistle Blowing Policy - Policy and Procedure for the Management of Commentts, Concerns, Complaints & Compliments - Policy on the Data Protection Act 1998 and Protection of Personal Information - Risk Management Strategy - Protocol for Root Cause Analysis (RCA) of MRSA bacteraemias, Clostridium difficile clusters and where MRSA or C difficile is listed on Part 1 of a death certificate July 2010. - BHSCT Medicines Code March 2017 - Procedure for Reporting and Managing Incidents - Procedure for Grading an Incident - Procedure for Investigating an Incident - The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 (RIDDOR) Procedural Arrangements - Guidance on Writing a Witness Statement - Serious Adverse Incident (SAI) Procedure - Policy for Sharing Learning		

Date	Version	Author	Comments
25th February 2008	1.0	Marie Bardgett	Adverse Incident Reporting and Management Policy
19th April 2010	2.0	Claire Cairns	Revised Adverse Incident Reporting and Management Policy
April 2014	3.0	Claire Cairns	Revised Adverse Incident Reporting and Management Policy
29th November 2017	4.0	Gillian Moore	Interim update pending regional policy

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CONTENTS

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1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

This policy provides the framework for reporting and managing all adverse incidents which affect service users[1], staff and visitors to its premises or have an impact on the Belfast Health and Social Care Trust[2] (BHSCT), its reputation or its legal duty of care.

The Trust is committed to an open and fair culture and reporting of adverse incidents is encouraged so that the organisation can learn from incidents and take actions to reduce the risk of reoccurrence.

1.2 Purpose

The purpose of this policy is to enable a robust and systematic approach to the management of adverse incidents that will be consistently applied across the Trust. This will contribute to ensuring that the Trust meets all relevant statutory or mandatory responsibilities and reporting requirements and safeguards the wellbeing of service users, staff and visitors.

The aim of adverse incident management is to ensure that systems are in place to secure service user, staff and visitor safety; ensure internal accountability and safeguard the Trust's assets and reputation. Learning from adverse incidents enables the Trust to proactively reduce risk and improve services.

2.0 DEFINITIONS/SCOPE OF THE POLICY

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

2.2 **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*)

2.3 **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*)

2.4 **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), Nov 2016[3] . The Trust will be responsible for the

[1] The term service user also refers to patients, clients, children and young people under 18 years and carers
[2] "the Trust"
[3] http://www.hscboard.hscni.net/download/PUBLICATIONS/policies-protocols-and-guidelines/Procedure-for-the-reporting-and-follow-up-of-SAIs-2016.pdf

onward reporting of SAIs relevant internally, and to their Independent Service Providers (ISPs) and contractors, and will ensure the appropriate investigation, learning and sharing of lessons regarding same.

2.5 **Memorandum of Understanding (MoU)**[4]. Incidents involving unexpected death or serious harm and requiring investigation by the police and/or Health and Safety Executive (HSENI) are rare and there is a statutory duty placed on individuals and organisations to report such incidents. Such incidents 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 is to better facilitate these complex interactions. The MoU compliments existing joint procedures in relation to the protection of children and vulnerable adults.

2.6 **Service User.** The term also refers to patients, clients (including children and young people under 18 years) and carers.

3.0 ROLES/RESPONSIBILITIES

3.1 Trust Board

The Trust Board is responsible for the implementation of the Trust Policy for Reporting and Management of Adverse Incidents (and related procedures). It will:

- Ensure that the organisational arrangements contained within the policy and its associated procedures are implemented;
- Monitor and review the overall reporting performance and receive regular reports from the Chief Executive ;
- Set corporate objectives for adverse incident management and decide on the appropriate performance indicators;
- Ensure adverse incident management is integrated within the Trust's performance management arrangements and the Assurance Framework.

3.2 Chief Executive

As Accountable Officer, the Chief Executive is responsible to the Trust Board for the management of adverse incidents for ensuring the Trust meets its statutory and mandatory requirements and adheres to the guidance issued by external bodies

The Chief Executive will:

[4] Memorandum of Understanding Investigating patient or client safety incidents (Unexpected death or serious untoward harm) DHSSPS, PSNI, Coroners Service and HSENI, March 2013 https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/mou-patient-client-safety-incidents.pdf

- Report at regular intervals to Trust Board on the management of adverse incidents;
- Set targets for safety and quality management.

The Chief Executive has delegated these executive functions to the Medical Director.

3.3 Medical Director

The Medical Director (or his/her deputy) has responsibility for the management of adverse incidents throughout the Belfast Health and Social Care Trust. The Medical Director will report to the Senior Trust Board Team and Assurance Committee in all matters relating to adverse incidents.

The Medical Director will:

- ensure the promotion of an open and fair culture for adverse incident reporting;
- ensure the development of suitable organisational arrangements for the management of adverse incidents;
- ensure the development and maintenance of systems to monitor and disseminate learning from adverse incidents across the organisation and when necessary externally;
- ensure that systems are in place for the reporting of adverse incidents to relevant regulatory and external agencies as required
- ensure that systems are in place for the reporting of adverse incidents relevant to professional bodies;
- oversee the prioritisation of action to prevent adverse incidents / risks.

3.4 Co-Director Risk and Governance

The Co-Director will support the Medical Director in meeting his/ her responsibility for the management of adverse incidents throughout the BHSCT and will:

- ensure the promotion of an open and fair culture for adverse incident reporting;
- ensure that systems are in place for the reporting of adverse incidents to relevant regulatory and external agencies as required;
- ensure that systems are in place for the reporting of adverse incidents to relevant professional bodies;
- ensure appropriate arrangements are in place for the investigation of serious adverse incidents (SAIs);
- ensure that subsequent learning from adverse incidents is shared across the Trust through appropriate management structures;
- ensure that the Trust has an appropriate risk management training programme which is accessible to relevant staff.

3.5 Senior Manager, Corporate Governance Services

The Senior Manager for Corporate Governance Services will support the

Co-Director Risk and Governance in meeting his/her responsibility for adverse incident management and will:

- ensure that systems are in place for the reporting, recording and analysing of adverse incidents;
- ensure that the Trust has an appropriate adverse incident reporting and investigating training programme which is accessible to relevant staff;
- fulfil the role of NIAIC (Northern Ireland Adverse Incident Centre) Liaison Officer
- ensure that serious adverse incidents (SAI's) and Early Alerts (EAs) are reported and followed up in accordance with HSCB procedures;

3.6 Senior Manager responsible for RIDDOR

The Senior Manager responsible for RIDDOR will support the Co-Director Risk and Governance in meeting his/her responsibility for adverse incident management and will ensure that systems are in place for the appropriate management and reporting of Health and Safety incidents including the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 (RIDDOR). (See The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 (RIDDOR) Procedural Arrangements).

They will ensure liaison with the enforcing authorities regarding subsequent investigation processes and provide direction as to the communication channels within the Trust.

3.7 Head of Pharmacy and Medicines Management

All adverse incidents or concerns involving the safe use and management of Controlled Drugs must be reported directly to the Trust Accountable Officer through one of the Designated Officers.

The Accountable Office for the Trust is the Head of Pharmacy and Medicines Management and the Deputy Heads of Pharmacy are the Designated Officers.

For further guidance see:
http://intranet.belfasttrust.local/policies/Documents/Controlled%20Drugs-%20dealing%20with%20discrepancies%20or%20concerns.pdf

3.8 Directors

It is the responsibility of Directors to:

- ensure the promotion of an open and fair culture for adverse incident reporting
- disseminate and promote this policy (and related procedures and guidelines) within their area of responsibility and ensure its implementation by providing support and advice to managers and staff;
- ensure reported adverse incidents are investigated appropriately;
- ensure that adverse incidents are monitored and reviewed within their area of responsibility and that any recommendations made as a result of investigations are implemented and monitored;

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- ensure that subsequent learning from adverse incidents is shared within their Directorate through appropriate assurance structures;
- ensure learning relevant to other areas is escalated through the Trust Assurance Framework.
- take account of relevant adverse incidents when reviewing their Risk Register and ensure that this is linked appropriately to the Corporate Risk Register and/or Principal Risk Document;
- ensure staff have access to advice and training on adverse incident reporting and management and, where appropriate, investigation and review;
- ensure all serious adverse incidents (SAI's) as defined by the HSCB are managed in line with Trust procedure and are reported to the Corporate Governance Department in a timely manner.

Senior Information Risk Owner (SIRO)

All adverse incidents or concerns involving the use of personal data must be reported through the relevant Information Asset Owner (IAO) to the SIRO (Nominated Director) to ensure that any data breaches are reported to the Information Commissioners Office with the designated 72 hours.

3.9 Co Directors and Senior Clinicians

Co-Directors and Senior Clinicians are responsible for supporting their Directors with the responsibilities outlined in section 3.8 of this policy, and in doing so they will ensure that this policy (and related procedures and guidelines) are effectively implemented across their area of responsibility.

3.10 Directorate Governance and Quality Managers

It is the responsibility of the Directorate Governance and Quality Manager on behalf of their Director to implement systems and processes to ensure that:

- all adverse incidents (including SAI's) within their Directorate are monitored and managed appropriately.

3.11 Line Managers

Line Managers have responsibility within their area to:

- promote an open and fair culture of reporting;
- ensure that their staff are aware of and adhere to this policy (and related procedures and guidelines);
- ensure that their staff are trained in adverse incident reporting and in the appropriate level of adverse incident investigation, including appropriate escalation as required;
- ensure that adverse incidents are reported as per Trust policies (and related procedures and guidelines);

- ensure the onward reporting of adverse incidents both internally and, where appropriate, externally and that their staff are aware of these particular local arrangements;
- ensure that copies of adverse incident forms are retained in line with the Data Protection Act and Freedom of Information Act and are not placed in the service user's file;
- secure all relevant evidence including materials, equipment, consumables, samples, records, witness details etc and ensure that these are not compromised until appropriate investigation is complete. (See Investigation and Evidence procedures);
- ensure that where a death or a major injury has occurred, the security of the location and/or equipment/consumables, is maintained for inspection purposes by senior managers and/or statutory authorities (See Investigation procedure);
- ensure that all possible remedial action is taken immediately following an adverse incident to prevent reoccurrence without compromising the investigation processes;
- ensure appropriate local investigation is carried out in conjunction with other relevant departments if required. (See Investigation Procedure);
- ensure staff are given appropriate support following an adverse incident;
- communicate with the service user and/or their relatives/carers as appropriate. (See Being Open Policy for guidance);
- provide feedback and share learning with staff and ensure that risk assessments and training needs are reviewed where relevant following adverse incident reviews.

3.12 All Staff

All Trust employees have a responsibility to:

- ensure individuals involved (service users, visitors or staff) and the environment / equipment are made safe;
- avoid putting themselves and others in situations of danger;
- report adverse incidents by completing the Trust incident report form;
- be aware of any particular local service arrangements/requirements for the onward reporting both internally and externally; depending on the initial grading of the adverse incident, you may also have to telephone to allow for the prompt escalation of these adverse incidents;
- co-operate with the adverse incident investigation process including the provision of witness statements (see Guidance for Writing a Witness Statement).

4.0 KEY POLICY PRINCIPLES

Key Policy Statement

The Trust recognises its duty to provide a safe environment for service users, staff and visitors and to report incidents in accordance with mandatory and statutory reporting requirements. This will also include cooperation with statutory agencies with regard to the response to, and investigation of, incidents of suspicious / unexpected death and serious untoward harm.

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4.1 Policy Principles

4.1.1 The Belfast Health and Social Care Trust is committed to providing and safeguarding the highest standards of care for service users, staff and visitors. The Trust recognises that adverse incidents will occur and that it is important to identify causes to ensure lessons are learned to reduce the likelihood of reoccurrence.

4.1.2 It is therefore essential that a responsive and effective adverse incident reporting and analysis system is in place to achieve this aim.

4.1.3 This policy (and its related procedures and guidelines) will ensure that staff have access to a comprehensive, clear and user-friendly adverse incident reporting system that will encourage the reporting of adverse incidents so that real opportunities for improvement and risk reduction are taken.

4.1.4 Learning from adverse incidents can only take place when they are reported and investigated in a positive, open and structured way. Where learning from such adverse incidents is identified the necessary changes will be put in place to improve practice.

4.1.5 Where learning from incidents will be relevant to other areas across the Trust, and externally, the learning should be shared as per the Policy for Sharing Learning.

4.1.6 All staff must report and manage adverse incidents according to this policy (and related procedures) for adverse incident reporting.

4.1.7 Crucial to the effectiveness of adverse incident reporting is the Trust commitment to the promotion of an open and fair culture where all staff can participate in reporting adverse incidents. Ultimately the Trust wants to encourage staff to report areas of concern and to foster a positive ethos around reporting.

4.1.8. Staff who make a prompt and honest report in relation to an adverse incident will not be disciplined except under the following circumstances:

- A breach of law
- Wilful or gross carelessness or professional misconduct
- Repeated breaches of Trust policy and procedure
- Where, in the view of the Trust, and/or any professional registration body, the action causing the incident is far removed from acceptable practice
- Where there is failure to report a serious incident in which a member of staff was involved or about which they were aware.

4.1.9 Mere completion of an Incident Report form does not discharge staff of their duty of care and their risk management responsibility.

4.1.10 There should be timely and appropriate follow-up of adverse incidents. Where preventative measures and/or procedural changes are identified these should be put in place to minimise the risk of the adverse incident reoccurring.

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4.1.11 All Trust employees must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty of openness, transparency and candour.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

5.1.1 All staff employed by the Trust, including agency staff and contractors, should be provided with access to this policy.

5.1.2. The latest version of this policy (and its related procedures and guidelines) will be available on the Trust intranet.

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5.2 Resources

5.2.1 Adverse Incident training is mandatory for all staff and appropriate training and guidance will be provided by the Corporate Governance Department to ensure that all Trust employees understand their responsibilities under this policy and are able to effectively fulfil their obligations to report adverse incidents and identified risks.

5.2.2 Managers must ensure the Trust training system (HRPTS) is appropriately utilised. Corporate Governance will maintain adverse incident training records on HRPTS

5.2.3 Managers must ensure availability of the Datixweb electronic incident reporting system where possible and should ensure that a hard copy incident book is retained as back-up.

5.3 Exceptions

5.3.1 Independent Service Providers (ISPs) and contractors will be required under their contractual arrangements to maintain a system of reporting and recording adverse incidents related to service users referred to them by the Trust for assessment and treatment and care.

5.3.2 ISPs are required to submit monitoring information as required. Adverse incidents and SAIs are discussed at contract monitoring meetings held with ISPs.

5.3.3 The Trust will decide whether an ISP adverse incident meets the criteria for reporting as a Serious Adverse Incident and is responsible for reporting the SAI to the Health & Social Care Board.

5.3.4 This policy does not provide for the DHSSPS Early Alert System which is the subject of separate DHSSPS guidance.

6.0 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

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7.0 EVIDENCE BASE / REFERENCES

A Protocol for the Investigation and Analysis of Clinical Incidents Clinical Risk Unit (CRU) and Alarm 1999 http://www.patientsafety.ucl.ac.uk/CRU-ALARMprotocol.pdf

An Assurance Framework: a Practical Guide for Boards of DHSSPS Arm's Length Bodies. 2009

An organisation with a memory; Report of an expert group on learning from adverse events on the NHS. Department of Health 2000 http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4065086.pdf

Being Open when Patients are Harmed, NPSA, NHS Commissioning Board Special Health Authority

Code of Practice on Protecting the Confidentiality of Service User Information C22 DHSSPS 2012

Confidentiality; NHS Code of Practice, Department of Health 2003

Confidentiality: Guidance for Doctors. General Medical Council 2009

Health and Social Care Regional Template and Guidance for Incident Investigation/Review Reports. DHSSPS, 2007

Health Services Information Sheet HSIS1(rev3), Reporting injuries, diseases and dangerous occurrences in health and social care: Guidance for employers.

How to classify adverse incidents and risk guidance 2006 DHSSPS Circular HSS(MD) 12/2006

HSC (SQSD) 33/07 – HSC Regional Template and Guidance for Incident Review Reports (DHSSPS, 2007)

HSE Information sheet No.1 (revised): Reporting of Injuries, Diseases and Dangerous Occurrences in Health and Social Care: Guidance for employers 2013

Human Rights Act 1998

Incident Decision Tree National Patient Safety Agency - currently being redeveloped for re-launch in early 2014
www.npsa.nhs.uk/idt

Investigating accidents and incidents A workbook for employers, unions, safety representatives and safety professionals Health and Safety Executive, 2005
ISBN 978 0 7176 2827 8

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Memorandum of Understanding Investigating patient or client safety incidents (Unexpected death or serious untoward harm) DHSSPS, PSNI, Coroners Service and HSENI. March 2013
https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/mou-patient-client-safety-incidents.pdf

Mental Health Commission for Northern Ireland: Monitoring of Untoward Events by the Mental Health Commission (Revised Guidance) S6/2006 2006.

NIAIC DB2010(NI)-01 (v.2.0) Reporting Adverse Incidents and Disseminating Medical Device/Equipment Alerts. Health Estates Northern Ireland Adverse Incident Centre, March 2013 (revision)

NIAIC MDA(NI)2011/001 All Medical Devices Health Estates Northern Ireland Adverse Incident Centre.

NISCC Code of Practice for Social Care Workers 2002

Procedure for the reporting and follow up of Serious Adverse Incidents, Nov 2016
http://www.hscboard.hscni.net/download/PUBLICATIONS/policies-protocols-and-guidelines/Procedure-for-the-reporting-and-follow-up-of-SAIs-2016.pdf

Promoting Quality Care – Good Practice Guidance on the Assessment and Management of Risk in Mental Health and Learning Disability Services (revised May 2010) DHSSPS

Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults NI 2009
http://www.hscboard.hscni.net/publications/Policies/261%20Joint%20Investigation%20of%20Alleged%20and%20Suspected%20Cases%20of%20Abuse%20of%20Vulnerable%20Adults%20-%20July%202009.pdf

Protocol for Joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse NI 2004

Public Interest Disclosure (Northern Ireland) Order 1998

Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Feb 2013

Root Cause Analysis (RCA) Report-Writing Tools and Templates NPSA
http://www.nrls.npsa.nhs.uk/resources/?entryid45=59847

Safeguarding Vulnerable Adults Regional Adult Protection and Procedural Guidance DHSSPS 2006

Safety First: A Framework for Sustainable Improvement in the HPSS DHSSPS 2006

Seven Steps to Patient Safety A guide for NHS staff SSG/2003/01 National Patient Safety Agency
http://www.nrls.npsa.nhs.uk/resources/?entryid45=59787

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The Northern Ireland Regional Infection Control Manual DHSSPS 2008

UTEC Committee Guidance Note, Mental Health Commission for Northern Ireland 2007

8.0 CONSULTATION PROCESS

Clinical Directors
Associate Medical Directors
Corporate Governance Managers
Governance and Quality Managers
Health and Safety Managers
Licensing and Regulations Manager
Performance and Service Delivery Managers
Pharmacy Managers

9.0 APPENDICES / ATTACHMENTS

None.

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 policy should be subject to a full impact assessment has been carried out.
The outcome of the Equality screening for this policy is:

Major impact ☐
Minor impact ☐

No impact. [x]

SIGNATORIES

Cathy Jack

24 January 2018

_____ **Date:** _____

Name Dr Cathy Jack
Title Deputy Chief Executive/ Medical Director

Martin Dillon

24 January 2018

_____ **Date:** _____

Name Martin Dillon
Title Chief Executive

Belfast Health and Social Care Trust
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Reference No: TP 08/08

Title:	**Adverse Incident Reporting and Management Policy**		
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Policy Type: (tick as appropriate)	*Directorate Specific ☐	Clinical Trust Wide ☐	Non Clinical Trust Wide ☒
If policy type is confirmed as ***Directorate Specific** please list the name and date of the local Committee/Group that policy was **approved**			
Date:			
Approval process:	Trust Policy Committee Executive Team Meeting	**Approval date:**	04 June 2020 10 June 2020
Operational Date:	June 2020	**Review Date:**	June 2025
Version No.	5	**Supercedes**	V4 – January 2018 – January 2023
Key Words:	Incident, Adverse incident, Incident reporting, Datix		
Links to other policies	BHSCT Being Open policy – saying sorry when things go wrong (2020) TP 80/11 BHSCT Serious Adverse Incident (SAI) procedure (2016) TP 97/14 BHSCT Policy on Memorandum of Understanding (MOU) - Investigating Service User Safety Incidents (2020) TP 111/20 BHSCT Guidance on Actions to be Taken after a Patient's Death in Hospital (2018) SG 04/09 BHSCT Medical Devices Procedures and Guidelines (2017) TP 41/07 BHSCT The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 (RIDDOR) Policy (2020) TP 42/08 BHSCT Procedure for Reporting and Managing Incidents (2018) TP 94/14 BHSCT Procedure for Grading an Incident (2018) TP 95/14 BHSCT Procedure for Investigating an Incident (2018) TP 93/14 BHSCT Guidance on Writing a Witness Statement (2018) TP 96/14 BHSCT Policy for Sharing Learning (2016) TP 98/14 BHSCT Policy and Procedure for the Management of Comments, Concerns, Complaints & Compliments (2020) TP 45/10 BHSCT Claims Management & Engagement of Legal Services Policy (2017) TP 27/08		

	BHSCT General Health and Safety Policy (2018) TP 50/08 BHSCT Policy on the Data Protection and Protection of Personal Information (2018) TP 26/08 BHSCT Risk Management Strategy (2020) TP 58/08 BHSCT Medicines Code Policy (2020) SG 09/11

Date	Version	Policy Author	Comments
25/02/2008	1.0	M Bardgett	Adverse Incident Reporting and Management Policy
19/04/2010	2.0	CR Cairns	Revised Adverse Incident Reporting and Management Policy
April 2014	3.0	CR Cairns	Revised Adverse Incident Reporting and Management Policy
29/11/2017	4.0	G Moore	Interim update pending regional policy
January 2020	4.1	Regional Group	After a period of Regional consultation Department of Health issued a template for the management of incidents and requested all Trust to update their existing Trust Policy to reflect Regional template
May 2020	4.2	G Moore R Henry	Adoption of Regional template customised to reflect BHSCT arrangements

1.0 INTRODUCTION / SUMMARY OF POLICY

1.1 Background

Belfast Health & Social Care Trust has had a Trust Policy that covers Incident management from 2008. Following recommendations of the Regional Learning System Project Report (August 2015), it was agreed to develop a regional policy on the reporting and management of adverse incidents to be used by all Health & Social Care Trusts, the Northern Ireland Ambulance Service (NIAS) and the Health & Social Care Board (HSCB) hereinafter called ("the organisation").

1.2 Introduction

This policy provides the framework for reporting and managing all adverse incidents which affect service users[1], staff and visitors to its premises or have an impact on the Belfast Health and Social Care Trust[2] (BHSCT), its reputation or its legal duty of care.

The manner in which an organisation manages and learns from adverse incidents is one of the key markers of success in relation to risk management, corporate and clinical and social care governance standards. Consistent identification, monitoring and review of incidents is central to the

organisation's strategic and operational processes to ensure it can achieve its vision for safe and effective care.

It recognises that no health and social care environment will ever be absolutely safe and, on occasions, errors or incidents will occur. Equally, it recognises that when incidents do occur it is important to identify causes to ensure that lessons are learned to prevent recurrence.

The organisation is committed to an open, honest and just culture and reporting of adverse incidents is encouraged so that the organisation can learn from incidents and take actions including changes in practice to reduce the risk of recurrence. It also will ensure that staff learn and are supported in making changes to their practice, post incidents, as required.

1.3 Purpose of policy

This policy provides guidance on the reporting and managing of adverse incidents which affect service users, staff and visitors to its premises or have an impact on the organisation, its reputation or its legal duty of care. It will also enable a robust and systematic approach to the management of adverse incidents that will be consistently applied across the organisation ensuring that it meets all relevant statutory[3] or mandatory responsibilities and reporting requirements thereby safeguarding the wellbeing of service users, staff and visitors.

It has been developed to ensure organisational wide learning takes place within a structured framework and that any lessons learned are disseminated widely throughout the organisation and to external agencies, as appropriate.

1.4 Policy Aims and Objectives

Adverse incident management systems assist organisations to ensure that systems are in place to secure service user, staff and visitor safety; ensure internal accountability and safeguard the organisation's assets and reputation. Learning from adverse incidents enables the organisation to proactively reduce risk and improve services. It recognises that most incidents occur because of problems with systems rather than individuals but may also on occasions be multifactorial in nature.

The objectives of this policy are:-

- To promote and provide a unified regional organisational wide system for the reporting, recording, review and analysis of all adverse incidents;

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[1] The term service user also refers to patients, clients, children and young people under 18 years and carers
[2] "the Trust"
[3] Health & Safety at Work Order 1978, Management of Health and Safety at Work Regulations (Northern Ireland) 2000 and the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997.

- To improve the safety and quality of care through reporting, analysing and learning from incidents involving service users, staff and visitors (including contractors);
- To comply with relevant legislation and standards relating to the reporting of incidents;
- To ensure all adverse incidents are dealt with appropriately and in a timely and consistent manner;
- To provide a means of analysing trends in incidents and identification of factors contributing to incidents to assist in implementation of service improvement and risk reduction strategies, thereby minimising risk to service users, staff and visitors and the organisation; and
- To support staff when mistakes happen and encourage staff to review and reflect on their practice post review of incidents.

1.5 Legislative Requirements

The key legislative reporting requirements for organisations in respect of adverse incidents are as follows:-

- Health & Safety at Work (NI) Order 1978;
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1997;
- Social Security Claims and Payments Regulations 1979; and
- The Public Interest Disclosure Act 1998.

2.0 SCOPE OF THE POLICY

This policy covers all areas of the organisation's business and applies to all incidents involving service users, staff and visitors, as well as those incidents where individuals are not affected. It also includes contractors, students, volunteers and bank and agency staff or locums and any others to whom the organisation owes a duty of care.

This policy excludes detailed arrangements in respect of the following areas, which are covered by separate regionally agreed policies:-

- Policy for Reporting Early Alerts to Department of Health;
- Being Open Policy;
- Policy for Reporting Adverse Incidents under RIDDOR Regulations;
- Supporting Staff Involved in Incidents, Complaint, Claims and Coroner's Inquests;
- Policy on Memorandum of Understanding (MOU) - Investigating Service User Safety Incidents

3.0 ROLES AND RESPONSIBILITIES

3.1 **Trust Board:** is responsible for ensuring that a robust system is in place for the reporting and management of adverse incidents and will receive regular management reports on this subject matter.

3.2 **Chief Executive**:is the Accountable Officer for the organisation and is responsible for ensuring that it meets its statutory and legal requirements in respect of adverse incident reporting and management. He/she will ensure that the Trust adheres to, and responds appropriately to, circulars and guidance issued by the Department of Health (DoH) in respect of adverse incident management. The Chief Executive has delegated these executive functions to the Medical Director.

3.3 **Medical Director:** is the lead Director responsible for the reporting and management of adverse incidents within the Trust. He/she will ensure that systems, policies and procedures are developed and implemented on an organisational basis including the onward reporting of relevant incidents to external agencies for eg, Health & Social Care Board (HSCB), Heath & Safety Executive for Northern Ireland (HSENI) and the Regulation, Quality Improvement Authority (RQIA). On a daily basis this function is delegated to the Co-Director for Risk & Governance

3.4 **Co Director for Risk & Governance:** will support the Medical Director in meeting his/ her responsibility for the management of adverse incidents throughout the BHSCT.

3.5 **Director/s:** are responsible for ensuring that the Trust's policy on adverse incident reporting and management is widely disseminated, promoted and implemented within their areas of responsibility.

3.6 **Co-Directors and Senior Clinicians:** are responsible and accountable to their respective Directors for ensuring that this policy and any associated procedures are effectively implemented within their areas of responsibility. They should also promote an open, honest and just reporting culture and ensure that appropriate reviews are carried out.

3.7 **Senior Manager, Corporate Governance Services:** will support the Co-Director Risk and Governance in meeting his/her responsibility for adverse incident management.

3.8 **Senior Manager responsible for RIDDOR (Corporate Standards and Risk):** will support the Co-Director Risk and Governance in meeting his/her responsibility for adverse incident management and will ensure that systems are in place for the appropriate management and reporting of Health and Safety incidents including the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 (RIDDOR).

3.9 Head of Pharmacy and Medicines Management: as Controlled Drugs Accountable Officer must ensure there are safe systems in place for the management and use of controlled drugs. Adverse incidents and concerns involving controlled drugs are reported to the Accountable Officer.

3.10 Medicines Governance Pharmacist: is responsible for the expert review, quality assurance and identification of learning from reported medication incidents. In the event an adverse incident is categorised as a Serious Adverse Incident, they should be involved in the review. He /she is also responsible for submission of HSC Trust medication incident data for regional analysis by the Medicines Governance Teams.

3.11 Senior Information Risk Owner (SIRO): is the lead Director for ensuring that Information Governance (IG) incidents are reported and appropriately managed including reporting to Information Commissioner's Office, if necessary. He/she (or nominee) will provide advice and support to managers in respect of IG incidents, as appropriate.

3.12 Senior Managers, Heads of Departments/Services: are responsible for:

- ensuring that this policy and associated procedures are effectively implemented across their area of responsibility;
- promoting an open, honest and just reporting culture;
- ensuring that staff are appropriately trained in the reporting and management of adverse incidents;
- ensuring that appropriate review of adverse incidents is carried out;
- ensuring staff are given appropriate support following an adverse incident;
- ensuring communication with the service user and/or their relatives/carers as appropriate. (See Being Open Policy for guidance);
- trend analysis of incidents and identification of factors contributing to incidents to assist in service improvement and risk reduction strategies

3.13 Incident Approver

The Approver is responsible for reviewing, approving and/or escalation of incidents via DatixWeb, and for:

- ensuring that all possible remedial action is taken immediately following an adverse incident to prevent reoccurrence without compromising the investigation processes;
- ensuring the onward reporting of adverse incidents both internally and, where appropriate, externally and that their staff are aware of these particular local arrangements;
- securing all relevant evidence including materials, equipment, consumables, samples, records, witness details etc and ensuring that these are not compromised until appropriate investigation is complete. (See Procedure for Investigating an Incident);
- ensuring that where a death or a major injury has occurred, the security of the location and/or equipment/consumables, is maintained for inspection purposes by senior managers and/or statutory authorities (See Procedure

for Investigating an Incident);
- providing feedback and sharing learning with staff and ensuring that risk assessments and training needs are reviewed where relevant following adverse incident reviews.
- trend analysis of incidents and identification of factors contributing to incidents to assist in service improvement and risk reduction strategies

3.14 All staff: have a responsibility to:

- ensure the safety of individuals involved (service users, visitors and staff), the environment and equipment;
- avoid putting themselves and others in situations of danger;
- ensure their line manager/s and/or person in charge of the area is informed of the incident;
- record and report all adverse incidents using the organisation's reporting systems as soon as possible and ideally within 24 hours of the occurrence or becoming aware of the adverse incident; and
- co-operate with any review process including the provision of witness statements, if appropriate.

4.0 CONSULTATION

This policy was developed by the Regional Adverse Incident Work Group chaired by the Assistant Director, Risk Management & Governance, South Eastern Health & Social Care Trust. Consultation was completed via email with relevant Assistant/Co-Directors and staff within all organisations included in the working group. Further consultation within BHSCT was completed via email with relevant Co-Directors/Senior Managers.

5.0 POLICY STATEMENT/IMPLEMENTATION

5.1 Definitions

5.1.1 Adverse Incident: Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation arising during the course of the business of a HSC organisation/Special Agency or commissioned service[4]. A suggested list of broad categories of adverse incidents to be reported is listed in Appendix 1, for guidance purposes.

5.1.2 Harm is defined as: "injury (physical or psychological), disease, suffering, disability or death".[5] In most instances, harm can be considered to be unexpected if it is not related to the natural cause of the patient's/client's illness or underlying condition.

[4] HSCB Policy and Procedure for the reporting and follow up of Serious Adverse Incidents, November 2016
[5] Doing Less Harm, NHS, National Patient Safety Agency 2001

5.1.3 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 2016[6].

5.1.4 Service User[7]: this term refers to a patient, service user, family (of a service user and/or family of a victim), carer or nominated representative.

5.2 Policy Statement

The Trust is committed to providing the best possible services for its service users, staff and visitors. It recognises that adverse incidents will occur and that it is important to identify causes to ensure that lessons are learnt to prevent recurrence. It is, therefore, essential that a responsive and effective incident recording, reporting and management system is in place to achieve this aim. Where learning from such adverse incidents is identified the necessary changes should be put in place to improve practice.

5.3 Policy Principles

5.3.1 The organisation's approach to Adverse Incident Reporting and Management: An open, honest and just culture[8]

As part of its proactive approach to risk management, the organisation promotes an open, honest and just culture in which errors or service failures can be admitted, reported and discussed without fear of reprisal. This will enable lessons to be identified and allow active learning to take place and the necessary changes made or reflected in policies, procedures and practices.

All staff must report and manage adverse incidents according to this policy (and any related operational procedures) for adverse incident reporting. Crucial to the effectiveness of adverse incident reporting and management is the organisation's commitment to the promotion of an open, honest and just culture where all staff can participate in reporting adverse incidents. Staff are encouraged to report incidents and to look critically at their own actions and those of their teams, to ensure the organisation can provide quality services for our service users, staff and visitors.

Ultimately, the organisation wants to encourage staff to report areas of concern and to foster a positive ethos around reporting. Staff who make a

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[6] HSCB Policy and Procedure for the reporting and follow up of Serious Adverse Incidents, November 2016

[7] As per the draft Statement of what you should expect in relation to a Serious Adverse Incident Review, January 2019

[8] *a just culture focuses on identifying and addressing systems issues that lead individuals to engage in unsafe behaviours, while maintaining individual accountability by establishing zero tolerance for reckless behaviour. Just organizations focus on identifying and correcting system imperfections, and pinpoint these defects as the most common cause of adverse events. Just culture distinguishes between human error (e.g., mistakes), at-risk behaviour (e.g., taking shortcuts), and reckless behaviour (e.g., ignoring required safety steps), in contrast to an overarching 'no-blame' approach" (Agency for Healthcare Research and Quality; Patient Safety Network 2016, US Department of Health).*

prompt and honest report in relation to an adverse incident should not expect to be subject to disciplinary action except under the following circumstances:-

- A breach of law;
- Wilful or gross carelessness or professional misconduct;
- Repeated breaches of Trust policy and procedure;
- Where, in the view of the Trust, and/or any professional registration body, the action causing the incident is far removed from acceptable practice; or
- Where there is failure to report a serious incident in which a member of staff was involved or about which they were aware.

Completion of an adverse incident report does not discharge staff of their duty of care and their risk management responsibility. There should be timely and appropriate follow-up of adverse incidents. Where preventative measures and/or procedural changes are identified these should be put in place to minimise the risk of the adverse incident recurring.

All employees must be honest, open and truthful in all their dealings with patients/clients and the public, and organisational and personal interests must never be allowed to outweigh the duty of openness, transparency and candour.

5.3.2 External reporting arrangements in respect of other incidents not covered by this policy

Depending on the nature of the adverse incident the organisation may be required to report relevant details to other statutory agencies and external bodies, for example, HSCB, RQIA, HSENI and NIAIC. Staff should ensure that they are aware of their local reporting requirements to other statutory agencies and external bodies as per their local policy/procedures. These incidents must also be recorded on the organisation's incident reporting system.

With regard to Independent Service Providers (ISPs) and contractors, they will be required under their contractual arrangements to maintain a system of reporting and recording of adverse incidents related to service users referred to them by the Trust for assessment, treatment or care. ISPs are also required to submit monitoring information to the organisation as required. Both adverse incidents and SAIs are discussed at contract meetings between Trusts and ISPs. As per the HSCB procedure for reporting SAIs (November 2016), the Trust will decide whether an ISP adverse incident meets the criteria for reporting as a SAI and is, therefore, responsible for reporting the SAI to the HSCB.

~~5~~.3.3 Operational Procedures for Reporting of Adverse Incidents

A summary of the process for reporting, recording and reviewing adverse incidents is detailed below and also included in diagrammatic format in Appendix 1. Detailed procedures for reporting and managing, grading and

investigating incidents are available and should be read in conjunction with this policy. Key points to remember are listed below.

5.3.4 What to do when an adverse incident occurs – immediate actions

The injured person or damaged property should be assessed immediately to ascertain extent of injury/damage and identify emergency or urgent treatment/action required. The situation must be made safe. Communicate with the service user and their relatives/carers, as appropriate following an adverse event. Ensure appropriate discussion with the service user and/or relatives/carers and give consideration to any additional support which may be required. (See the *Being Open Policy*). Any equipment involved in the adverse incident, even if not directly implicated, should be removed from use and the following action taken:-

- Clearly label “Do Not Use” including a short description of the nature of the fault, if possible;
- Retain any related evidence such as packaging (for batch or serial numbers) or consumables/accessories (e.g. giving sets for pumps etc.);
- Decontaminate any device that can be decontaminated without destroying evidence and attach a decontamination certificate to that effect (See the *Medical Devices Policy & Procedures*); and
- For medication – where packaging or labelling of a medicine is an issue, retain or photograph to facilitate further review and follow up with the pharmaceutical company/MHRA.

You must also follow the *Guidance on Actions to be Taken after a Patient’s Death in Hospital* in relation to immediate actions to be taken when finding a person deceased following a suspected incident.

5.3.5 Who should report?

Any member of staff can report an adverse incident. It is the responsibility of **ALL** staff who are involved in, witness to, or become aware of an adverse incident, to ensure it is reported using the organisation’s adverse incident reporting system. If the incident involves another area within the Trust, this area must be made aware of it and remedial actions agreed.

5.3.6 When to report?

It is important that all adverse incidents are reported as soon as possible and ideally within 24 hours of occurrence or becoming aware of the adverse incident. This supports effective review and timely learning, and ensures compliance with responsibilities for external reporting.

5.3.7 What types of incidents to report?

Any event which meets the definition in section 4.1.1 involving service users, staff and visitors must be reported promptly and action instigated, where necessary. Appendix 2 provides a list of broad categories of possible adverse

incidents which may assist reporters. This is not an exhaustive list but gives a broad indication of the types of adverse incidents to be reported.

5.3.8 How to report?

All incidents should be reported using the organisation's adverse incident reporting system (DatixWeb). This is accessed via the Hub (Trust Intranet).

In respect of incidents involving service users, please note that adverse incident reports are NOT health records and copies of any electronic reports (or paper forms) should NOT be filed in the service users' records. However, details of the incident (including the incident reference number, if available) that are relevant to the treatment and care being provided to the service user should be added separately within the service user's healthcare record.

5.3.9 Other Reporting Systems

Some departments have additional error and incident monitoring arrangements (e.g. Laboratories) as part of specific legal, accreditation or quality assurance framework requirements for these services. Staff using these systems must ensure that incidents which meet the organisation's definition of adverse incidents are also reported via the organisation's adverse incident reporting system.

5.3.10 Staff Support directly following an incident

The organisation recognises that it has a responsibility to support all staff following adverse incidents. All staff involved in an adverse incident will need an appropriate level of support consistent with the outcome of the incident. It is the line manager's responsibility to ensure that individuals are supported appropriately. Support can be provided by Occupational Health, Trade Unions and Staff Care. Staff involved should be kept informed of the progress of a review at all stages.

In addition, individuals who have been absent from work may require additional support and supervision to aid confidence when returning to work. Staff involved in the incident should also be involved in the review where appropriate, with feedback, when complete. Further guidance can be obtained via the Trust's policy on *Supporting Staff Involved in Incidents, Complaint, Claims and Coroner's Inquests*.

5.3.11 Arrangements for Incident Review & Grading

Deciding the level of review

Many organisations typically report thousands of incidents each year. It is therefore unrealistic to suggest that all incidents should be reviewed to the same degree, or at the same level, within the organisation. Furthermore, the outcome of an incident, including a 'near miss', at the time of occurrence is

sometimes a poor indicator of the level of review required. The application of a simple risk assessment process to incidents at the time of occurrence can enable the organisation to implement a much more structured approach to its incident management.

Organisations should grade all incidents in DatixWeb for severity (actual impact) at the time of reporting the incident. This is completed by the reporter of the incident using the Regional Risk Matrix (Impact Assessment Table) (see Appendix 3).

In addition, it is important to complete the potential risk grading also using the Regional Risk Matrix (Impact Assessment Table/ Likelihood Descriptors) on DatixWeb (See *Procedure for Grading an Incident*)

The Regional Risk Matrix is also used by a range of specialist advisers for grading of incidents. Not all incidents fit discreetly into individual categories within the matrix and therefore the grading/coding of incidents will be at the discretion of the relevant adviser.

5.3.12 Communication with Service Users and/or relatives

Harming a service user can have devastating emotional and physical consequences for the individuals, their families and carers, and can be distressing for the professionals involved. ***'Being Open'***[9] is a set of principles that health and social care staff should use when offering an explanation and apologising to service users and/or their carers when harm has resulted from an incident. **"Saying sorry is not an admission of liability".**

'*Being Open'* involves:

- acknowledging, apologising and explaining when things go wrong;
- keeping service users and carers fully informed when an incident has occurred;
- conducting a thorough review into the incident and reassuring service users, their families and carers that lessons learned will help prevent the incident reoccurring;
- providing support for those involved to cope with the physical and psychological consequences of what happened; and
- recognising that direct and/or indirect involvement in incidents can be distressing for health and social care staff. Staff are encouraged to seek emotional support.

The organisation is committed to improving the safety and quality of the care we deliver to the public. Our '*Being Open'* policy expresses this commitment to provide open and honest communication between health and social care staff and a service user (and/or their family and carers) when they have suffered harm as a result of their treatment. It is based on published guidance

by the National Patient Safety Agency (NPSA) and also complies with step 5 of '*Seven Steps to Patient Safety'*.

The main focus of the Being Open policy is for incidents with a severity of moderate and above. However, it is good practice to follow the principles for any incidents where service users have suffered harm.

Further guidance on communicating with service users and their relatives is available in the *Being Open* and/or *Serious Adverse Incident Policy*.

5.3.13 Communication with the Media

All media queries should be directed, in the first instance, to the Corporate Communications Dept.

5.3.14 Debriefing of Staff after Adverse Incidents

Co-Directors/Senior Managers and Heads of Department should ensure that local procedures are in place for the debriefing of staff after incidents. Agreed timescales for debriefing should be specified. The Line Manager should ensure that the staff member has access to appropriate help immediately post incident as necessary eg, referral for medical opinion in case of assault, counselling etc. Line managers should, where appropriate, seek medical advice as to whether it is advisable for the staff member to return to (or stay in) the workplace.

It should be standard practice at all debriefing sessions with staff to consider the contributing factors, which may have led to an incident. This should assist staff in reviewing practice and updating care plans, risk assessments etc. in order to minimise the risk of recurrence. Details of debriefing offered/arranged should be documented and retained in the staff member's local personnel file.

In the case of assaults on staff, line managers should discuss with the staff member whether or not they wish the police to be involved. Line managers should make staff aware of the availability of the services of Occupational Health Services and Staff Care.

5.3.15 Review, Monitoring and Analysis of Adverse Incidents

The organisation has in place mechanisms for the review, monitoring and analysis of adverse incidents both at Corporate and Divisional level. This involves production of reports for consideration and discussion at relevant governance related committees/sub committees and externally as required. Incidents should also be used with other sources of information to help inform the management of risks and effectiveness of actions taken following incident reviews, Quality Improvement projects and other quality and safety initiatives.

The Medicines Governance Pharmacist will lead on the multidisciplinary review, monitoring and analysis of medication related incidents and will link in

with the Regional Medicines Governance Team in respect of the production of regional Medication related governance reports.

5.3.16 Learning and Feedback

Learning from adverse incidents can only take place when they are reported and investigated in a positive, open and structured way. Where learning from such adverse incidents is identified the organisation will ensure that the necessary changes will be put in place to improve practice. Where learning from incidents is relevant to other areas across the organisation, and/or externally, the learning should be shared as per current organisational arrangements, e.g. established sub committees and groups. (See *Policy for Sharing Learning*)

Feedback to staff is vital in respect of incidents they report. Managers should ensure it occurs in their respective areas. This can be on a one to one basis or feedback can be given to all staff at regular Incident, Staff or Assurance / Governance Meetings.

5.4 Dissemination

This policy covers all areas of the organisation's business and applies to all incidents involving service users, staff and visitors, as well as those incidents where individuals are not affected. It also includes contractors, students, volunteers and bank and agency staff or locums and any others to whom the organisation owes a duty of care. All staff employed by the Trust should be provided with access to this policy. The latest version of this policy (and related documents) is available on the Trust's intranet.

5.5 Resources

5.5.1 Training

Adverse Incident Training is mandatory for all staff and appropriate training and guidance will be provided by the Corporate Governance Dept, to ensure that all Trust employees understand their responsibilities under this policy and are able to effectively fulfil their obligations to report adverse incidents. The organisation's training administration system should be used appropriately to record staff training. Senior Managers/Heads of Departments are responsible for ensuring that training on Incident Reporting is covered in local Directorate induction programmes.

5.6 Exceptions

There are no exceptions to this policy and to the organisation's commitment to learn from adverse incidents.

6.0 MONITORING AND REVIEW

An audit of the policy will be undertaken post implementation to ensure adherence to the principles and procedures outlined in this policy document. Changes will be made to the policy, as required. This policy will be reviewed on a regular basis in the light of best practice, changing legislation or new/updated policy guidance.

7.0 EVIDENCE BASE/REFERENCES

- Health & Safety at Work (Northern Ireland) Order 1978;
- Management of Health & Safety at Work Regulations (Northern Ireland) 2000;
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1997;
- HSCB Procedure for the Reporting and Follow up of Serious Adverse Incidents, November 2016;
- Six steps to Root Cause Analysis, 2002, Consequence UK Limited;
- National Patient Safety Agency;
- Seven Steps to Patient Safety (2004); and
- Being Open, Patient Safety Alert, November 2009.

8.0 APPENDICES

Appendix 1 – Incident reporting and review process flowchart
Appendix 2 – Examples of Adverse Incidents
Appendix 3 – Regional Risk Matrix

9.0 NURSING AND MIDWIFERY STUDENTS

Nursing and/or Midwifery students on pre-registration education programmes, approved under relevant 2018/2019 NMC education standards, must be given the opportunity to have experience of and become proficient **in Adverse Incident Reporting and Management Policy** where required by the student's programme. This experience must be under the appropriate supervision of a registered nurse, registered midwife or registered health and social care professional who is adequately experienced in this skill and who will be accountable for determining the required level of direct or indirect supervision and responsible for signing/countersigning documentation.

Direct and indirect supervision

- Direct supervision means that the supervising registered nurse, registered midwife or registered health and social care professional is actually present and works alongside the student when they are undertaking a delegated role or activity.

- Indirect supervision occurs when the registered nurse, registered midwife or registered health and social care professional does not directly observe the student undertaking a delegated role or activity. (NIPEC, 2020)

This policy has been developed in accordance with the above statement.

Wording within this section must not be removed.

10.0 EQUALITY IMPACT ASSESSMENT

The Trust has legal responsibilities in terms of equality (Section 75 of the Northern Ireland Act 1998), disability discrimination and human rights to undertake a screening exercise to ascertain if the policy has potential impact and if it must be subject to a full impact assessment. The process is the responsibility of the Policy Author. The template to be complete by the Policy Author and guidance are available on the Trust Intranet or via this **link**.

All policies (apart from those regionally adopted) must complete the template and submit with a copy of the policy to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

The outcome of the equality screening for the policy is:

Major impact ☐
Minor impact ☐
No impact ☐

Wording within this section must not be removed

11.0 DATA PROTECTION IMPACT ASSESSMENT

New activities involving collecting and using personal data can result in privacy risks. In line with requirements of the General Data Protection Regulation and the Data Protection Act 2018 the Trust considers the impact on the privacy of individuals and ways to militate against any risks. A screening exercise must be carried out by the Policy Author to ascertain if the policy must be subject to a full assessment. Guidance is available on the Trust Intranet or via this **link**.

If a full impact assessment is required, the Policy Author must carry out the process. They can contact colleagues in the Information Governance Department for advice on Tel: 028 950 46576

Completed Data Protection Impact Assessment forms must be returned to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

The outcome of the Data Protection Impact Assessment screening for the policy is:

Not necessary – no personal data involved ☐
A full data protection impact assessment is required ☐
A full data protection impact assessment is not required ☐

Wording within this section must not be removed.

12.0 RURAL NEEDS IMPACT ASSESSMENT

The Trust has a legal responsibility to have due regard to rural needs when developing, adopting, implementing or revising policies, and when designing and delivering public services. A screening exercise should be carried out by the Policy Author to ascertain if the policy must be subject to a full assessment. Guidance is available on the Trust Intranet or via this link.

If a full assessment is required the Policy Author must complete the shortened rural needs assessment template on the Trust Intranet. Each Directorate has a Rural Needs Champion who can provide support/assistance.

Completed Rural Impact Assessment forms must be returned to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

Wording within this section must not be removed.

13.0 REASONABLE ADJUSTMENT ASSESSMENT

Under the Disability Discrimination Act 1995 (as amended) (DDA), all staff/ service providers have a duty to make Reasonable Adjustments to any barrier a person with a disability faces when accessing or using goods, facilities and services, in order to remove or reduce such barriers. E.g. physical access, communicating with people who have a disability, producing information such as leaflets or letters in accessible alternative formats. E.g. easy read, braille, or audio or being flexible regarding appointments. This is a non-delegable duty.

The policy has been developed in accordance with the Trust's legal duty to consider the need to make reasonable adjustments under the DDA.

Wording within this section must not be removed.

SIGNATORIES

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

_____ **Date:** 04/06/2020

Chris Hagan
Medical Director

_____ **Date:** 10/06/2020

Cathy Jack
Chief Executive

Appendix 1 – Process for Reporting and Managing an Adverse Incident (including level of review based on severity and potential risk grading)

NOTE: For detailed guidance see the Procedures for Reporting and Managing, Grading and Investigating Incidents

INCIDENT

IMMEDIATE ACTION

1. Make person(s) / area safe.
2. Obtain medical aid if required.
3. Inform manager on duty ASAP.
4. Complete an incident form.
5. Consider level of communication with the patient.
6. Consider level of review required and action accordingly. If incident meets SAI criteria, follow relevant procedures.

GREEN INCIDENT (INSIGNIFICANT OR MINOR SEVERITY/LOW RISK)

Green incidents – Should normally be reviewed locally in the ward or department in which the event occurred. The review lead will normally be the Ward/Team/Department manager. It is the local team's responsibility to identify learning points, or safety improvement measures that are within the department's control, and ensure that those safety measures identified that are not within the control of the department are appropriately communicated to the relevant Management Team for consideration.

Incident types frequently falling into this grading should also be subject to aggregate analysis by the Ward/Team/Departmental Manager to identify any need for more targeted data collection. It is acceptable for the ward/departmental manager to close such incidents following review and recording of findings and lessons learned on Datix.

Review of this grade of incident should normally be completed and **closed within 5 working days**.

YELLOW INCIDENT (MODERATE SEVERITY/MEDIUM RISK)

Yellow Incidents – These should also be reviewed locally, as for Green Incidents, but overseen by the Service Manager/Asst Service Manager for that area. It is the local team's responsibility to identify learning points, or safety improvement measures within the departments control and ensure that those which are not, are appropriately communicated to the relevant Management Team for consideration. Frequently occurring events of this grading should also undergo Trust-wide aggregate review to identify any need for more targeted data collection.

It is acceptable for the Ward/Team/Departmental Manager to close such incidents following review and proper recording of findings and lessons learned on Datix.

Review of this grade of incident should normally be completed and **closed within 4 weeks**.

AMBER INCIDENT (MAJOR SEVERITY/HIGH RISK)

Amber Incidents – The Co-Director is accountable for ensuring that all investigations are carried out appropriately. The incident should be investigated and reviewed locally by more than one person and the team may include someone independent from the specialty, if required. Where the incident crosses professional and/or managerial boundaries, team membership should reflect this.

It is the responsibility of the relevant management team to ensure that all learning points and safety improvements are appropriately identified and those not within the control of the local management team are communicated to the relevant person/s and committee/s, whichever is the more appropriate. Improvement strategies arising out of this group of events should be monitored as part of the Division's Governance arrangements.

Advice can be sought from Directorate Governance staff.

Review of this grade of incident should normally be completed and **closed within 12 weeks**.

RED INCIDENT (CATASTROPHIC SEVERITY/EXTREME RISK)

Red Incidents – The Co-Director is accountable for ensuring that all reviews are carried out appropriately. The incident should be investigated and reviewed locally by more than one person and the team may include someone independent from the specialty, if required. Where the incident crosses professional and/or managerial boundaries, team membership should reflect this.

It is the responsibility of the relevant management team to ensure that all learning points and safety improvements are appropriately identified and those not within the control of the local management team are communicated to the relevant person/s and committee/s, whichever is the more appropriate. All of the resulting reports and improvement strategies arising from these events should be monitored through Division/Trust Governance arrangements.

Advice can be sought from Directorate Governance staff.

Review of this grade of incident should normally be completed and **closed within 12 weeks.**

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1997 (RIDDOR)
Report all RIDDOR reportable incidents to the Health & Safety team on 02895048722.

For advice on Medical Device incidents contact the Medical Devices Coordinator on 02895048840 or email [redacted]

Open, Honest and Just Culture

This Trust welcomes knowledge of adverse events as an opportunity to learn for the benefit of our service users, staff and visitors. Unless there is clear evidence of flagrant malpractice, a complete disregard for the safety of others, maliciousness, intent to harm, theft or fraud, the disciplinary policy will not be used for review purposes. Incidents will be investigated for the purposes of learning and change and staff are required to engage as active participants of this.

Appendix 2 – Examples of Adverse Incidents that should be reported

Broad categories of possible adverse incidents are shown below and may assist reporters. This list is not comprehensive but gives a broad indication of what should be reported

- Violence, aggression, behavioural issues
- Delays or difficulties during appointments, admissions, transfers or discharges
- Accidents e.g. falls, medical sharps injuries, manual handling, exposure to hazardous substance, burn or scalds
- Cardiac arrests involving CPR and/or Defib
- Issues with clinical investigations, scans, x-rays, lab tests etc.
- Communication breakdowns between staff and/or with service users, issues with consent and confidentiality
- Event which caused the dignity and respect of a service user to be compromised
- Diagnosis, missed or delayed
- Financial loss to the Trust
- Infrastructure or Resources (staffing, facilities, environment) – for example, unsafe environment, waste issues, misuse, failure or theft of IT equipment or systems, lack of facilities, equipment or supplies, inadequate staffing levels
- Infection control issues, pressure sores, fluid maintenance, pain management, any other issues relating to implementation of care or ongoing monitoring / review
- Labour or delivery adverse incidents
- Medical device/equipment related Incidents – any preventable equipment related event that could have or did lead to patient harm, loss or damage. Includes incidents related to training, servicing, storage, disposal and suitability of the device, as well as failure of the equipment itself
- Medication incident (ie, any preventable medication related event that could have or did lead to patient harm, loss or damage).
- Patient Information issues e.g. records, documents, test results, scans. This may also include any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed.
- Treatment, procedure – any adverse incident immediately before, during or immediately after
- Security – for example, fires and fire risks, theft or damage to personal property, premises or vehicles, intruders or break-ins

Appendix 3 – Regional Risk Matrix

DOMAIN	IMPACT (CONSEQUENCE) LEVELS [can be used for both actual and potential]				
	INSIGNIFICANT (1)	**MINOR (2)**	**MODERATE (3)**	**MAJOR (4)**	**CATASTROPHIC (5)**
PEOPLE *(Impact on the Health/Safety/Welfare of any person affected: e.g. Patient/Service User, Staff, Visitor, Contractor)*	• Near miss, no injury or harm.	• Short-term injury/minor harm requiring first aid/medical treatment. • Any patient safety incident that required extra observation or minor treatment e.g. first aid. • Non-permanent harm lasting less than one month. • Admission to hospital for observation or extended stay (1-4 days duration). • Emotional distress (recovery expected within days or weeks).	• Semi-permanent harm/disability (physical/emotional injuries/trauma) (Recovery expected within one year). • Admission/readmission to hospital or extended length of hospital stay/care provision (5-14 days). • Any patient safety incident that resulted in a moderate increase in treatment e.g. surgery required.	• Long-term permanent harm/disability (physical/emotional injuries/trauma). • Increase in length of hospital stay/care provision by >14 days.	• Permanent harm/disability (physical/ emotional trauma) to more than one person. • Incident leading to death.
QUALITY & PROFESSIONAL STANDARDS/ GUIDELINES *(Meeting quality/ professional standards/ statutory functions/ responsibilities and Audit Inspections)*	• Minor non-compliance with internal standards, professional standards, policy or protocol. • Audit / Inspection – small number of recommendations which focus on minor quality improvements issues.	• Single failure to meet internal professional standard or follow protocol. • Audit/Inspection – recommendations can be addressed by low level management action.	• Repeated failure to meet internal professional standards or follow protocols. • Audit / Inspection – challenging recommendations that can be addressed by action plan.	• Repeated failure to meet regional/ national standards. • Repeated failure to meet professional standards or failure to meet statutory functions/ responsibilities. • Audit / Inspection – Critical Report.	• Gross failure to meet external/national standards. • Gross failure to meet professional standards or statutory functions/ responsibilities. • Audit / Inspection – Severely Critical Report.
REPUTATION *(Adverse publicity, enquiries from public representatives/media Legal/Statutory Requirements)*	• Local public/political concern. • Local press < 1day coverage. • Informal contact / Potential intervention by Enforcing Authority (e.g. HSENI/NIFRS).	• Local public/political concern. • Extended local press < 7 day coverage with minor effect on public confidence. • Advisory letter from enforcing authority/increased inspection by regulatory authority.	• Regional public/political concern. • Regional/National press < 3 days coverage. Significant effect on public confidence. • Improvement notice/failure to comply notice.	• MLA concern (Questions in Assembly). • Regional / National Media interest > 3 days < 7days. Public confidence in the organisation undermined. • Criminal Prosecution. • Prohibition Notice. • Executive Officer dismissed. • External Investigation or Independent Review (eg, Ombudsman). • Major Public Enquiry.	• Full Public Enquiry/Critical PAC Hearing. • Regional and National adverse media publicity > 7 days. • Criminal prosecution – Corporate Manslaughter Act. • Executive Officer fined or imprisoned. • Judicial Review/Public Enquiry.
FINANCE, INFORMATION & ASSETS *(Protect assets of the organisation and avoid loss)*	• Commissioning costs (£) <1m. • Loss of assets due to damage to premises/property. • Loss – £1K to £10K. • Minor loss of non-personal information.	• Commissioning costs (£) 1m – 2m. • Loss of assets due to minor damage to premises/ property. • Loss – £10K to £100K. • Loss of information. • Impact to service immediately containable, medium financial loss	• Commissioning costs (£) 2m – 5m. • Loss of assets due to moderate damage to premises/ property. • Loss – £100K to £250K. • Loss of or unauthorised access to sensitive / business critical information • Impact on service contained with assistance, high financial loss	• Commissioning costs (£) 5m – 10m. • Loss of assets due to major damage to premises/property. • Loss – £250K to £2m. • Loss of or corruption of sensitive / business critical information. • Loss of ability to provide services, major financial loss	• Commissioning costs (£) > 10m. • Loss of assets due to severe organisation wide damage to property/premises. • Loss – > £2m. • Permanent loss of or corruption of sensitive/business critical information. • Collapse of service, huge financial loss
RESOURCES *(Service and Business interruption, problems with service provision, including staffing (number and competence), premises and equipment)*	• Loss/ interruption < 8 hour resulting in insignificant damage or loss/impact on service. • No impact on public health social care. • Insignificant unmet need. • Minimal disruption to routine activities of staff and organisation.	• Loss/interruption or access to systems denied 8 – 24 hours resulting in minor damage or loss/ impact on service. • Short term impact on public health social care. • Minor unmet need. • Minor impact on staff, service delivery and organisation, rapidly absorbed.	• Loss/ interruption 1-7 days resulting in moderate damage or loss/impact on service. • Moderate impact on public health and social care. • Moderate unmet need. • Moderate impact on staff, service delivery and organisation absorbed with significant level of intervention. • Access to systems denied and incident expected to last more than 1 day.	• Loss/ interruption 8-31 days resulting in major damage or loss/impact on service. • Major impact on public health and social care. • Major unmet need. • Major impact on staff, service delivery and organisation - absorbed with some formal intervention with other organisations.	• Loss/ interruption >31 days resulting in catastrophic damage or loss/impact on service. • Catastrophic impact on public health and social care. • Catastrophic unmet need. • Catastrophic impact on staff, service delivery and organisation - absorbed with significant formal intervention with other organisations.
ENVIRONMENTAL *(Air, Land, Water, Waste management)*	• Nuisance release.	• On site release contained by organisation.	• Moderate on site release contained by organisation. • Moderate off site release contained by organisation.	• Major release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service etc).	• Toxic release affecting off-site with detrimental effect requiring outside assistance.

SET Risk Matrix – April 2013 (based on HSC Regional Risk Matrix - April 2013, updated June 2016) - Clean

Risk Likelihood Scoring Table			
Likelihood Scoring Descriptors	**Score**	**Frequency (How often might it/does it happen?)**	**Time framed Descriptions of Frequency**
Almost certain	5	Will undoubtedly happen/recur on a frequent basis	Expected to occur at least daily
Likely	4	Will probably happen/recur, but it is not a persisting issue/circumstances	Expected to occur at least weekly
Possible	3	Might happen or recur occasionally	Expected to occur at least monthly
Unlikely	2	Do not expect it to happen/recur but it may do so	Expected to occur at least annually
Rare	1	This will probably never happen/recur	Not expected to occur for years

	Risk Matrix/Consequence (Severity Levels)				
Likelihood Scoring Descriptors	**Insignificant(1)**	**Minor (2)**	**Moderate (3)**	**Major (4)**	**Catastrophic (5)**
Almost Certain (5)	**Medium**	**Medium**	**High**	**Extreme**	**Extreme**
Likely (4)	**Low**	**Medium**	**Medium**	**High**	**Extreme**
Possible (3)	**Low**	**Low**	**Medium**	**High**	**Extreme**
Unlikely (2)	**Low**	**Low**	**Medium**	**High**	**High**
Rare (1)	**Low**	**Low**	**Medium**	**High**	**High**

EVIDENCE FILE
CONTROLS ASSURANCE STANDARD 7.

Title		Type	Status
SERIOUS ADVERSE INCIDENT POLICY & PROCEDURE		Policy	Approved
		Unique Identifier	**Version**
		Gov00003	1
Author / Originator		**Accountable Director**	
Name Ian Jamison	**Role** Assistant Director of Corporate Affairs	**Name** Eamonn Molloy	**Role** Director of Human Resources & Corporate Affairs
Document Checked for:		**Author Signature**	
NORTH & WEST BELFAST HEALTH & SOCIAL SERVICES TRUST	**Compatibility with other Trust Documents**	√	
	Equality and/or Human Rights Impact	√	
	Financial Impact	√	
	Training and Education Needs	√	
	Distribution List	√	
Approved by (Board Committee Group)		**Date**	
Trust Board		**29 June 2005**	

Review Date	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Month				Jun								

TABLE OF CONTENTS

1.0 INTRODUCTION

1.1 This policy sets out the framework and operational arrangements for the management of serious adverse incidents within the Trust.

1.2 This policy operates in conjunction with existing internal and external statutory reporting requirements such as the Registration and Inspection Units, Commissioning Boards, DHSSPS, Health and Safety Executive, Northern Ireland Adverse Incident Centre etc.

1.3 This policy should be read in conjunction with the undernoted Trust policies/procedures.

- Risk Management Strategy/Policy
- Management of Adverse/Events, Incidents and Near Misses
- Procedure for Investigating Incidents, Complaints and Claims
- Whistleblowing Policy
- Major Incident Policy

2.0 PURPOSE/OBJECTIVES OF THE POLICY

2.1 The purpose and objectives of the policy are:

- To ensure the Trust has clearly defined accountabilities, responsibilities and frameworks in place to appropriately, manage serious adverse incidents.

- To provide a Trustwide system for the management of all serious incidents ensuring they are dealt with appropriately and in a consistent manner.

- To improve our services through recording, reporting, analysing, evaluating and learning from serious adverse incidents involving patients, clients, staff and visitors.

3.0 SCOPE OF POLICY AND DEFINITION

3.1 The policy covers all aspects of the Trust's Business

3.2 A serious adverse incident in the context of Health and Social Services is described by the Department of Health Social Services and Public Safety as **"any event or circumstance arising during the course of the business of a HPSS Organisation/Special**

Agency or commissioned service that led, or could have led, to serious unintended or unexpected harm, loss or damage".

This may be because:

- It involves a large number of service users
- There is a question of poor professional/clinical or management judgement
- A serious service and/or equipment failure
- A service user(s) or staff member has died under unusual circumstances; or
- There is the possibility or perception that any of these might have occurred.

3.3 Factors that might suggest a serious incident include:

- Any incident involving serious harm or potentially serious harm to a patient, service user, member of staff or the public. This could include disease outbreaks, apparent clinical errors or lapses in care
- Any incident which has serious implications for patient or staff safety - involving potential or actual risk to patients or staff
- Any incident which may suggest that Trust policy is compromised and may give rise to serious consequences for the proper delivery of Trust business
- Any incident with the potential for serious adverse media attention/damage to reputation of the Trust

3.4 The above list is by no means an exhaustive list and if doubt remains regarding the classification of an adverse incident as serious, it must always be checked with the relevant Director.

4.0 MANAGEMENT PRINCIPLES

4.1 Roles and Responsibilities

4.1.1 The Chief Executive, as Accountable Officer, is responsible for ensuring all serious incidents are managed appropriately in accordance with Trust Policies.

4.1.2 Lead Director - The Chief Executive has nominated the Director of Planning Contracts and Information/Deputy Chief Executive to manage and review serious incidents. In the

absence of the aforementioned, the Chief Executive will nominate another Director supported by a Senior Manager who is competent to undertake the review using causal analysis methodologies.

4.2 Serious Incident Reporting

4.2.1 During Normal Working Hours (See Flowchart Appendix A)

All serious incidents should be reported to the relevant Director.

Should the relevant Director agree the incident is serious, a telephone report should be made immediately to the Administration Department on Tel: 90821202 followed by the adverse event/incident report form by post.

The relevant Director will also advise the Chief Executive directly.

Following consultation with the Lead Director (Deputy Chief Executive) and the relevant Director, the Chief Executive will decide whether or not to declare the event a "serious incident" and, if required, activate the relevant review and action team (see Appendix E).

4.2.2 Outside Normal Working Hours (See Flowchart Appendix B)

The Senior Duty Officer will contact the Administration On-call Officer through the Muckamore switchboard 028 94463333, who will inform the Director on call. The Director will decide, following appropriate consultation if the incident is to be classified as serious and notify the Chief Executive.

4.2.3 External Reporting

The relevant Director will ensure all relevant external bodies are informed of the serious incident.

In addition if the relevant Director considers that the incident is likely to:

- Be serious enough to warrant regional action to improve safety or care within the broader HPSS
- Be of public concern or
- Require an independent review.

The relevant Director should provide the Department with a brief report, using the proforma attached at Appendix C by Email adverse.incidents@dhsspsni.gov.uk or by Fax to 028 90528126.

4.3 Communicating with Patients/Clients and Relatives

The professional staff responsible for the treatment and/or care of the patient/client will retain the responsibility for communicating with them and their relatives about the incident. The following points should be noted:

- Following an assessment, patients/clients and relatives (bearing in mind issues of patient/client confidentiality) are provided with explanations of what has happened, why it happened, how it will be investigated and how lessons will be learned from the incident.

- If, in conjunction with the relevant Director, the professional head/consultant considers there are compelling professional reasons not to discuss the incident with the patient/clients relative (s) a clear record should be made of this in the patient/client records.

- If deemed appropriate, an apology should be given, acknowledging that an apology is not an admission of liability.

- If appropriate, a meeting should be offered to patient/client relative (s) with the relevant Trust personnel. A summary of the points discussed and any agreements made should form part of

the overall investigative paper work and a copy provided to the patient/client relative (s).

- The patient/client relative (s) will be informed of any external body the incident is being reported to and why.

4.4 Review and Action Team

The Lead Director (Deputy Chief Executive) will lead a Review and Action Team consisting of:-

- Relevant Director
- Lead Clinician/Professional and/or Directorate Service Manager
- A Senior Manager
- A nominated Senior Officer to deal with press and communications
- Other co-opted members as appropriate e.g. other Professionals, Risk Management, Health and Safety, Legal Advice, Estates etc.
- Dedicated administration support.

The Review Team through the Lead Director (Deputy Chief Executive) will report directly to the Chief Executive.

The Review Team will meet as soon as possible and no later than 48 hours after the incident to review the case. The Team will work to agree Terms of Reference (Appendix D).

The Team will decide how the incident is to be managed, the timescale of the review investigation and subsequent reporting (See Appendix E).

Where an incident involves more than one Directorate or Service Area, the Team will ensure co-ordinated communication with appropriate Clinicians/Professionals and Managers from all relevant areas. The incident will be investigated by a person(s), competent in causal analysis methodologies, appointed by the Team. Other members may be co-opted as required e.g. Trust Legal Advisers.

Following resolution of the incident, the Team will review action taken, document lessons learned and provide a report outlining conclusions and recommendations to the Chief Executive, Executive Management Board, Governance Committee and Trust Board.

4.5 Monitoring

The Lead Director (Deputy Chief Executive) will monitor implementation of remedial action agreed by the Governance Committee.

5.0 Document Control

5.1 Terms and Abbreviations

Term/Abbreviation	Meaning

5.2 Other Relevant or Associated Documents

Reference	Policy Identifier	Title
[1]	TBC	Risk Management Strategy/Policy
[2]	TBC	Management of Adverse/Events, Incidents & Near Misses
[3]	Gov00002	Procedure for Investigating Incidents, Complaints & Claims
[4]	TBC	Whistleblowing Policy
[5]	TBC	Major Incident Policy

5.3 Distribution List

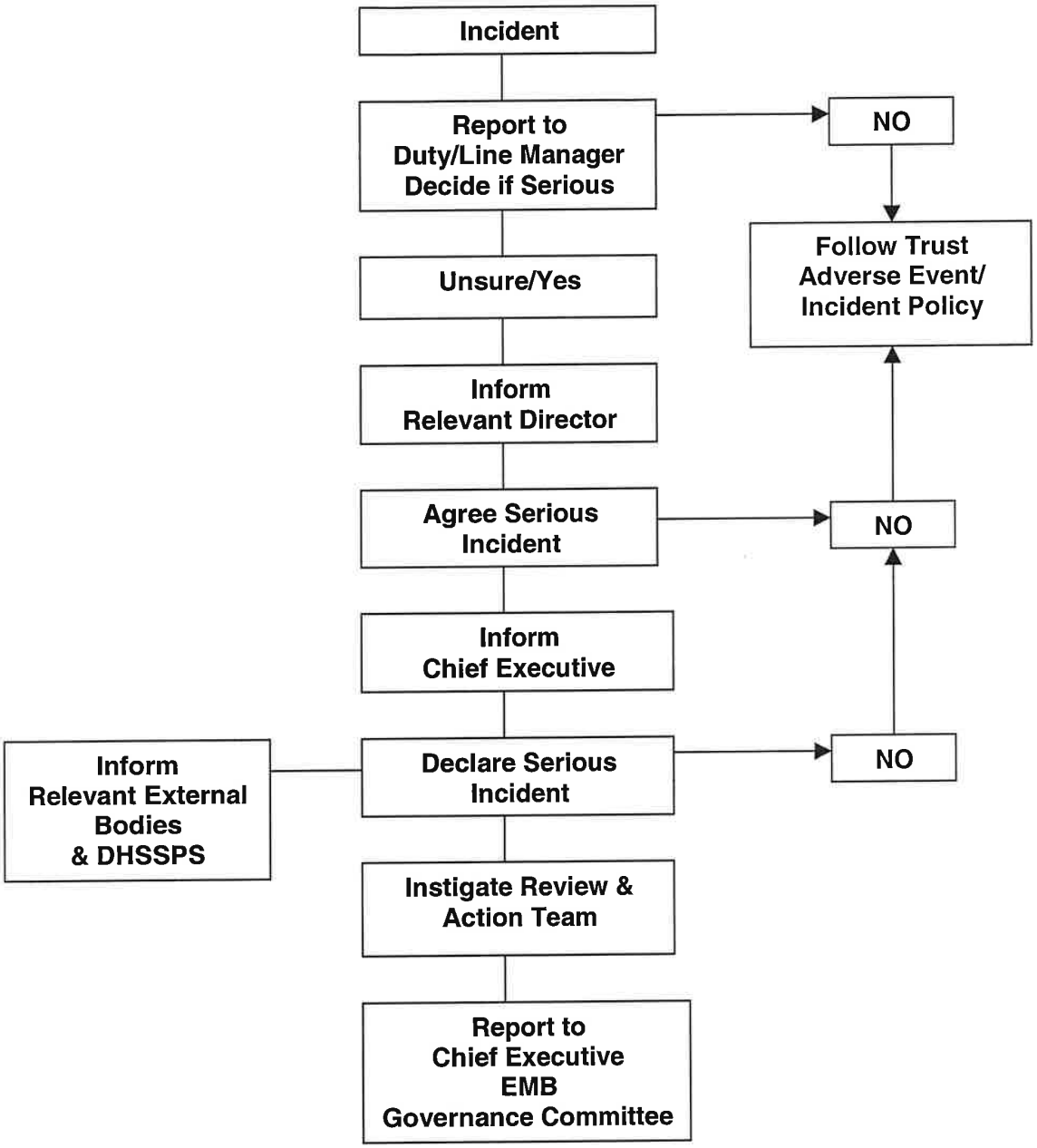
Name	Organisation/Location
Directors & Senior Managers	Various Trust facilities

5.4 Quality Control

Job Title	Risk Management and Controls Assurance Coordinator
Signature	
Date	16th September 2005

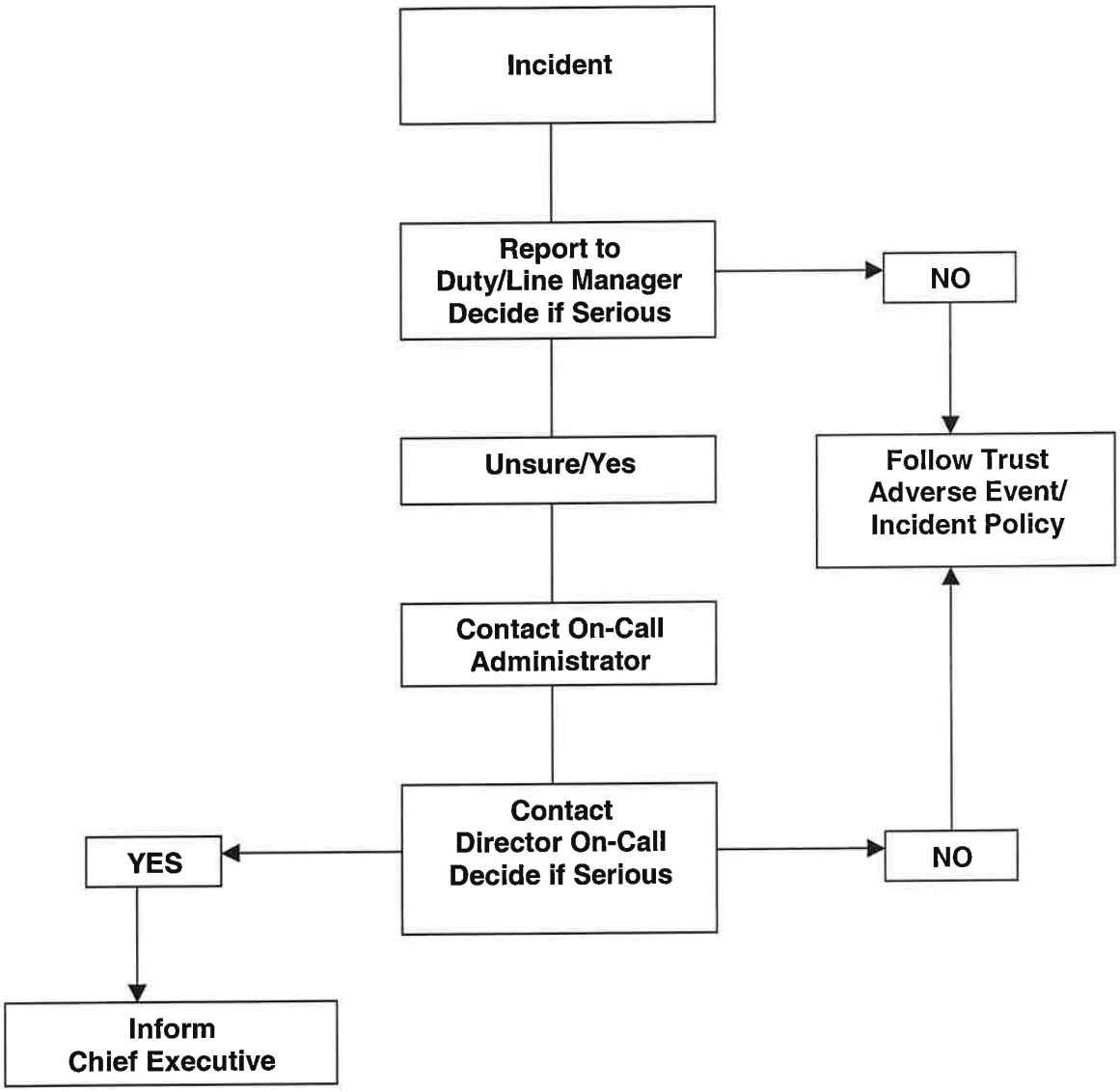
APPENDIX A

Serious Adverse Incident Reporting Flowchart (During Office Hours)



APPENDIX B

Serious Adverse Incident Reporting Flowchart (Out of Hours)



APPENDIX C

SERIOUS ADVERSE INCIDENT REPORT
1. Organisation:
2. Brief summary (and date) of incident:
3. Why incident considered serious:
4. Action taken:
5. Is any regional action recommended? (if so, full details should be submitted) Y/N -
6. Is an Independent Review being considerd? (if so, full details should be submitted) Y/N -
7. Other Organisations informed **HSS Board** Y/N - **PSNI** Y/N - **Coroner** Y/N - **NIHSE** Y/N - **Other (please specify)** Y/N -
8. Report submitted by (name and contact details of nominated Senior Manager or Chief Executive)

Completed proforma should be sent, by email, to:
adverse.incidents@dhsspsni.gov.uk

If email cannot be used, fax to 028 528126

APPENDIX D

Terms of Reference for the Review and Action Team

The Review and Action Team is to meet as soon as possible after the incident and no later than 48 hours. The Team will be led by the Lead Director (Deputy Chief Executive) or, in his/her absence, by a nominated Director. A team approach will assist in ensuring that all aspects of the incident are appropriately reviewed and that there is support available from within the team in assessing complex or sensitive areas. It may also be beneficial to appoint a member to the Team from outside the speciality/function area or from outside the Trust.

The terms of reference are as follows;-

- To undertake an initial review of the incident
- To consider any other relevant factors raised by the incident
- Scope the remit of the review/investigation
- To determine action required to manage the incident including
  - Identify the lead person to investigate
  - Identify the lead person to manage the press and communications
  - Identify other member to the Review Team e.g. administration support
- To ensure staff and patient/client confidentiality
- To review the outcome of the investigation, agreeing recommendations and actions and lessons learned
- To provide an outline report of the incident and its outcome to the Chief Executive within four weeks of the incident occurring
- To determine the action required to ensure effective implementation of the recommendations
- Implementation of the Action Plans.

The report produced by the Review Team should be in a standard format as detailed below:

- Statement of membership and terms of reference
- Brief description of the methods of enquiry
- Detailed description of the history and chronology of events
- Outline investigative techniques used
- Care management/service delivery problems identified
- Causal analysis of the problems identified
- The Review Team's conclusions on the sequence of events and the key lessons to be learned for the organisation
- Clear recommendations for remedial action
- Any areas of good practice.

APPENDIX E

The Review Process

Stage 1 - Triggering the Review and Establishing the Team

All serious clinical incidents should be reported to the relevant Director immediately. The Chief Executive should be advised. Following consultation with the Lead Director (Deputy Chief Executive) the relevant Clinicians/Professionals and the relevant Manager, the Chief Executive will decide whether or not to declare the event a "serious adverse incident", and activate the relevant action plans.

A telephone report should be made immediately to the Administration Department on Tel: 90821202 followed by the adverse event/incident report form by post.

Stage 2 - Framing the Review

Sensible judgements will need to be made by the Review Team in relation to the particular circumstances of the serious incident. In some cases, the full extent of the harm from an incident may not be possible to gauge immediately. A pragmatic approach needs to be adopted to determine the key areas of focus and the timescale of activity the Review Team will centre their attention upon.

Stage 3 - Gathering the Data

This is the most time consuming component of the incident review and can extend far beyond what may seem to be the initial parameters of the review.

Data gathering - some sources

- Health and Social Care Records
- Statements from witnesses
- Policies/Procedures/Protocols
- Duty rotas
- Equipment
- Interviews
- Site visits
- Risk assessments
- Training records
- Maintenance records

An examination of the case notes and other written material will provide critical information to the Review Team in relation to the incident. Patient/Client notes

will detail the key aspects of care provided and the specific circumstances and environment under which the incident may have arisen. A sequence of events can also be gleaned through properly documented records thus allowing the Review Team to understand in basic terms the sequence of events leading up to a particular event. As a contemporaneous document, the patient/client record should outline events as they occurred and this can provide the Review Team with information that may subsequently be lost owing to a failure to recollect specific occurrences. It is worth considering photocopying the relevant parts to help people with their statements.

The content of patient/client records can also be reviewed against existing policies and protocols to determine where they were followed. The Review Team can make appropriate judgement regarding the currency of key policy documents, the effectiveness of their sharing with staff and the review process in place for ensuring that they remain up-to-date.

Undertaking Interviews

Critical to the review process will be ascertaining facts pertinent to the incident. To be effective, participants must be assured of the process and objectives being adhered to by the Review Team. High levels of anxiety may be present and these concerns must be allayed if the interview process is to be of value in determining the facts. Interview sessions are usually conducted in pairs plus someone to take notes or record the interview and planning and preparation as to the role of each interviewer is important prior to the process. The importance of neutral and unambiguous language is essential as is appropriate body language. What is important is to elicit the facts and not necessarily opinions which can be verified and corroborated.

In conducting the interview stage of the review process there are 4 distinct phases. These are:

Phase 1 - Introduction

- Introduce those present and their roles
- Invite interviewee to tell you about themselves
- Explain scope and purpose of the interview
- Detail what will happen to the information from the interview
- Ask interviewee to give you an account of events
  - Don't interrupt at this point this will disturb them retrieving information from memory
  - Use positive body language.

Phase 2 - Questioning

- Where possible ask questions in the order of the interviewees account of events
- Reassure the interviewee it is acceptable for them to say 'I don't know'
- Use open questions e.g. tell me about, how did this make you feel, describe to me
- To clarify information use closed questions e.g. were you present when X happened?
  Don't use multiple questions.

Phase 3 - Summary

- The interviewer should summarise the interview using the interviewees language as far as possible
- Allow the interviewee to correct any inaccuracies or misunderstanding of facts.

Phase 4 - Closure

- Thank the interviewee for attending and sharing information
- Reiterate the review process and what will happen with the information shared at interview
- Ask the interviewee if they have any further information they would like to share
- Give details of support mechanisms available for them.

Site Visits

An inspection of the site/location will be of value in many cases to fully comprehend the environmental and physical lay out related factors that may have contributed towards the incident.

Policies and Protocols and other paper evidence will need to be examined. It is critical to ensure that policies and other documentation referred to bears relevance and is reflective of what actually transpired. For example, off duty roster documents may not be an accurate record of the shift patterns at the time of the incident.

Establishing the Chronology

This part of the investigation is to establish what happened. It is of value to convene a multi-professional team review meeting to ensure that there is relevant input from all concerned professional groups.

- Establishing the chronology
- Identifying the key care management problems
- Identifying the key contributory factors
- Distinguishing specific and general contributory factors.

Causal Analysis of the Incident

In undertaking the review, the focus is the why and how components of an incident. This part of the process will identify what went wrong and what contributed or caused this to happen.

A detailed chronology of events and other information from the data gathered will assist the reviewers in determining the various aspects of care and intervention leading up to the incident and any potential areas where there may have been a departure from what would be deemed to be normal practice or procedure. It will also highlight unusual aspects and circumstances that may have had a significant role in the development of the incident.

The next stage is identifying the key care management problems. A variety of techniques can be used to practically identify these including:

- Fish bone diagrams
- Five whys technique
- Brainstorming
- Brainwriting
- Nominal group technique
- Barrier analysis.

Care management problems may be categorised under the following headings:

- Institutional context
- Organisational and management factors
- Work environment components
- Team components
- Individual staff components
- Task components
- Patient/client components.

For each of these contributory factors are determined and may be framed as follows:

Institutional context

- Economic and regulatory aspects
- DHSSPS requirements
- External organisational links.

Organisational and Management Factors

- Organisational Structure
- Policies, Procedures, Guidelines, Standards and Goals
- Imported and exported risk factors
- Organisational safety culture
- Financial resources and constraints.

Work Environment Components

- Administrative issues
- Building and design
- The environment
- Equipment and supplies
- Staffing factors
- Training and education
- Time factors.

Team Components

- Verbal communication
- Written communication
- Supervision and availability of assistance
- Congruence and consistency of tasks
- Leadership and responsibility
- Team culture and support.

Individual Staff Components

- Competence and training
- Skills and knowledge
- Physical and mental stressors.

Task Components

Availability and use of protocols
Availability and accuracy of information (e.g. test results)
Decision making aids
Task design.

Patient/Client Components

Condition
Personal
Treatment
History
Staff-Patient/Client Relationship.

North & West Belfast Health & Social Services Trust
Serious Adverse Incident Policy & Procedure – v.2

Title		Type	Status
SERIOUS ADVERSE INCIDENT POLICY & PROCEDURE		Policy	Approved
		Unique Identifier	**Version**
		Gov00003	2
Author / Originator		**Accountable Director**	
Name Ian Jamison	**Role** Assistant Director of Corporate Affairs	**Name** Eamonn Molloy	**Role** Director of Human Resources & Corporate Affairs
Document Checked for:		**Author Signature**	
NORTH & WEST BELFAST HEALTH & SOCIAL SERVICES TRUST	**Compatibility with other Trust Documents**	√	
	Equality and/or Human Rights Impact	√	
	Financial Impact	√	
	Training and Education Needs	√	
	Distribution List	√	
Approved by (Board Committee Group)		**Date**	
Trust Board		**28 June 2006**	

Review Date	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Month					**May**							

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TABLE OF CONTENTS

1.0 INTRODUCTION

1.1 This policy sets out the framework and operational arrangements for the management of serious adverse incidents within the Trust.

1.2 This policy operates in conjunction with existing internal and external statutory reporting requirements such as the Registration and Inspection Units, Commissioning Boards, DHSSPS, Health and Safety Executive, Northern Ireland Adverse Incident Centre etc.

1.3 This policy should be read in conjunction with the undernoted Trust policies/procedures.

- Risk Management Strategy/Policy
- Management of Adverse/Events, Incidents and Near Misses
- Procedure for Investigating Incidents, Complaints and Claims
- Whistleblowing Policy
- Major Incident Policy

2.0 PURPOSE/OBJECTIVES OF THE POLICY

2.1 The purpose and objectives of the policy are:

- To ensure the Trust has clearly defined accountabilities, responsibilities and frameworks in place to appropriately, manage serious adverse incidents.
- To provide a Trustwide system for the management of all serious incidents ensuring they are dealt with appropriately and in a consistent manner.
- To improve our services through recording, reporting, analysing, evaluating and learning from serious adverse incidents involving patients, clients, staff and visitors.

3.0 SCOPE OF POLICY AND DEFINITION

3.1 The policy covers all aspects of the Trust's Business

3.2 A serious adverse incident in the context of Health and Social Services is described by the Department of Health Social Services and Public Safety as **"any event or circumstance arising during the course of the business of a HPSS Organisation/Special Agency or commissioned service that led, or could have led, to serious unintended or unexpected harm, loss or damage"**.

This may be because:

- It involves a large number of service users
- There is a question of poor professional/clinical or management judgement
- A serious service and/or equipment failure
- A service user(s) or staff member has died under unusual circumstances; or
- There is the possibility or perception that any of these might have occurred.

3.3 Factors that might suggest a serious incident include:

- Any incident involving serious harm or potentially serious harm to a patient, service user, member of staff or the public. This could include disease outbreaks, apparent clinical errors or lapses in care
- Any incident which has serious implications for patient or staff safety - involving potential or actual risk to patients or staff
- Any incident which may suggest that Trust policy is compromised and may give rise to serious consequences for the proper delivery of Trust business
- Any incident with the potential for serious adverse media attention/damage to reputation of the Trust

3.4 The above list is by no means an exhaustive list and if doubt remains regarding the classification of an adverse incident as serious, it must always be checked with the relevant Director.

4.0 MANAGEMENT PRINCIPLES

4.1 Roles and Responsibilities

4.1.1 The Chief Executive, as Accountable Officer, is responsible for ensuring all serious incidents are managed appropriately in accordance with Trust Policies.

4.1.2 Lead Director - The Chief Executive has nominated the Director of Planning Contracts and Information/Deputy Chief Executive to manage and review serious incidents. In the absence of the aforementioned, the Chief Executive will nominate another Director supported by a Senior Manager who is competent to undertake the review using causal analysis methodologies.

4.2 Serious Incident Reporting

4.2.1 During Normal Working Hours (See Flowchart Appendix A)

All serious incidents should be reported to the relevant Director.

Should the relevant Director agree the incident is serious, a telephone report should be made immediately to the Trust's Administration Department on Tel: 90821202 followed by the adverse event/incident report form. Where possible, this should be hand delivered to the Administration Department.

The relevant Director will also advise the Chief Executive directly.

Following consultation with the Lead Director (Deputy Chief Executive) and the relevant Director, the Chief Executive will decide whether or not to declare the event a "serious incident" and, if required, activate the relevant review and action team (see Appendix E).

4.2.2 Outside Normal Working Hours (See Flowchart Appendix B)

The Senior Duty Officer will contact the Administration On-call Officer through the Muckamore switchboard 028 94463333, who will inform the Director on call. The Director will decide, following appropriate consultation if the incident is to be classified as serious and notify the Chief Executive.

4.2.3 External Reporting

The Trust will report externally all serious incidents via Trust Headquarters Administration. Serious incident reports should not be sent externally through Directorates or Programmes. The relevant Director is responsible for notifying the Trust's Administration Department of Serious incidents to ensure all relevant external bodies are informed.

In addition if the relevant Director considers that the incident is likely to:

- Be serious enough to warrant regional action to improve safety or care within the broader HPSS
- Be of public concern (such as serious media interest) or
- Require an independent review,

the relevant Director via the Administration Department should provide the Department of Health Social Services and Public Safety with a brief anonymised report, using the proforma attached at Appendix C. Serious incidents must be reported to the DHSSPS within 72 hours of the incident occurring and 24 hrs if related to the death of a patient/client.

In all cases the Trust's Administration Department will ensure that the proforma is forwarded to the relevant Commissioning Board by email.

4.3 Communicating with Patients/Clients and Relatives

The professional staff responsible for the treatment and/or care of the patient/client will retain the responsibility for communicating with them and their relatives about the incident. The following points should be noted:

- Following an assessment, patients/clients and relatives (bearing in mind issues of patient/client confidentiality) are provided with explanations of what has happened, why it happened, how it will be investigated and how lessons will be learned from the incident.

- If, in conjunction with the relevant Director, the professional head/consultant considers there are compelling professional reasons not to discuss the incident with the patient/clients relative (s) a clear record should be made of this in the patient/client records.

- If deemed appropriate, an apology should be given, acknowledging that an apology is not an admission of liability.

- If appropriate, a meeting should be offered to patient/client relative (s) with the relevant Trust personnel. A summary of the points discussed and any agreements made should form part of the overall investigative paper work and a copy provided to the patient/client relative (s).

- The patient/client relative (s) will be informed of any external body the incident is being reported to and why.

4.4 Review and Action Team

The Lead Director (Deputy Chief Executive) will lead a Review and Action Team consisting of:-

- Relevant Director
- Lead Clinician/Professional and/or Directorate Service Manager
- A Senior Manager
- A nominated Senior Officer to deal with press and communications
- Other co-opted members as appropriate e.g. other Professionals, Risk Management, Health and Safety, Legal Advice, Estates etc.
- Dedicated administration support.

The Review Team through the Lead Director (Deputy Chief Executive) will report directly to the Chief Executive.

The Review Team will meet as soon as possible and no later than 48 hours after the incident to review the case. The Team will work to agree Terms of Reference (Appendix D).

The Team will decide how the incident is to be managed, the timescale of the review investigation and subsequent reporting (See Appendix E).

Where an incident involves more than one Directorate or Service Area, the Team will ensure co-ordinated communication with appropriate Clinicians/Professionals and Managers from all relevant areas. The incident will be investigated by a person(s), competent in causal analysis methodologies, appointed by the Team. Other members may be co-opted as required e.g. Trust Legal Advisers.

Following resolution of the incident, the Team will review action taken, document lessons learned and provide a report outlining conclusions and recommendations to the Chief Executive, Executive Management Board, Governance Committee and Trust Board.

4.5 Monitoring

The Lead Director (Deputy Chief Executive) will monitor implementation of remedial action agreed by the Governance Committee.

5.0 Document Control

5.1 Terms and Abbreviations

Term/Abbreviation	Meaning

5.2 Other Relevant or Associated Documents

Reference	Policy Identifier	Title
[1]	TBC	Risk Management Strategy/Policy
[2]	TBC	Management of Adverse/Events, Incidents & Near Misses
[3]	Gov00002	Procedure for Investigating Incidents, Complaints & Claims
[4]	TBC	Whistleblowing Policy
[5]	TBC	Major Incident Policy

5.3 Distribution List

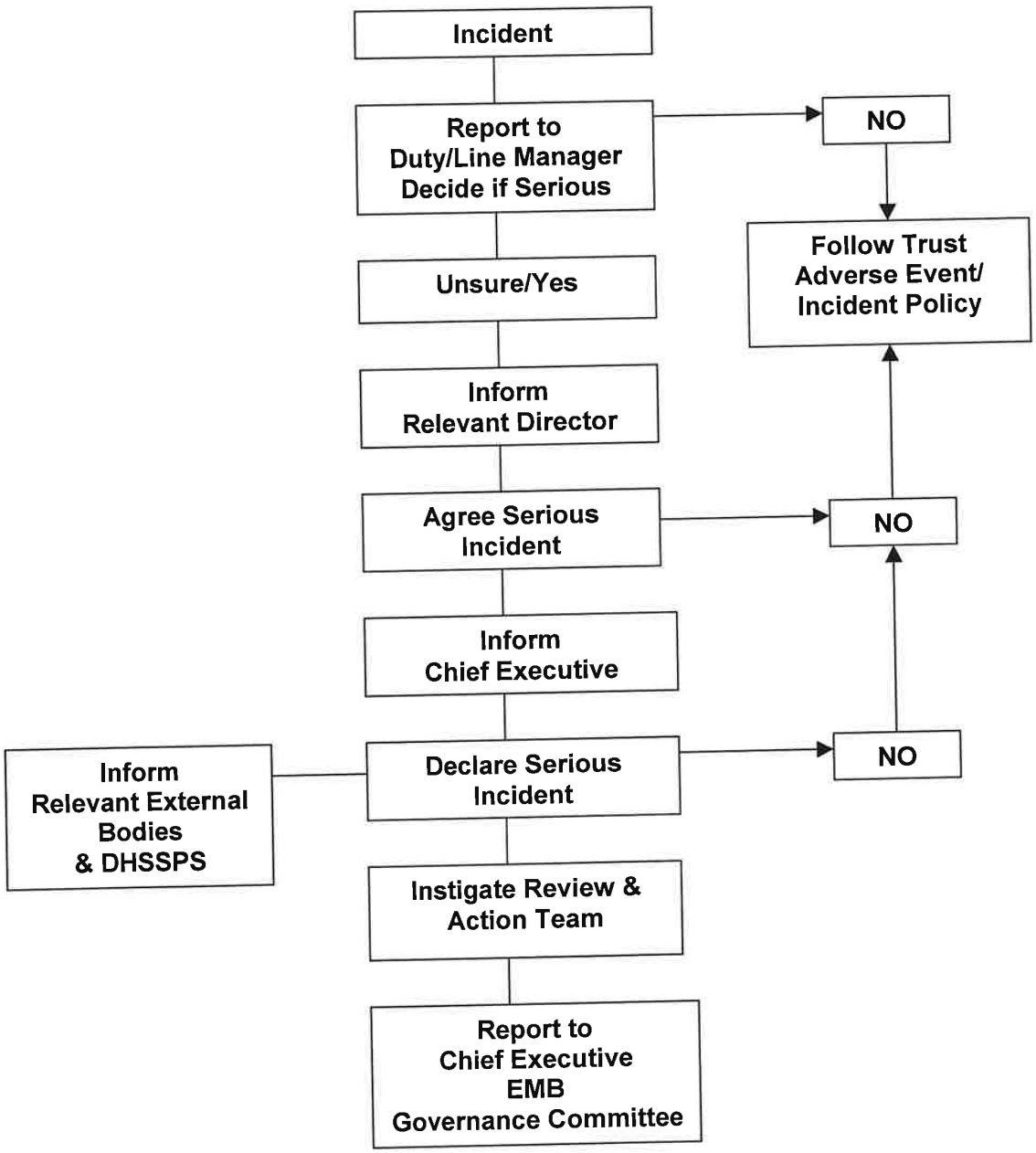
Name	Organisation/Location
Directors & Senior Managers	Various Trust facilities

5.4 Quality Control

Job Title	Risk Management and Controls Assurance Coordinator
Signature	
Date	3rd May 2006

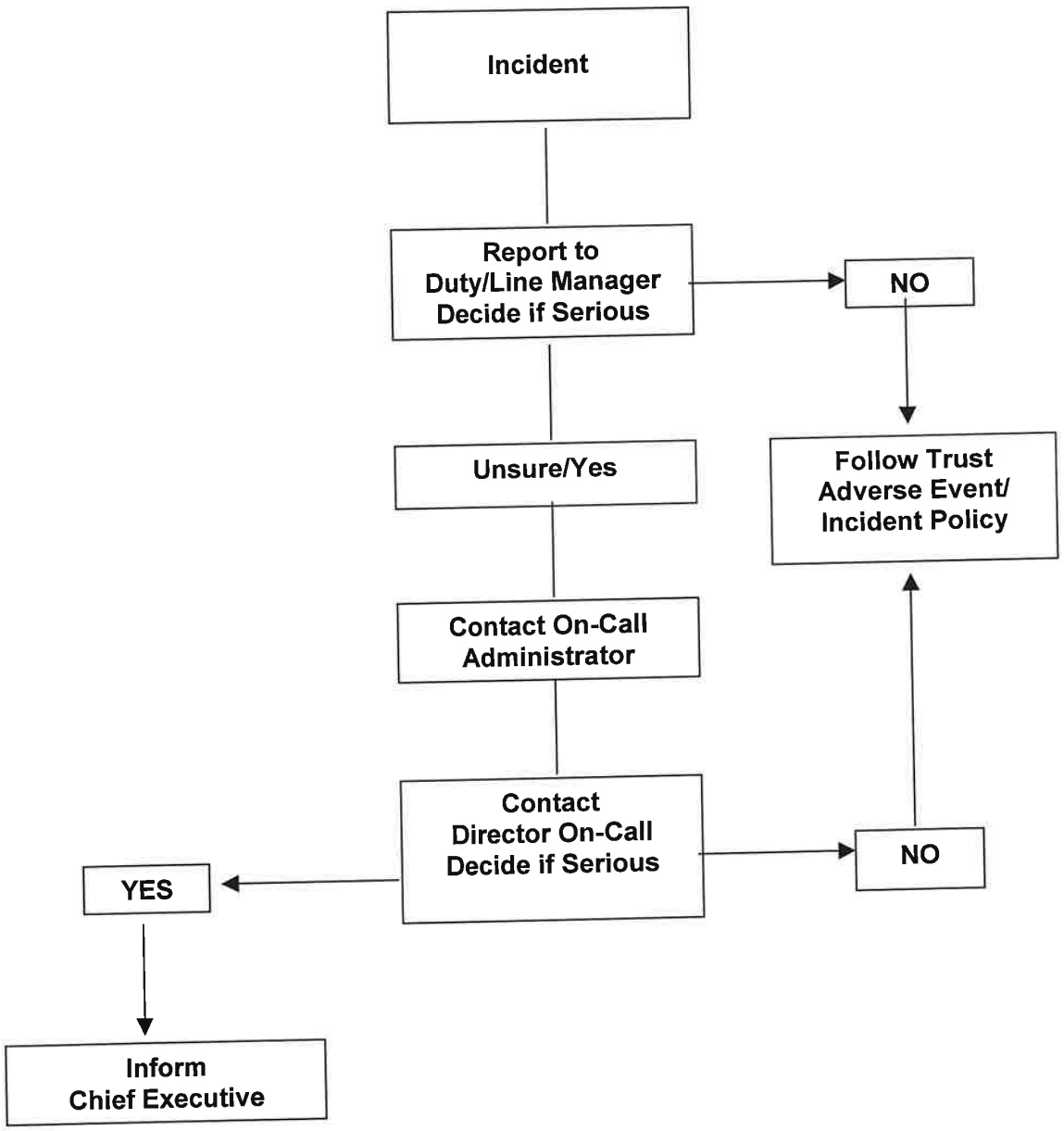
APPENDIX A

Serious Adverse Incident Reporting Flowchart (During Office Hours)



APPENDIX B

Serious Adverse Incident Reporting Flowchart (Out of Hours)



APPENDIX C

SERIOUS ADVERSE INCIDENT REPORT

1. Organisation:

Incident Identifier No.

2. Date and brief summary of incident:

3. Why incident considered serious:	**Briefly, explain why this SAI meets the criteria:**
(i) warrants regional action to improve safetyor care within the broader HPSS:	
(ii) is of public concern; or	
(iii) requires an independent review.	

4. Immediate action taken:

Classsification of incident as initially assessed by organisation: Catastrophic / Major / Moderate / Minor / Insignificant

5. Is any regional action recommended? Y/N (if 'Yes', full details should be submitted):

Are there any aspects of this incident which could contribute to learning on a regional basis?

6. Is an Independent Review being considered? Y/N (if 'Yes', full details should be submitted):

7. **Other Organisations informed:**		**Date informed**	**Other (please specify)** Y/N
HSS Board	**Y/N**		
HM Coroner	**Y/N**		
Mental Health Commission	**Y/N**		
NIHSE	**Y/N**		
PSNI	**Y/N**		
RQIA	**Y/N**		Date informed:

8. 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 Department. ***(delete as appropriate)***

Report submitted by:
(name and contact details of reporting officer)

Date:

Completed proforma should be sent, by email, to:
adverse.incidents@dhsspsni.gov.uk If email cannot be used, fax to (028) 9052 8126

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APPENDIX D

Terms of Reference for the Review and Action Team

The Review and Action Team is to meet as soon as possible after the incident and no later than 48 hours. The Team will be led by the Lead Director (Deputy Chief Executive) or, in his/her absence, by a nominated Director. A team approach will assist in ensuring that all aspects of the incident are appropriately reviewed and that there is support available from within the team in assessing complex or sensitive areas. It may also be beneficial to appoint a member to the Team from outside the speciality/function area or from outside the Trust.

The terms of reference are as follows;-

- To undertake an initial review of the incident
- To consider any other relevant factors raised by the incident
- Scope the remit of the review/investigation
- To determine action required to manage the incident including
  - Identify the lead person to investigate
  - Identify the lead person to manage the press and communications
  - Identify other member to the Review Team e.g. administration support
- To ensure staff and patient/client confidentiality
- To review the outcome of the investigation, agreeing recommendations and actions and lessons learned
- To provide an outline report of the incident and its outcome to the Chief Executive within four weeks of the incident occurring
- To determine the action required to ensure effective implementation of the recommendations
- Implementation of the Action Plans.

The report produced by the Review Team should be in a standard format as detailed below:

- Statement of membership and terms of reference
- Brief description of the methods of enquiry
- Detailed description of the history and chronology of events
- Outline investigative techniques used
- Care management/service delivery problems identified
- Causal analysis of the problems identified
- The Review Team's conclusions on the sequence of events and the key lessons to be learned for the organisation
- Clear recommendations for remedial action
- Any areas of good practice.

APPENDIX E

The Review Process

Stage 1 - Triggering the Review and Establishing the Team

All serious clinical incidents should be reported to the relevant Director immediately. The Chief Executive should be advised. Following consultation with the Lead Director (Deputy Chief Executive) the relevant Clinicians/Professionals and the relevant Manager, the Chief Executive will decide whether or not to declare the event a "serious adverse incident", and activate the relevant action plans.

A telephone report should be made immediately to the Administration Department on Tel: 90821202 followed by the adverse event/incident report form by post.

Stage 2 - Framing the Review

Sensible judgements will need to be made by the Review Team in relation to the particular circumstances of the serious incident. In some cases, the full extent of the harm from an incident may not be possible to gauge immediately. A pragmatic approach needs to be adopted to determine the key areas of focus and the timescale of activity the Review Team will centre their attention upon.

Stage 3 - Gathering the Data

This is the most time consuming component of the incident review and can extend far beyond what may seem to be the initial parameters of the review.

Data gathering - some sources

- Health and Social Care Records
- Statements from witnesses
- Policies/Procedures/Protocols
- Duty rotas
- Equipment
- Interviews
- Site visits
- Risk assessments
- Training records
- Maintenance records

An examination of the case notes and other written material will provide critical information to the Review Team in relation to the incident. Patient/Client notes will detail the key aspects of care provided and the specific circumstances and environment under which the incident may have arisen. A sequence of events

can also be gleaned through properly documented records thus allowing the Review Team to understand in basic terms the sequence of events leading up to a particular event. As a contemporaneous document, the patient/client record should outline events as they occurred and this can provide the Review Team with information that may subsequently be lost owing to a failure to recollect specific occurrences. It is worth considering photocopying the relevant parts to help people with their statements.

The content of patient/client records can also be reviewed against existing policies and protocols to determine where they were followed. The Review Team can make appropriate judgement regarding the currency of key policy documents, the effectiveness of their sharing with staff and the review process in place for ensuring that they remain up-to-date.

Undertaking Interviews

Critical to the review process will be ascertaining facts pertinent to the incident. To be effective, participants must be assured of the process and objectives being adhered to by the Review Team. High levels of anxiety may be present and these concerns must be allayed if the interview process is to be of value in determining the facts. Interview sessions are usually conducted in pairs plus someone to take notes or record the interview and planning and preparation as to the role of each interviewer is important prior to the process. The importance of neutral and unambiguous language is essential as is appropriate body language. What is important is to elicit the facts and not necessarily opinions which can be verified and corroborated.

In conducting the interview stage of the review process there are 4 distinct phases. These are:

Phase 1 - Introduction

- Introduce those present and their roles
- Invite interviewee to tell you about themselves
- Explain scope and purpose of the interview
- Detail what will happen to the information from the interview
- Ask interviewee to give you an account of events
  - Don't interrupt at this point this will disturb them retrieving information from memory
  - Use positive body language.

Phase 2 - Questioning

- Where possible ask questions in the order of the interviewees account of events
- Reassure the interviewee it is acceptable for them to say 'I don't know'
- Use open questions e.g. tell me about, how did this make you feel, describe to me
- To clarify information use closed questions e.g. were you present when X happened?
  Don't use multiple questions.

Phase 3 - Summary

- The interviewer should summarise the interview using the interviewees language as far as possible
- Allow the interviewee to correct any inaccuracies or misunderstanding of facts.

Phase 4 - Closure

- Thank the interviewee for attending and sharing information
- Reiterate the review process and what will happen with the information shared at interview
- Ask the interviewee if they have any further information they would like to share
- Give details of support mechanisms available for them.

Site Visits

An inspection of the site/location will be of value in many cases to fully comprehend the environmental and physical lay out related factors that may have contributed towards the incident.

Policies and Protocols and other paper evidence will need to be examined. It is critical to ensure that policies and other documentation referred to bears relevance and is reflective of what actually transpired. For example, off duty roster documents may not be an accurate record of the shift patterns at the time of the incident.

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- Written communication
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- Skills and knowledge
- Physical and mental stressors.

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Decision making aids
Task design.

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History
Staff-Patient/Client Relationship.

Belfast Health and Social Care Trust

Reference No TP097/14

Title:	Serious Adverse Incident (SAI) Procedure		
Author(s)	Claire Cairns, Senior Manager, Corporate Governance Shane McCaul, Governance Manager, Corporate Governance		
Ownership:	Medical Directorate		
Approval by:	Trust Policy Committee Executive Team	**Approval date:**	30 June 2014 09 July 2014
Operational Date:	June 2014	**Next Review:**	March 2015
Version No.	V(3) **Supersedes** V(2)		
Key words:	Serious Adverse Incident, SAI, Learning, Investigation, Action Plan		
Links to other policies	- Adverse Incident Reporting & Management Policy - HSCB Procedures for the Reporting and Follow up of Serious Adverse Incidents October 2013 - Being Open Policy		

Contents **Page Number**

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), Oct 2013 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 Trust will be responsible for the onward reporting of SAIs 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.
- any death of a child in receipt of HSC services (up to eighteenth birthday). This includes hospital and community services, a Looked After Child or a child whose name is on the Child Protection Register;
- unexpected serious risk to a service user and/or staff member and/or member of the public
- unexpected or significant threat to provide service and/or maintain business continuity
- serious self-harm or serious assault (including attempted suicide, homicide and sexual assaults) by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service;
- serious self-harm or serious assault (including homicide and sexual assaults)
  - - on other service users,
  - - on staff or
  - - on members of the public

  by a service user in the community who has a mental illness or disorder (as defined within the Mental Health (NI) Order 1986) and 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 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 report, 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 and give it a BHSCT 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 report 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 leaflet[1] 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 "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:-

[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.

- 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 Procedure for Sharing Learning procedure. 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 Procedure 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 Procedure for the Reporting and Follow up of Serious Adverse Incidents 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 Procedure 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 Procedure 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 SAIs 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 BHSCT 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 Child Protection and Adult Protection

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 so serious as 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.

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

							Responsible officer			
SAI type *(guide only)*	**Inv. level**	**Inv. tool/ Template**	**Timescale**	**Chair**	**Team**	**Extension**	**Approval**	**Action Plan**	**Learning**	**DRO Queries timescale**
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

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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 it 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 directorate 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.

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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

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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	X

SIGNATORIES

Name Dr Tony Stevens
Title Medical Director

Date: 9 July 2014

Name Martin Dillon
Title Interim Chief Executive

Date: 9 July 2014

Belfast Health and Social Care Trust

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: *(to be completed by Corporate Governance department)*	**2. UNIQUE INCIDENT IDENTIFICATION NO. / REF NO.** *(to be completed by Corporate Governance department)*
HOSPITAL / FACILTY / COMMUNITY LOCATION *(where incident occurred)*	**2.0 DATE OF INCIDENT: DD / MMM / YYYY** *Insert the date incident occurred*
3.0 **DEPARTMENT / WARD / LOCATION EXACT** *(where incident occurred)*	
6. CONTACT PERSON: *Insert the name of lead officer to be contacted should the HSCB or PHA need to seek further information about the incident*	**7. PROGRAMME OF CARE:** *(to be completed by Corporate Governance department)*

8. DESCRIPTION OF INCIDENT:

*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 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.*

In addition include the following:

***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 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;*

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.*

DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING

STAGE OF CARE: *(to be completed by Corporate Governance department)*	**DETAIL:** *(to be completed by Corporate Governance department)*	**ADVERSE EVENT:** *(to be completed by Corporate Governance department)*

9. IMMEDIATE ACTION TAKEN TO PREVENT RECURRANCE:

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.

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10. CURRENT CONDITION OF SERVICE USER: ***Where relevant*** *please provide details on the current condition of the service user the incident relates to.*			
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: • a service user • a staff member in the course of their work • a member of the public whilst visiting a HSC facility.	
Any death of a child in receipt of HSC services (up to eighteenth birthday). This includes hospital and community services, a Looked After Child or a child whose name is on the Child Protection Register	
Unexpected serious risk to a service user and/or staff member and/or member of the public	
Unexpected or significant threat to provide service and/or maintain business continuity	
serious self-harm or serious assault *(including attempted suicide, homicide and sexual assaults)* by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service	
serious self-harm or serious assault *(including homicide and sexual assaults)* - on other service users, - on staff or - on members of the public by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and 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 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	

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?** *If the service user suffered harm but was not informed of the SAI, or if the SAI involves the death of a Service User and their family / carer were not informed, please include here the reason for this.*

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16. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? ***where there appears to be a breach of professional code of conduct***	**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 AUTHORTIY**(RQIA)** OTHER – PLEASE SPECIFY BELOW		
if 'YES' ***(full details should be submitted including date notified):***		

17. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	**DATE INFORMED:**	**OTHER:** *(please specify where relevant).*
DHSS&PS EARLY ALERT		
SERVICE USER / FAMILY		**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)**		

18. Level of investigation	Level 1 *SEA*	Level 2 *RCA – Can be Trust and/or independent*	Level3 *RCA Complex / Multi organisational*

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**

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20. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION

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**

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Serious Adverse Incident Investigation Report Checklist **Appendix 2**

SAI REF NUMBER:	**HSCB REF NUMBER:**
1. FAMILY INVOLVEMENT	

(a) Notification

What was the level of Service User /Family involvement at the time the SAI was notified to HSCB
(This should reflect what was reported on notification form)

Additional Comments:

(b) Review Process

i. Were the Terms of Reference of the Review Team shared with the Service User / Family	Yes ☐ No ☐	**Date shared:** ...../...../..... **If No - Please comment:**
ii. Were Service User / Family given the opportunity to attend the review and/or meet with the chair and/or members of the review team	Yes ☐ No ☐	**Date attended:** ...../...../..... **If No - Please comment:**

(c) Investigation Report

i. Has the investigation report been shared with Service User / Family	☐ Yes ☐ No	**Date shared:** ...../...../..... **If No - Please comment**

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ii. Has Service User / Family been given the opportunity to meet with member/s of the review team to discuss the findings of the report	Yes ☐ No ☐	**Date attended:** ……/……/…… **If No - Please comment**

2. CORONER'S OFFICE ***(this section only to be completed for death related SAIs)***

i. Was the Coroner notified of this SAI	Yes ☐ No ☐	**Date notified:** ……/……/…… **If No - Please comment**
ii. If the Coroner was notified of this SAI, has this case been since closed by the Coroner	Yes ☐ No ☐ N/A ☐	**Date closed:** ……/……/…… **If No - Please comment**

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caring supporting improving together

Reference No: TP 097/14

Title:	**Serious Adverse Incident (SAI) Procedure**		
Author(s)	Claire Cairns, Senior Manager, Corporate Governance Shane McCaul, Governance Manager, Corporate Governance Colin McMullan, Senior Manager Corporate Governance		
Ownership:	Dr Cathy Jack, Medical Directorate		
Approval by:	Trust Policy Committee Executive Team	**Approval date:**	03 August 2016 10 August 2016
Operational Date:	August 2016	**Next Review:**	August 2017
Version No.	V4 **Supersedes**	V3 – June 2014-March 2015	
Key words:	Serious Adverse Incident, SAI, Learning, Investigation, Action Plan		
Links to other policies	- Adverse Incident Reporting & Management Policy - HSCB Procedures for the Reporting and Follow up of Serious Adverse Incidents October 2013 http://www.hscboard.hscni.net/download/PUBLICATIONS/policies-protocols-and-guidelines/Procedure-for-the-reporting-and-followup-of-Serious-Adverse-Incidents.pdf - Being Open Policy - Policy for Sharing Learning - Complaints Policy		

Contents **Page Number**

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 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.

1.2 Purpose and scope of this procedure

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

2.0 SCOPE OF THE POLICY

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 SAIs 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)
  - o - on other service users,
  - o - on staff or
  - o - 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 BHSCT 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 leaflet[1] 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 SAIs 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 BHSCT 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

							Responsible officer			
SAI type *(guide only)*	**Inv. level**	**Inv. tool/ Template**	**Timescale**	**Chair**	**Team**	**Extension**	**Approval**	**Action Plan**	**Learning**	**DRO Queries timescale**
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 it 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

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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 [X]

SIGNATORIES

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

Cathy Jack

10 August 2016

Date: _____

Name Dr Cathy Jack
Title Medical Director

Michael B McBride

10 August 2016

Date: _____

Name Dr Michael McBride
Title Chief Executive

Belfast Health and Social Care Trust

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: *(to be completed by Corporate Governance department)*	**2. UNIQUE INCIDENT IDENTIFICATION NO. / REF NO.** *(to be completed by Corporate Governance department)*
3. HOSPITAL / FACILTY / COMMUNITY LOCATION *(where incident occurred)*	**3. DATE OF INCIDENT: DD / MMM / YYYY** *Insert the date incident occurred*
5. DEPARTMENT / WARD / LOCATION EXACT *(where incident occurred)*	
6. CONTACT PERSON: *Insert the name of lead officer to be contacted should the HSCB or PHA need to seek further information about the incident*	**7. PROGRAMME OF CARE:** *(to be completed by Corporate Governance department)*

8. DESCRIPTION OF INCIDENT:

*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 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.*

In addition include the following:

***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 year) include the following details: the most recent HSC service context; the last point of contact with HSC services or their discharge into t he 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.*

DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING

STAGE OF CARE: *(to be completed by Corporate Governance department)*	**DETAIL:** *(to be completed by Corporate Governance department)*	**ADVERSE EVENT:** *(to be completed by Corporate Governance department)*

9. IMMEDIATE ACTION TAKEN TO PREVENT RECURRANCE:

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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.
10. CURRENT CONDITION OF SERVICE USER: ***Where relevant*** *please provide details on the current condition of the service user the incident relates to.*

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: - a service user (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit) - a staff member in the course of their work - a member of the public whilst visiting a HSC facility	
Unexpected serious risk to a service user and/or staff member and/or member of the public	
Unexpected or significant threat to provide service and/or maintain business continuity	
serious self-harm or serious assault *(including attempted suicide, homicide and sexual assaults)* by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service	
serious self-harm or serious assault *(including homicide and sexual assaults)* - on other service users, - on staff or - on members of the public by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including 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	

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?** *If the service user suffered harm but was not informed of the SAI, or if the SAI involves the death of a Service User and their family / carer were not informed, please*

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		include here the reason for this.

16. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? ***where there appears to be a breach of professional code of conduct***	**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 AUTHORTIY**(RQIA)**
OTHER – PLEASE SPECIFY BELOW

if 'YES' ***(full details should be submitted including date notified):***

17. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	**DATE INFORMED:**	**OTHER:** *(please specify where relevant).*
DHSS&PS EARLY ALERT		
HM CORONER		**Date informed:**
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 *(please select)*	Level 1 *SEA*	Level 2 *RCA – Can be Trust and/or independent*	Level3 *RCA Complex / Multi organisational*

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**

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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

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APPENDIX 2

Checklist for Engagement / Communication with Service User[1]/ 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:**	

INFORMING THE SERVICE USER[1] / 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: ***If multiple service users involved please indicate the number involved**						
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 USER[1] / 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 (✓)** *Continued overleaf*	**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*

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SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / 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	

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APPENDIX 3

HSC INTERFACE INCIDENTS NOTIFICATION FORM

1. REPORTING ORGANISATION:	**2. DATE OF INCIDENT:**
3. CONTACT PERSON AND TEL NO: SeriousAdverseIncident@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 FOLLW 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

Belfast Health and Social Care Trust
caring supporting improving together

Reference No: TP 97/14

Title:	**Procedure for Serious Adverse Incidents (SAIs)**		
Policy Author(s)	Claire Cairns, Co-Director, Risk and Governance Tel: [redacted] Robert Henry, Senior Manager, Corporate Governance Tel: [redacted] Gillian Harkness, Governance Manager, Corporate Governance Tel: [redacted]		
Responsible Director:	Chris Hagan, Medical Director		
Policy Type: (tick as appropriate)	*Directorate Specific ☐	Clinical Trust Wide ☐	Non Clinical Trust Wide ☒
If policy type is confirmed as ***Directorate Specific** please list the name and date of the local Committee/Group that policy was **approved**			

Approval process:	Trust Policy Committee Executive Team	**Approval date:**	08/10/2020 14/10/2020
Operational Date:	October 2020	**Review Date:**	October 2025
Version No.	5	**Supercedes**	V4 – August 2016 – August 2017
Key Words:	Serious Adverse Incident, SAI, Learning, Review, Action Plan		
Links to other policies	BHSCT Adverse Incident Reporting and Management Policy (2018) TP 94/14 BHSCT Policy and Procedure for the Management of Comments, Concerns, Complaints and Compliments (2020) TP 45/10 BHSCT Being Open Policy – saying sorry when things go wrong (2020) TP 80/11 BHSCT Policy for Sharing Learning (2020) TP 98/14 BHSCT Memorandum of Understanding policy - Investigating Service User Safety Incidents (2020) TP 111/20 HSCB Procedures for the Reporting and Follow up of Serious Adverse Incidents V1.1 (2016)		

Date	Version	Policy Author	Comments
October 2020	4.1		Policy reviewed

Content

1.0 INTRODUCTION / SUMMARY OF POLICY

This procedure covers the reporting, review 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 SCOPE OF THE POLICY

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 (version 1.1, November 2016) through guiding staff on their duties and responsibilities regarding:

- Reporting a Serious Adverse Incident
- Informing the Service User / family / carer
- Coroner Involvement
- Reviewing 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, including 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), version 1.1, November 2016" (see section 4.2). The Trust will be responsible for the onward reporting of SAIs relevant internally, and to their Independent Service Providers (ISPs) and contractors, and will ensure the appropriate review, learning and sharing of lessons regarding same.

3.0 ROLES AND RESPONSIBILITIES

3.1 Chief Executive

The Chief Executive is responsible for ensuring that a system is in place to notify the Department in a prompt and timely way of events or incidents which have occurred in the services provided or commissioned by the Trust, which may require urgent attention by the Minister, Chief Professionals or policy leads, and/or require urgent regional action by the Department.

3.2 Corporate Governance

The Corporate Governance team has responsibility for centrally managing the Trust's SAI Inbox (SeriousAdverseIncidents@belfasttrust.hscni.net) and ensuring that SAIs are reported and follow-up in line with Regional HSCB Procedures.

3.3 Directors

Directors are responsible for the reporting and follow-up of SAIs in line with Regional HSCB Procedures, including submission of an SAI Notification within 72 hours of becoming aware an incident meets SAI Criteria.

3.4 Co Directors

Co Directors are responsible for ensuring that incidents which may fall within the criteria for SAIs within their areas of responsibility are reported to the relevant Director as a matter of urgency to allow for a decision by their respective Director as to the merits of reporting to the HSCB.

3.5 Senior Managers

Senior Managers are responsible for making staff aware of this policy and ensuring discussion with the Co Director of any incident which may fall within the criteria for reporting as an SAI.

3.6 Staff

Trust staff (including permanent, temporary, locum, agency, bank, contractors and voluntary) are responsible for making themselves aware of, and adhering to, the content of this policy.

4.0 CONSULTATION

Serious Adverse Incident Group (SAIG)

5.0 POLICY STATEMENT/IMPLEMENTATION

5.1 REPORTING A SERIOUS ADVERSE INCIDENT (SAI)

5.1.1 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 a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit)
  - a staff member in the course of their work
  - a member of the public whilst visiting a HSC facility.
- unexpected serious risk to a service user and/or staff member and/or member of the public
- unexpected or significant threat to provide service and/or maintain business continuity
- serious self-harm or serious assault (including attempted suicide, homicide and sexual assaults) by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service;
- serious self-harm or serious assault (including homicide and sexual assaults)
  - on other service users,
  - on staff or
  - on members of the public
  - by a service user in the community who has a mental illness or disorder (as defined within the Mental Health (NI) Order 1986) and/or known to/referred to mental health and related services (including 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.

5.1.2 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 (Appendix 1), 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 BHSCT 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.

5.1.3 Timescale

Any adverse incident that meets the criteria indicated in section 3.1 should be reported within 72 hours of the incident being discovered using the SAI Notification Form (see Appendix 1).

5.1.4 General guidance on completing the SAI Notification form

Guidance on completing the SAI Notification Form can be found at Appendix 2 -Serious Adverse Incidents (SAIs). 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.

5.1.5 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 review. 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 leaflet 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’s confirmed an SAI Notification has been submitted.**

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.

5.1.6 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).

The Coroner's Reference Number should also be forwarded to Corporate Governance for recording on Datix where applicable.

5.1.7 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 review 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.

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 HSCB SAI Procedure 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.

5.1.8 "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 Directorate Governance & Quality Manager or equivalent 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
- A review report or if not applicable, a clear explanation of why the incident does not meet the criteria for reporting as an SAI. The review 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 seriousadverseincident@belfasttrust.hscni.net and any report should also be included within the Datixweb incident record and referenced in the investigation section.

5.2 PROCEDURE FOR REVIEWING SERIOUS ADVERSE INCIDENTS (SAIs)

The following procedures for the review 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 (version 1.1., November 2016).

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 review required and this must be indicated on section 18 of the SAI Notification form. There are 3 levels of review available for SAIs and these are explained below (see section 4.1).

5.2.1 Level of SAI Review

SAI reviews should be conducted at a level appropriate and proportionate to the complexity of the incident under review. In order to ensure timely learning of all SAIs reported, it is important the level of review 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:

5.2.1.1 Level 1 Significant Event Audit (SEA)

A level 1 review requires the use of Significant Event Audit (SEA) Review methodology to investigate the incident.

SAI notifications which indicate a level 1 review will enter the review 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 review.

An SEA report must be completed, approved by the relevant Director/Co-Director and sent to the Trust SAI mailbox seriousadverseincident@belfasttrust.hscni.net for processes and onward reporting to the HSCB within 8 weeks of the date of the SAI Notification.

To quality assurance SEA reports once submitted to Corporate Governance they will undergo both a clinical peer review and corporate governance review

before they are redacted and sent on to HSCB/PHA. This will ensure the robustness of the report and identification of learning prior to submission to HSCB.

On some occasions these reviews may raise queries which will be sent to the Directorate for action. Where subsequent amendments are made to the SEA report it should be sent for further approval by the relevant Director/Co-Director before being resubmitted to the Corporate Governance team for processing.

Once all queries have been addressed the SEA report will be redacted and the SEA Learning Summary Report (*see HSCB SAI Procedure Appendix 4 and 5*) will be submitted to HSCB/PHA. The HSCB will not routinely receive full SEA reports unless specifically requested by the DRO.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review, the review will move to either a Level 2 or 3 RCA review. In this instance the SEA Learning Report Summary will be forwarded to the HSCB within the timescales outlined above, with additional sections being completed to outline membership and Terms of Reference of the team completing the Level 2 or 3 RCA review and proposed timescales.

When a level 2 review is required then the process will then need to be initiated as outlined in section 4.1.2. The Director / Co-Director should contact Corporate Governance to identify suitably trained and independent individuals to chair the level 2 process supported by a team of the Directorate choosing and in agreement with the appointed chair.

In most circumstances, completed SEA reviews 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 review that will not produce new learning. NB Family Involvement (see section 4.4).

5.2.1.2 Learning from Level 1 Reviews

Any learning from these reviews should be shared as appropriate within the Directorate governance structures and in accordance with the BHSCT 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 BHSCT Policy for Sharing Learning Appendix 1*).

5.2.1.3 Level 2 Root Cause Analysis (RCA)

Level 2 reviews 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 review should include use of appropriate RCA analytical tools (see section 4.3 below and HSCB SAI Procedure Appendix 7 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 review should be chaired by someone independent to the service area involved as a minimum. The review report should be completed using the HSCB RCA report template within 12 weeks from the date of SAI Notification submitted to HSCB as outlined in regional policy (*see appendix 6 & 7 of HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents, November 2016*).

Team membership for level 2 reviews is the responsibility of the Director / Co-Director who commissioned the SAI and should consider team membership to include members independent of the division concerned where appropriate. The Chair will be selected by Corporate Governance from an established Trust wide pool of appropriately trained RCA Chairs held centrally. 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.

NB: The Trust has provided accredited training in RCA methodology for staff willing to lead/chair level 2 reviews following notification of serious adverse incidents to the HSCB. To further support these staff a twice-yearly forum has been established. This is intended to share best practice and challenges, which may be experienced by chairs of level 2 reviews, encouraging a standardised use of approved methodology and development of learning. In addition, a monthly SAI panel is in place, chaired by the Deputy Medical Director with membership of the Co - Director, Risk and Governance and representation from the pool of trained RCA Chairs on a rotational basis . All reports approaching finalisation are expected to be presented to this panel for peer review and is intended to support consideration of identified learning, consistent approach to use of agreed methodology and format of reports.

Level 2 SAI reviews 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 review 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 11 of (HSCB) Procedures for reporting and managing SAIs, November 2016 for further guidance.

Sections 2 and 3 of the Level 2 review 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 review. Details on service user/ family/ carer engagement can be found in section 4.4.

5.2.1.4 Learning from Level 2 Reviews

Any learning from these reviews 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 review process which requires urgent sharing outside the Directorate, this should be brought to the immediate attention of the appropriate Governance Manager for immediate action and inclusion on the weekly Governance call. This will also support formal inclusion at the next SAI Group meeting by the relevant Co-Director for discussion and agreement regarding further urgent actions.

5.2.1.5 Level 3 Independent Review (RCA)

Level 3 reviews will be considered for highly complex SAIs where a high degree of external/independent representation on the review 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 review 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. Interim updated guidance issued by HSCB in November 2018 must be followed as below:

The Commissioning Director must ensure there is engagement with the service user and their families in line with existing guidance (refer to Addendum 1 - HSCB Procedure for the reporting and follow up of SAIs - *Engagement/Communication with service user/family/carer following a SAI)*

The Commissioning Director should ensure the following arrangements are in place when the engaging with the family/families of the **victims** of homicide by a mental health patient:

- Communication to be made at the earliest opportunity, whilst being sensitive to the need/wishes of the family.
- a nominated person with the necessary skills and experience is identified, to act as a point of contact to link with the family of the victim(s).

- In line with the family's wishes, a meeting should be arranged to:
  - acknowledge, apologise and explain that the organisation wishes to review the care and treatment of the patient / service user;
  - explain why the incident has been categorised as a SAI and any immediate action that has been taken;
  - explain the purpose of the review in identifying learning opportunities for the HSC Trust and wider HSC family and the role of the HSC Trust in completing the review; outlining timescales;
  - agree information which can be shared; (Terms of Reference for the review and Recommendations from the review; in line with relevant data protection legislation and The Access to Health Records (Northern Ireland) Order 1993); and
  - Facilitate access to support and advocacy services where requested
  - All communication should be in an accessible format that meets the needs of the family.

5.2.2 Timescales

5.2.1 Notification

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

5.2.2 Review Reports

- **Level 1 SEA Review**

  SEA reports must be completed using the SEA template and submitted to the HSCB within 8 weeks of the SAI being notified.

  NB: 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 Review**
  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 12 weeks after notification to HSCB of a level 2 review.

  RCA review 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 review, 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 Review**

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

  NB: 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.

5.2.3 Timelines for Queries from HSCB Designated Review Officer (DRO)

- **Level 1 SEA Review**
  DRO queries must be responded to within 2 weeks of the query being received.

- **Level 2 RCA Review**
  DRO queries must be responded to within 6 weeks of the query being received.

- **Level 3 Independent Review**
  DRO queries must be responded to within 6 weeks of the query being received

5.2.4 Monitoring

The commissioning Director / Co-Director is responsible for ensuring that review progress is monitored and timetables are met. A performance report will be tabled at each SAI Group identifying any SAIs 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 review 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 review team before finalisation of the report for approval by relevant Director/Co-Director.

5.2.5 Actions

The level 2 & 3 report template (*appendix 6 & 7 of HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents November 2016*) 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.

5.3 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 & 7 respectively of the HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents November 2016.

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.

5.4 SERVICE USER/FAMILY/CARER INVOLVEMENT

HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents November 2016 Paragraph 5.4 should be adhered to and states the requirement for service user / family / carer involvement in SAI reviews is as follows:

Following a SAI it is important, in the spirit of honesty and openness to ensure a consistent approach is afforded to the level of service user / family engagement across the region. When engaging with Service Users/Family/Carers, organisations should refer to addendum 1 – A Guide for Health and Social Care Staff Engagement/Communication with Service User/Family/Cares following a SAI.

In addition a 'Checklist for Engagement/Communication with the Service User/Family/Carers following a SAI' must be completed for each SAI regardless of the review level, and where relevant, if the SAI was also a Never Event (refer to section 12.2).

The checklist also includes a section to indicate if the reporting organisation had a statutory requirement to report the death to the Coroner's office and that this is also communicated to the Family/Carer.

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

The Director / Co-Director responsible for the SAI should ensure the completion of an SAI Review Report checklist (appendix 2) when submitting Review reports to HSCB via the BHSCT 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 Review 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 reviews please refer to the HSCB SAI Procedure Addendum 1 'A Guide for HSC Staff Engagement following an SAI' November 2016.

Involvement specific to level 1 (SEA) reports

Under the HSCB timeframe for completing level 1 reviews it may not be possible to involve the service user / family / carer in the review process before the final report is submitted to the HSCB. Service User/family/carer often provide important information and insight into experiences which will be vital in support learning. 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 additional information or 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 review under the SAI process will take precedence and the Complaints review will be put on hold until the SAI review is complete. The Complaints Department should notify the Complainant of this as soon as possible. The leaflet '*What I need to know about a Serious Adverse Incident'* 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 review 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.

5.5 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 engagement checklist when submitting SAI reports to HSCB. This checklist will seek information regarding notification to the Coroner and current status of the case.

5.6 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 reviewed under the procedures set down in relation to a child and adult protection.

If during the review 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 to the SAI process with the relevant findings from these reviews informing the SAI review (*see HSC Procedure for Reporting and Follow-up of SAIs, appendix 17*). However, all such reviews 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 review and the likely timescales for completion of the SAI Report.

On occasion the incident under review may be considered so serious as 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.

5.7 MEMORANDUM OF UNDERSTANDING (MOU), MARCH 2013

Incidents involving unexpected death or serious harm and requiring review 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.

You can access the DoH Memorandum of Understanding (*Investigating Patient Safety Incidents Involving Unexpected Death and Serious Untoward Harm*, HSS(MD) 8/2018 - Published 15 March 2013) via the links below:

- https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-8-2013.pdf
- https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/mou-patient-client-safety-incidents.pdf

Table 1: SAI Review process – Teams, tools and timescales
For further details please see HSCB SAI Procedure for Reporting and Follow up of Serious Adverse Incidents November 2016

					Responsible officer			
SAI type *(guide only)*	**Review Level**	**Timescale**	**Chair**	**Team**	**Approval**	**Action Plan**	**Learning**	**DRO Queries timescale**
Not complex	Level 1 Significant Event Audit (SEA)	8 weeks	Outside Service Area. SEA trained	Local multi-disciplinary.	Director/Co-Director	Director/Co-Director	To SAI group if sharing beyond Directorate	2 weeks
SEA not sufficient, more complex issues	Level 2 Root Cause Analysis (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.	Director	Director/Co-Director & SAI Group	To SAI group if sharing beyond Directorate	6 weeks
Particularly complex/ multiple orgs involved; requires significant degree of independence; high profile.	Level 3 Independ Review (RCA)	To be agreed with HSCB	Outside Dir or Trust. RCA trained	Highly independent multi organisational	Director/ Chief Executive	Director & SAI Group	To SAI group if sharing beyond Directorate	6 weeks

5.8 ACTION PLANS

5.8.1 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 review 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 reviews into adverse incidents.

Action plans for SAIs should be approved by the Director / Co-Director responsible for the review. 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 it 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 reviews as appropriate.

5.8.2 Generating Actions from the Final Report

Whilst recommendations in a final report are drawn up and are the responsibility of the review 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 report, then 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.

5.8.3 Developing an Action Plan

- Overall responsibility for the SAI Action Plan (BHSCT Action Plan Monitoring & Tracking Template available on the HUB) must be with the Director / Co-Director responsible for the SAI Review and they must determine who draws up the action plan.
- Where the action identified is within the area of responsibility of the Director / Co-Director responsible for the review, 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.

5.8.4 Documentation

- Every Action Plan must be documented using the SAI Monitoring / Tracking Report template (see STAGE 3: SAI Action Plans - Serious Adverse Incidents) which complies with the minimum standard for Action Plans

- The SAI Monitoring / Tracking Report template for recording Action Plans includes the following:
  - The reference number of the SAI
  - Date of the SAI Review 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 Review 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

5.8.5 Monitoring

- The Director / Co-Director who commissioned the review 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 review 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.

5.9 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.

5.10 DISSEMINATION

Following approval, the policy will be disseminated widely to all levels of staff across the Trust, including Directors, Co Directors and Senior Managers.

5.11 RESOURCES

Directors are responsible for ensuring that all staff across their Directorates have awareness and understanding of this policy.

5.12 EXCEPTIONS

None.

6.0 MONITORING AND REVIEW

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

7.0 EVIDENCE BASE/REFERENCES

BHSCT Adverse Incident Reporting and Management Policy (2018) TP 94/14
BHSCT Policy and Procedure for the Management of Comments, Concerns, Complaints and Compliments (2020) TP 45/10
BHSCT Being Open Policy – saying sorry when things go wrong (2020) TP 80/11
BHSCT Policy for Sharing Learning (2020) TP 98/14
BHSCT Memorandum of Understanding policy - Investigating Service User Safety Incidents (2020) TP 111/20
HSCB Procedures for the Reporting and Follow up of Serious Adverse Incidents V1.1 (2016)

8.0 APPENDICES

Appendix 1 HSCB SAI Notification Form
Appendix 2 HSCB SAI Notification Form – Guidance Notes
Appendix 3 HSCB Interface Incident Form
Appendix 4 HSCB SAI Report Templates & Engagement Checklist

9.0 NURSING AND MIDWIFERY STUDENTS

Nursing and/or Midwifery students on pre-registration education programmes, approved under relevant 2018/2019 NMC education standards, must be given the opportunity to have experience of and become proficient in **Procedure for Serious Adverse Incidents (SAIs)**, where required by the student's programme. This experience must be under the appropriate supervision of a registered nurse, registered midwife or registered health and social care professional who is adequately experienced in this skill and who will be accountable for determining the required level of direct or indirect supervision and responsible for signing/countersigning documentation.

Direct and indirect supervision

- Direct supervision means that the supervising registered nurse, registered midwife or registered health and social care professional is actually present and works alongside the student when they are undertaking a delegated role or activity.
- Indirect supervision occurs when the registered nurse, registered midwife or registered health and social care professional does not

directly observe the student undertaking a delegated role or activity. (NIPEC, 2020)

This policy has been developed in accordance with the above statement.

Wording within this section must not be removed.

10.0 EQUALITY IMPACT ASSESSMENT

The Trust has legal responsibilities in terms of equality (Section 75 of the Northern Ireland Act 1998), disability discrimination and human rights to undertake a screening exercise to ascertain if the policy has potential impact and if it must be subject to a full impact assessment. The process is the responsibility of the Policy Author. The template to be complete by the Policy Author and guidance are available on the Trust Intranet or via this **link**.

All policies (apart from those regionally adopted) must complete the template and submit with a copy of the policy to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

The outcome of the equality screening for the policy is:

Major impact ☐
Minor impact ☐
No impact ☐

Wording within this section must not be removed

11.0 DATA PROTECTION IMPACT ASSESSMENT

New activities involving collecting and using personal data can result in privacy risks. In line with requirements of the General Data Protection Regulation and the Data Protection Act 2018 the Trust considers the impact on the privacy of individuals and ways to militate against any risks. A screening exercise must be carried out by the Policy Author to ascertain if the policy must be subject to a full assessment. Guidance is available on the Trust Intranet or via this **link**.

If a full impact assessment is required, the Policy Author must carry out the process. They can contact colleagues in the Information Governance Department for advice on Tel: 028 950 46576

Completed Data Protection Impact Assessment forms must be returned to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

The outcome of the Data Protection Impact Assessment screening for the policy is:

Not necessary – no personal data involved ☐
A full data protection impact assessment is required ☐
A full data protection impact assessment is not required ☐

Wording within this section must not be removed.

12.0 RURAL NEEDS IMPACT ASSESSMENT

The Trust has a legal responsibility to have due regard to rural needs when developing, adopting, implementing or revising policies, and when designing and delivering public services. A screening exercise should be carried out by the Policy Author to ascertain if the policy must be subject to a full assessment. Guidance is available on the Trust Intranet or via this link.

If a full assessment is required the Policy Author must complete the shortened rural needs assessment template on the Trust Intranet. Each Directorate has a Rural Needs Champion who can provide support/assistance.

Completed Rural Impact Assessment forms must be returned to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

Wording within this section must not be removed.

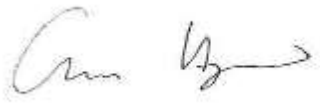
13.0 REASONABLE ADJUSTMENT ASSESSMENT

Under the Disability Discrimination Act 1995 (as amended) (DDA), all staff/ service providers have a duty to make Reasonable Adjustments to any barrier a person with a disability faces when accessing or using goods, facilities and services, in order to remove or reduce such barriers. E.g. physical access, communicating with people who have a disability, producing information such as leaflets or letters in accessible alternative formats. E.g. easy read, braille, or audio or being flexible regarding appointments. This is a non-delegable duty.

The policy has been developed in accordance with the Trust's legal duty to consider the need to make reasonable adjustments under the DDA.

Wording within this section must not be removed.

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



08/10/2020

_____ **Date:** _____

Name: Dr Chris Hagan
Medical Director

14/10/2020

_____ **Date:** _____

Dr Cathy Jack
Chief Executive

APPENDIX 1: HSCB SAI Notification Form

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM					
1. ORGANISATION:			**2.** UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE		
3. HOSPITAL / FACILTY / COMMUNITY LOCATION *(where incident occurred)*			**4.** DATE OF INCIDENT: DD / MM / YYYY		
5. DEPARTMENT / WARD / LOCATION EXACT *(where incident occurred)*					
6. CONTACT PERSON:			**7.** PROGRAMME OF CARE: *(refer to Guidance Notes)*		
8. DESCRIPTION OF INCIDENT: DOB: DD / MM / YYYY GENDER: M / F AGE: years *(complete where relevant)*					
9. IS THIS INCIDENT A NEVER EVENT?			If 'YES' *provide further detail on which never event - refer to DoH link below* https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars		
YES		NO			
DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING					
STAGE OF CARE: *(refer to Guidance Notes)*			DETAIL: *(refer to Guidance Notes)*		ADVERSE EVENT: *(refer to Guidance Notes)*
10. IMMEDIATE ACTION TAKEN TO PREVENT RECURRENCE:					
11. CURRENT CONDITION OF SERVICE USER: *(complete where relevant)*					
12. HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? *(please select)*				YES	NO / N/A
13. HAVE ALL RECORDS / MEDICAL DEVICES / EQUIPMENT BEEN SECURED? *(please specify where relevant)*				YES	NO / N/A
14. WHY IS THIS INCIDENT CONSIDERED SERIOUS?: *(please select relevant criteria below)*					
serious injury to, or the unexpected/unexplained death of: - a service user (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit) - a staff member in the course of their work - a member of the public whilst visiting a HSC facility.					
unexpected serious risk to a service user and/or staff member and/or member of the public					
unexpected or significant threat to provide service and/or maintain business continuity					
serious self-harm or serious assault *(including attempted suicide, homicide and sexual assaults)* by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service					
serious self-harm or serious assault *(including homicide and sexual assaults*) - on other service users, - on staff or - on members of the public					

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

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	

15. IS ANY IMMEDIATE REGIONAL ACTION RECOMMENDED: *(please select)*	YES	NO

if 'YES' (*full details should be submitted*):

16. HAS THE SERVICE USER / FAMILY BEEN ADVISED THE INCIDENT IS BEING REVIEWED AS A SAI?	YES	DATE INFORMED: DD/MM/YY
	NO	*specify reason:*

17. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? *(refer to guidance notes e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HCPC etc.) please specify where relevant*	YES	NO

if 'YES' (*full details should be submitted including the date notified*):

18. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	DATE INFORMED:	OTHERS: *(please specify where relevant, including date notified)*
DoH EARLY ALERT		
HM CORONER		
INFORMATION COMMISSIONER OFFICE (ICO)		
NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)		
HEALTH AND SAFETY EXECUTIVE NORTHERN IRELAND (HSENI)		
POLICE SERVICE FOR NORTHERN IRELAND (PSNI)		
REGULATION QUALITY IMPROVEMENT AUTHORITY (RQIA)		
SAFEGUARDING BOARD FOR NORTHERN IRELAND (SBNI)		
NORTHERN IRELAND ADULT SAFEGUARDING PARTNERSHIP (NIASP)		

19. LEVEL OF REVIEW REQUIRED: *(please select)*	LEVEL 1	LEVEL 2*	LEVEL 3*

* FOR ALL LEVEL 2 OR LEVEL 3 REVIEWS PLEASE COMPLETE AND SUBMIT SECTIONS 2 AND 3 OF THE RCA REPORT TEMPLATE WITHIN 4 WEEKS OF THIS NOTIFICATION REFER APPENDIX 6

20. 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 / MM / YYYY

21. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION: *(refer to Guidance Notes)*

Additional information submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

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

APPENDIX 2: HSCB SAI Notification Form – Guidance Notes

You can obtain the guidance notes for completion of the SAI Notification Form on the BHSCT HUB via the following link:

http://intranet.belfasttrust.local/directorates/medical/riskgovernance/Pages/Corporate%20Governance/Serious-Adverse-Incidents0911-9361.aspx

APPENDIX 3: HSCB Interface Incident Form

<table>
<tr><th colspan="3">HSC INTERFACE INCIDENT NOTIFICATION FORM</th></tr>
<tr><td>1. REPORTING ORGANISATION:</td><td colspan="2">2. DATE OF INCIDENT: DD / MM / YYYY</td></tr>
<tr><td>3. CONTACT PERSON AND TEL NO:</td><td colspan="2">4. UNIQUE REFERENCE NUMBER:</td></tr>
<tr><td colspan="3">5. DESCRIPTION OF INCIDENT:

DOB: DD / MM / YYYY GENDER: M / F AGE: years
(complete where relevant)</td></tr>
<tr><td rowspan="2">6. ARE OTHER PROVIDERS INVOLVED?
(e.g. HSC TRUSTS / FPS / OOH / ISP / VOLUNTARY / COMMUNITY ORG'S)</td><td>YES</td><td>NO</td></tr>
<tr><td colspan="2">if 'YES' (full details should be submitted in section 7 below)</td></tr>
<tr><td colspan="3">7. PROVIDE DETAIL ON ISSUES/AREAS OF CONCERN:</td></tr>
<tr><td colspan="3">8. <u>IMMEDIATE</u> ACTION TAKEN BY REPORTING ORGANISATION:</td></tr>
<tr><td colspan="3">9. WHICH ORGANISATION/PROVIDER (FROM THOSE LISTED IN SECTIONS 6 AND 7 ABOVE) SHOULD TAKE THE LEAD RESPONSIBILITY FOR THE REVIEW AND FOLLOW UP OF THIS INCIDENT?</td></tr>
<tr><td colspan="3">10. OTHER COMMENTS:

REPORT SUBMITTED BY: _____ DESIGNATION: _____

Email: Telephone: Date: DD / MM / YYYY</td></tr>
</table>

APPENDIX 4: HSCB SAI Report Templates & Engagement Checklist

You can obtain the templates and guidance notes on the BHSCT HUB via the following link:

- Level 1 SEA Report template including learning summery and engagement checklist
- Level 1 SEA Report guidance notes for completion

- Level 2 & 3 RCA Report template and engagement checklist
- Level 2 & 3 RCA Report guidance notes for completion

http://intranet.belfasttrust.local/directorates/medical/riskgovernance/Pages/Corporate%20Governance/Serious-Adverse-Incidents0911-9361.aspx

EVIDENCE FILE
CONTROLS ASSURANCE STANDARD 7

North & West Belfast Health & Social Services Trust
Investigation of Adverse Events/Incidents, Near Misses, Complaints and Claims – v.1

Title		Type	Status
INVESTIGATION OF ADVERSE EVENTS/INCIDENTS, NEAR MISSES, COMPLAINTS AND CLAIMS		Procedure	Approved
		Unique Identifier	**Version**
		Gov 00002	1
Author / Originator		**Accountable Director**	
Name Ian Jamison	**Role** Assistant Director of Corporate Affairs	**Name** Eamonn Molloy	**Role** Director of Human Resources & Corporate Affairs
Document Checked for:		**Author Signature**	
NORTH & WEST BELFAST HEALTH & SOCIAL SERVICES TRUST	**Compatibility with other Trust Documents**	√	
	Equality and/or Human Rights Impact	√	
	Financial Impact	√	
	Training and Education Needs	√	
	Distribution List	√	
Approved by (Board Committee Group)		**Date**	
Trust Board		**23 February 2005**	

Review Date	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Month				**Jan**								

Please check the Intranet to ensure you have the latest version

TABLE OF CONTENTS

1.0 INTRODUCTION

This guidance provides a framework to facilitate in depth analysis of and learning from events where there has been potential or significant harm/loss or death as a result. Throughout this document the terms adverse event, incident, accident, near miss, complaint or claim will be know as the 'event'.

It provides a framework to assist nominated lead investigators to successfully investigate and report on a wide range of events.

The depth of investigation of events will be determined in the relevant policy. This procedure should be read in conjunction with:-

- Risk Management Strategy/Policy
- Adverse Event/Incident and Near Miss Policy
- Serious Adverse Incident Policy
- Major Incident Policy
- Complaints Policy
- Claims Policy.

2.0 PURPOSE OF THE PROCEDURE

This procedure has been developed to:-

- Ensure in depth analysis of the event.
- Ensure appropriate experience and expertise is applied to the investigation.
- Ensure all the events leading up to the adverse outcome are considered.
- Ensure a structured and systematic approach is applied to the investigation, aiding mapping of the events, analysis and production of a formal report.
- Ensure that organisation wide learning takes place to reduce subsequent/similar risks and assist service improvement.
- Facilitate a climate of openness and an open and fair culture.

3.0 SCOPE

The procedure covers all areas of Trust Business and applies to all events involving patients, clients, service users, staff and members of the public.

What is investigated?

3.1 Adverse Events/Incidents and Near Misses

Investigation Categories

Red	The relevant Director will initiate a full investigation, the results of which will be subject to a root cause analysis to determine the underlying issues that require addressing.
Orange	The relevant Senior Manager will ensure appropriate investigation for this category of event and root cause analysis if required.
Yellow	These represent lower risk situations and the designated Line Manager should decide on the appropriate level of investigation.
Green	These events should be subject to aggregate review at Directorate/Programme/Service Area Level.

3.2 Complaints

All written and verbal complaints need to be investigated but the level of investigation and analysis required will be less in some complaints as they can be resolved relatively easily. The level of investigation will be determined by the relevant Director/Senior Manager.

3.3 Claims

All legal claims must be investigated and reviewed. The investigation will be commissioned by the relevant Director/Senior Manager.

4.0 CULTURAL AND DISCIPLINARY ISSUES

The key purpose of investigation is to learn lessons and consider wider organisational issues, rather than to seek to blame individuals.

All staff must feel safe to report issues and incidents and contribute to investigations. They need to be assured that information they share will be treated with respect and acted upon appropriately to improve the safety and quality of Health and Personal Social Services provided to service users. To achieve this, the investigation process must be:

- Fair and equitable
- Focused on learning and change
- Focused on identifying both contributing and root causes.

This will mean that:

It will be a rare occurrence for an event investigation to lead to the disciplinary procedure being instigated; and

The disciplinary process should only be used where it is clear that the actions of those involved included an intention to harm, a criminal act, or acts that foreseeably put the safety of service users, staff or members of the public at risk.

If during the course of the investigation, the team has serious concerns about any individuals actions or omissions, advice should be sought from the relevant Executive Director in conjunction with the Human Resources Department.

5.0 PRINCIPLES

5.1 Undertaking the Investigation

The investigation should concentrate on factual information from all available sources. It is essential that the investigation should not prejudge events and issues under investigation. The following process should be used.

5.2 Data Collection

All material facts surrounding the incident, its preceding circumstances and consequences must be collected as soon as possible after the event.

The start point for the event may be clear, on other occasions it may be much less so. For complex events it is only by starting at the point at which the event occurred and working backwards that the start point can be identified. On other occasions it may be appropriate to review the complete patient/client journey from admission/first contact through to the event.

There needs to be a consistent approach to gathering the evidence. Using the following "5P" process is a useful approach.

5.3 Place

Visit the environment; note the exact locations, general layout, ergonomic design and blind spots. Note physical locations of staff and witnesses. Consider making sketches or taking photographs.

5.4 Persons

All key members of staff/visitors/contractors/service users must be interviewed.
Interviews (Appendix 1)
Witness Statements (Appendix 2)

5.5 Parts

Any piece of equipment, or any implement directly involved should be preserved as evidential material. Unless the police or coroners office require the physical evidence, the investigating team must ensure that all physical object evidence is taken out of use, clearly labelled and preserved. Note that the equipment may need to be professionally examined.

5.6 Paper

Policies, procedures, protocols, guidelines, rotas, audits, incident reports, maintenance records, client records, correspondence that

has contributed to the event should be examined. A log must be maintained of all the documentation reviewed.

Assess the suitability of the service that was being run or delivered at the time of the event in view of the expected outcome e.g. the service user's care in relation to history and professional/clinical circumstances, procedures to protect employees from dangerous equipment etc. Determine the extent to which the service corresponded to statutory obligations, relevant guidance from the Department of Health & Social Services, local operational policies and contractual agreements.

5.7 Paradigms

It is important to elicit the general custom, practice and prevailing attitudes of the working environment. This information can help to shape the context in which factors leaving an area vulnerable to events have come to pass.

5.8 Chronology

The chronology of events is of the utmost importance in your investigation. There are two ways of recording a chronology; list all events as you identify them using the format in Appendix 3 or complete a timeline using the format in Appendix 4. The timeline is most useful when completing the chronology with a team of people as it is more visual. Whatever method you choose to record the chronology will affect the ease with which you can visualise the chain of events, and identify areas where further fact finding is required.

The mapped chronology should also enable you to identify quite clearly the key problem areas, and areas of good practice in the sequence of events.

The Timeline (see Appendix 4)

A timeline is very useful for viewing the event as a whole, it is particularly valuable for viewing events involving multiple specialities or agencies. The timeline enables you to map the interface between the involved agencies within a single document rather than having to try and map this across four or five narrative chronologies.

Each happening, plus the date and time of its occurrence are placed in a rectangular box in chronological order. Arrows that indicate the flow of time connect the boxes.

Additional or supporting information, will assist in building up the picture of what happened and should be attached to the relevant points in the timeline. It is also very important that the investigating team take note of all evidence of good practice and ensure that this is recorded in the final report.

As you map the chronology you will naturally generate your own questions to which you will want to seek answers. Some questions will relate to the actual chain of events and issues of clarification. These questions will need to be noted on the timeline, additional information may be needed and witnesses contacted to clarify the issues.

At the end of the process the investigating team should have identified key problem areas, it may be necessary to prioritise these problems using the Trust Risk Acceptability Framework (Matrix). It is much better to analyse five thoroughly, than seventeen superficially.

5.9 Analysis

A fundamental part of Root Cause Analysis investigation is the identification of the influencing and causal factors that contributed to the event. The fishbone diagram assists in this process.

5.9.1 Fishbone Diagram (Appendix 5)

The identified problem is written at the head of the fish, each spine of the fish is given a classification:-

Service User/Individual Factors

Factors that the individual involved in the event bring that are unique to them or related to patient/client condition and include home and lifestyle factors, work relationship factors, general health, and stress.

Communication

Aspects of verbal, non-verbal or written communication, records management, recognised channels of communication.

Equipment

Factors concerning manuals, user information, working order, maintenance safety features, positioning for use and storage.

Working Conditions

Factors affecting ability to function at optimum levels in the work place, administrative system factors, design of environment, general housekeeping, staffing levels and skill mix factors, retention and staff turnover.

Education & Training

Availability, quality and appropriateness of training that directly affects ability to perform the job, competence and skills in the job, supervision.

Team & Social

Aspects of communication but predominantly around management styles, leadership and perceptions of role and understanding, support networks, team openness.

Tasks

Aspects that support and aid in the safe and effective delivery of particular functions such as policy, procedures, task design, equipment resources, failure and maintenance.

Organisation & Strategic

Aspects inherent or embedded in the organisation, hierarchical structure, commissioning, risk safety and learning culture, externally imported risks such as contractors, service level agreements.

This grouping is useful to the investigator in two ways. Firstly, it provides an analysis framework to operate in, and a level of consistency that otherwise might be elusive. Secondly the user of a standardised framework provides the opportunity for the consistent collection and aggregation of causal data, which can then be further interrogated and analysed to identify issues that ought to be considered for further improvement work. Trends in causal factors can also be identified.

Consider each individual problem identified using the above classifications, for example, what was it in the team and social factors that influenced the identified problem, write the causal or influencing factors on the spine of the fish.

The ALARM protocol (available on Governance Intranet Site) details the type of issues you may wish to consider for each classification.

It is essential that all influencing and causal factors put forward as being significant to the problem are authenticated; 'might haves' and 'could haves' must always be authenticated. This element of the RCA process is important if the results of the investigation are to be credible.

5.10 Developing the Recommendations and Actions from the Issues to be Addressed

The information on the fishbone diagram should be the basis for the recommendations and actions. In order to eliminate or significantly reduce the risk of the same problems occurring again each individual causal factor should be addressed.

The relevant Senior Manager will review the issues to be addressed with the investigation team, make recommendations and

develop a DRAFT action plan. These will be submitted to the relevant Director for approval and then monitoring through the Local Governance Group.

5.11 Writing the Report

The headings of the report should relate directly to the terms of reference and should include the following:

- Title page with incident/event date, Trust identification number
- Names and designations of the investigation team and investigation completion date
- Summary of event
- Chronology
- Analysis
  - Patient/individual
  - Communication
  - Working condition
  - Education and training
  - Team and social
  - Task
  - Organisational/strategic
  - Equipment
- Conclusions
- Actions already taken
- Issues that need to be addressed
- Positive factors/good practice identified
- A record of who the report is to be shared with within the immediate service e.g. service user, carers, staff
- Appendices should be precise and include a list of the documentation reviewed, people interviewed and witness statements obtained. Copies of extracts from professional/clinical records should not be used unless absolutely material to the body of the report and referenced within it.

The report is a disclosable document in law and will be written presenting fact not opinion or personal judgement. The report should only contain the initials of any service user(s) and members of staff should be recorded as Doctor A or Staff Nurse B.

5.12 Risk Register

The recommendations should be written in terms of risk to facilitate transference onto the Trust risk assessment record/risk register. The Trust risk matrix should be completed identifying the current level of risk prior to the actions and also the anticipated level of risk after actions have been implemented. The risk assessment will be recorded on the electronic local risk register and forwarded to Risk Management and Controls Assurance Co-ordinator for entry on Corporate Risk Register as appropriate.

6.0 DOCUMENT CONTROL

Terms and Abbreviations

Term/Abbreviation	Meaning
RCA	Root Cause Analysis

Other Relevant or Associated Documents

Reference	Policy Identifier	Title
1.0 [1]	TBA	Risk Management Strategy
1.0 [2]	TBA	Adverse Event/Incident & Near Miss Policy
1.0 [3]	TBA	Serious Adverse Incident Policy & Procedure
1.0 [4]	TBA	Complaints Policy
1.0 [5]	TBA	Claims Policy

Distribution List

Name	Organisation/Location
All Senior Managers	Various Trust Facilities

Quality Control

Job Title	Risk Management & Controls Assurance Co-ordinator
Signature	
Date	21st March 2005

APPENDIX 1

GUIDELINES FOR STAFF INTERVIEWS

Critical to the investigation process will be ascertaining facts pertinent to the event. To be effective, participants must be assured of the process and objectives being adhered to by the Review Team. High levels of anxiety may be present and these concerns must be allayed if the interview process is to be of value in determining the facts. Interview sessions are usually conducted in pairs plus someone to take notes or record the interview. Planning and preparation as to the role of each interviewer is important prior to the process. The importance of neutral and unambiguous language is essential as is appropriate body language. What is important is to elicit the facts and not necessarily opinions which can be verified and corroborated.

In conducting the interview stage of the review process there are four distinct phases. These summarily are:

Phase 1 - Introduction

- Introduce those present and their roles
- Invite interviewee to tell you about themselves
- Explain scope and purpose of the interview
- Detail what will happen to the information from the interview
- Ask interviewee to give you an account of events
  - Don't interrupt at this point as this will disturb them retrieving information from memory
  - Use positive body language.

Phase 2 - Questioning

- Where possible ask questions in the order of the interviewees account of events
- Reassure the interviewee it is acceptable for them to say 'I don't know'
- Use open questions e.g. tell me about, how did this make you feel, describe to me
- To clarify information use closed questions e.g. were you present when X happened?
- Don't use multiple questions.

Phase 3 - Summary

- The interviewer should summarise the interview using the interviewees language as far as possible
- Allow the interviewee to correct any inaccuracies or misunderstanding of facts.

Phase 4 - Closure

- Thank the interviewee for attending and sharing information
- Reiterate the review process and what will happen with the information shared at interview
- Ask the interviewee if they have any further information they would like to share
- Give details of support mechanisms available for them.

APPENDIX 2

GUIDELINES ON THE WRITING OF STATEMENTS

These guidelines are intended to assist any individual who has been asked or wishes to prepare a written statement.

A statement may be required as part of an investigation into a complaint, incident, or particular situation under investigation.

- indicates that it is minimum requirement by the Trust of any statement produced.

Purpose of a Statement

A written statement is intended to inform another party (usually the Investigatory Officers) of exactly what happened at the time of an incident or situation.

Presentation of a Statement

- A statement should be written in black ink or preferably typed onto Trust headed A4 paper. The attached pro-forma may be used as guide.
- A statement should clearly state your name, designation, business address and the full date your statement was written/typed.
- The statement should always be signed with the date given when signed.
- The statement should not express opinions, particularly opinions about matters outside your expertise (e.g. nursing staff should avoid expressing opinions about other professionals/clinical competence or vice versa).
- If the statement runs to several pages, each page should be, numbered signed and dated.
- The statement should be headed with a reference to the nature of the incident or situation, the date of the incident and any Trust reference number that may be available.

Content of a Statement

- The statement should be in the first person singular (e.g. "I saw ..... ").
- Set out the story, **saying only what your involvement in the incident was** (other witnesses can explain their own involvement).
- Record facts - actions, dates, times - as clearly as possible. Only record something if you can remember.
- If you cannot be sure of a certain aspect of an incident or situation then state this. It might, however, be helpful to indicate what the normal practice would have been (e.g. "I cannot remember this patient being told to walk unassisted on Friday, 5 May 2000. Normal practice on the ward would be to ensure a patient was assessed as being capable of mobilising independently, and was safe to do so").
- If an action or decision was made jointly this should be set out in your statement (e.g. "and I agreed that I should do this with .....", it is not helpful to say, "it was decided we should .....". This neither explains who decided nor who was going to do the doing).
- When referring to other people, state clearly their full names and designations.
- If other documents (e.g. patient/client records) are relevant then it may be helpful to refer to these in your statement.
- If any shorthand notes or abbreviations are being referred to then these should be explained fully and a translation provided.
- Dates and times should always be referred to in full (e.g. 16.30 on Tuesday, 22 February 2000, not 4.30 on 22/2).
- Adverse Event/Incident Report: An incident report form will invariably need to be completed, however, if you are involved in an incident that may result in a complaint or a future claim it is advisable to write a statement following the above guidelines. Do not feel you need to wait until you are asked to prepare a statement.

Remember

- Signed and dated statements are legal documents.
- Always read and double-check a statement before submitting it.
- Always keep a copy for your own records.
- Give as much information as possible.
- Prepare a statement as near to the time of the incident as possible.
- As time passes, memory fades.
- Never place copies of statements in patient records.

Further Help

If you need further help or support in preparing a statement, please contact any of the following for advice:

- Your Line Manager
- Staff in the Risk Management Department
- Your professional organisation
- A Staff Association or Trade Union body.

PRIVATE AND CONFIDENTIAL

Statement Relating to Incident concerning [name of patient, client, relative, member of staff etc] (Hospital No/Ref No: [number] on the [date] on [location, including ward/department, hospital site]).

Statement prepared by:

Full Name: .....

Designation: .....

Facility: .....

Ward/Dept: .....

Date of Preparation: .....

[Statement]

Signed: .....

Date of signing: .....

APPENDIX 3

NORTH AND WEST BELFAST HEALTH AND SOCIAL SERVICES TRUST

EVENT INVESTIGATION

Chronology of Events

Name	
Address	
DOB	
GP (if relevant)	
Patient/Client/Staff No.	
Date of incident	
Notification by	
Compiled by	

The following is a tabulation of relevant events concerning this case presented in chronological order and interspersed with observations in ***bold italic***.

Date	Event	Source of Information

APPENDIX 4

NORTH AND WEST BELFAST HEALTH AND SOCIAL SERVICES TRUST

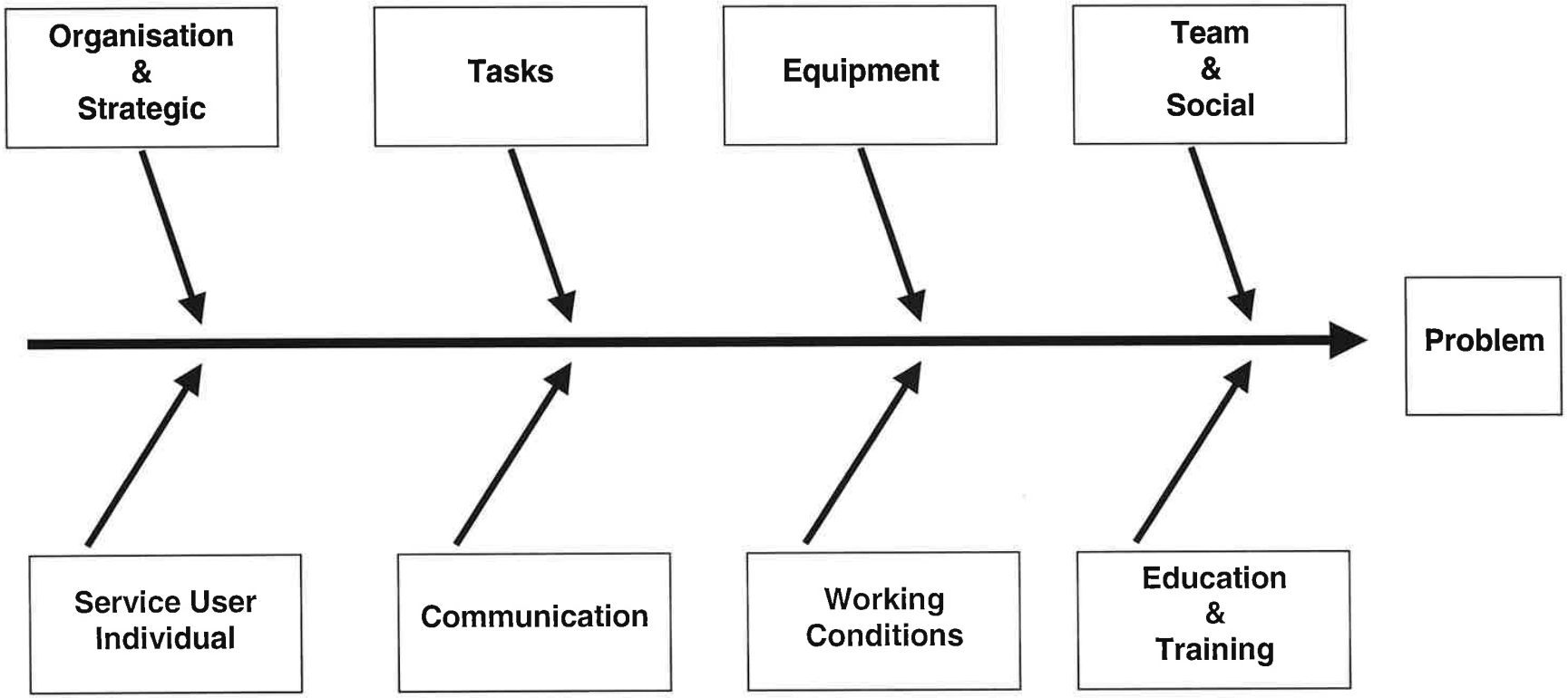
TIMELINE

Date	Time	Date	Time	Date	Time	Date	Time	Date	Time
Event →		Event →		Event →		Event →		Event →	
Supplementary Info		Supplementary Info		Supplementary Info		Supplementary Info		Supplementary Info	
Person(s) present		Person(s) present		Person(s) present		Person(s) present		Person(s) present	
Source of information		Source of information		Source of information		Source of information		Source of information	
Positive points		Positive points		Positive points		Positive points		Positive points	
Problems		Problems		Problems		Problems		Problems	
Further info required		Further info required		Further info required		Further info required		Further info required	

APPENDIX 5

NORTH AND WEST BELFAST HEALTH AND SOCIAL SERVICES TRUST

FISHBONE DIAGRAM



2.043

Belfast Health and Social Care Trust

Reference No: TP093/14

Title:	Procedure for Investigating an Incident (excluding SAIs)		
Author(s)	Claire Cairns, Senior Manager, Corporate Governance Patrick Keenan, Manager for Medical & Dental Workforce Shane McCaul, Governance Manager, Corporate Governance Gillian Moore, Admin & Datix Manager, Corporate Governance		
Ownership:	Medical Directorate		
Approval by:	Policy Committee Executive Team	**Approval date:**	30 June 2014 09 July 2014
Operational Date:	June 2014	**Next Review:**	June 2017
Version No.	V1 **Supercedes**		
Key words:	Incident, Learning, Investigation, Action Plan, Complaint, Litigation, Incident feedback, Evidence, Grading, Root Cause Analysis (RCA), Significant Event Audit (SEA),		
Links to other policies/ procedures	**Adverse Incident Reporting and Management Policy** Procedure for Reporting and Managing Adverse Incidents Procedure for Reporting and Managing Serious Adverse Incidents Procedure for Grading an Incident RIDDOR Procedural Arrangements Guidance on Writing a Statement following an Incident Procedure for Sharing Learning Being Open Policy Whistleblowing Policy		

Date	Version	Author	Comments
29/08/2013	0.1	S McCaul	Initial Draft
21/03/2014	0.2	P Keenan	Comments from Corporate Governance team
04/04/2014	0.3	S McCaul G Moore	Comments from Directorate & Corporate Governance colleagues
12/05/2014	0.4	S McCaul G Moore	Comments from Directorate & Corporate Governance colleagues
28/05/2014	0.5	S McCaul G Moore	Comments from Directorate & Corporate Governance colleagues

Contents **Page Number**

1.0 INTRODUCTION

This procedure applies to incidents which are considered *not* to meet Serious Adverse Incident (SAI) criteria. Please see SAI procedure for further guidance on SAI's.

It covers the process of adverse incident (excluding SAIs) investigation from determining what level and type of investigation to adopt, a guide through the investigation process itself, subsequent action planning, sharing of lessons learned and audit to assure appropriate compliance with lessons learned.

Many people feel that errors are random occurrences that are unpredictable and beyond control. It is true that chance will play a part in causing some incidents but a large majority of incidents are caused by systemic failures that follow a recurrent pattern. Moreover, if the cause of the incident can be identified, preventative changes can take place and true learning encouraged and shared.

The definition of an adverse incident is as follows:

"Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation"[1].

It is the responsibility of all staff who are involved in, witness to, or become aware of an adverse incident to ensure that this is reported and to complete a Trust Incident Report form.

The Belfast Health and Social Care Trust is committed to staff and service user safety and cooperation with statutory agencies with regard to the response to/and investigation of all incidents up to and including suspicious / unexpected death and serious untoward harm.

2.0 PURPOSE

The purpose of this procedure is to enable a robust and systematic approach to the investigation of adverse incidents that will be consistently applied across the Trust.

3.0 SCOPE

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

4.0 LEVEL OF INVESTIGATION REQUIRED

The grading of an incident by severity and risk will determine the requirements for investigating that incident. All incidents will therefore be graded according to severity (actual harm/impact) and risk. (See Procedure for Grading an Incident for further guidance.)

An immediate assessment of the incident grade should be undertaken to allow staff to progress appropriately, if in doubt staff should always grade the incident at the higher level. The incident severity and/or risk grade should be reviewed after further investigation and may be revised following further assessment and corresponding action taken as appropriate in line with grading.

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

Depending on the grade of incident an appropriate level of investigation should be carried out. All levels of investigation require some degree of evidence gathering, making sense of data, analysing problems, identifying cause(s), drawing up conclusions, identifying learning and actions to prevent reoccurrence. Investigations should be carried out in accordance with the grading as follows:

4.1 Green – Insignificant or Minor Severity / Low Risk

Who investigates
The investigation will be commissioned by the incident form approver. It should be investigated and reviewed locally in the ward/facility in which the event occurred by the incident approver and/or their staff.

Methodology
The investigation details should be recorded on the investigation and learning section of the incident form. This should include any causes identified, further action taken or planned and any learning. Where no learning or actions are identified, this should be explained as it may be necessary to justify the reasoning behind the decisions at a later date. The investigation should normally be completed no later than 7 working days after the event.

Once the investigation is complete, the approving manager should code the approval status of the incident on Datixweb as 'Approved, investigation complete'. This is not dependent on actions being outstanding.

Actions & Learning
The incident approver is responsible for ensuring all actions are completed and any learning shared as appropriate (see Procedure for Sharing Learning for further guidance). Any actions which are not within the local team's control or remain uncompleted should be communicated to a more senior manager for consideration.

4.2 Yellow – Moderate Severity / Medium Risk

Who investigates
The Service Manager or Assistant Service Manager is accountable for ensuring that all investigations are carried out appropriately. The incident can be investigated and reviewed locally in the ward/facility in which the event occurred by the incident approver and their staff, however where the incident crosses professional and/or managerial boundaries, team membership should reflect this.

Methodology
As a first step consider use of Significant Event Audit (SEA) methodology which is an appropriate technique for this level of investigation. The investigation details should be recorded on the SEA template (Appendix 1) which should be attached to the incident record. A note that the template has been attached should be added to the investigation and learning section of the incident form.

If SEA methodology is deemed not appropriate, the investigation details should be recorded on the investigation and learning section of the incident form. This should include any causes identified, further action taken or planned and any learning. Where no learning or actions are identified, this should be explained as it may be necessary to justify the reasoning behind the decisions at a later date. The investigation should normally be completed no later than 4 weeks after the event.

Once the investigation is complete, the approving manager should code the approval status of the incident on Datixweb as 'Approved, investigation complete'. This is not dependent on actions being outstanding.

Actions & Learning
The Service Manager or Assistant Service Manager are responsible for ensuring all actions are completed and any learning shared as appropriate (see Procedure for Sharing Learning for further guidance). Any actions which remain uncompleted should be communicated to a more senior manager for consideration.

4.3 Amber – Major Severity / High Risk (and not an SAI)

Who investigates
The Co-Director is accountable for ensuring that all investigations are carried out appropriately. The incident should be investigated and reviewed locally by more than one person and the team should include someone independent from the specialty. Where the incident crosses professional and/or managerial boundaries, team membership should reflect this. More guidance on team membership is available in the Significant Event Audit (SEA) guidance.

Methodology
As a first step consider use of Significant Event Audit (SEA) methodology which is an appropriate technique for this level of investigation. The investigation details should be recorded on the SEA template (Appendix 1) which should be attached to the incident record. A note to this effect should be added to the investigation and learning section of the incident form.

If during the SEA process, it is felt that further analysis is required, the process should transfer to Root Cause Analysis (RCA) methodology. A summary of the results of the investigation should be recorded on the investigation and learning section of the incident form. This should include any causes identified, further action taken or planned and any learning. The investigation report should also be attached to the incident record. Where no learning or actions are identified, this should be explained as it may be necessary to justify the reasoning behind the decisions at a later date. The investigation should normally be completed no later than 12 weeks after the event.

Once the investigation is complete, the approving manager should code the approval status of the incident on Datixweb as 'Approved, investigation complete'. This is not dependent on actions being outstanding.

Actions & Learning
The Co-Director is responsible for ensuring all actions are completed and any learning shared as appropriate (see Procedure for Sharing Learning for further guidance).

4.4 Red – Catastrophic Severity or Extreme Risk (and not an SAI)

Who investigates

The Co-Director or Director is accountable for ensuring that all investigations are carried out appropriately. The incident should be investigated and reviewed locally by more than one person and the team should include someone independent from the specialty. Where the incident crosses professional and/or managerial boundaries, team membership should reflect this. More guidance on team membership is available in the Significant Event Audit (SEA) guidance and RCA guidance.

Methodology

Depending on the nature of the incident it may be subject to specific formal Trust investigation process e.g. Case Management Review (CMR), Morbidity & Mortality (M&M) meeting or Cardiac Arrest review. If this is not the case the incident should be subject to SEA or RCA methodology as per Amber section.

A summary of the results of the investigation should be recorded on the investigation and learning section of the incident form. This should include any causes identified, further action taken or planned and any learning. The investigation report should also be attached to the incident record. Where no learning or actions are identified, this should be explained as it may be necessary to justify the reasoning behind the decisions at a later date. The investigation should normally be completed no later than 12 weeks after the event.

Once the investigation is complete, the approving manager should code the approval status of the incident on Datixweb as 'Approved, investigation complete'. This is not dependent on actions being outstanding.

Actions & Learning

The Co-Director or Director are responsible for ensuring all actions are completed and any learning shared as appropriate (see Procedure for Sharing Learning for further guidance). This should include any actions or learning identified as a result of other formal Trust investigation processes e.g. M&M, Cardiac Arrest review.

4.5 Summary Table: Level of Investigation

Severity / Risk Grade	Insig. / Minor	Moderate	Major	Catastrophic
	Low	Medium	High	Extreme
Investigation Commissioner	Incident form approver	Service Manager / Asst Service Manager	Co-Director	Director / Co-Director
Investigation duration (guide)	No more than 7 working days	No more than 4 weeks	No more than 12 weeks	No more than 12 weeks
Form	Datixweb Incident Form	Datixweb Incident Form (Consider use of SEA template)	SEA template / RCA template (and attach to Datixweb incident record)	SEA template / RCA template (and attach to Datixweb incident record)
Actions	Local implementation / record on Datixweb incident form.	Local implementation / record on Datixweb incident form.	Formally monitored.	Formally monitored.
Learning	Record on Datixweb incident form / shared locally. Patient / Service User / Family informed as appropriate	Record on Datixweb incident form / shared locally. Patient / Service User / Family informed as appropriate	Record on Datixweb incident form. Shared locally within Directorate. If learning applicable beyond Directorate, Co-Director to share through appropriate Assurance sub-committee. Patient / Service User / Family informed as appropriate	Record on Datixweb incident form. Shared locally within Directorate. If learning applicable beyond Directorate, Co-Director to share through appropriate Assurance sub-committee. Patient / Service User / Family informed as appropriate

4.6 Incidents involving Non-HSC Organisations

Where incidents are of a serious nature and may include required involvement from other organisations, the Memorandum of Understanding Investigating patient or client safety incidents (Unexpected Death & Serious Untoward Harm) should be used to ensure appropriate investigation on the part of the Trust. This document will guide on which organisation leads and the roles of each in the investigation. Certain investigations or aspects of them may be for others to take forward and therefore the scope of the Trust investigation may be affected.

4.7 Potential Disciplinary / Performance Issues

Incident investigation is designed principally to identify and draw out learning in order that this can be shared, however where an incident involves potential disciplinary or performance issues it is important to follow Human Resources policy and procedures at an early stage. The NPSA Incident Decision Tree can be helpful in identifying these issues early in the investigation process.

5.0 HOW TO INVESTIGATE

The investigation should focus on five key areas:

- **WHAT** - this is detail / specifics in relation to incident / investigation, the actual event and its impact and consequences if any
- **WHERE** - the location / site / area of the incident/ significant in that it may be important in securing evidence / making the scene safe for others and protecting any evidence that may contribute to the investigation
- **WHEN** - the timings / event / notification / resolution from the time of the actual event to the reporting and remedial action, the arrival of assistance and / or other persons involved.
- **WHO** - all persons involved in the incident / investigation, injured parties / witnesses and any others person who have a material contribution to make in terms of the investigation process (remembering that the person(s) affected may also be witnesses)
- **WHY** - findings of the investigation / cause identification / learning to be shared

Of the five areas the WHY is the last to be considered as this will reduce likelihood of jumping to an initial conclusion without due consideration of the facts and causes.

The following sections (5.1 to 5.6) outline the requirements for investigating an incident. The level of detail required should be proportionate to the grading and complexity of the incident.

5.1 Record keeping

Appropriate documentation, including written submissions of witness from staff (see Guidelines on Writing a Statement following an Incident) is required to be recorded and retained in line with good record keeping guidance.

A thorough record of all the investigation activity should be recorded in the appropriate field in Datixweb or added as an attachment to the incident record. Investigators should be aware that the investigation documentation will be covered by the Data Protection Act and will potentially be disclosed to persons outside of the organisation, including the subject of any report.

Once complete, the investigation file should be referenced and filed locally, together with a copy of the final report and completed action plan in accordance with the Trust's Records Retention Schedule. A copy of the final report and action plan, where available, should be attached to the Datixweb record.

5.2 Communicating with and involving service users / families / carers

Staff should follow the Being Open Policy in relation to communicating with service users/ families / carers.

It is important that teams involved in investigations of any incidents where harm occurred, ensure sensitivity to the needs of the service user/relatives/carers involved and agree communication arrangements, where appropriate.
The accountable person 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.
The level of involvement clearly depends on the nature of the incident and the service users/relatives/carers wishes to be involved.

5.3 Securing evidence & gathering information

Investigators may find it helpful to consider information from a range of sources including:

- The people involved in or witnessing the event
- The place or environment in which the event took place
- The equipment or objects involved in the event
- The paper work related to the event (e.g. policies, procedures, clinical records, incident reports, risk assessments, maintenance records, clinical audits, training records)
- The widely held beliefs about the normal work processes, team relationships and adequacy of leadership in the workplace.

This list is not exhaustive.

Where required the immediate area should be secured and access be limited until such time as to allow an opportunity to access the scene and record any relevant observations (this may include taking photographs of the scene or measurements). All material evidence, including written documentation (or copies of), relating to the incident should be gathered and secured as soon as possible after the event. This

is particularly important in relation to the timely seizing of CCTV where available, as such evidence may be on a time limited system.

5.3.1 Time Period to be Investigated

From the initial assessment, decide on the time period (start and end dates) that needs to be investigated. This is essential as it determines the information and evidence required. You may therefore need to consider the lead up to and aftermath, as well as the incident itself.
Describe what happened with facts, not opinions using tools such as a chronology narrative and/or tabular timeline. Avoid the use of abbreviations and medical terms as this may form part of the investigation report which may be read by service users / families/ carers etc. Investigators are encouraged not to pre-judge which events are significant / insignificant in advance of compiling a timeline.
Timeline template examples can be found on the Corporate Governance website.

5.3.2 Obtaining Personal Accounts of the Incident

Witnesses to the event and those involved in the incident should be given the opportunity to provide a personal account as to what has occurred.
The PEACE model can be utilised for structured discussion with staff to obtain accounts, if considered appropriate (Appendix 2).
This structured discussion should be carried out in a supportive way, to ascertain the following:

- the role of the witness or those involved in the event and the extent of their involvement.
- The patient and/or relatives/carers account of the incident should be obtained if appropriate.
- the chronology and details of the incident time period
- what problems, action(s), inaction(s) resulted in the incident
- what records, guidelines, equipment were involved
- any other contributory factors e.g. where custom and practice may have deviated from policy and procedure.

5.3.3 Witness statements

Once statements have been received, the lead investigator may wish to speak to staff in person to help clarify part of a statement or account. Any written evidence may become "disclosed" in the event of subsequent legal action and care should be taken in its formulation to include only relevant facts of what actually happened, not what people thought happened. There should be no opinion on who is at fault or any speculation on causes. Forms should be fully completed and all information requested completed.

For further details on Witness Statements please see Guidelines on Writing a Statement following an Incident.

5.3.4 Equipment

For some incidents site visit(s) and liaison with manufacturers and/or suppliers, contractors and/or other agencies/individuals involved may be needed. Any piece of equipment involved in the incident should be removed and preserved as evidence where possible. For further information see Medical Devices Procedures and Guidelines.

5.3.5 Environment – The place in which the incident occurred

Investigators should visit the actual area, if relevant, where the incident took place, preferably before any changes are made and note the layout. A sketch of the area and its layout may be useful particularly if annotated with the location of persons involved in the incident, and other witnesses to the incident. Photographic evidence of the environment can be invaluable.

5.3.6 Evidence storage

Any non-clinical evidence gathered should be attached to the Datixweb incident record e.g. documents, photographs, emails, letters, faxes etc., in order to maintain a complete record of the investigation. If attaching clinical evidence to the Datixweb incident record, the Data Protection Policy must be adhered to. Alternatively this evidence may be retained in a separate file and the location and holder of the file should be clearly recorded on the Datixweb record.

5.4 Identifying problems

A number of tools can be used for identifying the problems e.g. Multidisciplinary meeting, brainstorming / brainwriting, Nominal group technique etc. Please see the Corporate Governance website and SEA and RCA methodology for further guidance regarding these tools.

Problems may relate to the direct provision of care e.g. actions or omissions by staff or absence of guidance to enable action to take place – failure to monitor, observe or act, incorrect decision with hindsight, not seeking help when necessary.

Problems may be identified which are not associated with direct provision of care e.g. issues with decisions, procedures and systems – failure to undertake risk assessment, equipment failure.

5.5 Analysing the incident

The investigator (and/or team) should analyse the problems to identify contributory factors and root causes. For more detailed investigations an analytical tool such as fishbone, 5 Whys may be used to assist. Please see the Corporate Governance website and SEA and RCA methodology for further guidance regarding these tools. Contributory factors may be:

a) Communication factors (including verbal, written and non-verbal between individuals, teams and/or organisations)
b) Education and training factors (e.g. availability of and attendance at training)
c) Equipment and resource factors (e.g. clear machine displays, poor working order, size, placement, ease of use)

d) Medication factors (where one or more drugs directly contribute to the incident)
e) Organisation and strategic factors (e.g. organisational structure, contractor / agency use, culture)
f) Persons affected factors (e.g. clinical condition, social / physical / psychological factors, relationships)
g) Task factors (includes work guidelines / procedures / policies, availability of decision making aids)
h) Team and social factors (includes role definitions, leadership, support, and cultural factors)
i) Work and environment factors (e.g. poor/excess administration, physical environment, work load and hours of work, time pressures)

Root causes/causal factors

These are failures which had a direct causative affect on the incident. There may be more than one root cause in any incident although care should be taken to distinguish root causes from issues which merely contributed to the incident.
A root cause is a problem which, if resolved, will significantly reduce the risk of reoccurrence of the incident if not eliminate that risk entirely.

5.6 Generating solutions – Conclusions & Actions

5.6.1 Conclusions

Following analysis the key findings should be summarised along with issues that need to be addressed. Include any good practice identified as well as actions to be taken.
Formulate conclusions based upon available evidence.

5.6.2 Actions

Develop actions to help prevent or minimise recurrences thus reducing risk of future harm and ensuring patient safety is improved. Where appropriate include details of any ongoing engagement / contact with service users, family members or carers. Actions should be SMART i.e.:

- Specific (is it clear what is being asked and of who?);
- Measurable (ask yourself whether the action is auditable);
- Accountable (who is responsible for implementing the action);
- Realistic (consult with those persons able to deliver the action);
- Time-bound (there should be a clear timeframe for implementation).

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.*
Investigators should aim to have no more than 4-5 key actions (although it may be less); the important thing is that the actions reduce the likelihood of a reoccurrence of the incident.

5.6.3 Report and dissemination

The report should be clear, free of jargon, acronyms and names and using plain English. Where technical terms are necessary a glossary may be required.

It is important to note that unless there are specific exceptions, the patient or family of a patient have a right to the full investigation report under the Data Protection Act 1998 (ref NPSA Guidance on Writing and Investigation Report. Aug 08). The findings of the report should be shared with all other stakeholders as appropriate and ensuring confidentiality.
Further guidance on report writing, and example reports can be found on the Corporate Governance webpage on the hub.

5.6.4 Action Plans

Action Plans should be used for incidents graded Major severity or higher and high risk or higher. Lower grades than this may also use action plans where the actions require monitoring closely due to their complexity and/or cross service responsibility.
The individual accountable for the investigation has responsibility for ensuring the preparation of an action plan.

Developing an action plan

- Overall responsibility for the action plan must be with the individual who commissioned the Investigation.
- Where an action identified is outside the area of responsibility of the individual accountable for the investigation, discussion and agreement must be reached with the relevant manager for taking that action forward.
- Timescales for each action must be agreed with the person responsible for implementing the action.
- Every action plan should include the following:
    - The reference number of the incident
    - Date Investigation completed
    - Date of the latest version of the action plan
    - Version number

Monitoring
The individual accountable for the investigation is responsible for setting up directorate level monitoring and review processes to ensure actions are progressed as planned.

5.7 The Investigation process, where an Incident is also a Complaint.

When an adverse incident is being investigated and is also a complaint, the investigation will continue and the outcome of the investigation may form part of the complaint response.

6.0 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

7.0 CONSULTATION PROCESS

Clinical Directors
Associate Medical Directors
Corporate Governance Managers
Governance and Quality Managers
Health and Safety Managers
Licensing and Regulations Manager
Performance and Service Delivery Managers
Pharmacy Managers

8.0 EVIDENCE BASE

See Adverse Incident Reporting & Management Policy

9.0 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	X

SIGNATORIES

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

Date: 09.07.14

Name Dr T Stevens
Title Medical Director

Date: 09.07.14

Name Martin Dillon
Title Interim Chief Executive

Appendix 1

Belfast Health and Social Care Trust

LEVEL ONE – SIGNIFICANT EVENT AUDIT REPORT

TITLE:	
DATE OF SIGNIFICANT EVENT:	
DATE OF SIGNIFICANT EVENT MEETING:	
SEA FACILITATOR/ LEAD OFFICER:	
TEAM MEMBERS PRESENT:	

WHAT HAPPENED?

WHY DID IT HAPPEN?

WHAT HAS BEEN LEARNED?

WHAT HAS BEEN CHANGED?

RECOMMENDATIONS FOLLOWING THE LEVEL ONE SEA:

Where a Level two or three investigation is recommended please complete the sections below

THE INVESTIGATION TEAM :

INVESTIGATION TERMS OF REFERENCE:

LEVEL ONE – SIGNIFICANT EVENT AUDIT REPORT GUIDANCE

TITLE: *Insert unique identifier number*	*Self- explanatory*
DATE OF SIGNIFICANT EVENT:	*Self- explanatory*
DATE OF SIGNIFICANT EVENT MEETING:	*Self- explanatory*
SEA FACILITATOR/ LEAD OFFICER:	*Refer to guidance on Level one investigation team membership for significant event analysis –Appendix 9*
TEAM MEMBERS PRESENT:	*Self- explanatory*

WHAT HAPPENED?

(Describe in detailed chronological order what actually happened. Consider, for instance, how it happened, where it happened, who was involved and what the impact was on the patient/service user, the team, organisation and/or others).

WHY DID IT HAPPEN?

(Describe the main and underlying reasons contributing to why the event happened. Consider for instance, the professionalism of the team, the lack of a system or failing in a system, the lack of knowledge or the complexity and uncertainty associated with the event)

WHAT HAS BEEN LEARNED?

(Based on the reason established as to why the event happened, outline the learning identified. Demonstrate that reflection and learning have taken place on an individual or team basis and that relevant team members have been involved in the analysis of the event. Consider, for instance: a lack of education and training; the need to follow systems or procedures; the vital importance of team working or effective communication)

WHAT HAS BEEN CHANGED?

(Based on the understanding of why the event happened and the identification of learning, outline the action(s) agreed and implemented, where this is relevant or feasible. Consider, for instance: if a protocol has been amended, updated or introduced; how was this done and who was involved; how will this change be monitored. It is also good practice to attach any documentary evidence of change e.g. a new procedure or protocol.

Action plans should be developed and set out how learning will be implemented, with named leads responsible for each action point (Refer to Appendix 8 Minimum Standards for Action Plans). This section should clearly demonstrate the arrangements in place to successfully deliver the action plan).

RECOMMENDATIONS FOLLOWING THE LEVEL ONE SEA:

(Following the SEA it may become apparent that a more in depth investigation is required. Use this section to record if a Level two or three investigation is required).

Appendix 2

P.E.A.C.E. Interview Model

Planning & Preparation	Engage & Explain	Account Clarification & Challenge	Closure	Evaluation
•Plot events on a timeline for information retention •What is known about interviewee and what needs to be established •Points to prove, facts and issues •Practical issues (5 W's) •Aim & objectives •Written Plan	•Engage in a conversation •First impressions •Explain purpose of interview •Reasons, routines, outline, expectations •Assess needs of the interviewee	•Uninterrupted account •High use of questions summaries •Expanding & clarifying the account •Question loop.. Open, probe, summarise as appropriate, link •Done chronologically, methodically •Lock the person down into their account •Challenge the inconsistencies & contradictions •Use the words of the interviewee, words of others and contradictory information / evidence •Non accusatorial •Ask the interviewee to explain the differences between their account and the evidence	•Summarise account for mutual understanding •All areas fully covered •Explain future activities •Facilitate positive attitude of accurate and reliable information •Review needs of interviewee •Maintain professional style	• Evaluate information obtained • Aims & objectives reached • Re-evaluate evidence in investigation • Evaluate own performance • Evaluated by lead • Identify areas of improvement

Belfast Health and Social Care Trust
caring supporting improving together

Reference No: TP093/14

Title:	**Procedure for Investigating an Incident (excluding SAIs)**			
Author(s)	Claire Cairns, Senior Manager Corporate Governance Gillian Moore, Admin & Datix Manager			
Ownership:	Medical Directorate			
Approval by:	Policy Committee Executive Team		**Approval date:**	11th January 2018 24th January 2018
Operational Date:	January 2018		**Next Review:**	January 2023
Version No.	V2	**Supercedes**	V1 – June 2014 - 2017	
Links to other policies/ procedures	**Adverse Incident Reporting and Management Policy** Procedure for Reporting and Managing Adverse Incidents Procedure for Reporting and Managing Serious Adverse Incidents Procedure for Grading an Incident The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 (RIDDOR) Procedural Arrangements Guidance on Writing a Statement following an Incident Policy for Sharing Learning Being Open Policy Whistleblowing Policy			

Date	Version	Author	Comments
29/08/2013	0.1	S McCaul	Initial Draft
21/03/2014	0.2	P Keenan	Comments from Corporate Governance team
24th April 2013	1	Claire Cairns Gillian Moore	Final version
04/04/2014	0.3	S McCaul G Moore	Comments from Directorate & Corporate Governance colleagues
12/05/2014	0.4	S McCaul G Moore	Comments from Directorate & Corporate Governance colleagues
28/05/2014	0.5	S McCaul G Moore	Comments from Directorate & Corporate Governance colleagues
June 2014	0.6	Claire Cairns Gillian Moore	Revised version
29th November 2017	1.1	Gillian Moore	Interim update pending regional policy / procedures

1.0 INTRODUCTION

This procedure applies to ALL incidents which are considered *not* to meet Serious Adverse Incident (SAI) criteria. Please see SAI procedure for further guidance on SAIs.

All incidents should be subject to some level of review or investigation. The severity and / or risk grade of the incident will determine the level of review or investigation required.

For the purposes of this procedure the term 'investigation' will be used throughout to mean either informal review or formal investigation.

This procedure outlines the process of adverse incident (excluding SAIs) investigation including determining what level and type of investigation to adopt, a guide through the investigation process itself, subsequent action planning, sharing of lessons learned and audit to assure appropriate compliance with lessons learned.

2.0 PURPOSE

The purpose of this procedure is to enable a robust and systematic approach to the investigation of adverse incidents that will be consistently applied across the Trust.

3.0 SCOPE

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

1.0 INTRODUCTION TO INVESTIGATING AN INCIDENT

Many people feel that errors are random occurrences that are unpredictable and beyond control. It is true that chance will play a part in causing some incidents but a large majority of incidents are caused by systemic failures that follow a recurrent pattern. Moreover, if the cause of the incident can be identified, preventative changes can take place and true learning encouraged and shared.

The definition of an adverse incident is as follows:

"Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation"[1].

It is the responsibility of all staff who are involved in, witness to, or become aware of an adverse incident to ensure that this is reported and to complete a Trust Incident Report form.

The Belfast Health and Social Care Trust is committed to staff and service user safety and cooperation with statutory agencies with regard to the response to/and investigation of all incidents up to and including suspicious / unexpected death and serious untoward harm.

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

2.0 LEVEL OF INVESTIGATION REQUIRED

The grading of an incident by severity and risk will determine the requirements for investigating that incident. All incidents will therefore be graded according to severity (actual harm/impact) and risk. (See Procedure for Grading an Incident for further guidance.)

An immediate assessment of the incident grade should be undertaken to allow staff to progress appropriately, if in doubt staff should always grade the incident at the higher level. The incident severity and/or risk grade may require to be amended after further investigation.

Depending on the grade of incident an appropriate level of investigation should be carried out. All levels of investigation require some degree of evidence gathering, making sense of data, analysing problems, identifying cause(s), drawing up conclusions, identifying learning and actions to prevent reoccurrence.

A hot debrief should be considered. This is a review carried out as soon as possible after the incident. This is to identify any immediate learning that could influence future events as well as supporting staff involved.

Investigations should be carried out in accordance with the grading as follows:

2.1 Green – Insignificant or Minor Severity / Low Risk

Who investigates?
The investigation will be commissioned by the incident form approver. It should be investigated locally in the ward/facility in which the event occurred by the incident approver and/or their staff.

Methodology
The outcome of the investigation should be recorded on the investigation and learning section of the incident form. This should include any causes identified, further action taken or planned and any learning. Where no learning or actions are identified, this should be explained as it may be necessary to justify the reasoning behind the decisions at a later date. The investigation should normally be completed no later than 7 working days after the event.

If the investigation identifies any factual inaccuracies with the original incident details, these should be updated accordingly.

Once the investigation is complete and the incident record updated, the approving manager should code the approval status of the incident on Datixweb as ‘Approved, investigation complete’. This is not dependent on actions being outstanding.

Actions & Learning
The incident approver is responsible for ensuring all actions are completed and any learning shared as appropriate (see Policy for Sharing Learning for further guidance). Any actions which are not within the local team’s control or remain uncompleted should be communicated to a more senior manager for consideration.

2.2 Yellow – Moderate Severity / Medium Risk

Who investigates?
The Service Manager or Assistant Service Manager is accountable for ensuring that all investigations are carried out appropriately. The incident can be investigated and reviewed locally in the ward/facility in which the event occurred by the incident approver and their staff, however where the incident crosses professional and/or managerial boundaries, team membership should reflect this.

Methodology
As a first step consider use of Significant Event Audit (SEA) methodology which is an appropriate technique for this level of investigation. The investigation details should be recorded on the SEA template (Appendix 1) which should be attached to the incident record. A note that the template has been attached should be added to the investigation and learning section of the incident form.

If SEA methodology is deemed not appropriate, the outcome of the investigation should be recorded on the investigation and learning section of the incident form. This should include any causes identified, further action taken or planned and any learning. Where no learning or actions are identified, this should be explained as it may be necessary to justify the reasoning behind the decisions at a later date. The investigation should normally be completed no later than 4 weeks after the event.

If the investigation identifies any factual inaccuracies with the original incident details, these should be updated accordingly.

Once the investigation is complete and the incident record updated, the approving manager should code the approval status of the incident on Datixweb as 'Approved, investigation complete'. This is not dependent on actions being outstanding.

Actions & Learning
The Service Manager or Assistant Service Manager are responsible for ensuring all actions are completed and any learning shared as appropriate (see Policy for Sharing Learning for further guidance). Any actions which remain uncompleted should be communicated to a more senior manager for consideration.

2.3 Amber – Major Severity / High Risk (and not an SAI)

Who investigates?
The Co-Director is accountable for ensuring that all investigations are carried out appropriately. The incident should be investigated and reviewed locally by more than one person and the team should include someone independent from the specialty. Where the incident crosses professional and/or managerial boundaries, team membership should reflect this. More guidance on team membership is available in the Significant Event Audit (SEA) guidance.

Methodology
As a first step consider use of Significant Event Audit (SEA) methodology which is an appropriate technique for this level of investigation. The investigation details should be recorded on the SEA template (Appendix 1) which should be attached to the incident record. A note to this effect should be added to the investigation and learning section of the incident form.

If during the SEA process, it is felt that further analysis is required, the process should transfer to Root Cause Analysis (RCA) methodology. A summary of the results of the investigation should be recorded on the investigation and learning section of the incident form. This should include any causes identified, further action taken or planned and any learning. The investigation report should also be attached to the incident record. Where no learning or actions are identified, this should be explained as it may be necessary to justify the reasoning behind the decisions at a later date. The investigation should normally be completed no later than 12 weeks after the event.
If the investigation identifies any factual inaccuracies with the original incident details, these should be updated accordingly.

Once the investigation is complete and the incident record updated, the approving manager should code the approval status of the incident on Datixweb as 'Approved, investigation complete'. This is not dependent on actions being outstanding.

Actions & Learning
The Co-Director is responsible for ensuring all actions are completed and any learning shared as appropriate (see Policy for Sharing Learning for further guidance).

2.4 Red – Catastrophic Severity or Extreme Risk (and not an SAI)

Who investigates
The Co-Director or Director is accountable for ensuring that all investigations are carried out appropriately. The incident should be investigated and reviewed locally by more than one person and the team should include someone independent from the specialty. Where the incident crosses professional and/or managerial boundaries, team membership should reflect this. More guidance on team membership is available in the Significant Event Audit (SEA) guidance and RCA guidance.

Methodology
Depending on the nature of the incident it may be subject to specific formal Trust investigation process e.g. Case Management Review (CMR), Morbidity & Mortality (M&M) meeting or Cardiac Arrest review. If this is not the case the incident should be subject to SEA or RCA methodology as per Amber section.

A summary of the results of the investigation should be recorded on the investigation and learning section of the incident form. This should include any causes identified, further action taken or planned and any learning. The investigation report should also be attached to the incident record. Where no learning or actions are identified, this should be explained as it may be necessary to justify the reasoning behind the decisions at a later date. The investigation should normally be completed no later than 12 weeks after the event.

If the investigation identifies any factual inaccuracies with the original incident details, these should be updated accordingly.

Once the investigation is complete and the incident record updated, the approving manager should code the approval status of the incident on Datixweb as 'Approved, investigation complete'. This is not dependent on actions being outstanding.

Actions & Learning

The Co-Director or Director are responsible for ensuring all actions are completed and any learning shared as appropriate (see Policy for Sharing Learning for further guidance). This should include any actions or learning identified as a result of other formal Trust investigation processes e.g. M&M, Cardiac Arrest review.

2.5 Summary Table: Level of Investigation

Severity / Risk Grade	Insig.	Minor	Moderate	Major	Catastrophic
	Low		Medium	High	Extreme
Investigation Commissioner	Incident form approver		Service Manager / Asst Service Manager	Co-Director	Director / Co-Director
Investigation duration (guide)	No more than 7 working days		No more than 4 weeks	No more than 12 weeks	No more than 12 weeks
Form	Incident Form		Incident Form (Consider use of SEA template)	SEA template / RCA template (and attach to Datixweb incident record)	SEA template / RCA template (and attach to Datixweb incident record)
Actions	Local implementation / record on incident form.		Local implementation / record on incident form.	Formally monitored.	Formally monitored.
Learning	Record on incident form / shared locally. Patient / Service User / Family informed as appropriate		Record on Datixweb incident form / shared locally. Patient / Service User / Family informed as appropriate	Record on incident form. Shared locally within Directorate. If learning applicable beyond Directorate, Co-Director to share through appropriate Assurance sub-committee. Patient / Service User / Family informed as appropriate	Record on incident form. Shared locally within Directorate. If learning applicable beyond Directorate, Co-Director to share through appropriate Assurance sub-committee. Patient / Service User / Family informed as appropriate

2.6 Incidents involving Non-HSC Organisations

Where incidents are of a serious nature and may include required involvement from other organisations, the Memorandum of Understanding Investigating patient or client safety incidents (Unexpected Death & Serious Untoward Harm) should be used to ensure appropriate investigation on the part of the Trust. This document will guide on which organisation leads and the roles of each in the investigation. Certain investigations or aspects of them may be for others to take forward and therefore the scope of the Trust investigation may be affected.

2.7 Potential Disciplinary / Performance Issues

Incident investigation is designed principally to identify and draw out learning in order that this can be shared, however where an incident involves potential disciplinary or performance issues it is important to follow Human Resources policy and procedures at an early stage. The NPSA Incident Decision Tree can be helpful in identifying these issues early in the investigation process.

3.0 HOW TO INVESTIGATE

The investigation should focus on five key areas:

- **WHAT** - this is detail / specifics in relation to incident / investigation, the actual event and its impact and consequences if any
- **WHERE** - the location / site / area of the incident/ significant in that it may be important in securing evidence / making the scene safe for others and protecting any evidence that may contribute to the investigation
- **WHEN** - the timings / event / notification / resolution from the time of the actual event to the reporting and remedial action, the arrival of assistance and / or other persons involved.
- **WHO** - all persons involved in the incident / investigation, injured parties / witnesses and any others person who have a material contribution to make in terms of the investigation process (remembering that the person(s) affected may also be witnesses)
- **WHY** - findings of the investigation / cause identification / learning to be shared

Of the five areas the WHY is the last to be considered as this will reduce likelihood of jumping to an initial conclusion without due consideration of the facts and causes.

The following sections (3.1 to 3.6) outline the requirements for investigating an incident. The level of detail required should be proportionate to the grading and complexity of the incident.

3.1 Record keeping

Appropriate documentation, including written submissions of witness from staff (see Guidelines on Writing a Statement following an Incident) is required to be recorded and retained in line with good record keeping guidance.

A thorough record of all the investigation activity should be recorded in the appropriate field in Datixweb or added as an attachment to the incident record. Investigators should be aware that the investigation documentation will be covered by the Data Protection Act and will potentially be disclosed to persons outside of the organisation, including the subject of any report.

Once complete, the investigation file should be referenced and filed locally, together with a copy of the final report and completed action plan in accordance with the Trust's Records Retention Schedule. A copy of the final report and action plan, where available, should be attached to the Datixweb record.

3.2 Communicating with and involving patients / service users / families / carers

Staff should follow the Being Open Policy in relation to communicating with patients / service users/ families / carers.

It is important that teams involved in investigations of any incidents where harm occurred, ensure sensitivity to the needs of the patients/service user/relatives/carers involved and agree communication arrangements, where appropriate.
The accountable person should ensure the appropriate level of involvement of patient / service user / family / carer throughout the investigation including discussion / sharing of the final report with the patient / service user / family / carer. The level of involvement clearly depends on the nature of the incident and the patient/service users/relatives/carers wishes to be involved.

3.3 Securing evidence & gathering information

Investigators may find it helpful to consider information from a range of sources including:

- The people involved in or witnessing the event
- The place or environment in which the event took place
- The equipment or objects involved in the event
- The paper work related to the event (e.g. policies, procedures, clinical records, incident reports, risk assessments, maintenance records, clinical audits, training records)
- The widely held beliefs about the normal work processes, team relationships and adequacy of leadership in the workplace.

This list is not exhaustive.

Where required the immediate area should be secured and access be limited until such time as to allow an opportunity to access the scene and record any relevant observations (this may include taking photographs of the scene or measurements).

All material evidence, including written documentation (or copies of), relating to the incident should be gathered and secured as soon as possible after the event. This is particularly important in relation to the timely seizing of CCTV where available, as such evidence may be on a time limited system.

3.3.1 Time Period to be Investigated

From the initial assessment, decide on the time period (start and end dates) that needs to be investigated. This is essential as it determines the information and evidence required. You may therefore need to consider the lead up to and aftermath, as well as the incident itself.
Describe what happened with facts, not opinions, using tools such as a chronology narrative and/or tabular timeline. Avoid the use of abbreviations and medical terms as this may form part of the investigation report which may be read by service users / families/ carers etc. Investigators are encouraged not to pre-judge which events are significant / insignificant in advance of compiling a timeline.

3.3.2 Obtaining Personal Accounts of the Incident

Witnesses to the event and those involved in the incident should be given the opportunity to provide a personal account as to what has occurred.
The PEACE model can be utilised for structured discussion with staff to obtain accounts, if considered appropriate (Appendix 2).
This structured discussion should be carried out in a supportive way, to ascertain the following:

- the role of the witness or those involved in the event and the extent of their involvement.
- The patient and/or relatives/carers account of the incident should be obtained if appropriate.
- the chronology and details of the incident time period
- what problems, action(s), inaction(s) resulted in the incident
- what records, guidelines, equipment were involved
- any other contributory factors e.g. where custom and practice may have deviated from policy and procedure.

3.3.3 Witness statements

Once statements have been received, the lead investigator may wish to speak to staff in person to help clarify part of a statement or account. Any written evidence may become "disclosed" in the event of subsequent legal action and care should be taken in its formulation to include only relevant facts of what actually happened, not what people thought happened. There should be no opinion on who is at fault or any speculation on causes. Forms should be fully completed and all information requested completed.

For further details on Witness Statements please see Guidelines on Writing a Statement following an Incident.

3.3.4 Equipment
For some incidents site visit(s) and liaison with manufacturers and/or suppliers, contractors and/or other agencies/individuals involved may be needed. Any piece of equipment involved in the incident should be removed and preserved as evidence where possible. For further information see Medical Devices Procedures and Guidelines.

3.3.5 Environment – The place in which the incident occurred
Investigators should visit the actual area, if relevant, where the incident took place, preferably before any changes are made and note the layout. A sketch of the area and its layout may be useful particularly if annotated with the location of persons involved in the incident, and other witnesses to the incident. Photographic evidence of the environment can be invaluable.

3.3.6 Evidence storage
Any non-clinical evidence gathered should be attached to the Datixweb incident record e.g. documents, photographs, emails, letters, faxes etc., in order to maintain a complete record of the investigation. If attaching clinical evidence to the Datixweb incident record, the Data Protection Policy must be adhered to. Alternatively this evidence may be retained in a separate file and the location and holder of the file should be clearly recorded on the Datixweb record.

3.4 Identifying problems

A number of tools can be used for identifying the problems e.g. Multidisciplinary meeting, brainstorming / brainwriting, Nominal group technique etc. Please see the Corporate Governance Hub site and SEA and RCA methodology for further guidance regarding these tools.

Problems may relate to the direct provision of care e.g. actions or omissions by staff or absence of guidance to enable action to take place – failure to monitor, observe or act, incorrect decision with hindsight, not seeking help when necessary.

Problems may be identified which are not associated with direct provision of care e.g. issues with decisions, procedures and systems – failure to undertake risk assessment, equipment failure.

3.5 Analysing the incident

The investigator (and/or team) should analyse the problems to identify contributory factors and root causes. For more detailed investigations an analytical tool such as fishbone, 5 Whys may be used to assist. Please see the Corporate Governance Hub site and SEA and RCA methodology for further guidance regarding these tools.
Contributory factors may be:
a) Communication factors (including verbal, written and non-verbal between individuals, teams and/or organisations)
b) Education and training factors (e.g. availability of and attendance at training)
c) Equipment and resource factors (e.g. clear machine displays, poor working order, size, placement, ease of use)
d) Medication factors (where one or more drugs directly contribute to the incident)

e) Organisation and strategic factors (e.g. organisational structure, contractor / agency use, culture)
f) Persons affected factors (e.g. clinical condition, social / physical / psychological factors, relationships)
g) Task factors (includes work guidelines / procedures / policies, availability of decision making aids)
h) Team and social factors (includes role definitions, leadership, support, and cultural factors)
i) Work and environment factors (e.g. poor/excess administration, physical environment, work load and hours of work, time pressures)

Root causes/causal factors

These are failures which had a direct causative affect on the incident. There may be more than one root cause in any incident although care should be taken to distinguish root causes from issues which merely contributed to the incident.
A root cause is a problem which, if resolved, will significantly reduce the risk of reoccurrence of the incident if not eliminate that risk entirely.

3.6 Generating solutions – Conclusions & Actions

3.6.1 Conclusions
Following analysis the key findings should be summarised along with issues that need to be addressed. Include any good practice identified as well as actions to be taken.
Formulate conclusions based upon available evidence.

3.6.2 Actions
Develop actions to help prevent or minimise recurrences thus reducing risk of future harm and ensuring patient safety is improved. Where appropriate include details of any ongoing engagement / contact with service users, family members or carers.
Actions should be SMART i.e.:

- Specific (is it clear what is being asked and of who?);
- Measurable (ask yourself whether the action is auditable);
- Accountable (who is responsible for implementing the action);
- Realistic (consult with those persons able to deliver the action);
- Time-bound (there should be a clear timeframe for implementation).

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*.
Investigators should aim to have no more than 4-5 key actions (although it may be less); the important thing is that the actions reduce the likelihood of a reoccurrence of the incident.

3.6.3 Report and dissemination
The report should be clear, free of jargon, acronyms and names and using plain English. Where technical terms are necessary a glossary may be required.

It is important to note that unless there are specific exceptions, the patient / service user or family of a patient / service user have a right to the full investigation report under the Data Protection Act 1998 (ref NPSA Guidance on Writing and Investigation Report. Aug 08). The findings of the report should be shared with all other stakeholders as appropriate and ensuring confidentiality.

3.6.4 Action Plans

Action Plans should be generated for incidents graded as major or catastrophic severity and high or extreme risk. Lower grades than this may also use action plans where the actions require monitoring closely due to their complexity and/or cross service responsibility.

The individual accountable for the investigation has responsibility for ensuring the preparation of an action plan.

Developing an action plan

- Overall responsibility for the action plan must be with the individual who commissioned the Investigation.
- Where an action identified is outside the area of responsibility of the individual accountable for the investigation, discussion and agreement must be reached with the relevant manager for taking that action forward.
- Timescales for each action must be agreed with the person responsible for implementing the action.
- Every action plan should include the following:
    - The reference number of the incident
    - Date Investigation completed
    - Date of the latest version of the action plan
    - Version number

Monitoring

The individual accountable for the investigation is responsible for setting up directorate level monitoring and review processes to ensure actions are progressed as planned.

Learning

Where learning has been identified, this should be shared as appropriate (see the Policy for Sharing Learning)

3.7 The Investigation process, where an Incident is also a Complaint.

When an adverse incident is being investigated and is also a complaint, the investigation will continue and the outcome of the investigation may form part of the complaint response.

SIGNATORIES

_____ **Date:** 24 January 2018

Name Dr Cathy Jack
Title Deputy Chief Executive/ Medical Director

_____ **Date:** 24 January 2018

Name Martin Dillon
Title Chief Executive

Appendix 1

Belfast Health and Social Care Trust

LEVEL ONE – SIGNIFICANT EVENT AUDIT REPORT

TITLE:	
DATE OF SIGNIFICANT EVENT:	
DATE OF SIGNIFICANT EVENT MEETING:	
SEA FACILITATOR/ LEAD OFFICER:	
TEAM MEMBERS PRESENT:	

WHAT HAPPENED?

WHY DID IT HAPPEN?

WHAT HAS BEEN LEARNED?

WHAT HAS BEEN CHANGED?

RECOMMENDATIONS FOLLOWING THE LEVEL ONE SEA:

Where a Level two or three investigation is recommended please complete the sections below

THE INVESTIGATION TEAM :

INVESTIGATION TERMS OF REFERENCE:

LEVEL ONE – SIGNIFICANT EVENT AUDIT REPORT GUIDANCE

TITLE: *Insert unique identifier number*	*Self- explanatory*
DATE OF SIGNIFICANT EVENT:	*Self- explanatory*
DATE OF SIGNIFICANT EVENT MEETING:	*Self- explanatory*
SEA FACILITATOR/ LEAD OFFICER:	*Refer to guidance on Level one investigation team membership for significant event analysis –Appendix 9*
TEAM MEMBERS PRESENT:	*Self- explanatory*

WHAT HAPPENED?

(Describe in detailed chronological order what actually happened. Consider, for instance, how it happened, where it happened, who was involved and what the impact was on the patient/service user, the team, organisation and/or others).

WHY DID IT HAPPEN?

(Describe the main and underlying reasons contributing to why the event happened. Consider for instance, the professionalism of the team, the lack of a system or failing in a system, the lack of knowledge or the complexity and uncertainty associated with the event)

WHAT HAS BEEN LEARNED?

(Based on the reason established as to why the event happened, outline the learning identified. Demonstrate that reflection and learning have taken place on an individual or team basis and that relevant team members have been involved in the analysis of the event. Consider, for instance: a lack of education and training; the need to follow systems or procedures; the vital importance of team working or effective communication)

WHAT HAS BEEN CHANGED?

(Based on the understanding of why the event happened and the identification of learning, outline the action(s) agreed and implemented, where this is relevant or feasible. Consider, for instance: if a protocol has been amended, updated or introduced; how was this done and who was involved; how will this change be monitored. It is also good practice to attach any documentary evidence of change e.g. a new procedure or protocol.

Action plans should be developed and set out how learning will be implemented, with named leads responsible for each action point (Refer to Appendix 8 Minimum Standards for Action Plans). This section should clearly demonstrate the arrangements in place to successfully deliver the action plan).

RECOMMENDATIONS FOLLOWING THE LEVEL ONE SEA:

(Following the SEA it may become apparent that a more in depth investigation is required. Use this section to record if a Level two or three investigation is required).

Appendix 2

P.E.A.C.E. Interview Model

Planning & Preparation	Engage & Explain	Account Clarification & Challenge	Closure	Evaluation
•Plot events on a timeline for information retention •What is known about interviewee and what needs to be established •Points to prove, facts and issues •Practical issues (5 W's) •Aim & objectives •Written Plan	•Engage in a conversation •First impressions •Explain purpose of interview •Reasons, routines, outline, expectations •Assess needs of the interviewee	•Uninterrupted account •High use of questions summaries •Expanding & clarifying the account •Question loop.. Open, probe, summarise as appropriate, link •Done chronologically, methodically •Lock the person down into their account •Challenge the inconsistencies & contradictions •Use the words of the interviewee, words of others and contradictory information / evidence •Non accusatorial •Ask the interviewee to explain the differences between their account and the evidence	•Summarise account for mutual understanding •All areas fully covered •Explain future activities •Facilitate positive attitude of accurate and reliable information •Review needs of interviewee •Maintain professional style	• Evaluate information obtained • Aims & objectives reached • Re-evaluate evidence in investigation • Evaluate own performance • Evaluated by lead • Identify areas of improvement

Belfast Health and Social Care Trust
caring supporting improving together

Reference No: TP 111/20

Title:	**Memorandum of Understanding policy - Investigating Service User Safety Incidents**		
Author(s)	Claire Cairns, Co-Director, Risk & Governance Tel: [redacted] Robert Henry, Senior Manager, Corporate Governance Tel: [redacted] Gillian Harkness, Governance Manager, Corporate Governance Tel: [redacted]		
Ownership:	Dr Chris Hagan, Medical Director		
Approval by:	Trust Policy Committee Executive Team Meeting	**Approval date:**	04 June 2020 10 June 2020
Operational Date:	June 2020	**Next Review:**	June 2025
Version No.	1 **Supercedes**	New policy	
Key Words:	Memorandum of Understanding (MOU)		
Links to other policies	BHSCT Adverse Incident Reporting and Management Policy (2018) TP 08/08 BHSCT Serious Adverse Incident Procedure (2016) TP 97/14 BHSCT Being Open Policy – saying sorry when things go wrong (2020) TP 80/11 BHSCT Supporting Staff at Court Policy		

Date	Version	Author	Comments
14 May 2020	0.1	Gillian Harkness	Initial draft from Regional HSCB Policy for review by Trust Policy Committee

Table of Contents

1.0 INTRODUCTION/PURPOSE OF POLICY

1.1 Background

On 15 March 2013, the Department of Health (DoH) issued a revised Memorandum of Understanding (MOU) for Investigating Service User Safety Incidents involving unexpected death and serious untoward harm.

1.2 Purpose

The purpose of this policy is to promote effective relationships with the Police Service of Northern Ireland (PSNI), Coroner's Office and the Health & Safety Executive (HSENI), and improve appropriate information sharing and co-ordination to save time and other resources when joint or simultaneous investigations are required into a serious incident that caused unexpected death or serious untoward harm. **This is likely to be the case when an incident has occurred from, or involved, criminal intent, recklessness and/or gross negligence, or in the context of health and safety, a work-related death.**

1.3 Definitions

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

Service User[1] refers to a patient, service user, family (of a service user and/or family of a victim), carer or nominated representative.

2.0 SCOPE OF POLICY

2.1 The Trust has a responsibility to ensure the safety and well-being of service users and staff and to investigate when things go wrong, occasionally involving other agencies.

2.2 Some accidents to service users have a requirement to be reported to HSENI by the Trust, under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) Northern Ireland 1997. HSENI will normally investigate all reportable incidents 'arising out of or in connection with work' but not accidents that arise from medical treatment or diagnosis.

2.3 In situations where the same incident is subject to investigation by a number of separate organisations, it is essential there is clarity of roles and responsibilities by effective liaison and communication between all parties involved.

[1] As per the draft statement of what you should expect in relation to a Serious Adverse Incident (SAI) Review, January 2019.

3.0 ROLES AND RESPONSIBILITIES: TRUST STAFF AND OTHER RELEVANT BODIES

3.1 It is the responsibility of all line managers to ensure this policy is brought to the attention of relevant staff. Staff must familiarise themselves with, and adhere to, the contents of this policy. This policy should be read in conjunction with the Trust's Adverse Incident and SAI Reporting & Management Policies.

3.2 In cases where more than one organisation may have an involvement in investigating any particular incident it is the responsibility of the Director (or nominee) to liaise with each of the organisations.

3.3 The PSNI may investigate all criminal offences. The types of incident the Trust will report to the PSNI are those that display any one or more of the following characteristics: -

- Evidence or suspicion that the actions leading to harm were intended;
- Evidence or suspicion that adverse consequences were intended;
- Evidence or suspicion of gross negligence and/or recklessness including as a result of failure to follow safe practice or procedure or protocols.

3.4 The HSENI is responsible for the enforcement of the Health and Safety at Work (Northern Ireland) Order 1978 (HSWO). Generally, the HSENI does not seek to apply the HSWO to clinical judgment or to the level of provision of care. However, HSENI is responsible for enforcing work related health and safety legislation in a large variety of settings including nursing homes and hospitals. District councils have this responsibility for residential facilities within the Trust area.

3.5 Coroners have a responsibility under the Coroners Act (Northern Ireland) 1959 to investigate the cause and circumstances of deaths reported to them. Appendix 1 sets out guidelines on reporting deaths to the Coroner.

3.6 Other organisations may also investigate service user or safety incidents locally and/or nationally. These include the Health and Social Care Board (HSCB), the Regulation and Quality Improvement Authority (RQIA), Northern Ireland Adverse Incident Centre (NIAIC) and professional regulatory bodies.

3.7 In line with the Regional Procedure for Reporting and Follow Up of Serious Adverse Incidents (November 2016) – section 3.5.1, the Trust will consider invoking the Memorandum of Understanding when reviewing a serious adverse incident that involves any of those organisations noted above.

4.0 KEY POLICY PRINCIPLES

4.1 Definitions

4.1.1 Preliminary Meeting: An initial meeting between the Trust and relevant parties to collate initial information about the incident.

4.1.2 Incident Co-ordination Group (ICG): This group is set up to provide strategic oversight of a service user safety incident or direct safety incident involving multiple investigations.

4.2 Preliminary Meeting and Commissioning an Incident Coordination Group (ICG) Coordination of investigatory activities, responsibility and investigation and documenting the ICG

4.2.1 Where more than one organisation is involved, the Director (or nominee) will make arrangements with the relevant organisations to attend a preliminary meeting.

4.2.2 The purpose of this meeting will be for a Trust representative to brief the various parties on the circumstances so that they can decide where responsibility for investigation lies.

4.2.3 The Director (in conjunction with the Assistant Director /Co-Director) will be the named Trust contact to facilitate ongoing communication and liaison.

4.2.4 The preliminary meeting is to be followed by an Incident Coordination Group (ICG) meeting. The purpose of this is to provide strategic oversight of a service user safety incident involving multiple investigations. It allows each organisation involved to identify actions to be taken that do not prejudice the work of other organisations e.g. legal proceedings. The information that may be shared will be constrained by the requirements of any criminal investigation and disclosure restrictions.

4.2.5 The Trust should continue to ensure service user safety but not undertake any activity that might compromise subsequent statutory investigations. If in doubt the Trust's Assistant Director/Co-Director will seek legal advice and consult with the PSNI, Coroner, HSENI or other investigating bodies.

4.2.6 Those attending the ICG should be sufficiently senior to take decisions concerning the management of the incident. Police representation would be at the level of Detective Chief Inspector. The Trust's representation will be the Director (or nominee) supported by the Assistant Director /Co-Director of the Directorate where the incident occurred.

4.2.7 The statutory investigating bodies will come to an early decision about the nature of the incident and where responsibility for investigation should lie e.g. the PSNI and HSENI may conclude they have no further role in the matter. On some occasions the Trust may have to investigate further and if more information or evidence is found, another ICG meeting may have to be convened.

4.2.8 On some occasions the incident may cause concern about wider service user safety. In such circumstances the ICG needs to discuss if the necessary further investigation can be conducted to avoid the danger of prejudicing the police, coroner and/or HSENI investigation e.g. by interviewing members of staff who may subsequently give evidence at court. The PSNI have the authority to prevent the Trust from undertaking an investigation until its investigation is completed in the event that it might prejudice their investigation. However, this should not prevent the Trust from ensuring that immediate learning is undertaken.

4.2.9 The Trust is responsible for minuting the ICG meeting(s) and circulating them to other members. If the Trust has been excluded the ICG must agree who will minute the meeting.

4.3 Securing and Preserving Evidence

4.3.1 The safeguarding of physical, scientific and documentary evidence (including CCTV where applicable) may be critical to understanding what happened in a serious incident and promote a satisfactory investigation. Destruction of evidence may prevent or delay adequate safety measures being put in place and may lead to a more complex investigation. Documentation (including any CCTV footage) should be secured in line with the Trust's policy on securing records and any Trust Policy on the handling of forensic items.

4.3.2 Where a criminal offence is suspected, failure to retain evidence may mean that legal proceedings are undermined. Even in incidents where concerns arise after a long time period every effort to secure and preserve all available evidence should be made.

4.3.3 When Trust documents, records or other items are required to be passed to other agencies then the Director (or nominee) should liaise with the Information Governance Department to ensure that procedures are followed in line with relevant Trust policies and legislative requirements such as GDPR.

4.4 Sharing Information

4.4.1 There will be a need for organisations in the ICG to share information for the purposes of coordinating multiple investigations.

4.4.2 There are a number of factors to take account of when making judgments about information sharing including: -

- The nature and degree of risk;
- The purpose;
- Consent;
- Justification for breach of patient/client confidentiality;
- Current law and guidance; and
- Confidentiality agreements.

4.4.3 Advice on sharing of information can be sought from the Trust's Information Governance Department and/or the Trust's Legal team.

4.5 Supporting Those Affected

4.5.1 The Trust should agree and follow a liaison strategy for each incident, agreed at the first meeting and reviewed at subsequent meetings. This should include keeping the relevant affected parties informed.

4.5.2 When an incident involves litigation then reference should be made to the Trust Policy Supporting Staff a Court.

4.5.3 Staff involved in incidents should be made aware of the support available from a Trade Union Representative and/or Trade Union appointed legal representative.

4.6 Communications

4.6.1 A strategy will be agreed by all relevant parties for dealing with the media, service users and relatives. The organisations should take a common approach to communication although in the event of legal proceedings this may not be practicable. Legal advice will be sought by the Trust, as required.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

This policy will be disseminated to all relevant Operational and Corporate Directorates and will be available on the Trust's intranet site.

5.2 Resources

The Audit and Risk & Governance Departments will be responsible for organising awareness and/or training sessions for all relevant managers and staff in relation to this policy, as appropriate.

5.3 Exceptions

This policy is applicable to all service areas within the Trust.

6.0 MONITORING

This policy will be audited through the Audit and Risk & Governance Departments.

7.0 EVIDENCE BASE / REFERENCES

- Memorandum of Understanding: Investigating Patient Safety Incidents Involving Unexpected Death and Serious Untoward Harm: Promoting liaison and effective communications between the Health and Social Care, Police Service of Northern Ireland, Coroners Service for Northern Ireland, and the Health & Safety Executive for Northern Ireland [HSS(MD) 8/2013 – 15 March 2013
- https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-8-2013.pdf
- https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/mou-patient-client-safety-incidents.pdf
- HSENI Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) NI 1997
- Guidelines for Notifying the Coroner of a Death - https://www.health-ni.gov.uk/sites/default/files/publications/health/Guidelines%20for%20Notifying%20the%20Coroner%20of%20a%20Death.pdf

8.0 CONSULTATION PROCESS

- Standards & Guidelines Committee

9.0 APPENDICES / ATTACHMENTS

- Appendix 1 – Reporting Deaths to the Coroner

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 policy should be subject to a full impact assessment has been carried out.

The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact. ☒

11.0 DATA PROTECTION IMPACT ASSESSMENT

New activities that involve collecting and using personal data can result in privacy risks. In line with requirements of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 the Trust has to consider the impacts on the privacy of individuals and ways to mitigate against the risks. Where relevant an initial screening exercise should be carried out to ascertain if this policy should be subject to a full impact assessment. The guidance for conducting a Data Protection Impact Assessments (DPIA) can be found via this **link**.
The outcome of the DPIA screening for this policy is:

Not necessary – no personal data involved ☐

A full data protection impact assessment is required ☐

A full data protection impact assessment is not required ☐

If a full impact assessment is required the author (Project Manager or lead person) should go ahead and begin the process. Colleagues in the Information Governance Team will provide assistance where necessary.

12.0 RURAL IMPACT ASSESSMENTS

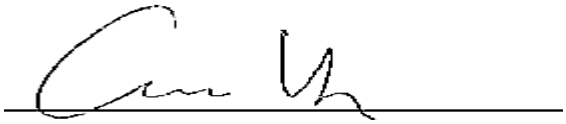
From June 2018 the Trust has a legal responsibility to have due regard to rural needs when developing, adopting, implementing or revising policies, strategies and plans, and when designing and delivering public services.
It is your responsibility as policy or service lead to consider the impact of your proposal on people in rural areas – you will need to refer to the shortened rural needs assessment template and summary guidance on the Belfast Trust Intranet. Each Directorate/Division has a Rural Needs Champion who can provide support/assistance in this regard if necessary.

13.0 REASONABLE ADJUSTMENTS ASSESSMENT

Under the Disability Discrimination Act 1995 (as amended), the Trust has a duty to make reasonable adjustments to ensure any barriers disabled people face in gaining and remaining in employment and in accessing and using goods and services are removed or reduced. It is therefore recommended the policy explicitly references "reasonable adjustments will be considered for people who are disabled - whether as service users, visitors or employees.

SIGNATORIES

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



Date: 17/08/2020

Chris Hagan
Medical Director

Date: 18/08/2020

Cathy Jack
Chief Executive

Appendix One: Deaths that must be reported to the Coroner

The duty to report arises if a medical practitioner has reason to believe that the deceased person (to include a fetal demise in utero, beyond the legal limit for viability (24 weeks) and considered to be 'then capable of being born alive') died directly *or* indirectly,

- as a result of violence, misadventure or by unfair means;

- as a result of negligence, misconduct or malpractice (e.g. where a medical mishap is alleged);

- from any cause other than natural illness or disease, for example:

    i. homicidal deaths or deaths following assault;
    ii. road traffic accidents or work-related accidents;
    iii. injury, direct or indirect (including birth injury);
    iv. deaths associated with the misuse of drugs (whether accidental or deliberate);
    v. any apparently suicidal death; or
    vi. all deaths from industrial or occupational disease e.g. asbestosis.

- from natural illness or disease if the deceased had not been seen and treated for it by a registered medical practitioner within 28 days prior to death; or

- in other circumstances that may require investigation; for example:

    i. the death, although apparently natural, was unexpected;
    ii. Sudden Unexpected Death in Infancy (SUDI);
    iii. as the result of an operation, following a procedure or where a person has had an accident or adverse incident in the hospital environment;
    iv. as the result of the administration of an anaesthetic, e.g. hypoxia, circulatory failure, drug reaction, (there is no statutory requirement to report a death occurring within 24hours of an operation – though it may be prudent to do so).

Doctors should also consider the extra-statutory list of causes of death that are referable to the Coroner. If in doubt, seek advice from the Coroner's Office.

1. Industrial diseases or poisoning and other poisonings

    a. Industrial lung diseases e.g. asbestosis, pneumoconiosis, extrinsic allergic alveolitis.
    b. Other industrial diseases e.g. mesothelioma, leptospirosis.
    c. Industrial poisoning e.g. heavy metal, chemicals.
    d. Other poisonings e.g. Food poisoning, Tetanus.

2. Death resulting from an injury

    a. Injury e.g. Asphyxia, Drowning, Intracranial Haemorrhage.
    b. Indirect injury e.g. pneumonia following a fractured femur.
    c. Birth injury.
    d. Operation / Anaesthetic.

NB: There is no requirement to report Clostridium deaths to the Coroner's Office. Deaths which are considered to be due to the Coronavirus are considered "natural" and do not need to be reported to the Coroner, however, where there is any concern surrounding a death, as per section 7 of the Coroners Act (NI) 1959, the death must be reported. A Coroner has discretion to investigate any death about which a concern has been raised. Therefore, should concerns be raised in relation to a death from Covid-19, the Coroner could investigate on a case by case basis, based on the individual merits of each case.