NHS
National Patient Safety Agency
National Reporting and Learning Service

National Framework for Reporting and Learning from Serious Incidents Requiring Investigation

Contents

Document overview

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Contact Details	Patient Safety Direct Programme Team National Patient Safety Agency 4-8 Maple Street, LONDON W1T 5HD Tel: 020 7927 9500 Email: patientsafetydirect@npsa.nhs.uk

Foreword

Commissioners, providers and managers of NHS care want to ensure that when a serious event or incident occurs, there are systematic measures in place for safeguarding patients, property, NHS resources and reputation.

One of the building blocks for doing this is a clear, nationally agreed approach to notifying, managing and learning from serious incidents.

Working closely with individuals from across the NHS, this framework has been developed to provide a system-wide perspective on serious incidents occurring in the NHS and for the independent sector where it provides NHS services in England. The framework seeks to provide a consistent definition of a serious incident, clarify roles and responsibilities, draw together legal and regulatory requirements, provide information on timescales and to signpost tools and resources that support good practice. It is designed to facilitate openness, trust, continuous learning and service improvement.

The framework is an important foundation for Patient Safety Direct. The National Patient Safety Agency leads on developing Patient Safety Direct in partnership with other arm's length bodies, taking forward recommendations from the NHS Next Stage Review.

Patient Safety Direct will build on the national Reporting and Learning System. The vision is for a clearer governance framework for reporting and learning from the most serious incidents. This supports preventative measures and reduces the risk of serious harm to patients. The framework is also the first stage in the development of a consolidated Serious Incident Management System that will replace the current Strategic Executive Information System (STEIS) serious untoward incident system in 2010.

I commend the *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*.

Bruce Keogh
NHS Medical Director

Executive summary

Serious incidents in healthcare are uncommon but when they occur the National Health Service (NHS) has a responsibility to ensure there are systematic measures in place for safeguarding people, property, NHS resources and reputation. This includes responsibility to learn from these incidents to minimise the risk of them happening again.

This is the first release of a new national framework for reporting and management of serious incidents for investigation (previously known as Serious Untoward Incidents/SUIs) occurring in the NHS and those parts of the independent sector that provide NHS services in England.

The purpose of the framework is to:

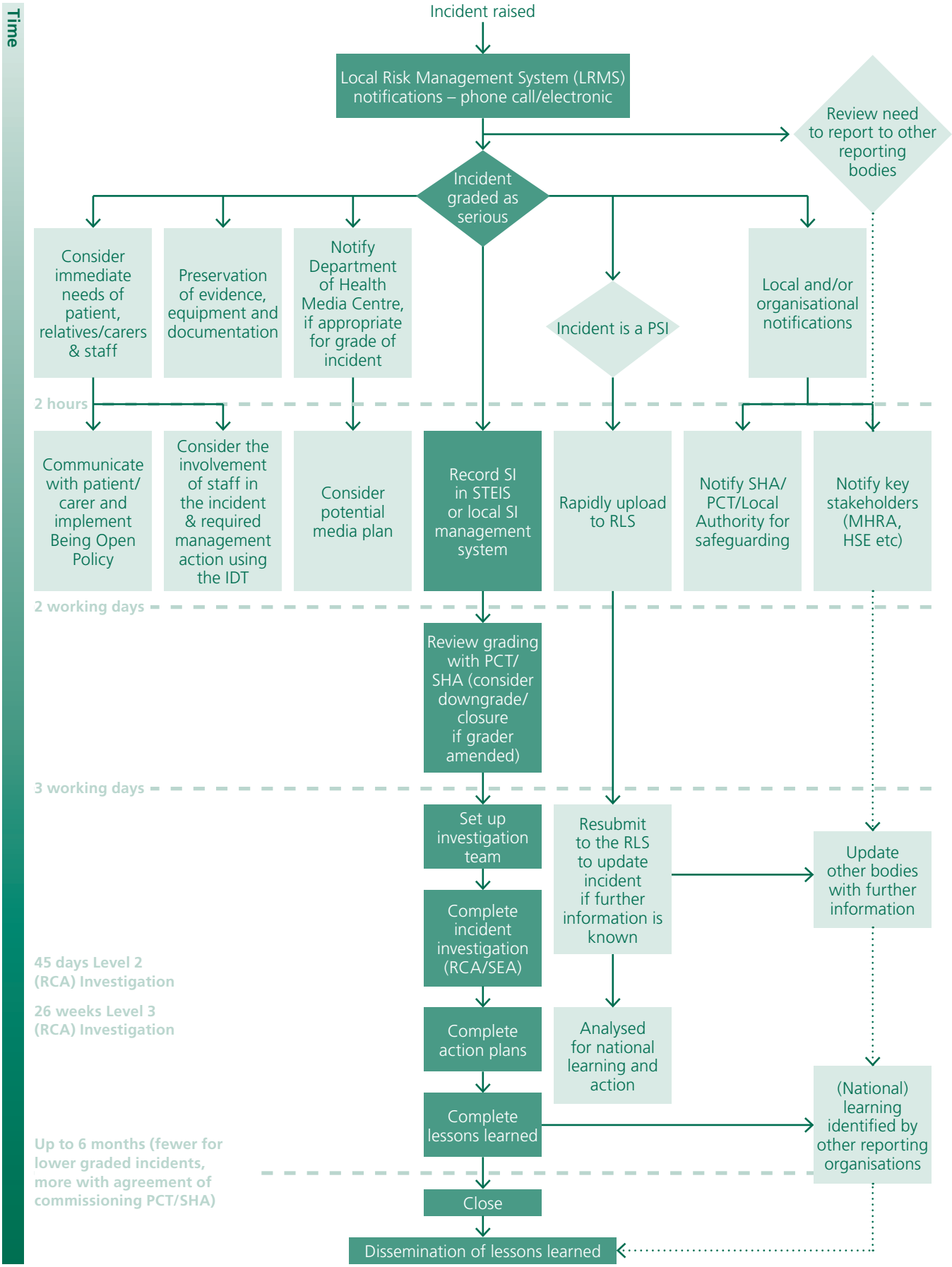
- provide a nationally consistent definition of a serious incident that requires investigation;
- clarify roles and responsibilities;
- provide information on requirements and timescales;
- draw together legal and regulatory requirements associated with the management of serious incidents and which form the basis of this framework;
- provide an overarching framework developed from good practice, along with signposting tools and resources that support good practice;
- provide guidelines to ensure that all incidents are reported to the relevant bodies to ensure full investigation (including independent investigations) and learning from the event.

The framework supports openness, trust, continuous learning and service improvement from serious incidents. The overall process is encapsulated in a flow chart (page 5).

One of the components of the framework is a nationally consistent definition of a serious incident that minimises ambiguity and improves consistency. A further element is to provide clarity around roles and responsibilities for providers of NHS care, commissioning Primary Care Trusts (PCTs) and Strategic Health Authorities (SHAs). This includes arrangements in place with respect to governance, reporting mechanisms and responsibilities, investigation, learning and dissemination of information about serious incidents. It provides guidance on the legal and regulatory requirements for reporting serious incidents to national organisations and partners, such as the Care Quality Commission (CQC), Medicines and Healthcare products Regulatory Agency (MHRA), Health Protection Agency (HPA), National Screening Programmes and the Health and Safety Executive (HSE). It sets out the role of the National Patient Safety Agency (NPSA) as the primary NHS organisation for the collation of, and learning from, serious patient safety incidents.

At the time of publication, reporting processes require serious incidents to be reported to the NPSA and either the Strategic Executive Information System (STEIS) or local serious incident reporting systems. In addition, some serious incidents require organisations to fulfil reporting requirements to other bodies as appropriate. STEIS will be replaced by a single reporting system, the National Serious Incident Management System (SIMS) in 2010 as part of Patient Safety Direct. This framework will form the basis of SIMS.

Serious Incident Reporting Process



Abbreviations:

IDT: Incident Decision Tree
PSI: Patient Safety Incident
RLS: Reporting & Learning System
SEA: Significant Event Audit
RCA: Root Cause Analysis
SI: Serious Incident

For adult safeguarding process / clinical governance flow chart see Appendix A

1. Purpose, scope and responsibilities

When a serious incident occurs it can have a devastating and far reaching effect. It may have an impact on those directly involved, patients, relatives, staff or visitors, and also on the reputation of the healthcare organisation, the service or the profession within which the incident occurred, and the wider NHS.

1.1. Purpose of the serious incident reporting framework

The purpose of this framework is to introduce and ensure consistency in definitions, roles and responsibilities and to clarify legal and regulatory requirements by providing an overarching framework.

The systems-improvement approach to safety acknowledges that causes of incidents cannot simply be linked to the actions of individual people. The framework therefore uses a system-wide perspective for notification, management and learning from serious incidents. It supports openness, trust and continuous learning and service improvement. Where relevant, it highlights where engagement with relevant bodies for full investigation and identification of learning from a serious incident is needed.

1.2. Definition of a serious incident requiring investigation

A serious incident requiring investigation is defined as an **incident** that occurred in relation to **NHS-funded services and care** resulting in one of the following:

- **Unexpected** or **avoidable** death of one or more patients, staff, visitors or members of the public;
- **Serious harm** to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, **major surgical/medical** intervention, **permanent harm** or will shorten life expectancy or result in **prolonged pain or psychological harm** (this includes incidents graded under the NPSA definition of severe harm);
- A scenario that prevents or threatens to prevent a provider organisation's ability to continue to deliver healthcare services, for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment, or IT failure;
- Allegations of **abuse**;
- Adverse media coverage or public concern about the organisation or the wider NHS;
- One of the core set of 'Never Events' as updated on an annual basis and currently including:
  - wrong site surgery
  - retained instrument post-operation
  - wrong route administration of chemotherapy
  - misplaced naso-gastric or orogastric tube not detected prior to use
  - inpatient suicide using non-collapsible rails
  - escape from within the secure perimeter of medium or high security mental health services by patients who are transferred prisoners
  - in-hospital maternal death from post-partum haemorrhage after elective caesarean section
  - intravenous administration of mis-selected concentrated potassium chloride

Supplementary terms

1. **Incident** – an event or circumstance that could have resulted, or did result, in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitors or members of the public.[1]
2. **NHS-funded services and care** – healthcare that is partially or fully funded by the NHS, regardless of the location.[2,3]

3. **Unexpected death** – where natural causes are not suspected.[3] Local organisations should investigate these to determine if the incident contributed to the unexpected death.[2]
4. **Permanent harm** – directly related to the incident and not to the natural course of the patient's illness or underlying conditions, defined as permanent lessening of bodily functions, including sensory, motor, physiological or intellectual.[3]
5. **Prolonged pain and/or prolonged psychological harm** – pain or harm that a service user has experienced, or is likely to experience, for a continuous period of 28 days.[4]
6. **Severe harm** – a patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.[3]
7. **Major surgery** – a surgical operation within or upon the contents of the abdominal or pelvic, cranial or thoracic cavities or a procedure which, given the locality, condition of patient, level of difficulty, or length of time to perform, constitutes a hazard to life or function of an organ, or tissue (if an extensive orthopaedic procedure is involved, the surgery is considered 'major').[5]
8. **Abuse** – a violation of an individual's human and civil rights by any other person or persons. Abuse may consist of single or repeated acts. It may be physical, verbal or psychological, it may be an act of neglect or an omission to act, or it may occur when a vulnerable person is persuaded to enter into a financial or sexual transaction to which he or she has not consented, or cannot consent. Abuse can occur in any relationship and may result in significant harm or exploitation of the person subjected to it. This is defined in *No Secrets* for adults[6] and in Care Quality Commission (CQC) guidance about compliance.[4] *Working together to safeguard children (2006)*[7] states that 'abuse and neglect are forms of maltreatment of a child. Somebody may abuse or neglect a child by 'inflicting harm' or by failing to act to prevent harm'.

For further details of the definition of abuse and the serious incident reporting processes[7] see flow chart Appendix A.

The NPSA has published a series of definitions covering the full range of harms that we associate with a patient safety incident.[3] As a minimum, patient safety incidents leading to unexpected death or severe harm should be investigated to identify root causes and enable ameliorating action to be taken to prevent recurrence.

The definition of serious incident requiring investigation extends beyond those which affect patients directly and includes incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare. All serious patient safety incidents should be reported to the National Patient Safety Agency (NPSA) and currently also to the Strategic Executive Information System (STEIS), and to notifiable partner organisations as detailed in the information resource that supports this framework (found on the NPSA website at **www.nrls.npsa.nhs.uk/patientsafetydirect**).

From April 1 2010, as part of the new registration requirements arising from the Health and Social Care Act 2008[8], organisations are required to notify the CQC about events that indicate or may indicate risks to ongoing compliance with registration requirements, or that lead or may lead to changes in the details about the organisation in the CQC's register. Reports about serious incidents and deaths are defined in the CQC's guidance, *Essential Standards of Quality and Safety*.[4] For English NHS Trusts most of these requirements are met by reporting via the NPSA, and the NPSA will forward relevant information to the CQC.

If there is uncertainty about the status of an incident, provider organisations are advised to err on the side of caution and if in doubt to seek advice from their SHA and/or commissioning PCT (see also section 1.4).

1.3. Scope of the serious incident reporting framework

This framework covers serious incidents that meet the criteria described in the definition in section 1.2 that occur in **NHS-funded services and care in England**. This includes services provided by:

- NHS Trusts,
- Foundation Trusts,
- Primary Care Trust (PCT) providers,
- Independent healthcare provider organisations,
- Independent practitioners (including general practitioners [GPs]),
- Community pharmacists,
- Community optometrists,
- General dental practitioners (GDPs)
- Prison healthcare services.
- Integrated services and Care Trusts

The framework complements existing serious incident, incident and risk management policies in healthcare provider organisations and local policies should be aligned to this framework. It does not replace each provider organisation's duty to inform other organisations or agencies as required under legislation and NHS policy. All clinicians have a professional responsibility to report serious incidents.

Serious incidents occurring in Wales

Wales has its own serious incident management process covering Welsh patients and organisations. Serious incidents involving NHS patients from England, receiving care in Welsh provider organisations, are covered by the requirements of this framework.

The framework complements existing procedures and policies, particularly guidance for national reporting, and some are referenced in more detail in the 'Information resource to support the reporting of serious incidents' available at **www.nrls.npsa.nhs.uk/patientsafetydirect.**

The framework will be reviewed by the Patient Safety Direct team at the NPSA prior to the launch of the Serious Incident Management System (SIMS) and amended as needed in the light of experience and any new requirements.

1.4. Roles and responsibilities

Organisations providing NHS-funded care in England are required to demonstrate accountability for effective governance and learning following a serious incident.

The NHS has a responsibility to ensure that when a serious incident does happen, there are systematic measures in place for:

- safeguarding people, property, the service's resources and its reputation
- understanding why the event occurred,
- ensuring that steps are taken to reduce the chance of a similar incident happening again,
- reporting to other bodies where necessary, and
- sharing the learning with other NHS organisations and providers of NHS-funded care.

Healthcare provider organisations are divided broadly into three categories - each with their own lines of accountability (see Figure 1).

- NHS Trusts, including PCT providers, are accountable to commissioning PCTs through contracting and commissioning arrangements, with PCTs accountable to SHAs. NHS Trusts are also regulated by the CQC (see also below).
- NHS Foundation Trusts and their boards of directors are accountable to commissioning PCTs through contracting and commissioning arrangements, and to their governors and members. Foundation Trusts are also regulated by Monitor for compliance with their terms of authorisation.

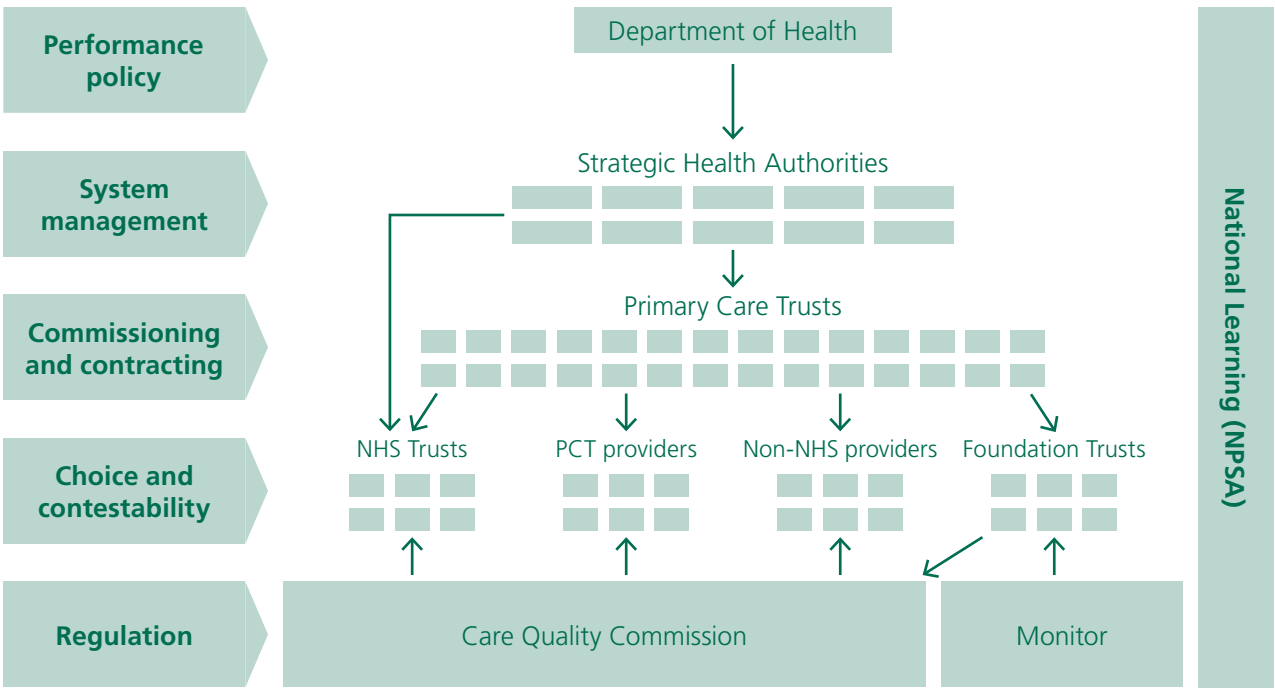
- Non-NHS providers, including independent provider organisations and practitioners, GP practices and pharmacists are accountable to commissioning PCTs through contracting and commissioning arrangements, and through national contracts.

The CQC will be registering NHS Trusts against the new Health and Social Care Act 2008 (Registration Requirements) Regulations 2009, and monitoring ongoing compliance against the essential standards of quality and safety.[4] The information obtained from the new notification system will be used as part of the monitoring system.

The NPSA works across NHS-funded care to promote actionable learning on a national basis.

At time of publication of this framework the performance management role of the commissioning PCT and SHA is in transition hence the two are used interchangeably throughout the document and will be dependent on local developments.

Figure 1: the accountability structure (Adapted from the Department of Health publication The NHS performance regime)[9]



1.4.1. Role of the NPSA

The NPSA is the primary NHS organisation responsible for the collation of, and learning from, serious patient safety incidents in healthcare (frequently in partnership with other national bodies), and works across NHS-funded care to promote actionable learning on a national basis. This responsibility includes:

- dissemination of national learning from serious incidents, including Never Events, through the National Reporting and Learning Service;
- joint working arrangements across national bodies to reduce overlap and duplication in reporting requirements;
- providing relevant experience and expertise to offer advice and support to local provider organisations, commissioning PCTs and SHAs and Government Offices; and
- development and dissemination of tools and national guidance emanating from reporting and learning.

1.4.2. Expectations of providers of NHS-funded care

Boards of healthcare provider organisations should be assured and able to demonstrate that the following elements are in place.

Governance

- Arrangements for clinical governance - to provide assurance of the quality of clinical care and patient safety. Further requirements are specified in the Primary Care Act 1998; *Clinical Governance in the NHS*[10] and *National Standards, Local Action; a planning framework for health and social care.*[11]
- A formal mechanism such as a committee accountable to the board (or equivalent) that has responsibility for monitoring management and follow-up of serious incidents, implementation of action plans and identification of themes and trends. This will include Local Safeguarding Adults Boards (LSAB) and Local Safeguarding Children Boards (LSCB).
- A local policy for incident reporting and management that clearly sets out how serious incidents will be identified and reported by staff and managed within the provider organisation. The policy should meet the requirements of the NHS Litigation Authority *Risk Management Standards NHSLA*[12] and Local Safeguarding Boards (Adults and Children).
- Clear board-level responsibility for implementing and monitoring requirements of the framework, and for ensuring compliance with the Health and Social Care Act 2008 (Registration Requirements) Regulations 2009 as set out by the CQC[4] ensuring that there is alignment of existing policies.

Reporting

- Recording of all serious incidents on a local risk management system (LRMS).
- Agreed processes for reporting serious patient safety incidents to the NPSA (for independent providers via commissioning bodies).
- An auditable process/mechanism for reporting serious incidents to relevant bodies and authorities including the SHA, commissioning PCT, police, local authority and other provider organisations (where applicable), and further stakeholders, providing additional information where requested. An information resource to support reporting of serious incidents to be used to determine accurate reporting is available on the NPSA's website. **www.nrls.npsa.nhs.uk/patientsafetydirect**
- Agreed processes for reporting Never Events (see Appendix B) to the NPSA and to commissioning bodies, with discussion as appropriate.
- Procedures to ensure that, where appropriate, referrals of incidents and/or individuals to the LSAB/LSCB and Independent Safeguarding Authority (ISA) and professional bodies are made.

- Arrangements for ensuring staff and patients/carer/relatives receive support following a serious incident. For communicating with patients and their families following a serious incident, recommended actions are provided in the NPSA's *Being Open* guidance **www.nrls.npsa.nhs.uk/beingopen.**
- Arrangements for ensuring that any medicines or equipment that has been involved in the incident are quarantined, labelled and stored as appropriate.
- Arrangements that fulfil the requirement for English NHS Trusts to notify the CQC about events that indicate or may indicate risks to ongoing compliance with the registration requirements, or that lead or may lead to changes in the details about the organisation in the Commission's register from April 1 2010. This will be met by making reports about serious incidents and deaths as defined in the CQC's guidance about compliance *Essential Standards of Quality and Safety*[4] via NPSA reporting systems. The NPSA will forward relevant information to the CQC.

Investigation and action planning

- Arrangements for ensuring investigations take place within required timescales and use best practice methodologies such as root cause analysis (RCA). RCA toolkit **www.nrls.npsa.nhs.uk/rca**
- Arrangements for ensuring information from local investigations is given to other relevant reporting organisations to help national learning.
- Arrangements for ensuring that commissioning PCTs are publicly reporting on Never Events that occur in their providers as part of annual quality reporting.
- Provision of training for staff in investigative and analysis techniques and methodologies such as RCA.
- Arrangements to ensure that following investigations and serious case reviews, action plans to address root causes are drawn up and their implementation monitored and reported to the board, and to commissioners as part of contracting arrangements.

Learning and follow-up

- Arrangements for the dissemination of learning within the organisation and, where appropriate, across the wider NHS through other mechanisms.
- Mechanisms to ensure appropriate actions are taken where referral of a health professional to his/her professional body is indicated.
- Arrangements for ensuring that improvement in practice following serious incidents is implemented and evaluated.

Media management

- Handling arrangements are in place to manage any press and media enquiries and, if necessary, to inform the PCT and/or the SHA and the Department of Health Media Centre via the following e-mailbox: **MB-Health-Alert@dh.gsi.gov.uk** and the Ministerial Briefing Unit. Where appropriate for child/adult safeguarding, inform the Government Office through the local authority.
- There should be close working with other stakeholders to ensure that media messages and management reflect the perspective and needs of these.

1.4.3. Expectations of commissioning Primary Care Trusts (PCTs)

Commissioning PCT boards should be assured and able to demonstrate that the following elements are in place.

Governance

- Contracts with local healthcare provider organisations exist which clearly set out the provider organisation's obligation to meet the requirements of this framework.
- Procedures and relevant skills and resources to receive and appropriately manage, monitor, follow up and, where appropriate, escalate serious incidents in accordance with this framework.
- Arrangements providing assurance to the SHA that the requirements of this framework are being met.
- Local procedures agreed with LSAB/LSCB that set out the arrangements for notification and management of serious case reviews, including action planning and learning from incidents.

Reporting

- Arrangements to assure that serious incidents are reported by provider organisations to the NPSA and other bodies as appropriate.
- A process to report serious incidents, including Never Events, to the PCT board and plans for recording Never Events in annual reporting arrangements.

Investigation and action planning

- Monitoring arrangements to ensure that serious incidents are managed and investigated by providers according to best practice.
- Arrangements for receiving assurance from provider organisations that action plans have been implemented following a serious incident, and advising provider organisations when incidents are closed formally.
- Arrangements for agreeing commissioning of independent investigations with provider organisations and SHAs if there is a requirement to do so.
- Support or leadership for independent contractors in undertaking an investigation.
- Coordination of complex multiagency investigations/RCA.

Learning and follow-up

- Arrangements for the dissemination of learning from serious incidents and recommendations from independent investigations are implemented across the PCT and, where appropriate, across the wider NHS through other mechanisms.
- Arrangements for sharing national information on serious incidents and risks across the PCT to providers of services (including independent contractors).
- Arrangements to carry out regular thematic reviews of serious incidents to identify trends and patterns across the PCT and ensure the wider implications and key learning points are disseminated across the PCT, and the wider NHS.
- Arrangements for ensuring that improvement in practice following serious incidents is implemented and monitored.
- Arrangements are in place annually for public reporting of Never Events in their providers: the numbers, type and actions taken.

Media management

- Arrangements to ensure any press and media enquiries are managed by the provider organisation, if necessary, informing the SHA and the Department of Health Media Centre via the following e-mailbox: **MB-Health-Alert@dh.gsi.gov.uk** and the Ministerial Briefing Unit. Where appropriate for child/adult safeguarding, inform the Government Office through the local authority.

- There should be close working with other stakeholders to ensure that media messages and management reflect the perspective and needs of these.

1.4.4. Expectations of Strategic Health Authorities

SHAs should be assured and able to demonstrate that the following elements are in place.

Governance

- Mechanisms that ensure the framework is translated into regional policies and cascaded to accountable organisations in the region.
- Ensure PCTs are performance-managing serious incidents occurring in their commissioned services in accordance with the requirements of this framework.
- Collaborative work and links with LSAB/ LSCB to make sure knowledge around child protection and safeguarding adults is shared among PCTs and providers.

Reporting

- Arrangements to ensure all serious incidents for the regional population are reported to the NPSA and other bodies as appropriate.
- Arrangements to ensure that commissioning PCTs are publicly reporting on Never Events that occur in their providers as part of annual quality reporting.

Investigation and action planning

- Arrangements to ensure skills, expertise and commissioning resources are in Patient Safety Action Teams to advise provider organisations on RCA investigations as required by the Department of Health[13] and the Never Events framework (Appendix B).
- Arrangements for receiving assurance from provider organisations through commissioning PCTs that action plans have been implemented following a serious incident.
- The SHA is responsible for commissioning independent investigations for serious incidents in mental health services.

Learning and follow-up

- Arrangements for dissemination of lessons learned to PCTs and provider organisations to minimise the risk of similar incidents occurring in the future including recommendations from independent investigations and that learning is shared across the wider health community including between SHAs.
- Arrangements for liaison with the Government Office to follow up actions arising from serious case reviews (for children and young people).
- Arrangements to carry out regular thematic reviews of serious incidents to identify trends and patterns across the region and ensure that wider implications and key learning points are disseminated across the region and other SHAs.
- Undertake specific investigations as directed by national guidance or the SHA board on incidents (or clusters of incidents) that require further external investigation.

Media management

- Arrangements to ensure press and media enquiries are managed by the commissioning PCT and, if necessary, the Department of Health Media Centre Department of Health Media Centre via the following e-mailbox: **MB-Health-Alert@dh.gsi.gov.uk** and the Ministerial Briefing Unit are informed. Where appropriate for child safeguarding, inform the Government Office through the local authority.

There should be close working with other stakeholders to ensure that media messages and management reflect the perspective and needs of these.

2. Management of a serious incident

The circumstances surrounding each incident vary in terms of levels of harm and numbers of people involved, risk exposure, financial loss, media interest and the need to involve other reporting stakeholders; therefore the response to each incident should be proportionate to the scale, scope and complexity of each incident. This section outlines suggested steps to manage a serious incident.

2.1. Identification and response

Immediate response by the provider organisation

In all instances, the first priority for the provider organisation is to ensure the needs of individuals affected by the incident are attended to, including any urgent clinical care which may reduce the harmful impact.

A safe environment should be re-established, all equipment or medication retained and isolated, and relevant documentation copied and secured to preserve evidence and facilitate investigation and learning. If there is a suggestion that a criminal offence has been committed, the provider organisation should contact the police.*

The organisation should give early consideration to the provision of information and support to patients, relatives and carers and staff involved in the incident, including information regarding support systems which are available to patients/relatives/visitor/contractors. The organisation should follow guidance provided in the local *Being Open* policy.

The needs and involvement of staff in the incident should also be considered. The NPSA's *Incident Decision Tree* resource can assist here.

If the incident is potentially a child[7] or adult safeguarding concern,[6] organisations should have established and robust local processes in place and a safeguarding alert raised. It is also important to identify where other agencies need to be brought into the management of a serious incident when required (see Appendix A).[8]

Tools and resources

For communicating with patients and their families following a serious incident, recommended actions are provided in the NPSA's *Being Open* guidance: **www.nrls.npsa.nhs.uk/beingopen**

Clinical governance and adult safeguarding: **www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_112361**

For information on action and support for staff see the NPSA's *Incident Decision Tree*: **www.npsa.nhs.uk/idt**

For information that summarises the principles of patient safety, see the NPSA's *Seven Steps to Patient Safety*: **www.nrls.npsa.nhs.uk/sevensteps/**

* Refer to local procedures and the national memorandum of understanding that outlines the general principles for the NHS, police and HSE to observe when liaising with one another: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4129918

2.2 Reporting

Provider organisations should designate a senior member of staff (usually an executive director with board level responsibility for risk and patient safety) to have responsibility for reporting and follow-up of serious incidents with the appropriate body or bodies within given timescales.

This officer is also responsible for ensuring relevant internal staff are informed of the incident including, as appropriate, the Chief Executive, Chief Operating Officer, Head of Communications and other members of the senior management team.

Reporting arrangements

The organisation should then begin the process of reporting the incident internally and to the relevant external bodies and convening the investigation team (see subsequent sections).

Where the incident involves a child or young person, considerations should be given to raising the alert as a Serious Incident under section 8 of *Working Together to Safeguard Children*,[7] which relates to the Children Acts 1989 and 2004. If the incident involves vulnerable adults, an alert should be raised as described in *No Secrets*[6] and *Clinical Governance and Adult Safeguarding*[8] *flow chart* (see Appendix A).

Foundation trust reporting of serious incidents

Serious incidents in foundation trusts should be reported to the lead commissioning PCT and the NPSA.

Foundation trusts that breach or risk breaching their terms of authorisation are also required to report all serious incidents to Monitor. They are required to have adequate processes and procedures in place to identify, report and take appropriate action on a timely basis in relation to serious incidents, and to identify key stakeholders and inform these as appropriate.

At the time of publication of this framework, all serious patient safety incidents should be reported to the NPSA and to the Strategic Executive Information System (STEIS) or local serious incident reporting systems. In addition, some serious incidents require organisations to fulfil reporting requirements to other bodies as appropriate, as described in the information resource to support the reporting of serious incidents on the NPSA's website **www.nrls.npsa.nhs.uk/patientsafetydirect.**

The STEIS system will be superseded by SIMS in 2010, and all organisations will be expected to report to SIMS. SHAs may disseminate separate requirements for using STEIS or locally agreed serious incident reporting systems to complement this policy until the introduction of the new system in 2010.

Reporting timescales

All identified serious incidents must be notified to the relevant bodies without delay and within **two working days**** of the incident occurring.

** **Working day - Days that exclude weekends and bank holidays** (Run from 23:59 on the day the incident is raised to 23:59 on the day the incident is reported)

2.3. Immediate action by the commissioning PCT or SHA

Each SHA and/or commissioning PCT (depending on locally agreed arrangements) will designate a member of staff to have responsibility for receipt of serious incidents from provider organisations, and have deputising arrangements as appropriate. This officer is also responsible for ensuring relevant internal staff are notified of the incident including (as appropriate) the SHA and/or PCT Chief Executive, Director of Public Health, Chief Operating Officer, head of communications and other members of the senior management team as required. The officer should liaise with the executive board lead for adult/child protection whose responsibility it should be to ensure that local safeguarding procedures for adults/children are followed.

Within two working days maximum (this will be sooner for some incidents) following receipt of details of the incident, the designated SHA and/or PCT lead or their deputy will ensure that:

- the serious incident has been received and reviewed by the SHA/PCT; and
- contact has been made with the reporting provider organisation to:
  - ascertain further information or clarification regarding the incident as required
  - agree the serious incident grading with the reporting provider organisation; this will determine subsequent actions and responses required by each organisation.

Serious incident grading for the purposes of investigation

Once an incident is designated as serious, and is reported, the incident grade should be identified by the provider organisation and agreed by the PCT and/or SHA jointly for the purposes of determining the investigation and monitoring approach.

Serious incident grading is a component of the national framework that may be new for some organisations. Its purpose is to help reduce under-reporting of serious incidents by encouraging early reporting of all possible serious incidents and allowing the provider organisation to use a three day fact finding period to re-grade the incident (up or down) if it wishes.

Table 1 is a guide to the incident grades developed by the NPSA, timescales and monitoring requirements. Grading should be agreed by the accountable SHA and/or PCTs and provider organisations on an individual **case-by-case basis** and with advice from specialist sources where appropriate.

Table 1: Grading of serious incidents

<table>
<tr><td>Grade 0</td><td colspan="3">Action required
Notification only - it is unclear if a serious incident has occurred.
The provider organisation must update the PCT/SHA with further information within three working days of a grade 0 incident being notified.
If within three working days it is found not to be a serious incident, it can be downgraded with the agreement of the accountable SHA/PCT.
If a serious incident has occurred it will be regraded as a grade 1 or 2</td></tr>
<tr><td>Grade 1</td><td>Action required
Commissioning PCTs will monitor the case and report findings, recommendations and associated action plans to the SHA.
SHA will monitor progress on a quarterly basis with PCT unless earlier discussion is required or the serious incident is regraded.
Comprehensive Investigation Root Cause Analysis (RCA) required (level 2 Investigation)
See Appendix C</td><td>Monitoring required
Local monitoring
• The PCT and/or SHA will close the incident when it is satisfied the investigation, recommendations and action plan are satisfactory, and local monitoring arrangements are in place and working efficiently.
• Publish incident details within Annual Reports
Timescales: Up to 45 working days/9 weeks from the date the incident is notified to the PCT/SHA.</td><td>Examples of cases
• Mental Health – deaths in the community*
• HCAI outbreaks
• Avoidable/unexplained death
• Mental health – attempted suicides as inpatients*
• Ambulance services missing target for arrival resulting in death/severe harm to patient
• Data loss and information security (DH Criteria level 2, see Information Resource)
• Grade 3 pressure ulcer develops
• Poor discharge planning causes harm to patient
See Information Resource Tool</td></tr>
<tr><td>Grade 2</td><td>Action required
Case will be monitored by the SHA/PCT/LA in conjunction with the provider organisation.
The SHA will review findings, recommendations and associated action plans.
For Never Events, the commissioning PCT will be obliged to monitor overall numbers and actions and report these in its annual reporting arrangements
Comprehensive Investigation (RCA level 2 investigation) (as above) or Independent Investigation (RCA level 3 Investigation)*
See Appendix C</td><td>Monitoring required
SHA/PCT monitoring
• Incidents leading to an independent investigation or inquiry or those considered high risk will continue to be monitored by the SHA/PCT or Local Authority until evidence is provided that each action point has been implemented. Incidents involving adult or child abuse are referred to local safeguarding arrangements
• Publish quarterly reports
Timescales: For Independent Investigations allow up to 26 weeks/6 months for completion of investigation. Extensions can be granted on an individual case-by-case basis by the SHA/PCT.</td><td>Examples of cases
• Maternal deaths
• Inpatient suicides (including following absconsion)*
• Child protection
• Data loss and information security (DH Criteria level 3-5)
• Never Events
• Accusation of physical misconduct or harm is made
• Homicides following recent contact with mental health services*
See Information Resource Tool
* Mental Health incidents should refer to DH guidance: Independent investigation of adverse events in mental health services[14]</td></tr>
</table>

Grading of incidents supports a proportionate and appropriate response on a case-by-case basis. Timescales and levels of investigation reflect the scale, scope and complexity of each incident and are consistent with the triggers and levels of RCA investigation published by the NPSA (see tools and resources).

The SHA will notify the Department of Health Media Centre of incidents in either grades 1 or 2 that may attract national or significant media attention within two hours of receiving a potentially high profile serious untoward incident.

All other appropriate serious incidents will be notified to the Media Centre within two working days (or fewer) via e-mail to: **MB-Health-Alert@dh.gsi.gov.uk**

Caldicott, data protection and information governance

In the majority of circumstances, healthcare provider organisations must comply with Caldicott data protection and information governance requirements when reporting serious incidents. They should not refer to individuals by their name or give other identifiable information and should 'restrict access to patient information within each organisation by enforcing strict need to know principles'[15] For example, the content of a report should not contain the names of practitioners or patients. Person identifiers must be documented separately.

However, the principle should be that the safety of patients is paramount and staff should act in the public interest. In certain circumstances, therefore, it will be necessary to identify an individual; for example in making a 'safeguard' alert. In this case, the serious incident lead in the provider organisation must contact the senior member of the SHA/PCT or Local Authority (LA) to discuss the incident and provide more detailed information.

Incidents occurring across the boundaries of two or more PCTs

Where a serious incident crosses the boundary of two or more PCTs, the PCTs concerned will liaise to ensure all are notified, a lead PCT is identified and a timescale is agreed locally.

Incidents involving more than one provider organisation

If more than one organisation is involved in a serious incident, the organisation that identified the incident may make the initial notification. Wherever possible this organisation must first make contact with the organisation where the incident originated.

The lead organisation must be identified and agreed at this point with the others involved and clear roles and responsibilities agreed. Once the lead has been agreed, STEIS or local serious incident management systems need to be updated and closed (if appropriate) so the serious incident is investigated in a joined-up way. The named lead/point of contact should be identified clearly to the SHA and/or commissioning PCT. Social care may be the lead agency in child protection/safeguarding adult's issues, or the police where a crime has occurred.

NHS organisations have a responsibility to investigate and take preventative action when things go wrong to ensure the safety and well-being of patients and staff, so all stakeholders have an obligation to collaborate. The only exception to this may be when dealing with a 'safeguarding' alert and this will be decided by the LSAB for adults or LSCB for children.

Reporting of serious incidents to the Care Quality Commission

From April 1 2010, as part of the new registration requirements arising from the Health and Social Care Act 2008, healthcare provider organisations are required to notify the CQC about events that indicate or may indicate risks to ongoing compliance with the registration requirements, or that lead or may lead to changes in the details about the organisation in the CQC's register. For English NHS Trusts most of the requirements are met by providing incident reports about serious incidents and deaths, as defined in the CQC's guidance about compliance,[4] via NPSA reporting systems. The NPSA will forward relevant information to the CQC. Some incident notifications have to be made directly to the CQC.

Incidents involving work-related deaths

Incidents involving work-related deaths should follow the Work Related Deaths Protocol, an agreed protocol between the Health and Safety Executive, the police, the Crown Prosecution Service and the British Transport Police. This deals with incidents where, following a death, evidence indicates that a serious criminal offence other than a health and safety offence may have been committed.[16]

Incidents involving coroners

An unexpected death (where natural causes are not suspected) is reported to the coroner and/or the police by the Trust Pathologist following a post mortem. The coroner's report following an unexpected death may be the point at which a serious incident is raised.

Incidents involving national screening programmes

Where an incident involves a national screening programme, the Director of Public Health (DPH) of the commissioning PCT is responsible for taking oversight of the incident with the provider organisation in which the incident has occurred. The provider organisation must involve this DPH in decision-making around identification, grading management, action, dissemination and learning from the incident.[17] The provider organisation and commissioning DPH are responsible for involving an expert advisor for that screening programme, to be identified by the SHA for each national screening programme in their area.

Incidents involving physical and non-physical assaults against NHS staff

Where a member of staff is subjected to a physical or non-physical assault, from April 2010 there will be a requirement to report this to the NHS Security Management Service (NHS SMS) via the Security Incident Reporting System (SIRS).[18] This includes all assaults, and not only those which reach the threshold of a "serious incident" as described at 1.2. SIRS will replace the Physical Assault Reporting System (PARS), which has been in place for a number of years, and which has its basis in directions from the Secretary of State to NHS trusts.

Incidents involving loss or damage to property and assets of NHS health bodies, staff and patients

Where a security related incident results in loss or damage to the property or assets of health bodies, staff or patients, this should be reported to the NHS Security Management Service (NHS SMS) via the Security Incident Reporting System (SIRS). This includes all non-accidental incidents of this nature, and not only those which reach the threshold of a serious incident as described at 1.2. SIRS will be operational from April 2010.

Independent sector healthcare provider (ISHP) organisations and practitioners

A serious incident involving a patient in receipt of NHS-funded care provided by an independent sector provider healthcare organisation or practitioner must be notified by that provider to the relevant bodies as follows:

National contracts

In the case of an independent sector treatment centre (ISTC) responsible for providing healthcare services under a national contract, serious incidents should be reported:

- to the lead commissioning/sponsoring PCT or
- to NHS Contracting at the Department of Health, and
- where appropriate in accordance with local safeguarding arrangements, and
- to the CQC.

The commissioning PCT will report the incident to the SHA and the NPSA.

Only serious incidents should be reported in accordance with the requirements of this framework. However, independent providers of health care may also be required to report other types of incident to their lead commissioning PCT as part of their NHS contract or to other bodies as required in national legislation.

Local contracts

In the case of an ISTC or other independent sector healthcare provider (ISHP) organisation responsible for providing healthcare services under local contract, serious incidents are reported directly to the lead commissioning/ sponsoring PCT (and where appropriate, to local safeguarding arrangements). The commissioning PCT will report the incident to the SHA through an agreed, secure protocol.

If the ISHP is registered with the CQC, serious incidents involving patients are required to be reported by the provider organisation to the CQC.

Where a serious incident from an ISHP is discovered in the first instance by an NHS organisation, it should be immediately reported to the ISHP concerned. The only exception to this would be where the incident is or may be abuse, in which case local safeguarding procedures should be followed. The ISHP is then required to report the adverse incident in line with their contractual obligations. The NHS organisation concerned should also inform the lead commissioning/sponsoring PCT about the incident. Subsequently, agreement should be reached between the parties about which one leads the investigation.

Serious incidents involving English patients occurring in Wales

Serious incidents involving NHS patients from England receiving care in Welsh provider organisations are covered by the requirements of this framework. The Welsh provider organisation is required to notify the commissioning PCT/SHA for patients' care in England.

Serious incidents involving Welsh patients occurring in England

When serious incidents involve NHS patients from Wales receiving care in English provider organisations, the commissioner of these patients' care in Wales must be informed. This will be the local health board, unless it is specialist care being provided in which case Health Commission Wales must be informed.

At the time of development of this framework the health service in Wales was being restructured and these arrangements may change.

Other bodies with a remit for serious incidents

The NPSA is the primary NHS organisation responsible for the collation of, and learning from, serious patient safety incidents occurring in healthcare.

Other bodies such as the Medicines and Healthcare products Regulatory Agency (MHRA), Health Protection Agency (HPA), Serious Hazards of Transfusion (SHOT), National Screening Programmes, Health and Safety Executive (HSE), Monitor or Local Safeguarding Boards should be notified about incidents relevant to their remit in accordance with their reporting guidance.

The new national Serious Incident Management System (SIMS) being developed to replace STEIS (launch planned for 2010) incorporates several improvements. There will be methods by which initial reporting results in automatic notification of the appropriate organisations. In addition, the outputs of incident investigations (RCAs) can be recorded and collated to facilitate improved national learning.

In circumstances where several bodies are notified, these will liaise with each other, the relevant commissioning organisation, either the PCT or Strategic Health Authority, and the provider organisation(s) in formulating an appropriate national response (if one is needed). Healthcare provider organisations should support investigations by other bodies as required, to facilitate national learning.

Local safeguarding procedures for adults and children must also be followed and safeguarding alerts made whenever appropriate.

Tools and resources

RCA toolkit **www.nrls.npsa.nhs.uk/rca**

Information resource to support the reporting of serious incidents
www.nrls.npsa.nhs.uk/patientsafetydirect

Clinical Governance and adult safeguarding:
www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_112361

HSG245 "Investigating accidents and incidents – A workbook for employers, unions, safety representatives and safety professionals
www.hse.gov.uk/involvement/

Work Related Death Protocol and Guidance
www.hse.gov.uk/PUBNS/misc491.pdf

NHS Security Management Service (NHS SMS) - the Security Incident Reporting System (SIRS).
www.nhsbsa.nhs.uk/428.aspx

2.4. Investigation

All serious incidents as defined by this framework should be investigated.

This section mirrors the NPSA's best practice on conducting investigations using root cause analysis methodologies. Provider organisations will have local policies that set out how investigations will be conducted to comply with these requirements. The principles of RCA will be applied to all investigations, but the scale and scope of investigation should be appropriate to the incident itself. The grading level of the serious incident will determine the level of the investigation and its timescale for completion (see Appendix C).

It is recommended that investigations follow NPSA guidance and identify both active (e.g. acts and omissions by staff) and latent (e.g. organisational or environmental) failures. If only active failures are identified, resulting solutions are unlikely to maintain sustainable prevention.

Where the investigation involves more than one organisation, anything uncovered by local investigations that may be pertinent e.g. timelines and delays, care/service delivery problems and causal factors should be communicated to the agreed lead (organisation) to ensure a full analysis of the incident and root causes.

Action plans to reduce or eliminate risks to other patients, staff or the organisation must demonstrate clear links between cause and effect.

Guidance and templates developed by the NPSA for the investigation of patient safety incidents are recommended for all types of serious incidents, including the NPSA's RCA report writing tools and templates as they will enable a more systematic approach to learning and provide quality assurance to Boards, PCTs and SHAs.

Allegations of abuse are always referred immediately to local multi-agency safeguarding arrangements for adults and children and a safeguarding alert raised. As stated in *Clinical Governance and Adult Safeguarding*[8] investigations are coordinated by those arrangements and should not begin independently of them.

Commissioning PCTs and SHAs will have policies setting out arrangements for commissioning independent investigations, including clear roles and responsibilities for the organisations involved and responsibility for payment.

Investigation teams

Provider organisations will ensure there is an up to date list of competent staff within the organisation familiar with the organisation's investigation policies and protocols, skilled in good practice root cause analysis methodologies and techniques. The identified team must have no conflicts of interest in the incident concerned and must be available, possibly at short notice, to undertake serious incident investigations.

These staff will be kept up to date through the provision of regular investigation officer training (in-house or external) and this training will include the following as a minimum:

- RCA investigation methodologies and techniques,
- statement taking and
- report writing.

The SHA will ensure that RCA investigation and advice and support are available to provider organisations via Patient Safety Action Teams as set out in *Safety First*.[13]

Identifying issues which may be of national significance

Investigations may identify issues of national significance or where the dissemination of national learning is appropriate. Organisations such as the NPSA, MHRA, HPA, HSE etc. have review, response and alert mechanisms for urgent incidents. As already stated, relevant incidents should be notified to these bodies as part of the serious incident reporting process and provider organisations should subsequently share findings from investigations

with these bodies where issues of potential national learning for wider sharing are identified.

The National Serious Incident Management System (SIMS) being developed to replace STEIS (launch planned for 2010) incorporates means by which notification to the appropriate organisations will be automatic and the outputs of incident investigations (RCAs) can be recorded to facilitate improved national learning.

Involving patients and their families in investigations into serious incidents

The level of patient/family involvement clearly depends on the nature of the incident and the patient or family's wish to be involved, but provider organisations should have a *Being open* policy in place, which staff are aware of and the principles of which are in current use.

Unless there are specific indications to the contrary or the patient/their family requests other arrangements, these issues should be covered in a series of open discussions between staff providing the patient's care and the patient and/or their relatives or carers.

Note: Patients and families have the right to request information held by public authorities (Freedom of Information Act 2000). This includes 'access to medical records and any associated documentation' (Public Sector Information Regulations 2005). This should be considered when writing incident investigation reports and actions.

Tools and resources

Root Cause Analysis report writing tools and templates: **www.nrls.npsa.nhs.uk/rca**

Being Open guidance provides a number of recommended actions:
www.nrls.npsa.nhs.uk/beingopen

Guidance on Freedom of Information:
www.ico.gov.uk/

2.5. Action plan development and implementation

Following the investigation of a serious incident an agreed action plan will be drawn up by the provider organisation (or organisations/stakeholders if more than one agency is involved) that sets out how each recommendation from the investigation will be implemented, with timescales.

The action plan should be in a format that can be presented to the provider organisation's board, the commissioning PCT and SHA and local safeguarding boards (if appropriate) and attached to an executive summary for internal/external circulation following approval of recommendations.

On receipt of an investigation report, the SHA and /or PCT will review its content (grade 1 and 2 incidents), taking clinical and/or other advice as appropriate to determine whether all aspects of the incident have been adequately investigated including *an evidence-based review for independent investigations*[19] and whether there is a clear action point to address each root cause and evidence of implementation of actions to improve safety provision.

The SHA and/or PCT will give feedback to the provider organisation (although will be involved in the process) within **20 working days** of receipt of the action plan and if it requires further development, will refer back to the provider organisation requesting additional information within a specified timescale.

The NPSA has developed an action plan template to standardise serious incident action plans and provide quality assurance.

Tools and resources

www.nrls.npsa.nhs.uk/rca

2.6. Monitoring & closure

One of the key elements of successful serious incident management and the governance process is an efficient and effective monitoring programme.

Provider organisation/s where the incident occurred

Provider organisations must ensure there is a formal committee accountable to the board (or equivalent) that has responsibility for monitoring serious incidents.

Commissioning PCTs and Strategic Health Authorities

The level of monitoring and agreement for closure undertaken by the PCT and /or SHA will be appropriate and proportionate to the grading level of the individual incident (Appendix D).

Other bodies with a remit for serious incidents

Despite monitoring the outcome and learning from a serious incident by the provider organisation and the PCT and/or SHA it may still be considered open to other bodies such as the MHRA, HSE, SHOT, NHS Contracting, Department of Health Informatics Directorate, National Screening Programme, etc, who may be in the process of developing and issuing national guidance or further information. Where relevant, it is important to maintain ongoing dialogue with external bodies and to inform them of the local status of a serious incident and its management.

The CQC will also review serious incidents for evidence of a breach of regulations, taking appropriate action if necessary.

2.7. Dissemination of learning

One of the key aims of the serious incident reporting and learning process is to reduce the risk of recurrence, both where the original incident occurred and elsewhere in the NHS. The timely and appropriate dissemination of learning following a serious incident is core to achieving this and to ensure that these lessons are embedded in practice.

Under the requirements of this framework all organisations with a responsibility for notifying or receiving details of serious incidents have a responsibility for the dissemination of learning.

Definition of learning within patient safety

Learning from patient safety incident is a collaborative, decentralized and reflective process that draws on experience, knowledge and evidence from a variety of sources. This will lead to co-production and national sharing of safety solutions and improvements, increased visibility to lessons learned and participation in the learning process leading to enhanced patient safety:

- Learning can be demonstrated at organisational level by sustainable changes and improvements in process, policy, systems and procedures relating to patient safety within healthcare organisations.
- Individual learning can be demonstrated by sustainable changes and improvements in behaviour, beliefs, and attitudes and knowledge of workers at the front line of healthcare delivery.

What constitutes learning?

Learning following an incident is defined as safety-related policy, practice and process issues that have contributed to the incident, from which others can learn. Examples of learning are given below:

- Solutions to address incident root causes that may be relevant to other teams, services and provider organisations.
- Identification of the components of good practice that reduced the potential impact of the incident, and how they were developed and supported.
- Systems and processes that allow early detection or intervention that will reduce the potential impact of the incident.
- Lessons from conducting the investigation that may improve the management of investigations in future.
- Documentation of identification of the risks, the extent to which they have been reduced, and how this is measured and monitored.

An investigation executive summary (using the template in Appendix E) should be published for each serious incident. It should include a précis of the incident and investigation and be fully anonymised to preserve confidentiality of the people involved and the ward/team/unit/hospital and provider organisation. This will enable the executive summary to be widely shared.

Learning points should be grouped or themed to help the reader/s identify those points applicable to their team, service, speciality or division or wider organisation (Table 2).

Table 2: Summary points for dissemination of learning from a serious incident

Responsibilities for sharing learning	With whom	Example of communication methods
Local and organisational learning Provider organisation/s where the incident occurred	**Local** • Patient and their family/carers directly involved in the incident where appropriate • Staff directly involved in the incident • Similar services/ specialities to the service involved in the incident **Organisational** • Other departments/ divisions for lessons with wider organisational applicability • Across the organisation by Improvements in process/policy and systems	• Meetings with patients and their families • Presentations at staff meetings • Team meetings • E-bulletins and Newsletters • Intranet site • Public web site • Public Board Papers • Notice boards • Email • Internal alert systems • Risk and Governance Committee Meeting Minutes • Risk management, incident reporting and investigation training courses (e.g. use of case studies)
National learning Commissioning PCT	**National** • Organisations to whom the learning may be applicable including independent sector provider organisations and practitioners within the PCT • SHAs • The public should be informed about learning from serious incidents, including Never Events, in providers	• Performance management review meetings • Assurance mechanisms • Newsletters • Annual quality reporting arrangements
SHA	**National** • Other organisations across the region to whom the learning may be applicable • Other Strategic Health Authorities for sharing in their regions • Media • Government office (for child protection concerns)	• Regional network meetings • Local conferences, seminars and workshops • Periodic serious incident summary reports • Letters to Chief Executives in provider organisations • Press statements

Responsibilities for sharing learning	With whom	Example of communication methods
NPSA and other bodies with a remit for safety and serious incidents (CQC, MHRA, HPA, HSE, Counter Fraud and Security Management Service, SHOT etc)	As appropriate: • All relevant healthcare sectors and organisations • Professional networks, bodies and associations • Manufacturers and commercial enterprises • International safety and quality networks and partners as appropriate • Other bodies with a remit for safety and serious incidents	• Central Alerting System (CAS), Chief Executive Bulletin, CMO Bulletin, etc • Conferences, seminars and workshops • Alerts, guidance, information, newsletters • E-networks • Local organisation Liaison/link officers • Professional networks, bodies and associations
Professional networks, bodies and associations	• Members • Other networks and associations	• E-networks • Letters to members • Newsletters and bulletins • Educational meetings

Learning from Serious Case Reviews (SCRs)

Executive representatives from the NHS are part of the local Safeguarding Adults Board (SAB) and local Safeguarding Children Board (SCB) arrangements in each area and they are responsible for ensuring that communication between the SAB/SCB and the NHS Board is maintained.

Learning lessons is the prime rationale of SCRs, and SABs/SCBs are responsible for commissioning each SCR, sharing the learning across all organisations and monitoring at agreed review periods whether lessons have been taken on board. The SAB is responsible for ensuring that they receive regular progress reports on a commissioned SCR and to take action if the delay appears unreasonable.

NHS organisations in partnership with the SAB/SCB should have local policies for implementing the findings from SCR, a process to report to their own boards and action plans to implement and monitor changes in practice.

Acting on lessons learned from elsewhere

Commissioning PCTs and SHAs are responsible for ensuring that learning from a single incident, or from the review of aggregated incidents, are shared with other organisations in their area.

Provider organisations are responsible for ensuring that learning acquired from investigations in other organisations is reviewed and assessed for relevance and priority and where appropriate, acted upon.

Tools and resources

Root cause analysis tools and templates:
www.nrls.npsa.nhs.uk/rca

2.8. Communication and the media

Communications are a vital element of supporting and delivering effective management of serious incidents. All bodies with a remit under the requirements of this policy framework are responsible for ensuring that robust communications and media management arrangements are in place for both internal and external communication.

In many cases serious incidents can lead to a high level of media attention and not only in the immediate aftermath. The management, investigation and learning from incidents can be triggers for media coverage for an extended period after the incident itself. Each organisation should have media relations policies in place that include appropriate action to take in relation to serious incidents, including protocols with other local organisations and agencies on media handling, and strategies for ongoing and longer term management of media coverage.

Local policies will include the requirement for communications leads in provider organisations to work closely with SHA/PCT communications professionals to agree appropriate media handling strategies, working alongside relevant colleagues responsible for the wider management of the incident. Responsibility for briefing the Department of Health Ministerial Briefing Unit or Media Centre rests with the Strategic Health Authority, therefore it needs to be accurately briefed in a timely manner.

In forensic/criminal cases, the police lead all communications with the media and work in partnership with the relevant agencies where they have involvement in the incident.

Guidance on media management strategies

Organisations should have policies and guidance in place for media management following a serious incident. Provider organisations, SHAs and PCTs must show that a problem is understood and steps are being taken to put it right, to provide reassurance that the risks of the same thing happening again have been minimised. This should inform all public and media contact.

Local judgment will be applied in deciding when help lines and counselling are necessary, how patients are contacted and when to hold press briefings on and off the record, as well as press conferences. Decisions should be taken between the communications professional at the SHA/PCT in consultation with the serious incident team and the provider organisation.

Generally there are three communications categories that will determine how a serious incident may be handled:

- the media is unaware of a serious incident,
- the media is unaware of a serious incident but the media should be informed so it can help with the handling of the incident by notifying the general public and/or section of the public of, for example, the need to come forward for re-testing following a screening programme incident, or
- the media is aware of an incident first and in this case the SHA/PCT/provider organisation may have only learned of a problem because it has been publicised by the media or the handling of an ongoing serious incident has 'leaked' into the public domain.

Media unaware of serious incident

It is essential that a holding statement for the media is prepared as soon as possible so that the organisation is prepared. This will require revision depending upon how well a subsequent media inquiry is informed.

Some types of incident such as those involving screening programmes can involve contacting patients for recall or reassurance. Where this is the case attempts should be made to contact patients before the media is alerted (where the media is unaware of the serious incident or where the media's assistance is sought), as long as it does not compromise patient safety.

However, contacting patients hugely increases the chances of the serious incident reaching the public domain and the media ahead of planned management. Prior to making contact with patients a reactive media handling strategy should be in place; however, any delay should not place patients at any increased risk of harm.

It is essential that there is cross health organisation agreement to the strategy with pre-arranged key messages for spokespeople, a full work through of scenarios to effectively manage media relations and a comprehensive reactive Question and Answer (Q&A) document.

Another source of information reaching the public domain is from healthcare staff. Such instances may be accidental or deliberate. For example, if frontline staff believe managers are not taking their concerns about an incident seriously or if have not seemed to have acting on their warnings then there is a high likelihood of the story 'leaking' to the media. Therefore health care managers should:

- keep staff informed,
- show they are taking their concerns seriously and acting upon them, and
- include staff so they have ownership and understand the need to observe patient and service confidentiality. The former is readily accepted by staff, but the latter only if they understand and believe that by going to the press they will cause more harm than good for patients and the service.

Media unaware but proactive media handling necessary

A proactive media approach should be followed where time and wider public health concerns can only be addressed through this route, for example, after the loss of personal data records where the only way a large number of patients can be contacted is by public appeal.

Communications leads should ensure they know the extent of the problem, explain why the media's assistance is needed, how those affected will be supported and what will be or has been done to ensure there will be no repeat of the incident. In summary, organisations need to show they:

- understand the problem,
- are putting it right,
- can reassure the public, and
- have robust and secure feedback channels (help lines if appropriate).

Media aware of serious incident

Those directly involved in the incident, including the investigation team and Head of Communications, need time and support. It is the role of professional communicators to provide this space whilst keeping journalists informed. This includes planning for the next stage, posing solutions and recommended handling to help support investigation and use the team most effectively. Under these circumstances the need to rapidly establish the facts and fully understand the extent of the problem and its cause is essential.

It is important to keep the public and media informed and share communications with partner agencies in advance of public information release, whilst balancing the needs of the affected people, staff and patients. Staff should be kept informed so they understand why and how the organisation is acting, their role and ownership in fixing the problem and overall communication plans.

Freedom of Information Act 2000

Healthcare organisations should be aware that information relating to serious incidents including information held on national systems such as STEIS, local databases and internal reports, investigation reports and root cause analysis and other documents, could be subject to a request for disclosure under the Freedom of Information Act. A request for information regarding a serious incident/s should follow Freedom of Information Act policies of the organisation that has received the request.

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Glossary of terms

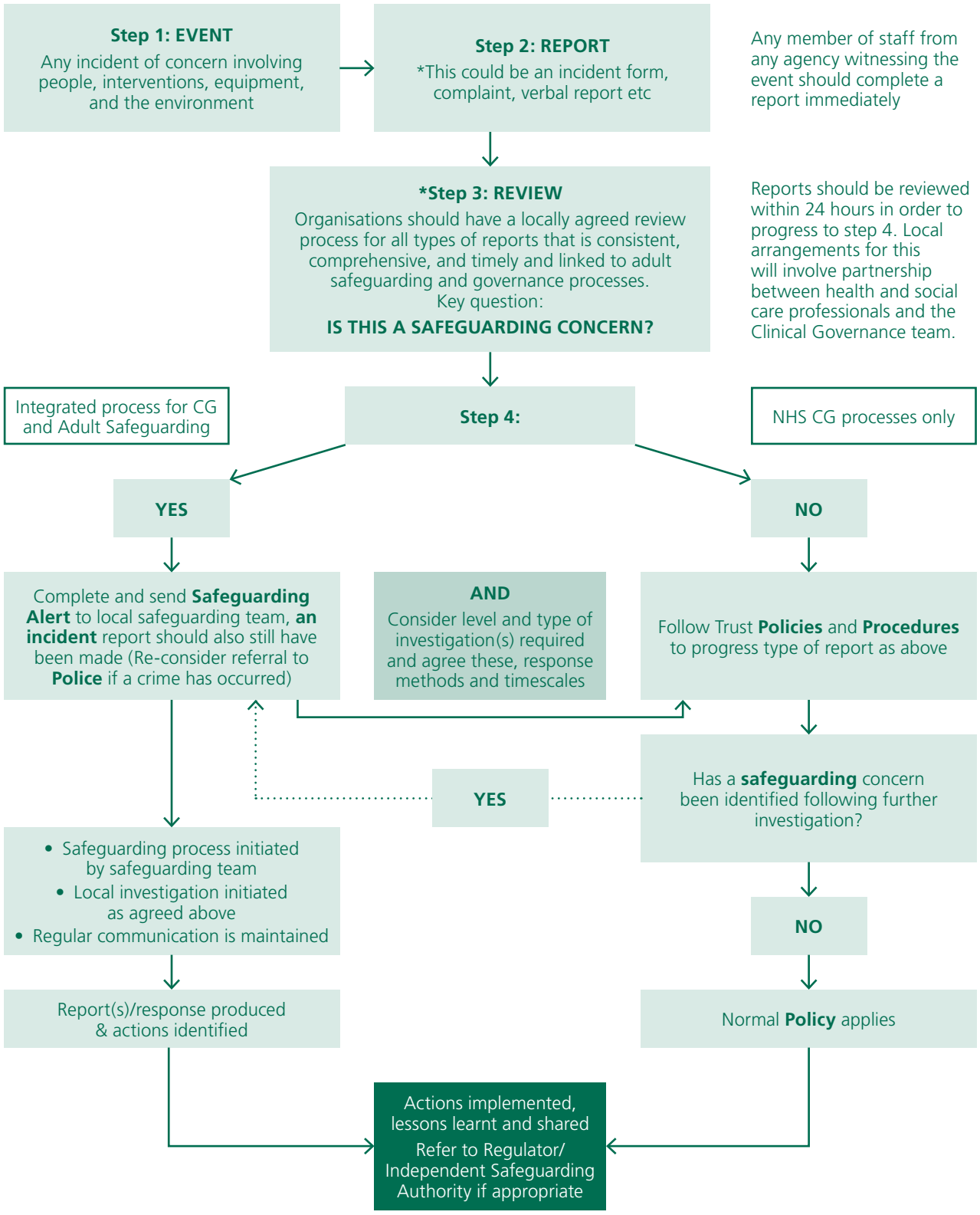
Abuse	A violation of an individual's human and civil rights by any other person or persons. Abuse may consist of single or repeated acts. It may be physical, verbal or psychological, it may be an act of neglect or an omission to act, or it may occur when a vulnerable person is persuaded to enter into a financial or sexual transaction to which he or she has not consented, or cannot consent. Abuse can occur in any relationship and may result in significant harm, or exploitation, of the person subjected to it. As defined by No Secrets for adults[5]. In *Working together to safeguard children (2006)*[6] abuse is defined as follows: 'abuse and neglect are forms of maltreatment of a child. Somebody may abuse or neglect a child by 'inflicting harm' or by failing to act to prevent harm'.
Adverse Drug Reaction	An unwanted or unexpected reaction to a medicine.
Adverse Event	See Patient Safety Incident
Being Open	Open communication of patient safety incidents that result in harm or the death of a patient while receiving healthcare.
Carers	Family, friends or those who care for the patient. The patient has consented to their being informed of their confidential information and to their involvement in any decisions about their care.
Child	The Children Act 1989 and the Children Act 2004 define a child as being a person up to the age of 18 years. The Children Act 2004 states that safeguarding, protection and cooperation between services may, in certain circumstances, be continued through to a young person's 19th birthday or beyond.
Clinical Governance	A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.
Commissioner	A person with responsibility for buying services from service providers in either the public, private or voluntary sectors.
Commissioning PCT	Primary Care Trust (PCT) that commissions NHS-funded healthcare.
Controlled Drug	One of a group of medicines that have the potential for abuse. For this reason, they are "controlled" by the Misuse of Drugs Act 1971. Many controlled drugs are essential to modern clinical care, treatment and support. They include narcotics, such as morphine and diamorphine that are used in a wide variety of clinical treatments, for example, relieving acute pain after a heart attack or fracture, relieving chronic pain, treating drug dependence and in anaesthesia.
Culture	Learned attitudes, beliefs and values that define a group or groups of people.
Discharge	The point at which a patient leaves hospital to return home or be transferred to another service or the formal conclusion of a service provided to a person who uses services.

Equipment	Machines and medical devices used to help, prevent, treat or monitor a person's condition or illness. The term may also be used to refer to aids that may support a person's care, treatment, support, mobility or independence, for example, a walking frame, hoist, or furniture and fittings. It excludes machinery or engineering systems that are physically affixed and integrated into the premises.
Expert Bodies	Professional organisations that develop, issue and design technical and operational standards relating to specialist areas.
General Practitioner	A medical practitioner who provides primary care and specialises in family medicine. General practitioners treat acute and chronic illnesses and provide preventative care and health education for all ages and tender.
Healthcare	The preservation of mental and physical health by preventing or treating illness through services offered by the health professions, including those working in social care settings.
Healthcare Professional	Doctor, dentist, nurse, pharmacist, optometrist, allied healthcare professional or registered alternative healthcare practitioner.
Healthcare Provider Organisation	Organisation that provides healthcare including NHS Trust (including PCT providers), NHS Foundation Trust, and non-NHS provider.
Healthcare-associated infection	An avoidable infection that occurs as a result of the healthcare that a person receives.
Incident	An event or circumstance which could have resulted, or did result in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitors or members of the public.
Incident Decision Tree	Developed as an aid to improve the consistency of decision making about whether human error or systems failures contributed to an incident. It is designed for use by anyone who has the authority to exclude a member of staff from work following a patient safety incident (including medical and nursing directors, chief executives and human resources staff).
Independent Healthcare	Private, voluntary and not-for-profit healthcare organisations that are not part of the NHS.
Investigation	The act or process of investigating – a detailed enquiry or systematic examination.
Lead Commissioning PCT	Lead Commissioning Primary Care Trust (PCT) where PCTs work together to commission NHS-funded healthcare.

Medical Device	Any instrument, apparatus, appliance, software, material or other article (whether used alone or in combination) (including software intended by its manufacturer to be used for diagnostic and/or therapeutic purposes and necessary for its proper application), intended by the manufacturer to be used for the purpose of: • diagnosis, prevention, monitoring, treatment or alleviation of disease, • diagnosis, monitoring, alleviation of or compensation for an injury or disability, • investigation, replacement or modification of the anatomy of a physiological process, and/or • control of conception, and which does not achieve its physical intended action on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.
Medicine	A substance or substances administered for the purpose of modifying, controlling, treating, or diagnosing a medical condition, disease or illness.
Major Surgery	A surgical operation within or upon the contents of the abdominal or pelvic, cranial or thoracic cavities or a procedure which, given the locality, condition of patient, level of difficulty, or length of time to perform, constitutes a hazard to life or function of an organ, tissue (if an extensive orthopaedic procedure is involved, the surgery is considered 'major').
Never Events	Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare provider.
NHS-Funded Healthcare	Healthcare that is partially or fully funded by the NHS, regardless of the location.
Notification	The act of notifying to one or more organisations/bodies.
Patient Safety	The process by which an organisation makes patient care safer. This should involve risk assessment, the identification and management of patient-related risks, the reporting and analysis of incidents, and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring. The term 'patient safety' is replacing 'clinical risk', 'non-clinical risk' and the 'health and safety of patients'.
Patient Safety Incident	Any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare. The terms 'patient safety incident' and 'prevented patient safety incident' will be used to describe 'adverse events'/'clinical errors' and 'near misses' respectively.
Professional Body	An organisation that exists to further a profession and to protect both the public interest, by maintaining and enforcing standards of training and ethics in their profession, and the interest of its professional members.
Permanent Harm	Directly related to the incident and not related to the natural course of a patient's illness or underlying condition is defined as permanent lessening of bodily functions; including sensory, motor, physiological or intellectual.

Risk	The chance of something happening that will have an impact on individuals and/or organisations. It is measured in terms of likelihood and consequences.
Risk Management	Identifying, assessing, analysing, understanding and acting on risk issues in order to reach an optimal balance of risk, benefit and cost.
Resources	The things needed to carry out a task or a piece of work. Resources can include appropriately qualified staff, suitable buildings and sufficient equipment.
Root Cause Analysis (RCA)	A systematic process whereby the factors that contributed to an incident are identified. As an investigation technique for patient safety incidents, it looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which an incident happened.
Safety	A state in which risk has been reduced to an acceptable level.
Safeguarding	Ensuring that people live free from harm, abuse and neglect and, in doing so, protecting their health, wellbeing and human rights. Children, and adults in vulnerable situations, need to be safeguarded. For children, safeguarding work focuses more on care and development; for adults, on empowerment, independence and choice.
Severe Harm	A patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.
Significant Event Audit	An audit process where data is collected on specific types of incidents that are considered important to learn about to improve patient safety.
Treatment	Broadly, the management and care of a patient to prevent or cure disease or reduce suffering and disability.
Unexpected Death	Where natural causes are not suspected. Local organisations should investigate these to determine if the incident contributed to the unexpected death.
Working Day	Days that exclude weekends and bank holidays

Appendix A
Clinical governance and adult safeguarding flow chart



Appendix B
Never Events framework

Never Events were identified in Lord Darzi's report High Quality Care for All, published in June 2008. The NPSA has developed and is testing a list of Never Events and a process for use in the NHS in 2009/10 and subsequent years.

www.nrls.npsa.nhs.uk/neverevents

Never Events in providers should have been monitored by commissioning PCTs and will be publicly reported on an annual basis. This should influence patient safety by promoting discussion between commissioners and providers of Never Events, as well as serious incidents in general, their prevention and any learning from investigations by providers if they occur.

There were eight core Never Events in the core list for 2009/10, and for 2010/11 these will remain, commissioning PCTs can add additional Never Events to their contracting process. All Never Events in the core list for 2009/10 link to existing national guidance. The eight core Never Events are:

- Wrong site surgery
- Retained instrument post-operation
- Wrong route administration of chemotherapy
- Misplaced naso or orogastric tube not detected prior to use
- Inpatient suicide using non-collapsible rails
- Escape from within the secure perimeter of medium or high secure mental health services by patients who are transferred prisoners
- In-hospital maternal death from post-partum haemorrhage after elective caesarean section
- Intravenous administration of mis-selected concentrated potassium chloride

Appendix C
Grading and timescales for investigation

Incident Grading	Investigation type	Timescales for completion of investigation
Grade 1	**Comprehensive Investigation (RCA level 2 Investigation)** • Conducted with a high level of detail, including all elements of a thorough and credible investigation. • Conducted by a multidisciplinary team, or involves experts/expert opinion/independent advice or specialist investigator(s). • Conducted by staff not involved in the incident, locality or directorate in which it occurred. • Overseen by a director level chair or facilitator. • Led by person(s) experienced and/or trained in RCA, human error and effective solutions development. • Includes patient/relative/carer involvement and should include an offer to patient/relative/carer of links to independent representation or advocacy services. • May require management of the media via the organisation's communications department. • Includes robust recommendations for shared learning, locally and/or nationally as appropriate. • Results in full report with an executive summary and appendices.	Up to **45 working days/9 weeks** from the date the incident is notified to the PCT/SHA. Comprehensive investigations can be completed more quickly if the provider organisation wishes and extensions beyond the 45 days can be agreed between the provider organisation and PCT/SHA.
Grade 2	**Comprehensive Investigation (RCA level 2 Investigation** (As above) **or Independent Investigation (RCA level 3 Investigation)** • Must be commissioned and co-ordinated by the Commissioning PCT or Strategic Health Authority and independent to the provider organisation service/s and organisation/s involved in the incident, **for independent investigations only** • Commonly considered for incidents of high public interest or attracting media attention. • An **independent investigation** must be conducted for mental health homicides (where there has been recent contact with mental health services) that meet Department of Health guidance. • Should be conducted where Article 2 of the European Convention on Human Rights is, or is likely to be, engaged.	Up to **60 working days/12 weeks** from the date the incident is notified to the PCT/SHA. Comprehensive investigations can be completed more quickly if the provider organisation wishes and extensions beyond the 60 days can be agreed between the provider organisation and PCT/SHA. For independent investigations allow up to **26 weeks/6 months** for completion of the investigation.

Appendix D
Summary of responsibilities for different grades

Grade 1	**Local monitoring** • The PCT and/or SHA will close the incident when it is satisfied the investigation, recommendations and action plan is satisfactory, and local monitoring arrangements (above) are in place and working efficiently. • Publish incident details within Annual Reports
Grade 2	**SHA/PCT monitoring** • Incidents involving an independent investigation or inquiry or those considered high risk will continue to be monitored by the SHA/PCT or LA until evidence is provided that each action point has been implemented. Incidents involving adult or child abuse are referred to local safeguarding arrangements • Publish quarterly reports **Closure Checklist** Prior to considering an incident closed, commissioning PCTs and SHAs should ensure the following have been provided: • an appropriate investigation that identifies findings, based on root causes and recommendations, • an Action Plan with action points to address each root cause and with a named lead and timescale for implementation, • lessons learned have been identified and partners or stakeholders with whom the learning has been shared, • evidence demonstrates that each action point has been implemented, • Never Events must be documented for inclusion in the annual reporting arrangements of commissioners. **Note: An approved action plan to address long term issues will be subject to monitoring by each organisation's lines of accountability.**

Appendix E
Investigation report executive summary template

NHS
National Patient Safety Agency

Root Cause Analysis Investigation Report

Executive Summary for Learning

Brief incident description
• **Incident date:**
• **Incident type:**
• **Healthcare specialty:**
• **Actual effect on patient and/or service:**
• **Actual severity of the incident:**
Level of investigation conducted
Involvement and support of the patient and/or relatives
Detection of incident
Care and service delivery problems
Contributory factors
Root causes
Lessons learned
Recommendations

Appendix F
Summary of responsibilities by organisation

	Identification of serious incidents	Reporting	Response	Investigation	Action Plan development & implementation	Monitoring & closure	Dissemination of learning	Audit and evaluation	Communications and media management
Health care provider organisations	✔	✔ To all relevant bodies and SHA or PCT	✔	✔	✔	✔	✔ In local organisation to all relevant staff	✔ of Action Plan implementation	✔
Commissioning PCTs		✔ To SHA	✔	✔ Commissioning Independent Investigations		✔	✔	✔ of Action Plan implementation & provider organisation compliance with this policy	✔
Strategic Health Authorities		✔ To DH & CQC as appropriate	✔	✔ Expert support to provider organisations via PSATS Commissioning Independent Investigations		✔	✔	✔ of Action Plan implementation, provider organisation compliance with this policy & PCT compliance with this policy	✔
Regulators (Care Quality Commission, MHRA, etc)			✔	✔	✔	✔	✔	✔	✔
Department of Health									✔
Other bodies with a remit for quality and safety (NPSA, Health Protection Agency, Central Screening Programme bodies) Social Care			✔				✔	✔	✔
Expert bodies and professional associations (e.g. Royal Colleges)							✔		

Appendix G
Stakeholder organisations

The following bodies have been involved in the development of this framework:

- Department of Health Patient Safety Policy Branch
- Department of Health NHS Contracting
- Welsh Assembly Government
- Strategic Health Authorities
  - North East
  - North West
  - Yorkshire & Humber
  - East Midlands
  - West Midlands
  - East of England
  - London
  - South East Coast
  - South Central
  - South West
- Care Quality Commission
- Monitor
- NHS Litigation Authority
- Medicines and Healthcare products Regulatory Agency
- NHS Confederation
- Health & Safety Executive
- Health Protection Agency
- NHS Business Services Authority – Counter Fraud and Security Management
- Connecting for Health
- National Blood Service
- Audit Commission
- Confidential Enquiries – Maternal & Child Health, Patient Outcome and Death, Suicides & Homicides
- (NPSA) National Clinical Assessment Service
- Independent Healthcare Advisory Service
- NHS Information Centre for Health and Social Care
- (NPSA) National Research Ethics Service
- National Screening Programmes
- SHOT (Serious Hazards of Transfusion)
- CORESS (Confidential Reporting System for Surgery)

Organisations endorsing the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation.

Notes

National Reporting and Learning Service
National Patient Safety Agency
4 - 8 Maple Street
London W1T 5HD

T 020 7927 9500
F 020 7927 9501

www.nrls.npsa.nhs.uk

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