NATIONAL FRAMEWORK
FOR REPORTING AND LEARNING FROM
SERIOUS INCIDENTS REQUIRING
INVESTIGATION
## DOCUMENT OVERVIEW

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**Document purpose and description**

Policy requirements for the identification, notification, investigation, action planning & implementation, monitoring, closure and communication of serious incidents in NHS funded care in England. This document provides a consistent national approach to the management and prevention of the occurrence of serious incidents.

**Author/s**

Patient Safety Direct Programme Team, National Patient Safety Agency

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**Job title of person responsible for review**

Serious Incident Reporting & Learning Project Lead, National Patient Safety Agency

**Applies to**

- Strategic Health Authorities
- Commissioning PCTs
- NHS Trusts
- Foundation Trusts
- Independent Practitioners (GPs, Pharmacists, etc)
- Independent Service Provider organisations of NHS funded care

**Consultation process**

Consultation with commissioning PCTs, SHAs, provider organisations, frontline staff and stakeholder organisations from August – November 2009.

**Equality Impact Assessment**

NO

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FOREWORD

Commissioners, providers and managers of NHS care want to ensure that when a serious event or incident occurs, there are systemic measures in place for safeguarding people, 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.

That is why this consultation paper is so important.

It seeks your views on this first release of a National Framework for Reporting and Learning from Serious Incidents Requiring Investigation (previously known as Serious Untoward Incidents or SUIs).

Working closely with individuals from across the NHS, the 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, information on timescales and signpost tools and resources that support good practice. It is designed to support openness, trust and continuous learning and service improvement.

The framework is an important foundation for Patient Safety Direct. The National Patient Safety Agency is leading on the development of Patient Safety Direct as part of taking forward Lord Darzi’s recommendations from the Next Stage Review.

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

I commend the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation and look forward to your feedback.

Martin Fletcher
Chief Executive
National Patient Safety Agency
NATIONAL FRAMEWORK FOR REPORTING AND LEARNING FROM SERIOUS INCIDENTS FOR INVESTIGATION

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Abbreviations:
IDT: Incident Decision Tree
PSI: Patient Safety Incident
RCA: Route Cause Analysis
RLS: Reporting & Learning System
SEA: Significant Event Audit
SI: Serious Incident
1. EXECUTIVE SUMMARY

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

This is the first release of a new national framework for the 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 which provide NHS services in England.

The purpose of this framework is to:-
- provide a nationally consistent definition of a serious incident for investigation
- clarify roles and responsibilities
- provide information on notification requirements and timescales
- draw together legal and regulatory requirements associated with the notification and management of serious incidents and which form the basis of this framework.

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

One of the key components of the framework is a nationally consistent definition of a serious incident; the variability of previous definitions has led to confusion about what constitutes a serious incident. This framework seeks to present a definition which minimises ambiguity and improves consistency.

A key element of the framework is the clarity of roles and responsibilities for providers of NHS care, Commissioning Primary Care Trusts (PCTs) and Strategic Health Authorities (SHAs). This includes governance arrangements, reporting mechanisms and responsibilities, investigation, learning and dissemination from serious incidents.

The framework aims to provide clear guidance on the legal and regulatory requirements for reporting serious incidents to key national organisations, such as the Medicines and Healthcare Products Regulatory Agency (MHRA), Health Protection Agency (HPA), National Screening Programmes, Health and Safety Executive (HSE) and the Care Quality Commission (CQC). It also sets out the role of the National Patient Safety Agency as the primary NHS organisation for the collation of, and learning from, serious patient safety incidents.

At the time of publication of this framework, 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. These systems will be replaced by a new national Serious Incident Management System (SIMS) in 2010 as part of Patient Safety Direct. This framework will form the basis of the new SIMS.
2. PURPOSE, SCOPE AND RESPONSIBILITIES

Healthcare is a complex, high risk activity where it is inevitable that occasionally some things will go wrong.

However serious incidents in healthcare are relatively uncommon considering the high number of people who receive care.

When a serious incident does occur it can have a devastating and far reaching effect. The effect may impact not only on those people directly involved, be they patients, relatives, staff or visitors, but also to the reputation of the health care organisation, the service or the profession within which the incident occurred, and also on the wider National Health Service (NHS).

2.1. PURPOSE OF THE SERIOUS INCIDENT REPORTING FRAMEWORK

The purpose of this framework is to:

- provide a nationally consistent definition of a serious incident that requires investigation;
- clarify roles and responsibilities;
- draw together legal and regulatory requirements associated with the management of serious incidents and which form the basis of this framework;
- provide information on requirements and timescales;
- provide an overarching framework developed from good practice, along with signposting tools and resources that support good practice.

The systems-improvement approach to safety acknowledges that the causes of incidents cannot simply be linked to the actions of individual people. Therefore, the framework has been developed based on a system-wide perspective for the notification, management and learning from serious incidents. It is also designed to support openness, trust, and continuous learning and service improvement.

2.2. 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:

- the unexpected or avoidable death of one or more patients, staff, visitors or members of the public;
- permanent harm to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention or major surgical/medical
intervention or will shorten life expectancy (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 health care services, for example, actual or potential loss or damage to property, reputation or the environment;
- a person suffering from abuse;
- adverse media coverage or public concern for the organisation or the wider NHS;
- 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 which could have resulted, or did result in unnecessary damage, loss or harm to a patient, staff, visitors or members of the public\(^1\).

2. **NHS funded services and care** – The treatment of patients in: NHS establishments or services; in independent establishments including private healthcare; or the patient’s home or workplace. Either all or part of the patient’s care in these settings is funded by the NHS\(^2\).

3. **Permanent harm** - permanent lessening of bodily functions; including sensory, motor, physiologic or intellectual\(^3\).

4. **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 or (an extensive orthopaedic procedure is involved, the surgery is considered ‘major’)\(^4\).

5. **Abuse** - as defined by *No secrets* for adults and *Working together to safeguard children*(2006)\(^5\).

The definition of serious incident for investigation extends beyond those which impact directly on patients and includes incidents which may indirectly impact on patient safety or an organisation’s ability to deliver on-going healthcare services. All serious patient safety incidents should be reported to the NPSA and currently also to the Strategic Executive Information System (STEIS) or local Serious Incident Reporting Systems
The National Patient Safety Agency (NPSA) has published a series of definitions covering the full range of harms which may result from a patient safety incident\(^{(3)}\). There is an expectation that, 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 reoccurrence.

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 PCT.

### 2.3. SCOPE OF THE SERIOUS INCIDENT REPORTING FRAMEWORK

This framework covers all serious incidents which meet the criteria described in the definition in section 2.2, occurring in NHS funded services and care in England. This includes services provided by NHS trusts, foundation trusts, independent healthcare provider organisations, independent practitioners (general practitioners (GPs), community pharmacists, community optometrists and general dental practitioners) and prison healthcare services.

This framework complements the serious incident, incident and risk management policies in healthcare provider organisations. 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.

**Serious incidents occurring in Wales:**

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

The framework aims to complement other requirements, particularly existing guidance for national reporting. Some of these procedures/policies are referenced in more detail in the ‘Information resource to support the reporting of serious incidents’ available at: [http://www.npsa.nhs.uk/nrls/reporting/patient-safety-direct/](http://www.npsa.nhs.uk/nrls/reporting/patient-safety-direct/)

This framework will be reviewed by the Patient Safety Direct team at the NPSA prior to the launch of the new SIMS and amended as needed in the light of experience and any new requirements.
2.4. 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 systemic measures in place for safeguarding people, property, the service’s resources and its reputation, and for understanding why the event occurred. There is also a responsibility to ensure that steps are taken to reduce the chance of a similar incident happening again. The NPSA works across NHS funded care to promote actionable learning on a national basis.

All organisations should ensure their staff understand what constitutes a serious incident, as defined in section 2.2 and are familiar with the requirements of this framework, and have procedures in place to ensure relevant incidents are investigated and managed in a way which is consistent with this approach.

For serious incidents, health care provider organisations are divided broadly into three categories - each with their own lines of accountability (see figure 1):

- **NHS trusts** are accountable to commissioning PCTs through contracting and commissioning arrangements and to SHAs.

- **NHS foundation trusts and their board of directors** are accountable to their governors and members, regulated by Monitor for compliance with their terms of authorisation and held to account for performance through their contractual relationships with commissioners.

- **Independent provider organisations and practitioners including GP practices and independent sector provider organisations** are held to account through contractual relationships with commissioners and through national contracts.

In addition, all organisations providing NHS (and independent sector) care are regulated by the Care Quality Commission.
2.4.1. ROLE OF THE NPSA

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

- dissemination of national learning from serious incidents 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;
- development and dissemination of tools and national guidance emanating from reporting and learning

2.4.2. 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 \(^{(7)}\) and National Standards, Local Action; a planning framework for health and social care \(^{(8)}\).

- A formal mechanism, such as a committee accountable to the board, which has responsibility for monitoring the management of serious incidents.

- 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. This policy should meet the requirements of the NHS Litigation Authority Risk Management Standards NHSLA \(^{(9)}\).

- Clear board-level responsibility for implementing and monitoring the requirements of this framework, 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 all serious patient safety incidents to the NPSA.

- An auditable processes for reporting serious incident to all relevant bodies and authorities including the SHA, commissioning PCT, police, local authority and other provider organisations (where applicable) and other key stakeholders, providing additional information to stakeholders where requested.

- A mechanism for notifying commissioning PCTs of all serious incidents, including Never events (see appendix F).

- Procedures to ensure that, where appropriate, referrals of individuals to the Independent Safeguarding Authority are made.

- Arrangements for ensuring staff and patients receive support following a serious incident.

From April 2010, it will also be a requirement that providers improve the service to comply with the Health and Social Care Act 2008 (Registration Requirements) Regulations\(^{2009}\) and accompanying guidance about compliance, which should be available by the end of 2009.

Investigation and Action Planning

- Arrangements for ensuring investigations take place within required time scales and use best practice methodologies such as root cause analysis (RCA).
- 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.

**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.

**Media Management**

- Arrangements to manage any potential press and media enquiries and, if necessary, inform the PCT, SHA and the Department of Health Media Centre and the Ministerial Briefing Unit. Where appropriate for child safeguarding, inform the Government Office through the local authority.
2.4.3. 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 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 the local safeguarding children board 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 all serious incidents are reported by provider organisations to the NPSA and other bodies as appropriate.
- A process to report all serious incidents, including ‘Never events’, to the PCT board and plans for recording ‘Never events’ in their 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 that incidents have been formally closed.
- Arrangements for commissioning independent investigations if there is a requirement to do so.

Learning and Follow up

- Arrangements for the dissemination of learning from serious incidents 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).

**Media Management**

- Arrangements to manage any potential press and media enquiries and, if necessary, inform the SHA and the Department of Health Media Centre and the Ministerial Briefing Unit. Where appropriate for child safeguarding, inform the Government Office through the local authority.
2.4.4. EXPECTATIONS OF STRATEGIC HEALTH AUTHORITIES

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

**Governance**

- Arrangements to ensure that PCTs are performance-managing serious incidents occurring in their commissioned services in accordance with the requirements of this framework.
- Arrangements to ensure that PCTs are monitoring local compliance with this framework.
- Strong links with the local safeguarding children boards in order to share relevant knowledge and information around child protection and safeguarding among PCTs and providers.

**Reporting**

- Arrangements to assure that all serious incidents are reported to the National Patient Safety Agency and other bodies as appropriate.

**Investigation and Action Planning**

- Arrangements to ensure relevant skills and expertise and commissioning resources in Patient Safety Action Teams to advise provider organisations on RCA investigations as required by the Department of Health (10) and the Never events framework 2009/10 (Appendix F)
- Commission independent investigations if there is a requirement to do so.
- Arrangements for receiving assurance from provider organisations through commissioning PCTs that action plans have been implemented following a serious incident.

**Learning and Follow up**

- Arrangements for the dissemination of lessons learned to all provider organisations in order to minimise the risk of similar incidents occurring in the future 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 the 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 those incidents (or clusters of incidents) that require further external investigation.

**Media Management**

- Arrangements to manage any potential press and media enquiries and, if necessary, inform the Department of Health Media Centre and the Ministerial Briefing Unit. Where appropriate for child safeguarding, inform the Government Office through the local authority.
3. MANAGEMENT OF A SERIOUS INCIDENT

The circumstances surrounding each incident varies in terms of levels of harm and numbers of people involved, risk exposure, financial loss, media interest, the need to involve other reporting stakeholders etc, 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.

3.1. 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 all relevant documentation copied and secured.

The organisation should give early consideration to the provision of information and support to patients, relatives and carers and staff involved in the incident. 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.

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 http://www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/beingopen/

For information on action and support for staff http://www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/incidentdecisiontree
3.2. REPORTING

All provider organisations should designate a senior member of staff (usually an executive director with board level responsibility for risk and patient safety) with responsibility for ensuring the reporting of serious incidents, to 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 as required.

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 (5) which relates to the Children Acts 1989 and 2004.

Foundation trusts reporting of serious incidents

Serious incidents occurring in foundation trusts should be reported to the lead commissioning PCT and the NPSA, where the foundation trust decides to do so, to the SHA. Foundation trusts are not currently required to report serious incidents to the SHA. However a voluntary agreement is often sought to promote a service-wide approach to serious incident management to facilitate the sharing of learning across the NHS as a whole.

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

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.

The STEIS will be superseded by a new national Serious Incident Management System (SIMS) in 2010. At that time, all organisations will be expected to use SIMS. SHAs may disseminate separate requirements for using STEIS or local 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 body without any delay and within two working days of the incident being identified locally. These timescales apply to evenings, weekends and bank holidays.

3.3. IMMEDIATE ACTION BY THE COMMISSIONING PCT OR SHA

Each SHA or commissioning PCT (depending on locally agreed arrangements) will designate a member of staff with 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/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 is also responsible for ensuring that local safeguarding procedures for adults and/or children are followed.

Within two working days maximum (this will be much sooner for some incidents) following receipt of details of the incident, the designated SHA/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 the subsequent actions and responses required by each organisation.

Serious Incident grading for the purposes of investigation

Once an incident is designated as serious and reported, the SHA/PCT should grade the seriousness of the incident for the purposes of determining the investigation and monitoring approach.

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

Table 1 is a guide to the incident grades developed by the NPSA. Grading should be agreed by SHA/PCTs and provider organisations on a case-by-case basis and with advice from specialist sources where appropriate. (The list of examples is not exhaustive).
Table 1: Grading of serious incidents

| Grade 0 | 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 hours it is found not to be a serious incident, it can be closed with the agreement of the SHA/PCT.  
If a serious incident has occurred it will be re-graded as a grade 1 or 2 |
|---|---|

| Grade 1 | PCT will monitor the case and report to the SHA, findings and recommendations and associated action plans.  
SHA will monitor progress on a quarterly basis with PCT unless earlier discussion is required or the serious incident is re-graded.  
Examples:  
• Drug errors leading to severe harm or death  
• Unavoidable/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) |
|---|---|

| Grade 2 | Case will be monitored by the SHA/PCT 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 report these in its annual reporting arrangements  
Examples:  
• Homicides  
• Serious or intentional harm to patients  
• Maternal deaths  
• In-patient suicides  
• Child protection  
• Data loss and information security (DH Criteria level 3-5) |

Grading of incidents supports a proportionate and appropriate response on a case-by-case basis so timescales and level of investigation reflect the level of 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 Department of Health Media Centre will be notified by the Strategic Health Authority of those incidents either grades 1 or 2 which may potentially attract national or significant media attention. This will happen within two hours of receiving a potentially high profile serious untoward incident. All other appropriate serious untoward incidents will be notified within two working days (or less).
Caldicott, Data Protection and Information Governance

In the majority of circumstances provider organisations must comply with Caldicott Data protection and information governance requirements when reporting serious incidents, and should not refer to any individuals by their name or other identifiable information: ‘restricting access to patient information within each organisation by enforcing strict need to know principles ‘Caldicott Guardian Manual’ 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. It will therefore be necessary to identify an individual in certain circumstances, for example making a ‘safeguard’ alert. In these circumstances the serious incident lead in the provider organisation will contact the senior member of the SHA or PCT 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 each other is notified, a lead PCT is identified and a timescale is locally agreed.

Incidents involving more than one provider organisation

If more than one organisation is involved in a serious incident, the organisation which identified the incident can make the initial notification having first made contact, wherever possible, with the organisation where it originated.

The lead organisation must be identified and agreed (with clear responsibilities) at this point with the other organisations involved. The named lead/point of contact should be clearly identified to the SHA/commissioning PCT.

NHS organisations have a primary responsibility to investigate and take preventative action when things go wrong in order 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.

Incidents involving the Health & Safety Executive and the police

The Memorandum of understanding: investigating patient safety incidents involving unexpected death or serious untoward harm published by the Department of Health in February 2006 provides a protocol for liaison and effective communication between the NHS, the Health & Safety Executive and the Association of Chief Police Officers with regard to investigating patient safety incidents (unexpected death or serious untoward harm). A summary is provided in Appendix B.
Reporting of serious incidents to the Care Quality Commission

From 1 April 2010, providers will also be required to notify the Care Quality Commission (CQC) either directly or via other bodies, of certain categories of incidents. The types of incident and reporting arrangements are to be defined in the final Health and Social Care Act (Registration Requirements) Regulations 2009 and accompanying guidance about compliance, which should be available by the end of 2009.

Independent healthcare provider organisations and practitioners

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

- National Contracts

In the case of an independent sector provider organisation responsible for providing health care services under national contract, all serious incidents should be reported directly to:

- the lead commissioning/sponsoring PCT;
- NHS Contracting at the Department of Health;
- where appropriate, to comply with local safeguarding arrangements;
- 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 PCT as part of their NHS contract or to other bodies as required in national legislation.

- Local Contracts

In the case of an independent sector provider organisation responsible for providing health care services under local contract, all 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 independent sector provider organisation is registered with the CQC all serious incidents involving patients are also required to be reported by the provider organisation to the CQC.

Where a serious incident from an independent sector provider organisation is discovered in the first instance by an NHS organisation, it should be immediately reported to the independent sector service provider organisation 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 independent sector provider organisation 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 that 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 that patient’s 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), National Screening Programmes, Health and Safety Executive (HSE) and Monitor should be notified about incidents relevant to their remit in accordance with their reporting guidance.

In such circumstances these bodies will liaise with each other, the relevant commissioning PCT and/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.npsa.nhs.uk/rca](http://www.npsa.nhs.uk/rca)
3.4. 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 which set out how investigations will be conducted in order 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 A.

It is recommended that investigations follow the NPSA guidance and identify both active (e.g. acts and omissions by staff) and latent (e.g. organisational or environmental issues) failures. If only active failures are identified the resulting solutions and are unlikely to maintain sustainable prevention. The findings of investigations inform the action plan development and implementation and the identification of lessons learned is a key stage in the serious incident management process.

Guidance and templates are available from the NPSA and although developed for the investigation of patient safety incidents are applicable to all types of serious incidents. The use of the NPSA’s RCA report writing tools and templates by provider organisations is strongly recommended in order to standardise serious incident investigation reports and provide quality assurance.

Allegations of abuse are always referred immediately to local multi-agency safeguarding arrangements for adults and children. 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 including responsibility for payment.

Investigation teams

Provider organisations will ensure there is an up to date list of staff within the organisation familiar with the organisations investigation policies and protocols, skilled in good practice root cause analysis investigation methodologies and techniques that can be made 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;
- 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* (10)

**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 new national serious incident management system being developed to replace STEIS (launch planned for 2010) aims to incorporate a means by which 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 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 ongoing open discussions between the 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. Further information can be found at the Information Commissioners Office: - [www.ico.gov.uk](http://www.ico.gov.uk)

**Tools and resources:**


3.5. 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) which 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 attached to an executive summary for internal/external circulation following approval of recommendations.

On receipt of an investigation report, the SHA/PCT will review its content, taking clinical and/or other advice as appropriate to determine whether all aspects of the incident have been adequately investigated and whether there is a clear action point to address each root cause and reduce the risk of reoccurrence.

The SHA/PCT will give feedback to the provider organisation (although will be involved in the process) within four weeks 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:
http://www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-
guidance/rootcauseanalysis/rca-investigation-report-tools/

3.6. MONITORING & CLOSURE

One of the key elements of a successful serious incident management process and of 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 which has responsibility for monitoring serious incidents.
Commissioning PCTs and Strategic Health Authorities

The level of monitoring undertaken by the PCT/SHA will be appropriate and proportionate to the grading level of the individual incident (Table 2)

Table 2 Grading monitoring

<table>
<thead>
<tr>
<th>Grade 1</th>
<th>Local monitoring</th>
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<tr>
<td></td>
<td>• The PCT/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.</td>
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<thead>
<tr>
<th>Grade 2</th>
<th>SHA/PCT monitoring</th>
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<td></td>
<td>• Incidents involving an independent investigation or inquiry or those considered high risk will continue to be monitored by the SHA/PCT until evidence is provided that each action point has been implemented. Incidents involving adult or child abuse are referred to local safeguarding arrangements</td>
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Closure Checklist

Prior to considering an incident to be closed commissioning PCTs and SHAs should ensure the following have been provided:

• an appropriate investigation has been completed which identifies findings, root causes and recommendations

• an Action Plan has been developed 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 has been received to demonstrate that each action point has been implemented

• if a ‘Never event’, then it must be documented for inclusion in the annual reporting arrangements of commissioners

Other bodies with a remit for serious incidents

Despite closure of a serious incident by the provider organisation and the PCT/SHA it may still be considered open to other bodies such as the NPSA, MHRA, HSE, NHS Contracting, Connecting for Health, 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.
3.7. DISSEMINATION OF LEARNING

One of the key aims of the serious incident reporting and learning process is to reduce the risk of re-occurrence, 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.

What constitutes learning?

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

- Solutions to address incident root causes which may be relevant to other teams, services and provider organisations
- Good practice which reduced the potential impact of the incident
- Early detection or intervention which reduced the potential impact of the incident
- Lessons from conducting the investigation which may improve the management of investigations in future

An investigation executive summary template (see 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 3).
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<thead>
<tr>
<th>Responsibilities for sharing learning:</th>
<th>With whom:</th>
<th>Example of communication methods:</th>
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</thead>
<tbody>
<tr>
<td><strong>Specific and Common Learning</strong></td>
<td>Local</td>
<td>Meetings with patients and their families</td>
</tr>
</tbody>
</table>
| Provider organisation/organisation/s where the incident occurred | • 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 | • Presentations at staff meetings  
• Team meetings  
• E-bulletins and Newsletters  
• Intranet site  
• Public web site  
• Public Board Papers |
| Organisational                        | • Other departments/ divisions for lessons with wider organisational applicability | • 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) |
| **Broad Universal Learning by:**      | National   | Performance management review meetings  
Newsletters |
| Commissioning PCT                     | • Organisations to whom the learning may be applicable including independent sector provider organisations and practitioners within the PCT  
• SHAs | |
| SHA                                   | National   | Regional network meetings  
Local conferences, seminars and workshops  
Periodic Serious Incident Summary Reports  
Letters to Chief Executives in provider organisation organisations  
Press statements |
| NPSA and other NHS bodies with a remit for safety and serious incidents (MHRA, HPA, CII, CFSMS, CQC etc) | As appropriate:  
• All relevant health care 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 |
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: -

3.8. 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 and extended period after the incident itself. Each organisation should have media relations policies in place which include the appropriate action to be taken 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 the Communications Team at the SHA/PCT on agreeing appropriate media handling strategies, working alongside the 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.

In forensic/criminal cases, the police lead all communications with the media.
Guidance on Media Management Strategies

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

Local judgment will be applied in deciding when help lines and counseling is 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 which 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
- 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 all attempts should be made to contact patients before the media is alerted (where the media is unaware of the serious incident or where you have to seek the media’s assistance), as long as it does not compromise patient safety in any way.

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 there should ideally be a reactive media handling strategy in place. However, any delay in such circumstances should not place patients at any increased risk of harm.

It is essential that there is cross health organisation agreement to this strategy with agreed key messages for spokespeople and a full work through of scenarios to effectively manage media relations.
Another source of information reaching the public domain is from health care staff. Such instances may be accidental or deliberate. For example, if staff believe managers are not taking seriously their concerns about a serious incident or if they do not seem to be 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
- 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.

- Understand the problem
- Put it right
- Reassure

**Media aware of serious incident**

Those directly involved in the incident, including the investigation team, need time and space and support and it is the role of professional communicators to provide this space whilst keeping journalists informed. Under these circumstances the need to rapidly establish the facts and fully understand the extent of the problem and its cause is even more essential.

It is important to keep the public and media informed whilst balancing the needs of the affected people, staff and patients. Staff should be kept informed so they understand why and how you are acting, their role and ownership in fixing the problem and why your communication plans.
Freedom of Information Act 2000

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


## APPENDIX A: GRADING AND TIMESCALES FOR INVESTIGATION

<table>
<thead>
<tr>
<th>Incident Grading</th>
<th>Investigation type</th>
<th>Timescales for completion of investigation</th>
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<tbody>
<tr>
<td><strong>Grade 1</strong></td>
<td>Comprehensive Investigation (RCA Level 2 Investigation)</td>
<td>Up to 45 working days/9 weeks from the date the incident is notified to the PCT SHA.</td>
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<td></td>
<td>▪ Conducted to a high level of detail, including all elements of a thorough and credible investigation.</td>
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<td>▪ Conducted by a multidisciplinary team, or involves experts/expert opinion/independent advice or specialist investigator(s).</td>
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<td>▪ Conducted by staff not involved in the incident, locality or directorate in which it occurred.</td>
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<td>▪ Overseen by a director level chair or facilitator.</td>
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<td>▪ Led by person(s) experienced and/or trained in RCA, human error and effective solutions development.</td>
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<td>▪ Includes patient/relative/carer involvement and should include an offer to patient/relative/carer of links to independent representation or advocacy services.</td>
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<td>▪ May require management of the media via the organisation’s communications department.</td>
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<td>▪ Includes robust recommendations for shared learning, locally and/or nationally as appropriate.</td>
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<td>▪ Results in full report with an executive summary and appendices.</td>
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<tr>
<td><strong>Grade 2</strong></td>
<td>Comprehensive Investigation (RCA level 2 investigation) (as above) or Independent Investigation (RCA level 3 Investigation)</td>
<td>Up to 60 working days/12 weeks from the date the incident is notified to the PCT SHA.</td>
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<td></td>
<td>▪ 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.</td>
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<td></td>
<td>▪ Commonly considered for incidents of high public interest or attracting media attention.</td>
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<td></td>
<td>▪ Conducted for mental health homicides which meet Department of Health guidance.</td>
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<td></td>
<td>▪ Should be conducted where Article 2 of the European Convention on Human Rights is, or is likely to be, engaged.</td>
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<td>▪ 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.</td>
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<td>For Independent Investigations allow up to 26 weeks/6 months for completion of the investigation.</td>
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APPENDIX B: MEMORANDUM OF UNDERSTANDING

INVESTIGATING PATIENT SAFETY INCIDENTS INCLUDING UNEXPECTED DEATH OR SERIOUS UNTOWARD HARM

In November 2006, the Department of Health produced ‘Guidelines for the NHS: In support of the Memorandum of Understanding- Investigating patient safety incidents involving unexpected death or serious untoward harm’ (DH Guidance. 22/11/2006). These guidelines provide practical advice to NHS organisations about what to do when faced with a patient safety incident that may require investigation by the Police and/or Health and Safety Executive (HSE).

A ‘Memorandum of understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm’ was published by the Department of Health in February 2006 and sets out a protocol for liaison and effective communications between the National Health Service (NHS), Association of Chief Police Officers and the Health & Safety Executive (HSE).

The purpose of the protocol is to promote effective working relationships between the three organisations, setting out the general principles for the NHS, Police and Health & Safety Executive to observe when liaising with each other.

The protocol applies to those patient safety incidents involving unexpected death or serious untoward harm requiring investigation by the police or by the police and Health & Safety Executive jointly.

It will sometimes be immediately obvious to NHS Trusts that the police and/or the Health & Safety Executive should be contacted, but in other cases the need may not come to light until the Trust, coroner or other body such as the Medicines and Healthcare products Regulatory Agency has carried out its own investigations. The decision to report an incident to the police should be made at a sufficiently senior level, for example, by either the chief executive or another executive director.

Once such a decision has been taken, representatives of the Trust, police and, where appropriate Health & Safety Executive, should arrange an initial meeting. The meeting of this ‘Incident Coordination Group’ should be called as soon as practicable following the referral and, in any case, the group should meet within five working days of the referral. All three organisations are entitled to call an Incident Coordination Group meeting, but responsibility for organising the meeting rests with the NHS.

The police and/or the Health & Safety Executive may also call an Incident Coordination Group meeting in response to a complaint, referral from a coroner or in response to other concerns.

Until the first meeting of the Incident Coordination Group, the Trust should continue to deal with concerns about patient safety but not undertake any activity that may compromise any subsequent investigations conducted by the police and/or the Health & Safety Executive. If
in doubt about this matter, the Trust should seek legal advice and consult the police, the Health & Safety Executive or where appropriate, other investigating bodies.

It is also critical that any relevant physical, scientific and documentary evidence is secured and preserved.

Some patient safety incidents may result in the police or Health & Safety Executive investigating possible offences by individual NHS employees and/or the NHS employer. Investigation of the NHS employer will normally involve the Health & Safety Executive because health and safety legislation places the primary responsibility on the employer. In such cases, it may not be appropriate for those who may be investigated or could be defendants in a criminal case to be members of the Incident Coordination Group. When this issue arises, it should normally be discussed at the outset by the agencies involved and, if necessary, the Strategic Health Authority should take on the role of liaising with the police and Health & Safety Executive on behalf of the Trust. In the case of Foundation Trusts, this liaison may be taken on by the appropriate Primary Care Trust.

For child protection/safeguarding concerns, the process outlined under *Working Together to Safeguard Children* should be followed. This requires each organisation to conduct an Individual Management Review (IMR), including detailed chronology, which is co-ordinated by a nurse or doctor designated by the PCT. The local safeguarding children board is then responsible for drawing the various IMR’s together to produce an overview report and executive summary for the case, from which an action plan will be developed.
## APPENDIX C: SUMMARY OF RESPONSIBILITIES

<table>
<thead>
<tr>
<th>Identification of serious incidents</th>
<th>Reporting</th>
<th>Response</th>
<th>Investigation</th>
<th>Action Plan development &amp; implementation</th>
<th>Monitoring &amp; closure</th>
<th>Dissemination of learning</th>
<th>Audit and evaluation</th>
<th>Communications and media management</th>
</tr>
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<tbody>
<tr>
<td>Health care provider organisations</td>
<td>✓</td>
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<td>To all relevant bodies and SHA or PCT</td>
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<td>Commissioning PCTs</td>
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<td>Strategic Health Authorities</td>
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<td>To DH &amp; CQC as appropriate</td>
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<td>Regulators (Care Quality Commission, MHRA, etc)</td>
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<td>Department of Health</td>
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<td>Other bodies with a remit for quality and safety (NPSA, Health Protection Agency, Central Screening Programme bodies)</td>
<td>Identification of serious incidents</td>
<td>Reporting</td>
<td>Response</td>
<td>Investigation</td>
<td>Action Plan development &amp; implementation</td>
<td>Monitoring &amp; closure</td>
<td>Dissemination of learning</td>
<td>Audit and evaluation</td>
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<td>Expert bodies and professional associations (e.g. Royal Colleges)</td>
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APPENDIX D: 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
- Human Tissue Authority
- 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 Service
## 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: NEVER EVENTS FRAMEWORK 2009/10

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 (www.npsa.nhs.uk/nrls/neverevents/).

The document *The NHS in England: The Operating Framework for 2009/10* proposes that Never Events in providers should be monitored and publicly reported by commissioning PCTs. 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 are eight core Never events in the core list for 2009/10, and 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:

1. **Wrong site surgery**

   **Description:** A surgical intervention performed on the wrong site (for example wrong knee, wrong eye, wrong patient, wrong limb, or wrong organ); the incident is detected after the operation and the patient requires further surgery, on the correct site, and/or may have complications following the wrong surgery.

   **Main care setting:** Organisations that provide major, minor and/or day case surgery. Dentistry is to be excluded for the first phase.

2. **Retained instrument post-operation**

   **Description:** One or more instruments are unintentionally retained following an operative procedure, and an operation or other invasive procedure is needed to remove this, and/or there are complications to the patient arising from its continued presence. This Never Event does not include interventional radiology or cardiology procedures, and the definition of instrument does not include guide wires, screws, swabs or other similar material.

   **Main care setting:** Organisations that provide major, minor and/or day case surgery
3. **Wrong route administration of chemotherapy**

   **Description:** Intravenous or other chemotherapy (for example, vincristine) that is correctly prescribed but administered via the wrong route (usually into the intrathecal space).

   **Main care setting:** Acute care

4. **Misplaced naso or orogastric tube not detected prior to use**

   **Description:** Naso or orogastric tube placed in the respiratory tract rather than the gastrointestinal tract and not detected prior to commencing feeding or other use.

   **Main care setting:** All

5. **Inpatient suicide using non-collapsible rails**

   **Description:** Suicide using curtain or shower rails by an inpatient in an acute mental health setting.

   **Main care setting:** Mental health

6. **Escape from within the secure perimeter of medium or high secure mental health services by patients who are transferred prisoners**

   **Description:** A patient who is a transferred prisoner escaping from medium or high secure mental health services where they have been placed for treatment on a Home Office restriction order.

   **Main care setting:** Mental health

7. **In-hospital maternal death from post-partum haemorrhage after elective caesarean section**

   **Description:** In-hospital death of a mother as a result of a haemorrhage following elective caesarean section, excluding cases where imaging has identified placenta accrete.

   **Main care setting:** Acute care maternity services

8. **Intravenous administration of mis-selected concentrated potassium chloride**

   **Description:** Intravenous administration of mis-selected concentrated potassium chloride.

   **Main care setting:** All.