

# Serious Untoward Incident Policy

## Document Reference Information

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## Version Control Record

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v1.0	N/A	First draft of policy	Catherine Afolabi	14/06/2007
V2.0	incorporating NHSLA and Standard for Better Health requirements	Second draft of policy	Catherine Afolabi	05/07/2007
V3	Incorporating NHS London, NHSLA and Standard for Better requirements	Third draft of policy	David Hobbs (External Governance Consultant)	14/06/2008
V4	The policy and procedure states the roles and responsibilities of the Trusts, host PCT and SHA in reporting and investigating SUIs.  It also clarifies the roles and responsibilities of all parties in relation to SUIs involving children	Revised NHS London guidance	Bridget Pratt	30/08/09

### To be read with:

Serious & Untoward Incident Policy  
 Risk Management Strategy/Policy  
 Being Open Policy  
 Major Incident Plan  
 Safeguarding Children Policy

**“The PCT incorporates and support the human rights of the individual as set out in the European Convention on Human Rights and the Human Rights Act 1998”**

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## **Introduction**

The vast majority of NHS patients receive high standards of care. However, incidents do occur and it is important they are reported and managed effectively in order to mitigate the effects and to learn lessons. The aim of this document is to put in place effective mechanisms for identifying, managing, investigating and monitoring all serious untoward incidents (SUIs). This SUI policy is intended to clarify reporting lines, ensure lessons are learnt from all SUIs and help strengthen the conduct, management and handling of investigations following an incident. The policy includes the definition of an SUI, accountabilities and responsibilities and the procedures for reporting and investigation.

## **Scope**

This policy has been reviewed to incorporate recent changes in NHS London Guidance. The policy incorporates themes relating to "A Safer NHS" including guidance for Safeguarding Children and Vulnerable Adults.

NHS Brent has a number of distinct roles in the management of SUIs:-

- for the Autonomous Provider Organisation (Brent Community Services (BCS) monitor the progress of SUI investigations, including the implementation of action plans and recommendations
- as host PCT for North West London Hospitals NHS Trust monitor the progress of SUI investigations including the implementation of action plans. This will be the responsibility of the acute commissioning vehicle from November 2009.
- Monitor the progress of investigations, including the implementation of action plans and recommendations for Central and North West London Foundation
- as commissioner of primary care contractors ensure that SUIs are reported via the relevant Contracts Manager, investigated and followed-up with action taken (i.e. implementation of the action plan)
- as commissioner of services from independent care homes ensure that they comply with the requirements of the National Care Standards Commission (NCSC) in reporting and follow up actions.

## **Policy Statement**

NHS Brent recognises that in a healthcare environment, things will sometimes go wrong. When they do, NHS Brent supports the view that the response should not be one of blame and retribution, but of organisational learning with the aim of encouraging participation in the overall process and supporting staff, rather than exposing them to recrimination.

NHS Brent is committed to developing an open and fair culture and to encouraging a willingness to admit mistakes without fear of punitive measures.

## **Culture**

NHS Brent is actively engaged in promoting and developing a safety culture where staff have a constant and active awareness of the potential for things to go wrong. Through the development of this culture, NHS Brent is able to acknowledge mistakes, learn from them and take action to put things right with the opportunity to learn from the SUI and improve patient safety. Having a safety culture encourages a working environment where many components are taken into account and recognised as contributing to an SUI or to the events leading up to it. It is recognised that the causes of any SUI frequently extend far beyond the actions of the individual staff involved, and are often out of their control. While human error might immediately precede an SUI, in a technically and socially complex system like healthcare, there are usually entrenched systemic factors at work. NHS Brent is

committed to using root cause analysis, during the investigation of SUIs and requires all NHS Brent staff to use this technique when investigating SUIs.

## **Being Open**

A commitment to improving communication between NHS Brent and patients who have been harmed is integral to the NHS Brent's policy to improve patient safety. NHS Brent expects all Trusts to demonstrate "being open" principles which involve acknowledging, apologising and explaining what happened to patients and/or their carers who have been involved in a patient safety incident.

## **What constitutes an SUI?**

The principle definition of an (SUI) is something out of the ordinary or unexpected, with the potential to cause serious harm, and/or likely to attract public and media interest that occurs on NHS Brent premises or in the provision of an NHS Brent or a commissioned service. This may be because it involves a large number of patients, there is a question of poor clinical or management judgement, a service has failed, a patient has died under unusual circumstances, or there is the perception that any of these has occurred. SUIs are not exclusively clinical issues, for example an electrical failure may have consequences that make it an SUI.

The definition of a serious untoward incident (SUI), as outlined by NHS London, is any incident involving:-

- the unexpected death of, or serious/life threatening injury to, a patient under the direct care of a health professional, member of the public or member of staff. Foul play may or may not be suspected.
- cases involving vulnerable adults.
- a number of unexpected/unexplained deaths or serious adverse outcomes.
- suspicion of serious error or repeated serious complaints or incidents about an individual member of staff or repeated serious concerns about poor clinical or management judgement, which would give rise to public concern.
- where a death occurred, an injury took place, or where someone was seriously put at risk as a result of a lack of or faulty, procedures or instructions or faulty equipment, or drugs.
- the failure of clinical or non-clinical procedures or their application so serious as to endanger life of a patient, member of the public or member of staff, or to pose a serious security risk or situations when a patient requires additional intervention(s) as a result of failures in the diagnosis/treatment process.
- known, or suspected, case of health care associated infection, which falls within the definitions of the minimum data set or which are deemed a significant outbreak or involve failure of systems, such as decontamination or hospital acquired legionella.
- infected healthcare workers/patient incidents that necessitate consideration of a look back exercise.
- failures of screening or infection control systems that necessitate consideration of a look back exercise.
- failure or misuse of equipment or plant which either caused or could have constituted a risk of injury, harm or danger to the life of a patient, member of the public/member of staff
- a number of low level incidents which aggregate to suggest a potentially more serious problem.
- any Health & Safety Improvement Notices or potential convictions being served upon an NHS Trust.

- any incident or incidents that might lead or give rise to criminal charges including violent attacks on either staff or patients, or hostage situations.
- serious breach of confidentiality.
- major incidents, fires, floods or other events, which cause death or injury or seriously endanger the life of patients or staff, or which threaten the business continuity of a Trust.
- homicide, or suspected homicide, by a patient

There are other incidents/near misses for which local parts of this policy will need to be followed. A definition of these is any incident involving patients, member of staff, visitor which:-

- causes moderate harm to health or psychological well being of the individual involved.
- causes moderate financial loss or damage to trust property, or moderate disruption to its services

Examples include breach of patient/staff confidentiality (depending on severity of case this could also be categorized as a major incident), allegations of harassment, racist remarks, unexpected or unwanted outcomes to clinical treatment (which result in limited or short-lived harm), injury sustained by staff member as the result of work activity (which is limited or short-lived in nature), repeated pattern of those incidents categorized as “low”.

In deciding whether or not the incident being dealt with constitutes an SUI, consider the possible impact the incident could have, including in the media. If it could be damaging to the NHS, it should be reported as an SUI. NHS Brent works on the principle of “no surprises”. It is better to report something early and then de-escalate it than delay reporting. If you are unsure whether or not an issue needs reporting, please check with the Head of Corporate Affairs or BCS Head of Governance.

As the risk assessment process that evaluates whether incidents are SUIs are fundamentally judgement calls and may be open to interpretation, it is advised that clear evidence that the assessment process has been applied is available and audited.

### **Safeguarding Children (child aged between 0-18 years)**

NHS London has issued new guidance and developed the SUI system to include safeguarding child protection notifications. The National Guidance for NHS Organisations regarding Safeguarding Children Investigations related to SUIs comes from Working Together to Safeguard Children (HM Gov 2006). This is the multi-agency statutory Guidance that underpins the Children Acts of 1989 and 2004 and must be followed when reporting an SUI relating to a child. Chapter seven of the Working Together to Safeguard Children Guidance (reference 1) pertains to the unexpected death of any child aged between 0 -18 years old, and chapter eight gives comprehensive guidance as to how to conduct a multi-agency Serious Case Review (SCR) for a child who has died or been seriously injured and abuse or neglect is a factor in their history. The Local Safeguarding Children Board take the coordinating role in both processes, using separately defined Guidance for the monitoring of unexpected deaths and for conducting and producing multiagency Serious Case Reviews. The process for reporting and investigating safeguarding children SUIs is in Appendix 6 and 7.

## **Responsibilities**

### **NHS Brent Board**

The Board has responsibility for agreeing policy which meets statutory requirements and for assuring itself that arrangements are in place to comply with the policy; this includes the receipt of periodic reports from the relevant Executive.

### **Chief Executive**

The Chief Executive has overall responsibility for ensuring that risk is managed throughout the organisation and that appropriate arrangements are in place for reporting, investigating and managing SUIs.

### **Chief Operating Officer - BCS**

The Chief Operating Officer is responsible to the chief executive for ensuring that risks are managed within BCS. BCS as an APO has its own governance process for reporting and managing SUIs. The BCS Governance Committee is responsible for monitoring and scrutinising all BCS SUIs and developing Key performance indicators to monitor compliance with the handling of SUIs.

### **Directors:**

- The relevant Service Director will appoint an investigating officer to undertake the preliminary investigation as required by NHS London
- Identify a suitable investigator/panel consisting of the appropriate manager, and where possible an independent person such as patient and public representative or manager from a different service
- Appoint an 'independent' manager from another department as investigating officer, where failure to do so could prejudice the investigation. The introduction of an independent manager or external manager may be decided at the beginning of an investigation or following re grading of an incident.
- Report progress with SUIs to the Confidential Trust Board

### **Governance EMT**

The Governance EMT:-

- will monitor and scrutinise all SUIs to ensure learning and follow up on relevant action plans to ensure they are implemented
- develop and use key performance and risk indicators to monitor the PCT's compliance with this policy and proficiency with the handling of SUI

### **Head of Corporate Affairs & BCS Head of Governance**

These are to separate posts in the Commissioning PCT and BCS.

**The Head of Corporate Affairs** (Commissioning PCT) has the Lead responsibility for implementing and monitoring the risk management process including the reporting, management and learning from serious untoward incidents.

**The BCS Head of Governance** has the lead responsibility for implementing and monitoring the risk management process including the reporting, management and learning from serious untoward incidents. Both roles will ensure:-

- the reporting manager has provided the appropriate initial information for the 24 hour notification required by NHS London

- the Chief Executive, appropriate Commissioning Director and Chief Operating Officer (BCS) is notified of the SUI within 24 hrs
- NHS London Strategic Executive Information System (STEIS) can be completed within 24 hour time frame.
- an action plan for implementation of recommendations and lessons learned are shared with the Governance Committee for monitoring.
- the investigation is managed appropriately and completed to deadlines.
- there are sound and comprehensive procedures in place for the management of SUI's and that performance targets across the Trust are met
- the quality of the investigation report is of a good standard and is in keeping with the trust requirements and format
- aggregated qualitative and quantitative data on SUI's is produced for the governance Committee quarterly to ensure both local and organisational learning from incidents
- The minimum content of the analysis report will include the incident, causal factors speciality, status, investigation update, NHS London deadline, progress update, action plan implementation
- lessons learned are cascaded and embedded in practice. This will be done through discussion in team meetings, training, newsletter, posters and intranet and the NPSA
- an annual audit of SUIs is carried out to encompass learning and ensure staff alter their practice in response to lessons learnt
- information related to the Trust's performance in relation to numbers of incidents and trend analysis are presented to the Governance Committee, to raise awareness of incident activity and to engage in the processes of Trust wide learning and development.
- risks highlighted from SUIs are incorporated into the risk register with effective risk reduction measures
- decisive action is taken to address trends through learning from incident workshop and the communications bulletin.
- the Trust Board is informed of SUI performance, activity and trends, through exception reports
- liaise with NHS London on issues related to serious incidents, independent inquiries, areas of media interest, etc
- make provision for key staff to be trained in investigating incidents.

#### **Commissioned services:**

**The Head of Corporate Affairs and Lead Commissioners** are responsible for:

- ensuring mechanisms are in place for the PCT to be informed of SUIs occurring within all services commissioned by the PCT
- Ensuring Commissioned services set up internal investigation panels for their SUIs
- working with the Lead Commissioners to review the aggregated qualitative and quantitative data on to ensure both local and organisational learning from incidents
- working with the Lead Commissioners to ensure risk discovered from trends and themes in the aggregated data is transferred into the clinical risk register.
- Working with Lead Commissioners to monitor Never Events ( see appendix 4)
- timely collation of all SUI initial reports received from commissioned services
- ensuring final reports are received and directed appropriately
- ensuring SUI reports produced for the PCT Trust Board specifies any breaches in the NHS London 60 day deadline.

#### **Director of Human Resources**

- ensure the workforce have access to the development of effective skills in the management of SUI processes.

- ensure Occupational Health support e.g. counseling services are available for staff affected by SUI's.
- ensure structures are in place to provide on-going support to staff following SUIs, linked to the PCT Sickness & Absence policy.
- ensure external bodies e.g. GMC, MNC etc are alerted (in line with the relevant Code of Practice) where failures to provide care to the expected standards are identified.

## **Head of Communications**

The Head of Communication must always be informed of any situation where there may be press interest or ramifications for the PCT following an incident. The Head of Communication is responsible for all media relations and acts as the link between the trust and NHS London in the preparation of press statements.

## **Departmental Managers**

Departmental managers are responsible for ensuring that their staff and professionals who work for, or who provide services to the NHS, are informed of this policy and procedure and are supported in its implementation. Departmental managers must also ensure their staff attend risk management training which includes SUI. This is defined in the Trust training needs analysis.

## **All staff**

All staff have a duty to comply with this policy and report adverse events and near misses. They also have a duty to cooperate with internal and external investigations in respect of untoward incidents.

## **Investigation Officer**

For each SUI an Investigation Officer will be identified by the relevant service Director. The role of an SUI investigation Officer will be to:-

- ensure that the incident is investigated in a systematic and timely manner, achieving the 60 working day performance target set by NHS London and expected as part of this policy using Root Cause Analysis template in appendix 13
- bring to the attention of the Director concerns which may come to light during the course of the investigation to ensure patient safety is not further compromised or otherwise.
- take statements from staff as necessary as soon as possible, post incident
- ensure the investigation report follows a root cause analysis format
- report issues of concern as they arise to the service director with line management responsibility for the area of investigation, so that safety is not compromised.

## **Reporting SUIs**

### **Who should report SUIs?**

- All staff in NHS Brent and Brent Community Services
- All commissioned services who provide a service for NHS Brent patients
- Foundation Trusts (FTs) (Central & North West London Mental Health Trust report SUIs to NHS Brent as part of their contract.
- NHS Brent as host PCT for North West London Hospitals NHS Trust is automatically informed of an SUI via NHS London when a STEIS record for NWLH is completed.

### **How are SUIs reported (NHS Brent & BCS)?**

The key elements of SUI reporting are contained in more detail in appendix 8. All SUIs must be reported to the Head of Corporate Affairs or BCS Head of Governance using the SUI notification form (Appendix 15). The on-line incident form should also be completed. Appendix 1 lists examples of incidents that must be reported as SUIs. The list is not exhaustive and further discussion with the Corporate Affairs or Governance team should take place if advice or guidance is required. Commissioned services will have their own local reporting process but must notify the Head of Corporate Affairs and the Lead Commissioners of all SUIs.

### **What information will Head of Corporate Affairs or BCS Head of Governance require?**

The Head of Corporate Affairs or Governance will need full details of the incident including when and how it happened, information about how it is being managed, including media handling arrangements, if appropriate. All reports must contain anonymised information. The names of any practitioners or staff involved must not be included on the form or the final SUI report. Staff should be referred to by their job title. Other individuals should be referred to by initials only. The Information Background Analysis approach should be used (see appendix 16).

### **When should SUIs be reported?**

This should be reported as soon as the incident becomes known and on the same working day wherever possible. Limited information early is better than full information late in order to ensure that there are 'no surprises' and SUIs can be briefed to NHS London. This should be followed up with full information at the earliest opportunity.

The individual who suspects the incident they are managing to be an SUI must act immediately to inform their line manager/on call manager (out of hours). The manager must contact the Director/On call. The on-call Director contact is 0844 822 2888, Pager number 806961 and the Senior Manager on Call contact is 806215. Contemporaneous records must be kept detailing the immediate actions taken. This record should reflect who did what, where authorisation came from, a time line is useful for this. The manager dealing with the SUI at this time should be the person to keep this record.

The manager must take any immediate action necessary to prevent danger to staff, service users and the public.

If there is a need to inform or consult NHS London verbally during office hours, contact must be with the relevant Director of Service. Out of hours urgent notification should be made to 08700 555 500 Pager # LON 01.

### **De-escalation Requests**

On occasions where SUIs are reported with limited information which on further investigation does not meet the criteria for an SUI, the SUI can be de-escalated. Request for an SUI to be de-escalated should be sent to the Head of Corporate Affairs and BCS Head of Governance who will contact NHS London. The request must include information on why the incident does not warrant further investigation under the SUI process. NHS London will review the de-escalation request and inform the Trust of its decision within 10 working days. NHS London may decide that the SUI should not be de-escalated and a full SUI report is required.

## Investigation and submission of SUI reports

### Investigation

Following notification and declaration of a SUI, an internal investigation panel must be promptly initiated. The internal investigation panel must be set up for all NHS Brent, BCS and Independent Contractor SUIs. This investigation should be conducted using root cause analysis techniques (appendix 13) and in accordance with other best practice guidance issued by the NPSA. Where court proceedings in relation to the incident have started, or are likely, legal advice should be sought with a view to ensuring that the investigation does not prejudice those proceedings. Delay in receiving the findings of a coroner or outcome of a police inquiry is not, however, reason for delay in setting up and conducting a review. The Memorandum of Understanding (Investigating patient safety incidents involving unexpected death or serious untoward harm, a protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and Health and Safety Executive) between the Police, the HSE and the NHS should be followed; it is available at the following link:

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_062975](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_062975). The investigation does not need to duplicate others such as fraud, prison health, safeguarding children, HPU/A (Health Protection Unit/Agency), SHOT (Serious Hazards of Transfusion) or RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations).

The internal investigation panel will:-

- have a Chair with sufficient skills and demonstrable independence from the setting in which the incident arose
- the Chair will be appointed by the relevant Service Director, and, in the most serious cases, by agreement with the Chief Executive, could be a non-executive director nominated by the Chair of the PCT
- include individuals with appropriate investigation skills, such as root cause analysis
- be established within two weeks of notification of the incident
- have the active co-operation and participation of internal staff and other relevant agencies (e.g. Social services, criminal justice agencies, private providers) in the review process, with representation depending on the extent of the organisation's involvement in the case
- establish and agree clear terms of reference
- have access to such evidence as it needs in order to review the incident
- maintain appropriate records
- follow the NHS Brent 'Being Open' policy (for patient safety incidents with moderate to severe harm) and appropriately communicate with and supports families and other key personnel
- report promptly, with clear recommendations and an action plan within 60 working days of declaring the SUI; mechanisms for monitoring the action plan should be included and will normally include provision for review of actions at three and six months.
- the report will be agreed with the relevant Service Director and sent to the Head of Corporate Affairs or BCS Head of Governance and Chief Executive for review before submission to NHS London. To this effect, it is recommended that reports are sent to the Head of Corporate Affairs or Governance 5 days before the NHSL 60 working days deadline for review.

The proceedings of the investigation team are separate from any disciplinary proceedings that may have arisen from the incident. Where such disciplinary proceedings occur, professional human resources advice should be obtained.

## **Report Format**

SUI reports should be based on the NPSA Level 2 investigation template. See Appendix 13. The minimum content of an SUI final report is in Appendix 5. For Healthcare Associated Infections (HCAIs) the NPSA tool, Learning through Action to Reduce Infection may be used.

For the minimum content of safeguarding children report, see Appendix 6c.

## **External review**

As required by HSG (94) 27 Department of Health it is the responsibility of NHS London to commission investigations, as outlined in the criteria below:

- when a homicide has been committed by a person who is or has been under the care, i.e. subject to a regular or enhanced care programme approach, of specialist mental health services in the six months prior to the event.
- when it is necessary to comply with the State's obligations under Article 2 of the European Convention on Human Rights. Whenever a State agent is, or may be, responsible for a death, there is an obligation on the State to carry out an effective investigation. This means that the investigation should be independent, reasonably prompt, provide a sufficient element of public scrutiny and involve the next of kin to an appropriate extent.
- where the NHSL determines that an adverse event warrants independent investigation, for example if there is concern that an event may represent significant systemic service failure, such as a cluster of suicides.

## **SUI Report monitoring process**

Completed reports will be reviewed by the Head of Corporate Affairs or BCS Head of Governance, agreed by the relevant Service Director and signed off by the Chief Executive before sending this to NHS London. The report will be monitored at the Governance Committee and presented by Directors to the Board in part two of their meeting. The Head of Corporate Affairs or BCS Head of Governance will notify the Lead Investigator once the report has been approved by the Chief Executive. Following approval by the Chief Executive and Governance Committee, the Lead investigator will share the completed investigation report and action plan with the relevant services, organisations and departments. The Head of Corporate Affairs or BCS Head of Governance will send the approved report to NHSL. On receipt of the report, NHS London reviews its content and structure and provides feedback to the Trust.

## **Closure of the SUI**

The GEMT recommend SUIs for closure following evidence of successful action plan implementation. However the final decision to close an SUI on STEIS lies with NHS London once it is satisfied that the report and action plan address the issues to minimise the risk of recurrence.

## **Extension of timescales**

Where Investigation Manager knows that the report will not be submitted within the deadline, this should be communicated to the Head of Corporate Affairs or BCS Head of Governance with the reason. Requests for extensions will be discussed at the monthly GEMT before contacting NHS London.

## **Submission of SUI reports relating to children**

See appendix 7

## **PCT as Commissioner: Reviewing the SUI final report for relevant Foundation Trusts (FTs)**

In line with NHSL guidance, the PCT will notify NHSL when a Foundation Trust SUI has been reviewed and is ready for closure. NHSL expects to receive notification of closure within 80 working days of the SUI being reported. NHSL will performance manage PCT SUI management systems and processes through planned meetings, review of policies and working practice and random 'spot checks' of PCT reviews of provider SUI investigation reports and action plans. A risk-based approach will be taken. The NPSA evaluation checklist is recommended when reviewing reports for FTs.

## **Process of monitoring the effectiveness of the Policy**

NHS Brent will monitor the effectiveness of this policy through key performance indicators (KPIs) which will include an annual review to ensure the policy meets the minimum requirements within the relevant National Health Service Litigation Authority (NHSLA) Standards.

The KPIs which also include the NHSLA minimum standards are:

- The duties and responsibilities
- The organisation's expectations in relation to staff training, as identified in the training needs analysis
- The SUI investigation process
- The process for involving and communicating with internal and external stakeholders to share safety lessons
- The process for following up relevant action plans
- 100% of SUIs have a final investigation report within 60 days of declaring the incident an SUI
- 100% of SUI investigation reports are entered onto the SHA STEIS incident database within 24 hours of the incident occurring
- Quarterly SUI risk management reports contain incident and causal factors trend analysis, quantitative and qualitative data
- Quarterly SUI risk management reports contain benchmark information comparing NHS Brent performance with similar organisations
- At least 2 collation of lessons learnt reports are produced and disseminated each year
- The Trust regularly uploads to the NPSA NRLS system
- Lessons learnt from analysis result in change
- Process for reducing risk identified from SUIs
- All SUI investigation reports contain information on key Care and Service delivery problems, key contributing and causal factors, recommendations and action plans
- An annual risk management report containing results of the audit and improvement actions is produced for the Board committee responsible for overseeing risk management

The Head of Corporate Affairs and BCS Head of Governance will be responsible for ensuring the audit is conducted

The Head of Corporate Affairs and BCS Head of Governance will develop audit tools enabling the measurement of the key performance indicators.

The audit will be conducted once a year.

The results of the audit will be included in the annual risk management report together with recommendations for improvement. The annual risk management report will be submitted to the Governance Committee.

## Implementation of the Policy

Service Managers will use the Assurance form (appendix 17) to monitor embedment of the policy.

### Appendix 1: Types of incidents to be reported to SHA as SUIs, including guidance as to the type of incident code in STEIS

Sub-type	Definition	STEIS categorisation
Child/Vulnerable Child	Any incident reported to the Local Safeguarding Board for follow up. Examples include death or injuries where abuse or neglect is suspected or where a child has suffered further harm as a result of a health careworker failing to follow procedures or where a serious Part 8 Joint Services Case Review is to be undertaken. Significant cases involving children	Child serious injury Child death Child abuse (family, inst., multiple) Child abuse – family Child abuse – institutional Child abuse – multiple Child serious injury Admission of under 16s to adult mental health ward
Cluster	A number of low level incidents which aggregate to suggest a potentially more serious problem  A cluster of unexpected/unexplained deaths or serious adverse outcomes	Unless specifically listed in other STEIS codes then Serious incident indicating what type of incident Unexpected death general inpatient or outpatient
Infection/HCAI	Known, or suspected, cases of health care associated infection, which fall within the definitions of this minimum data set or which are deemed a significant outbreak or involve failure of systems, such as decontamination or hospital acquired legionellosis  Death in which MRSA bacteraemia or C difficile are recorded on part one of the death certificate (parts 1a, 1b or 1c) Two or more cases of C difficile in the same ward within the same week and/or third case within the same ward and month.	Communicable disease & infection issue  MRSA bacteraemia  C.Diff & HCAI *
Sub-type	Definition	STEIS categorisation
Look back	Infected healthcare workers/patient incidents that necessitate consideration of a look back exercise  Failures of screening or infection control systems that necessitate consideration of a look back exercise	Hep B infected HC professional HIV infected HC professional Infected HC worker Communicable disease & infection issue Screening issues
Vulnerable adult	Any case referred to an Adult Safeguarding board.  Fraud against a vulnerable adult  Serious harm to a vulnerable adult including sexual and physical assault	The description of the incident on the case form should always indicate if the patient is a vulnerable adult
Serious	Significant cases of a specified nature	Accident whilst in hospital Ambulance accidental injury Ambulance (general) Dentistry Drug incident (general) Maternity service Health and Safety

Prisons	Death in custody Administration/Handling of medication	Prisoner in receipt of care Drug incident
Maternal	Maternal Death Post Partum Haemorrhage greater than 2 .5 litres Unplanned Hysterectomy Unexpected maternal admission to ICU Retained Swabs / instruments Any time a decision is made to suspend maternity services (regardless of outcome) Intrauterine Deaths at 24 weeks and above where service or clinical factors might have contributed Unexpected Intrapartum deaths (ie during labour) regardless of gestational age where service or clinical factors might have contributed Unexpected admissions to the Neonatal Intensive Care unit for longer than 24 hours. Unexpected Neonatal deaths (death of a baby aged 0- 28 days	Maternity Service Unexpected death Ward/unit closure
Unexpected	The unexpected death of, or serious/life threatening injury to, a patient under the direct care of a health professional, member of the public or member of staff. Foul play may or may not be suspected	Unexpected death Attempted homicide/ suicide Homicide / suicide Death on GP premises Prisoner in receipt of care
MRSA/ C.Diff	Deaths in which MRSA bacteraemia or C.diff are implicated as primary or secondary cause.	MRSA bacteraemia * C.Diff & HCAI *
Complaint	A serious complaint or allegation about a member of staff, or suspicion of serious error(s) or repeated serious concern about poor clinical or management judgment, which would give rise to public concern	Allegation against HC professional Allegation against HC professional (assault) or (fraud) Surgical error
Staff	Suspicion of serious error or repeated serious complaints about an individual member of staff	Allegation against HC professional Allegation against HC professional (assault) or (fraud) Surgical error
Confidentiality	Serious breach of confidentiality	Confidential information leak
Criminal	Incidents, which might give rise to serious criminal charges  Any incident that might lead to criminal charges including violent attacks on either staff or patients, or hostage situations	A number are provided for e.g. fire, assault, and allegations against health care professional. If none are applicable then the Serious incident field can be used.
Sub-type	Definition	STEIS categorisation
Major	Major incidents, fires, floods or other events, which cause death or injury or seriously endanger the life of patients or staff, or which threaten the business continuity of a Trust	Serious incident, Fire Ward/unit closure Security threat Bogus Health Worker Chemical Incident
Suicide	Suicide of any person on NHS premises	Attempted suicide Suicide Serious self-inflicted injury
Surgical Error	Suicide of any person on NHS premises	Surgical error

Never Events	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 Absconding of transferred prisoners from medium or high secure mental health Services In-hospital maternal death from post-partum haemorrhage after elective Caesarean Section IV administration of concentrated potassium chloride	Surgical error Suicide Abscond Unexpected death Drug Incident (general)
Equipment	Where a death occurred, an injury took place, or where someone was seriously put at risk as a result of a lack of, or faulty procedures, instructions or faulty equipment or drugs Failure or misuse of equipment or plant which either caused or could have constituted a risk of injury, harm or danger to the life of a patient, member of the public/member of staff Misuse or diversion of significant quantities of controlled drugs or systematic loss of small quantities of controlled drugs	Transfusion incident Unexpected death Hospital equipment failure Drug incident Delayed diagnosis Home oxygen Critical Care Transfer Hospital Transfer Issue Medical Equipment failure
Procedures	The failure of clinical or non-clinical procedures or their application so serious as to endanger life of a patient, member of the public or member of staff, or to pose a serious security risk or situations when a patient requires additional intervention(s) as a result of failures in the diagnosis/treatment process	If not specifically provided for by the other codes then the Serious incident code can be used.
Criminal	Any incident that might lead to criminal charges including violent attacks on either staff or patients, or hostage situations	A number of specific situations have been provided for (e.g. assault, fire, homicide, suicide) or the Serious incident code can be used.
HSE	Any Health & Safety Improvement Notices or potential prosecution of an NHS Trust	Chemical incident Serious incident Health & safety

*Supplementary notes*

Incidents that involve serious hazards of transfusion (SHOT) or RIDDOR investigations are not normally required to be reported as SUIs unless they result in an unexpected death or serious injury.

## Appendix 2: Detailed Information about specific SUIs

The examples given below do not preclude other incidents from being reported as SUIs. If you require further advice on whether an incident is considered an SUI please contact the Head of Corporate Affairs or BCS Head of Governance

### Health Care Associated Infections

The SUI reporting process should be used for the following types of Health Care Associated Infections (HCAI).

Known or suspected cases of infection or communicable disease which fall within the parameters of media interest

HCAI which result in death and significant outbreaks of HCAI:

Death in which MRSA bacteraemia or C difficile are recorded on part one of the death certificate (parts 1a, 1b or 1c)

Two or more cases of C difficile in the same ward within the same week and/or third case within the same ward and month.

Infection control outbreaks: The significance and impact of infection control outbreaks should be considered before reporting as an SUI. For example, an outbreak of Norovirus during the winter months need not be an SUI unless it has a significant impact on the ability of the trust to maintain its core services.

All HCAI SUIs should have a root cause analysis completed with the NPSA HCAI RCA template used.

### **Protection of Vulnerable Adults (POVA)**

Trusts should report as a SUI any incident where the nursing or residential home may close due to allegations relating to care and / or where allegations may have media interest. In addition, any incidents which are going to a POVA panel should be reported.

### **Information Security Incidents**

- All incidents relating to breaches of confidentiality involving person identifiable data and data losses scoring between 3 to 5 should be reported as SUIs in accordance with Department of Health (DoH) Gateway letter 9571 (29th February 2008). This letter outlines that as a guide, any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious.
- When a Trust becomes aware of such an incident they should use the matrix below to grade the incident. Incidents of grade 3 to 5 should be reported and must include the grading score. The Trust should inform the Information Commissioner once the initial facts are known. On receiving the STEIS notification NHS London will escalate to DoH Business Unit and Media Handling teams. Consideration should be given to informing patients when person identifiable information about them has been lost or inappropriately placed in the public domain. Where there is any risk of identify theft it is strongly recommended that this is done.
- The loss or theft of removable media (including laptops, removable discs, CDs, USB memory sticks, PDAs and media card formats) upon which data has been encrypted to the approved standard, is not a Serious Untoward Incident unless there is reason to believe that the protections have been broken or were improperly applied.

### **Controlled Drugs**

- All Incidents and SUIs involving controlled drugs must also be reported to the NHS Brent Accountable Officer for Controlled Drugs (Head of Prescribing) on 020 8795 6226.

## Appendix 3: Grading Matrix

0	1	2	3	4	5
No significant reflection on any individual or body Media interest very unlikely	Damage to an individual's reputation. Possible media interest. Potentially serious breach.	Damage to a team's reputation. Some local media interest that may not go public.	Damage to services reputation. Low key local media coverage.	Damage to an organisation's reputation. Local media coverage.	Damage to NHS reputation. National media coverage.
Minor breach of confidentiality. Only a single individual affected.	Potentially serious breach. Less than 5 people affected or risk assessed as low e.g. files were encrypted	Serious potential breach & risk assessed high e.g. unencrypted clinical records lost. Up to 20 people affected	Serious breach of confidentiality e.g. up to 100 people affected	Serious breach with either particular sensitivity e.g. sexual health details or up to 1000 people affected	Serious breach with potential for ID theft or over 1000 people affected.

For confidentiality SUIs, the Description of the Incident and Action Taken sections of SUI notification form must include the following information:

Theft, accidental loss, inappropriate disclosure, procedural failure etc.

The number of patients/ staff (individual data subjects) involved

The number of records involved

The media (paper, electronic) of the records

If electronic media, whether encrypted or not

The type of record or data involved and sensitivity

Whether the SUI is in the public domain

Whether the SUI could damage the reputation of an individual, a work-team, an organisation or the NHS as a whole

Whether there are legal implications for the trust

Initial assessment of level of SUI (see table above). If you do not know the grading at the time of completing the SUI notification form, please state "assessing risk" and then notify the Head of Corporate Affairs or BCS Head of Governance when the grading is known.

State whether the following have been notified (formally or informally):

Data subjects

Caldicott Guardian (Jim Conelley)

Senior Information Risk Owner (Jonathan Wise)

Chief Executive (Mark Easton)

Accounting Officer

Information Commissioner for SUI level 2 and above

Police, Counter Fraud

Any incidence of a Serious Untoward Incident should be reported in the Statement of Internal Control (SIC) as a significant control issue. These are incidents with a severity rating of 3,4 or 5."

## Appendix 4: Never Events

From 2010/11 PCTs will be required to monitor the occurrence of 'never events' developed by the NPSA, within the services they commission, report these to the NPSA and publicly report them as part of their annual reporting on quality and safety.

Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. (National Patient Safety Never Events Framework 2009/2010).

Theoretically, a "Never Event" is an incident or event that should never happen. A Never Event is a serious incident; however, it is not automatically considered to be a Serious Untoward Incident. The process of decision making should follow that of any serious incident. It is essential that these incidents are reported and identified. They must be reported as per SUIs to the Head of Corporate Affairs for NHS Brent or the Head of Governance for BCS

The eight never events identified by the NPSA are considered serious and largely preventable. Never Events is a developing area of reporting and learning and therefore this list may increase and expand over time and this policy will be updated accordingly:

The list of never events are as follows:

Number	Theme	Definition	Main care setting
1	Wrong site surgery	A surgical intervention performed on the wrong site (e.g. wrong knee, wrong eye, wrong limb, and 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.	Organisations that provide major, minor and/or day case surgery
2	Retained instrument post-operation	One or more instruments retained following an operative procedure	Organisations that provide major, minor and/or day case surgery
3	Wrong route administration of chemotherapy	Intravenous or other chemotherapy (e.g. vincristine) that is correctly prescribed but administered via the wrong route [usually into the epidural space].	Acute care
4	Misplaced naso or orogastric tube not detected prior to use	Naso or orogastric tube placed in the respiratory tract rather than the intestinal tract and not detected prior to commencing feeding or other use.	All care settings
5	Inpatient suicide using non-collapsible rails	Suicide using curtain or shower rails whilst an inpatient in an acute mental health setting.	Mental health
6	Absconding of transferred prisoners from medium or high	A prisoner absconding from medium or high secure mental health services where they have been placed for treatment on a Home	Mental health

	secure mental health services	Office restriction order.	
7	In-hospital maternal death from post-partum haemorrhage after elective Caesarean Section	In-hospital death of a mother as a result of a haemorrhage following elective Caesarean Section.	Acute care maternity services
8	IV administration of concentrated potassium chloride	Intravenous administration of concentrated potassium chloride.	All care settings

## Appendix 5: Recommended Content of SUI report (based on NPSA template)

Incident description and consequences including:

Incident date:

Incident type:

Specialty:

Effect on patient:

Severity level:

Pre-investigation risk assessment (potential x severity = likelihood)

Background and context

Terms of reference

The investigation team

Scope and level of investigation

Investigation type, process and methods used

Involvement and support of patient and relatives

Involvement and support provided for staff involved

Information and evidence gathered

Chronology of events

Detection of incident

Notable practice

Care and service delivery problems

Contributory factors

Root causes

Lessons learned

Recommendations

Arrangements for shared learning

Action Plan

Distribution list

Appendices

Author, Job title, Date

NHS London require 100% compliance with each of the above headings.

## Appendix 6: Safeguarding Children (Guidance)

Child deaths may not trigger a report to NHS London. All deaths are followed up in some way by the Local Safeguarding Children Board (LSCB). If at any stage during or after initial enquiries suspicious circumstances emerge, this alters the action that must be taken and a SUI must be notified to the SHA.

### 6a) Unexpected Death of a child and possible suspicious circumstances or child protection concerns are identified

Definition: Where the death of the child that was NOT anticipated as a significant possibility 24 hours before the death, or when there was a similarly unexpected collapse leading to or precipitating the events that led to the death. In addition the presentation or initial enquiries indicate that there may be suspicious circumstances or factors relating to abuse or neglect.

Action required:

- Report immediately to single point of contact for child death review
- Report immediately to designated professionals expressing clearly the concerns that have been identified.
- The designated professional completes the NHS SUI notification. The NHS Brent SUI process is followed

The decision for referring a child death to the SCR panel is made by the chair of the child death rapid response team. The cause of the death will be discussed by the Child Death Review (Rapid Response) Professionals but it may remain unknown or unclear until a later date.

The final outcome will rest on post mortem investigations and further information gathered. Investigations and historical information may take some time to collect and enable a conclusion to be reached. Complex cases can take several weeks to ascertain whether or not a LSCB Serious Case Review should be considered.

Should at any stage the case meet the criteria for a Serious Case Review as determined in chapter 8 of Working Together, NHS Brent (as the health representative on the local safeguarding children board) leading the Serious Case Review takes over the management of the SUI. The designated professional must notify the Head of Corporate Affairs or BCS Head of Governance that a Serious Case Review is to be undertaken. Designated and Named professionals for safeguarding children and child protection are responsible for undertaking and coordinating safeguarding children SCR investigations in NHS Brent

The Designated Professionals for NHS Brent who sits on the LSCB SCR Panel is responsible for coordinating all the health agencies involved to write an Individual Management Report. The IMRs will be used by the Designated Professionals to inform the PCT Overview report of practice for the whole health economy.

The designated and named professionals are expected to work together with the Head of Corporate Affairs or BCS Head of Governance to ensure that each are informed of the progress of the investigation and any emerging issues arising from it. Terms of reference of the investigation must be agreed by the multi-agency SCR panel.

The NHS Safeguarding Executive Group is responsible for reviewing and signing off the Health Overview report.

## **6b) Report to NHS London**

NHS London expects to receive:

- An integrated health chronology
- A PCT Overview Report and Action Plan
- All Health Individual management reports and Action Plans
- The LSCB SCR final report or executive summary

NB. Where Court proceedings are involved, release of the multi-agency SCR may be delayed until after the trial. This should not delay submission of the final health reports to the NHSL once accepted by the LSCB SCR panel. NHSL must be notified of the reasons

why the final SCR cannot be submitted via the Head of Corporate Affairs and BCS Head of Governance

### 6c) Content of reports

NHS SUI reporting systems and LSCB commissioned Internal Management Reports are similar with regards to purpose and outcome. The SCR IMR reports will satisfy both processes. The production of two reports is unnecessary duplication.

Reports will need to follow the LSCB agreed outline, and meet the TOR reference set by the LSCB SCR panel in relation to the analysis.

As a minimum NHS London expects that Internal Management Reports and the associated PCT Overviews pertaining to safeguarding and child protection matters will include the following:

- Family Composition (Genogram)
- Ethnicity
- Incident date
- Incident description
- List of services Involved
- List of professionals interviewed
- List of records reviewed
- SCR Panel TOR
- Analysis of practice (single and multi-agency)
- Clear, fact based chronology of events leading up to the incident in a format agreed by the Safeguarding Children Board (merged NHS Chronology for PCT overview report)
- Care and Service Delivery/systems problems
- Contributory Factors
- Root Causes
- SMART Recommendations (with audit timescale)
- Timed Action Plan

## Appendix 7: Summary of Management of SUIs involving children

Timeline	Action
<b>Day 1</b>	Incident occurs and decision made by Trust to report as an SUI. Incident notified by Trust on STEIS
	Trust begins investigation and updates STEIS as further information comes to light.
	Trust updates STEIS and emails NHS London with regards to LSCB decision to proceed to serious case review
	SCR initiated. PCT re-notifies on STEIS and assumes lead responsibility
	PCT updates STEIS and emails NHS London in relation to any emerging issues including any criminal proceedings or LSCB agreed extension to 5 month timescale.
3 months after PCT SUI notification that SCR has been Triggered (60 days)	NHS London sends reminder that NHS reports should be at or near completion. Position statement to be forwarded to SHA. Trust updates STEIS and emails NHS London in relation to progress and any emerging issues including any LSCB agreed extension to timescale
	Single agency IMRs of NHS Trusts involved in review sent to PCT Designated Professionals to enable PCT Overview to be pulled together. Single agency IMRs also sent to SCR panel for discussion
<b>SCR deadline approaching</b> (Overview to LSCB)	PCT Overview submitted to LSCB SCR Panel Overview Writer for inclusion in final SCR.

at least 2 weeks prior to deadline)	PCT Overview Report must be submitted in enough time for the LSCB SCR writer to write the final SCR
<b>Deadline</b> 5 months from incident, 4 months from SCR start date	PCT Overview, Single NHS IMRs, Action Plans and SCR (if released) is submitted to NHS London for performance monitoring

## Appendix 8: Reporting and monitoring flowchart (NHS Brent & BCS)

The individual who suspects the incident they are managing to be an SUI must act immediately to notify their departmental manager or on-call manager



Service manager/on call manager notifies their Director/ on call Director and takes any immediate action necessary to prevent danger to staff, service users and the public.



Ensure NHS Brent electronic incident report form completed within 24 hours by staff member who identified the incident.



Designated Director assumes leadership of the SUI, completes an initial report (**appendix 7**) and sends it to **Head of Corporate Affairs (for NHS Brent) or Head of Governance for BCS.**

The Service Director (with advice from the Head of Corporate Affairs or Governance) will make the final decision whether or not to grade the incident an SUI in association with the Chief Executive.



The Head of Corporate Affairs or BCS Head of Governance notifies the SHA within 24 hours or as soon as possible. If incident is of particular gravity report to SHA **immediately** by telephone within 24 hours or as soon as practicable to the Head of Performance and Finance. Out Of Hours Communications on call (08700 555 500 Pager# LON01)

Complete SHA STEIS notification database within 24 hours



Commence initial investigation within 24 hours.

Head of Corporate Affairs or BCS Head of Governance updates STEIS on initial findings (approx 3 days after notification) and confirms whether still SUI.



Full investigation using RCA or similar technique to be completed within 60 working days of the incident. The NPSA Root Cause Analysis tool can be found on <http://www.msnpsa.nhs.uk/rcatoolkit/course/iindex.htm>

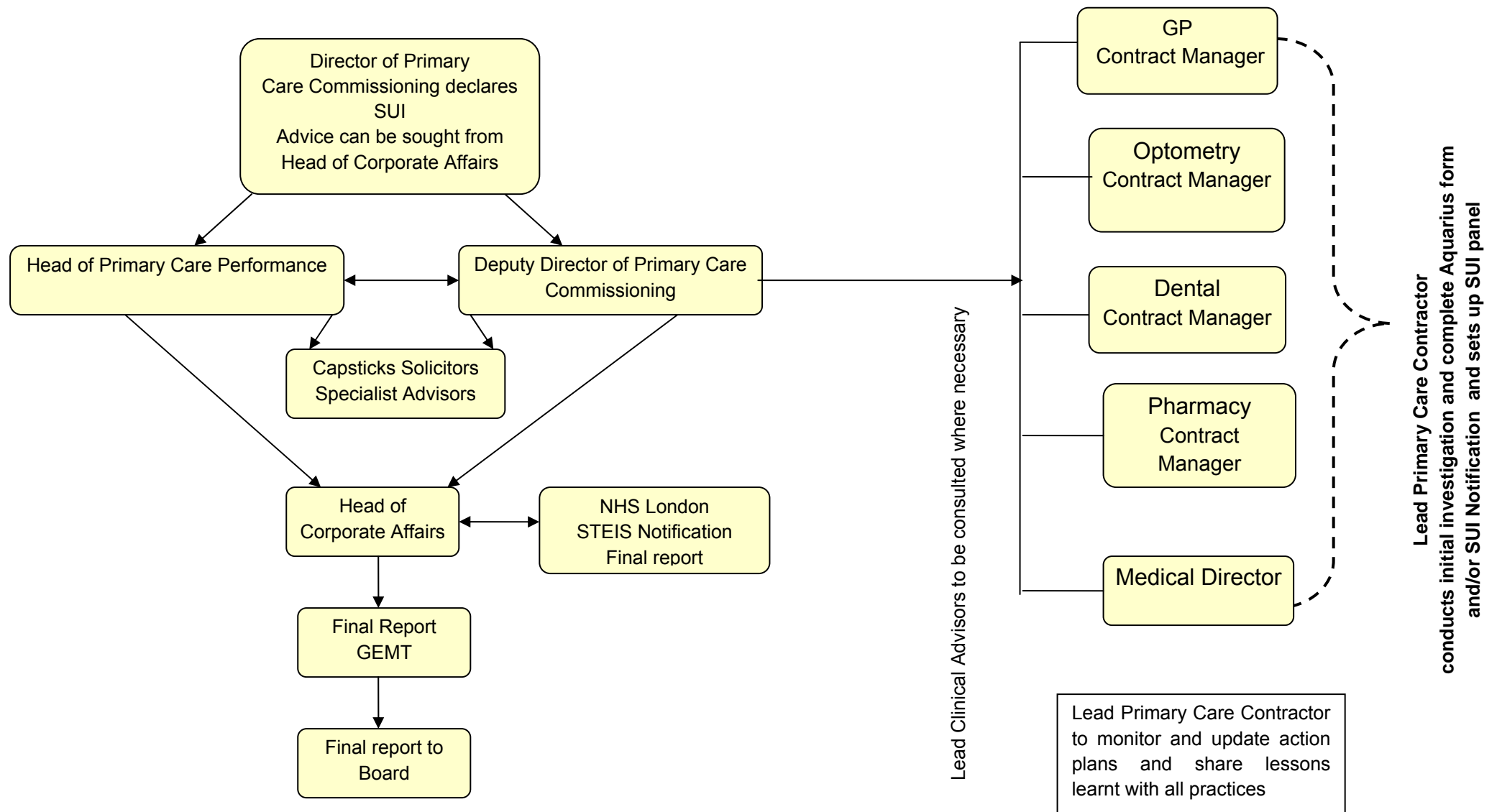


Final SUI report submitted to CEO before submission to SHA. Report submitted to Governance Committee & Board for scrutiny. Root cause and lessons learned updated on STEIS. Full report to SHA on [sui@london.nhs.uk](mailto:sui@london.nhs.uk)



Produce regular updates on action plan progress, updating SHA on STEIS on all critical dates in managing SUI, eg coroner inquest. The Board will receive reports at every Board meeting

# Appendix 9: SUI Reporting Structure for Independent Contractors



## Appendix 10: Checklist for managing SUIs

- confirm you are dealing with a serious untoward incident
- establish immediate arrangements to respond to the needs of those directly affected
- report the incident to the appropriate Trust Director
- establish other arrangements to support patients or service users, their families and carers in a timely and sensitive manner
- establish arrangements to support staff
- implement any immediate response that needs to take place (e.g. security de-brief, securing patient notes and other evidence intact, encouraging staff to make an immediate written record of their recollection of events – this will be invaluable for later investigations)
- detail reporting arrangement within the organisation
- identify a named individual as the person who is responsible for alerting relevant organisations (such as strategic health authorities and other statutory bodies) of any serious untoward incidents
- report incidents procedures at the earliest opportunity to the relevant authorities and organisations, such as strategic health authorities, DH Counter Fraud and Security Management Service and keep them informed of developments as appropriate
- investigate the incident using root cause analysis
- identify any involvement by other agencies and agree the lead responsibilities and inform them as appropriate
- co-operate with internal and external inquiries, as appropriate
- confirm proposed handling arrangements with NHS London and, where necessary, agree the process for investigation of the incident
- consider the need for a communications/media handling strategy involving relevant agencies (e.g. a joint press statement with other organisations, internal communications mechanisms such as staff briefings)
- consider seeking legal advice
- consider whether it is appropriate to report the incident to the relevant professional body (e.g. UKCC, GMC)
- prepare a written report of the incident, actions taken and lessons learned
- ensure the outcome of the investigation informs future practice both within the Trust and in the wider health and care system through improvement strategies and action plans
- monitor and review the effectiveness of those strategies and action plans
- liaise with stakeholders as appropriate
- provide training, support and supervision for staff to implement the above and embedding a culture of reporting in the organisation
- monitor and review the effectiveness of policies and procedures

## Appendix 11: Incidents Reportable to External Agencies

<u>Type of Incident</u>	<u>External agency Reportable to</u>	<u>Responsible Manager</u>
SUIs incidents involving patients	Strategic Health Authority where the patient is resident	Head of Corporate Affairs or BCS Head of Governance
All incidents relating to breaches of confidentiality involving person identifiable data and data losses scoring between 3 to 5	Strategic Health Authority where the patient is resident  The Information Commissioner.	Head of Corporate Affairs or BCS Head of Governance  Information Governance Officer
Medical Devices	MHRA	<ul style="list-style-type: none"> <li>• Heads of department involved in development of products that are supplied to patients</li> <li>• Lead Manager for Accuro Facilities Management (Willesden Centre PFI)</li> <li>• All other sites, Health &amp; Safety Advisor</li> </ul>
Medical products – adverse drug reactions (Yellow Card)	MHRA	Practitioner responsible for Prescribing
Non-medical equipment	NHS Estates Defect Office*	Head of Estates & Facilities
Special dietary and enteral food and ready to feed preparations for hospital use	Medical Devices Agency*	Deputy Director of Nursing & Clinical Standards
**Food contamination - microbiological or chemical	Local Authority Environmental Health Department	Lead Manager (for Willesden Centre PFI Lead Manager for Accuro Facilities Management)
**Fire	NHS Estates	Environmental & Fire Safety Advisor
**Accidents	Health & Safety Executive	Health & Safety Advisor
**Unexpected patient deaths	Coroner	Medical Director/ Consultant or Lead Clinician
<p>* May also need reporting to the Health &amp; Safety Executive under Reporting of Injuries, Diseases and Dangerous Occurrences regulations (RIDDOR)</p> <p>** Normally reported and investigated via other procedures (e.g. Accident/Incident procedure/ fire policy etc.) unless particularly serious to qualify as a Serious Untoward Incident. <b>Details of all reports must be sent to the Head of Corporate Affairs or BCS Head of Governance</b></p>		

## Appendix 12: Witness Statement

### WITNESS STATEMENT

A copy of one of these forms is to be completed by all witnesses to the incident. They must complete the form in their own words and they should sign the statement immediately after the last line. Any amendments made to the statement should be initialled by the witness. They can add diagrams if necessary.

Name:

Date

Contact Telephone Number:

Location of Incident:

Contact Address:

Signature:

# Appendix 13: National Patient Safety Agency Root Cause Analysis Investigation Report Template

The following headings are designed to improve the recording of information

## **PLEASE READ - Instruction for use of this RCA Report Template**

1. **Determine the level of investigation to be undertaken**  
Refer to the NPSA's 'Three Levels of investigation' (Level 1 = Concise; Level 2 = Comprehensive; Level 3 = Independent), to the NPSAS's 'Triggers for Investigation', and to your own organisational policy and terms of reference.
2. **Delete all ROWS not required for the level of investigation being undertaken**  
The investigation level numbers in the middle column provide a guide to which rows are needed for which level of investigation. (i.e. for a Level 1 - Concise investigation you only need rows which have the number 1 in the 'Level' column)
3. **Write your investigation report in the right hand column**
  - Delete examples (in green), and refer to summary guidance in the left hand column as you go. For detailed guidance refer to the NPSA's 'Guide to RCA investigation report writing'.
  - If an investigation produces no information against a heading, add an explanation on why this is the case.
  - If issues arise which require a new heading this can be added as a new row
4. **On completion, delete the guidance to produce your final report**
  - Delete all guidance both here and in the template below (i.e. all green and red type, all green coloured rows and all green coloured columns)
  - Realign the remaining table containing your own report, so that it fits the whole page.
  - Save the document with the chosen file name for each individual investigation report.

Quick reference guide	Level	Type your investigation report in this column
<b>Cover page</b> <ul style="list-style-type: none"> <li>• Organisation name and / or logo</li> <li>• Title or <i>Brief</i> outline of incident</li> <li>• Incident date</li> <li>• Incident number</li> <li>• Author(s)</li> <li>• Report date</li> <li>• Page numbers</li> <li>• Document version</li> <li>• Computer File Path</li> </ul>	2 + 3	
<b>Contents page</b>	2 + 3	<b>CONTENTS</b> Executive summary Incident description and consequences Pre-investigation risk assessment Background and context Terms of reference The investigation team Scope and level of investigation Investigation type, process and methods used Involvement and support of patient and relatives Involvement and support provided for staff involved Information and evidence gathered Chronology of events Detection of incident Notable practice Care and service delivery problems

		Contributory factors Root causes Lessons learned Recommendations Arrangements for shared learning Distribution list Appendices
<b>Executive summary</b>	2 + 3	<b>EXECUTIVE SUMMARY</b>
A one page summary of the main report presented succinctly under the following headings:-	2 + 3	<b>Brief Incident description</b>
	2 + 3	<ul style="list-style-type: none"> <li><b>Incident date:</b></li> </ul>
	2 + 3	<ul style="list-style-type: none"> <li><b>Incident type:</b></li> </ul>
	2 + 3	<ul style="list-style-type: none"> <li><b>Healthcare specialty:</b></li> </ul>
	2 + 3	<ul style="list-style-type: none"> <li><b>Actual effect on patient and/or service:</b></li> </ul>
	2 + 3	<ul style="list-style-type: none"> <li><b>Actual severity of the incident:</b></li> </ul>
	2 + 3	<b>Level of investigation conducted</b>
	2 + 3	<b>Involvement and support of the patient and/or relatives</b>
	2 + 3	<b>Detection of Incident</b>
	2 + 3	<b>Care and Service Delivery Problems</b>
	2 + 3	<b>Contributory Factors</b>
	2 + 3	<b>Root Causes</b>
	2 + 3	<b>Lessons Learned</b>
	2 + 3	<b>Recommendations</b>
	2 + 3	<b>Arrangements for Sharing Learning</b>
<b>Main Report</b>	1, 2 + 3	<b>MAIN REPORT</b>
<b>Incident description and consequences</b>	1, 2 + 3	<b>Incident description and consequences</b>
<ul style="list-style-type: none"> <li>Concise incident description</li> </ul>		<b>Example only (please delete and add your own findings)</b>
		A lady with asthma sustained brain damage following IV administration of a drug to which she was known to be allergic.
<ul style="list-style-type: none"> <li>Incident date</li> </ul>	1, 2 + 3	Incident date:
<ul style="list-style-type: none"> <li>Incident type</li> </ul>	1, 2 + 3	Incident type:
<ul style="list-style-type: none"> <li>Healthcare specialty involved</li> </ul>	1, 2 + 3	Specialty:
<ul style="list-style-type: none"> <li>Actual effect on patient and / or service</li> </ul>	1, 2 + 3	Effect on patient:
<ul style="list-style-type: none"> <li>Actual severity of incident</li> </ul>	1, 2 + 3	Severity level:

<p><b>Pre-investigation assessment</b> <span style="float: right;"><b>risk</b></span></p> <p>Assess the realistic likelihood and severity of recurrence, using your organisation's Risk Matrix</p>	2 + 3
<p><b>Background and context to the incident</b></p> <p>A brief description of the service type, service size, clinical team, care type, treatment provided etc.</p>	2 + 3
<p><b>Terms of reference - Outline :-</b></p> <ul style="list-style-type: none"> <li>• Specific problems to be addressed</li> <li>• Who commissioned the report</li> <li>• Investigation lead and team</li> <li>• Aims, Objectives and Outputs (see examples opposite)</li> <li>• Scope, boundaries and collaborations</li> <li>• Administration arrangements (accountability, resources, monitoring)</li> <li>• Timescales</li> </ul>	2 + 3
<p><b>Investigation team</b></p> <p>Names, Roles, Qualifications, Dept.'s</p>	2 + 3
<p><b>Scope and level of investigation</b></p> <ul style="list-style-type: none"> <li>• State level of investigation (NPSA -1.Concise; 2.Compre.; 3.Independent)</li> <li>• Describe the start and end points</li> <li>• List services &amp; orgs involved</li> </ul> <p>NB: for Level 3 "Independent" Investigations 'scope' could be included under Terms of Reference</p>	1, 2 + 3
<p><b>Investigation type</b> (i.e. Single / Aggregation / Multi-incident), <b>process, and methods used</b></p> <ul style="list-style-type: none"> <li>• Gathering information e.g. <i>Interviews</i></li> <li>• Incident Mapping e.g. <i>Tabular timeline</i></li> <li>• Identifying Care and service delivery problems e.g. <i>Change analysis</i></li> <li>• Identifying contributory factors &amp; root causes e.g. <i>Fishbones</i></li> <li>• Generating solutions e.g. <i>Barrier</i></li> </ul>	2 + 3

**Pre-investigation risk assessment**

A <b>Potential Severity (1-5)</b>	B <b>Likelihood of recurrence at that severity (1-5)</b>	C <b>Risk Rating (C = A x B)</b>

**Background and context**

**Terms of reference**

**Example only (please amend to build your own aims)**

To establish the facts i.e.:- **what** happened (the *effect*), to **whom**, **when**, **where**, **how** and **why** (*root causes*)

To establish whether failings occurred in care or treatment

To look for improvements rather than to apportion blame

To establish how recurrence may be reduced or eliminated

To formulate *recommendations and an action plan*

To provide a *report* as a record of the investigation process

To provide a means of *sharing learning* from the incident

**The investigation team**

**Scope and level of investigation**

**Investigation type, process and methods used**

## Involvement and support of patient and relatives

1, 2 +3

## Involvement and support of patient and relatives

e.g. Meetings to discuss questions the patient anticipates the investigation will address and to hear their recollection of events (anonymised in line with the patient/relative wishes).

e.g. Family liaison person appointed, information given on sources of independent support.

## Involvement and support provided for staff involved

2 + 3

## Involvement and support provided for staff involved

Refer (anonymously) to involvement of staff in the investigation, and to formal & informal support provided to those involved and not involved in the incident.

## Information and evidence gathered

2 + 3

## Information and evidence gathered

### Example only (please delete and add your own findings)

A summary list of relevant local and national policy / guidance in place at the time of the incident, and any other data sources used:-

(Include:-Title and date of Guidance, Policies, Medical records, interview records, training schedules, staff rotas, equipment, etc)

Interviews with the four staff on duty - 01.02.08

Interviews with patient relatives - 05.02.08

A visit to the location of the incident -14.02.08

The patient's clinical records

## Chronology of events

1, 2 +3

## Chronology of events

For complex cases any summary timeline included in the report should be a summary

See table below

## Detection of incident

1, 2 +3

## Detection of incident

Note at which point in the patients treatment the error was identified. i.e.

- At risk assessment of new/changed service
- At pre-treatment patient assessment
- Error recognition pre-care/treatment
- Error recognition post-care/treatment
- By Machine/System/Environ. change/Alarm
- By a Count/Audit/Query/Review
- By Change in patient's condition

Select from the list on the left

Add additional information

## Notable practice

2 + 3

## Notable practice

### Example only (please delete and add your own findings)

Points in the incident or investigation process where care and/or practice had an important positive impact and may provide valuable learning opportunities.

Actions taken to inform the patient and relatives of the error in an open and honest way, and to subsequently involve them in the RCA process was valued by all and greatly enhanced the investigation.

(e.g. Exemplar practice, involvement of the patient, staff openness etc)

## Care and service delivery problems

1, 2 +3

A themed list of the *key* problem points. (Where many problems have been identified the *full* list should be included in the appendix)

## Care and service delivery problems

### Example only (please delete and add your own findings)

Nurses on the short stay ward routinely failed to complete the section in the patient notes to highlight the existence of known allergies

## Contributory factors

1, 2 +3

A list of significant contributory factors (where many contributory factors are identified a full list or 'fishbone diagrams' should be included in the appendix)

## Contributory factors

### Example only (please delete and add your own findings)

Over years numerous assessments for nutrition, pressure ulcers, falls risk etc. had been added, causing short stay wards to see the completion of all documentation as impossible.

## Root causes (numbered)

1, 2 +3

These are the most fundamental underlying factors contributing to the incident that can be addressed. Root causes should be meaningful, (not sound bites such as communication failure) and there should be a clear link, by analysis, between root CAUSE and EFFECT on the patient.

## Root causes

### Example only (please delete and add your own findings)

1. When adding or updating patient assessments and care plans, risk assessment of the wider implications of their use should be conducted and acted upon to reduce the risk of impact on patient safety

## Lessons learned (numbered)

1, 2 +3

Key safety and practice issues identified which may not have contributed to this incident but from which others can learn.

## Lessons learned

### Example only (please delete and add your own findings)

1. A distinction should be made between essential and desirable documentation in clinical records

**Recommendations** (numbered and referenced) Recommendations should be directly linked to root causes and lessons learned. They should be clear but not detailed (detail belongs in the action plan). It is generally agreed that key recommendations should be kept to a minimum where ever possible.

1, 2 +3

## Recommendations

### Example only (please delete and add your own findings)

1. Ensure allergy records and other priority assessment sheets are routinely filed prominently for ease of completion
2. Ensure essential assessment criteria are set as mandatory fields in new electronic record development

## Arrangements for shared learning

1, 2 +3

Describe how learning has been or will be shared with staff and other organisations (e.g. through bulletins, PSAT/Regional offices, professional networks, NPSA, etc.)

## Arrangements for shared learning

### Example only (please delete and add your own findings)

- Share findings with other departments caring for short stay patients and include them in piloting solutions
- Share findings with patient Safety Action Team to identify opportunities for sharing outside the organisation

## Distribution list

2 + 3

Describe who (e.g. patients, relatives and

## Distribution list

staff involved) will be informed of the outcome of the investigation and how

## Appendices

2 + 3

## Appendices

Include key explanatory documents. e.g. Tabular timeline, Cause + effect chart, Acknowledgements to patients, family, staff or experts etc.

**Author:**

**Job Title:**

**Date:**

### Chronology (timeline) of events

Date & Time	Event

### Appendix 14: SUI Report Action plan Template

Recommendation	Action	Lead with responsibility for coordinating actions	Due Date	Progress	Evidence of lessons learnt

## Appendix 15: Serious Untoward Incident (SUI) Initial Report

The Designated Director should use this Briefing template to record the details of an SUI. It should be used to record all SUIs including those reported to the PCT by external agencies. Each version of the briefing note should be signed and dated, and emailed or faxed to the Head of Corporate Affairs or BCS Head of Governance.

INCIDENT FORM NUMBER:-	CRIME NUMBER:- <i>(If Police involved)</i>
DATE & TIME OF THE SUI:	DATE & TIME OF GRADING:
DESCRIPTION OF THE SUI:	
RATIONALE BEHIND SUI GRADING.  Impact:  Likelihood:  Overall Risk Rating	
ISSUES	
ACTION ALREADY TAKEN:-	BY WHOM:-
ACTION PROPOSED:-	BY WHOM:-
NAME:-	DESIGNATION

## Appendix 16: Information-Background-Action (IBA)

In order to improve the quality of information and reduce the amount of queries it is proposed IBA (Incident-Background-Action) is used for SUIs. This is adapted from SBAR (Situation-Background- Assessment-Recommendation) which is more commonly used when sharing information clinically about patients. The information provided in the incident and background part should be included in the 'Description of what happened' section of STEIS. The action part should be included in the 'Immediate action taken' section.

Outlined below are examples a number of examples for the most common reported incidents. A scenario is given with the relevant information extracted using IBA.

**Confidential Information Leak**

A staff member who is based at a number of sites (both PCT and non PCT) was using a memory stick to store demographic details for 50 patients seen at the non PCT site. The staff member attended the PCT site the following day and went to transfer the information from their memory stick to the PCT database. The staff member discovered that the memory stick was missing from their handbag. The memory stick had not been encrypted. Search of both sites has not found the memory stick. Memory stick contained identifiable information on 50 patients. Information Governance lead and Caldicott Guardian for Trust have been informed, as has the Information Commissioner.

Incident: Unencrypted memory stick containing identifiable demographic information on 50 patients lost. Risk Grading 2.

Background: Information was collected as part of assessing patients at a non PCT site. Information is usually transferred to the PCT database the following day and then deleted from the stick.

Action: Decision taken not to inform patients concerned. To be investigated as an SUI. Information Governance Lead and Caldicott Guardian informed. Information Commissioner informed.

**Appendix 17: Assurance Form**

*(For documents associated with risks to patients/ staff/ public/ PCT)*

**(Title of document)**

**Department:** .....

**I have read and understood the above document and agree to abide by its content.**

Name	Signature	Date

**Appendix 18: Glossary**

**Autonomous Provider Organisations (APO)** - the provider arm of a PCT

**Child** - a child for the purposes of this policy and procedure refers to any child between 0-18 years

**Host PCT** - the key commissioner linked to the Trust in which the incident occurs

**IMR** – Individual Management Review. Is undertaken by a single organisation and submitted to inform the PCT Overview and the final SCR.

**NHS London** - the Strategic Health Authority for London.

**NHS Trusts in London** - all London NHS Trusts, PCTs, APOs

**PCT Overview Report** - A review which evaluates and pulls together health aspects in a whole health economy context for inclusion in the SCR.

**SCR - Serious Case Review** – Local Authority led multi-agency review of a child protection serious incident) underpinned by national legislation and guidance and is undertaken when a child dies or is seriously injured from abuse or neglect. It involves all agencies involved with the child and its family and may extend back over several years.

**STEIS** - The Strategic Executive Information System (STEIS) developed by the Department of Health and launched in 2002, is a web-based system currently being used by Strategic Health Authorities to gather situation report (SITREP) information and data directly from the Trusts. STEIS contains a serious untoward incident module which allows Trusts to add serious untoward incident data directly onto STEIS and is then accessible by the Strategic Health Authority.

**SUI** – Serious Untoward Incident. The principle definition of an SUI is something out of the ordinary or unexpected, with the potential to cause serious harm, and/or likely to attract public and media interest that occurs on NHS premises or in the provision of an NHS or a commissioned service. SUIs are not exclusively clinical issues, for example an electrical failure may have consequences that make it an SUI.

### Appendix 19: Risk scoring = consequence x likelihood ( L x C )

	Most Likely Consequence				
	1) Negligible	2) Minor	3) Moderate	4) Major	5) Catastrophic
<b>Likelihood of occurrence</b>	No obvious injury or harm  Loss of 0.1–0.25 per cent of budget Claim less than £10,000	More than 3 days off sick due to injury  Loss of 0.25–0.5 per cent of budget Claim(s) between £10,000 and £100,000	Hospitalised or medium term injury  Major financial loss (£20K to £100K) including litigation settlement.	Significant / permanent harm  Uncertain delivery of key objective/Loss of 0.5–1.0 per cent of budget. Claim(s) between £100,000 and £1 million Purchasers failing to pay on time	Death or major disaster / loss  Non-delivery of key objective/ Loss of >1 per cent of budget Failure to meet specification/ slippage Loss of contract / payment by results Claim(s) >£1 million
<b>1) Rare</b> - Can't believe the risk will ever happen	1	2	3	4	5
<b>2) Unlikely</b> - Do not expect the risk to happen but it is possible	2	4	6	8	10
<b>3) Possible</b> - The event may occur occasionally	3	6	9	12	15
<b>4) Likely</b> - The event will probably occur but is not a persistent issue	4	8	12	16	20
<b>5) Almost certain</b> - The event will undoubtedly occur, possibly frequently	5	10	15	20	25

## Appendix 20: Equality Impact Assessment

DOCUMENT AUTHOR: Bridget Pratt- Head of Corporate Affairs	DIRECTORATE: Corporate Affairs & Governance
NAME OF DOCUMENT/POLICY/STRATEGY/PROCEDURE Serious Untoward Incident Policy	NEW EXISTING <input checked="" type="checkbox"/> ASSOCIATED POLICIES, STRATEGIES OR PROCEDURES Risk Management Strategy/Policy Being Open Policy Major Incident Plan Safeguarding Children Policy
DATE 9/9/09	

### Aim/Status

[a] What is the aim/purpose of the policy/strategy/procedure? To provide a clear policy, procedure and protocols for staff in NHS Brent.
[b] Who is intended to benefit from this policy/strategy/procedure and in what way? Staff and patients in NHS Brent leading to improved communication and an enhanced service
[c] How have they been involved in the development of this policy/strategy/procedure? Policy consulted on with key stakeholder and ratified by GEMT
[d] How does it fit into the broader corporate aims? The policy ties in with the corporate objectives of the Trust: CO6: Develop NHS Brent as a World Class Commissioning Organisation
[e] What outcomes are intended from this policy/strategy/procedure? Improved quality of patient care
[f] What resource implications are linked to this policy/strategy/procedure? None

### Impacts

[a] what is the likely impact [whether intended or unintended, positive or negative] of the initiative on individual users or on the public at large? Raise staff awareness		
[b] Is there likely to be differential impact on any group? If yes, please state if this impact may be adverse and give further details [e.g. which specific groups are affected, in what way, and why you believe this to be the case] No		
[i] Grounds of race, ethnicity, colour, nationality or national origin	Please tick box no	Please tick box Adverse? <input type="checkbox"/> Please give further details
[ii] Grounds of sex or marital Status Women and Men	no	Adverse? <input type="checkbox"/> Please give further details
[iii] Grounds of gender: Transgender or	no	Adverse? <input type="checkbox"/> Please give

Transsexual People		Further details
[iv] Grounds of religion or belief: Religious /faith or other Groups with a recognised belief system	no	Adverse? <input type="checkbox"/> Please give further details
[v] Grounds of disability	no	Adverse? <input type="checkbox"/> Please give further details
[vi] Grounds of age: Older people, children and Young people	no	Adverse? <input type="checkbox"/> Please give further details
[vii] Grounds of sexual orientation: Lesbian, gay, bisexual	no	Adverse? <input type="checkbox"/> Please give further details
[viii] Grounds of carers: Older relatives, children	no	Adverse? <input type="checkbox"/> Please give further details
[ix] Grounds of human rights	no	Adverse? <input type="checkbox"/> Please give further details
Is the policy directly discriminatory?  No	Is the policy indirectly discriminatory? No If you said yes, is this objectively justifiable or proportionate in meeting a legitimate aim yes <input type="checkbox"/> no <input type="checkbox"/>	Is the policy intended to increase equality of opportunity by permitting positive action or action to redress disadvantage  No
If the policy is unlawfully discriminatory it must go to a full impact assessment (please Contact the Equality, Diversity & Human Rights Advisor – Human Resources Directorate)		
Persons conducting EqIA	Bridget Pratt	
Signed: Bridget Pratt	Date: 9/9/09	

## Appendix 21: Policy Ratification and Publication Flowchart

