NHS
Hertfordshire

SERIOUS INCIDENTS REQUIRING INVESTIGATION POLICY

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Contents

Executive Summary

NHS Hertfordshire is committed to making patient safety the highest priority within all services it commissions with the aim of achieving 'no avoidable deaths' and 'no avoidable harm' across the NHS in Hertfordshire. A key contribution to patient safety is the way in which organisations deal with Serious Incidents (SIs) and investigate how they occur. It is vital that all healthcare organisations identify what actions need to be taken to prevent recurrence and ensure that learning from such incidents is communicated and shared.

The SI policy describes how the Primary Care Trust (PCT) will performance manage and monitor on a county wide basis, these incidents as outlined by the East of England (EoE) Strategic Health Authority's (SHA) Serious Incident Policy and National Patient Safety Agency (NPSA) ' National Framework for Reporting and Learning from Serious Incidents requiring investigation'.

The policy also outlines the reporting requirements for the PCT and provides guidance for Independent Contractors and private providers who report a SI.

The purpose of this policy is to ensure that: -

- The PCT is able to effectively performance manage SIs occurring in all commissioned services and ensure that lessons from such events are effectively learnt

- All providers understand their responsibilities in providing the PCT and SHA with assurance following serious incidents.

- SIs are robustly investigated, within required timescales and that recommendations resulting are considered and, where agreed, implemented to improve quality of service and patient safety.

- All NHS Hertfordshire members of staff understand what constitutes a SI and how to respond, to report and manage SIs when they occur.

- All NHS Trust providers, independent contractors and PCT commissioners understand their responsibilities to manage SIs as well as their obligation to distribute notifications, reports and action plans to the PCT.

- There is understanding around the need for co-ordinated multi-organisation approaches to SI investigation and the role the PCT plays in facilitating this

- Lessons learned in the process of investigating and reporting on SIs are appropriately shared, both locally and if relevant, nationally in order to minimise the risk of similar incidents re-occurring.

NHS Trusts, including PCT providers, are accountable to commissioning PCTs through contracting and commissioning arrangements, with PCTs accountable to SHAs. NHS Trusts are also regulated by the Care Quality Commission (CQC) with specific requirements to notify about events that indicate or may indicate risk to ongoing compliance with registration requirements.

NHS Foundation Trusts and their boards of directors are accountable to commissioning PCTs through contracting and commissioning arrangements, and to their governors and members. Foundation Trusts are also regulated by Monitor for compliance with their terms of authorisation.

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

All provider organisations will be required to develop and adhere to their own SI policy, based on the set requirements outlined within this policy, the SHA Policy and NPSA Framework

1. Introduction

1.1 NHS Hertfordshire is committed to being an organisation within which diversity, equality and human rights are valued. We will not discriminate either directly or indirectly and will not tolerate harassment or victimisation in relation to gender, marital status (including civil partnership), gender reassignment, disability, race, age, sexual orientation, religion or belief, trade union membership, status as a fixed-term or part-time worker, socio - economic status and pregnancy or maternity.

1.2 NHS Hertfordshire works to a framework for handling personal information in a confidential and secure manner to meet ethical and quality standards. This enables National Health Service organisations in England and individuals working within them to ensure personal information is dealt with legally, securely, effectively and efficiently to deliver the best possible care to patients and clients.

1.3 NHS Hertfordshire, via the Information Governance Toolkit, provides the means by which the NHS can assess our compliance with current legislation, Government and National guidance.

1.4 Information Governance covers: Data Protection & IT Security (including smart cards), Human Rights Act, Caldicott Principles, Common Law Duty of Confidentiality, Freedom of Information Regulations and Information Quality Assurance

2. Terms / Acronyms Used

CDOP	Child Death Overview Panel
CEMACE	Confidential Enquiry into Maternal and Child Health
CQC	Care Quality Commission
DH	Department of Health
E&NHT	East & North Hertfordshire NHS Trust
EoE	East of England
GP	General Practitioner
HCAI	Healthcare Associated Infection
HOR	Health Overview Report

HPA	Health Protection Agency
HPFT	Hertfordshire Partnership Foundation Trust
HSCB	Hertfordshire Safeguarding Children Board
HSE	Health and Safety Executive
HSG	Health Service Guidance
ICD	International Classification of disease
LSAB	Local Safeguarding Adults Board
LSAMO	Local Supervising Authority Midwifery Officer
LSCB	Local Safeguarding Children Board
MHRA	Medicines & Healthcare Products Regulatory Agency
MRSA	Methicillin Resistant Staphylococcus Aureus
NCAS	National Clinical Advisory Service
NHS	National Health Service
NPSA	National Patient Safety Agency
NRES	National Research Ethics Service
NRLS	National Reporting & Learning System
RCA	Root Cause Analysis
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
SAFA	Safeguarding Adults From Abuse
SCR	Serious Case Review
SHA	Strategic Health Authority
SI	Serious Incident
WHHT	West Hertfordshire Hospitals NHS Trust

3. Definition of a SI requiring investigation

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

- Unexpected or avoidable death of one or more patients, staff, visitors or members of the public.
- Serious harm to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy or result in prolonged pain or psychological harm (this includes incidents graded under the NPSA definition of severe harm).
- A scenario that prevents or threatens to prevent a provider organisation's ability to continue to deliver healthcare services, for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment, or IT failure.
- Allegations of abuse.
- Is a death in custody e.g. prison, probation hostels and immigration detention accommodation and includes expected deaths. Guidance on clinical reviews undertaken in those circumstances and the responsibilities of the NHS are available on www.dh.gov.uk/socialcare (navigate to prison health) or from the regional health and social care justice team.
- Serious potential or actual adverse media coverage or public concern about the organisation or the wider NHS.
- One of the core set of NPSA 'Never Events' as updated on an annual basis and currently including:
    - wrong-site surgery;
    - retained instrument post-operation;
    - wrong route administration of chemotherapy;
    - misplaced nasogastric 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.

3.2 As a minimum, patient safety incidents leading to unexpected death or severe harm should be investigated to identify root causes and enable effective action to be taken to prevent recurrence.

3.3 The definition of serious incidents requiring investigation extends beyond those which affect patients directly, and includes incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

3.4 If there is uncertainty about the status of an incident, potential SI reporters are advised to err on the side of caution and report where in doubt. Advice can be sought from the Nursing and Quality Team within the PCT (01707 367231) or the Clinical Quality and Patient Safety Team at the East of England SHA (01223 597567).

3.5 Excluded from this definition are adverse outcomes reasonably associated with routine NHS activity such as major surgical procedures or radiotherapy treatment.

4. Special Circumstances

4.1 The following more specific incident types should generally be regarded as serious incidents and be rapidly escalated under the SI process. In addition the incidents may require further attention in respect of other processes applied. These incidents are also likely to be closely scrutinised by PCTs/SHAs due to the nature of their severity and or sensitivity.

Maternal Deaths

4.2 In order to comply with Nursing and Midwifery Council Midwives Rules and Standards 2004 all maternal deaths are to be reported to the Local Supervising Authority Midwifery Officer (LSAMO). This will be via the LSA coordinator on 01223 597568 or via their secure email address and sent from a secure e-mail address to: **Eoesha.matsui@nhs.net**

4.3 CEMACE (Confidential Enquiry into Maternal and Child Health) reporting will continue in the normal way.

4.4 **Although not all maternal deaths are classified as serious incidents the EOE SI initial report form should be utilised in all cases being notified to the LSAMO.**

4.5 For further guidance on reporting processes around Maternal Deaths

please see **Appendix A**

Information security incidents

4.6 The reporting of SIs relating to breaches of confidentiality involving person identifiable data and data losses should be reported to the SHA, via the PCT in accordance with Department of Health Gateway letter 9571 dated 29 February 2008 and refer to the definitions and risk assessment methods contained in Annex B (see **Appendix B**). The SHA will utilise the risk assessment matrix in the DH guidance to determine the SHA level of seriousness applied to the incident. The SHA will publish a quarterly report of such incidents on its website in accordance with the Gateway letter.

4.7 As part of reporting serious incidents relating to Information Security, all providers and Independent Contractors should also complete **Appendix C** to provide further specific information.

4.8 Further to this all SIs involving data losses and breaches in confidentiality should be published in the annual reports of all East of England NHS organisations in accordance with Department of Health Gateway letter 9912 of 20 May 2008 utilising the format at Annex A of the gateway letter. This can be found at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_084991.pdf

Healthcare Associated Infections (HCAI)

4.9 Some incidents involving infections, HCAIs should be reported to commissioning PCTs and the SHA via the East of England SI reporting process. The categories for reporting include:

- Outbreaks of healthcare associated infection (this includes the presumed transmission within a hospital and causes significant morbidity, mortality and or impacts significantly on hospital activity). A clinical area closed as a result of an outbreak would constitute an SI.

- Infected healthcare workers (incidents which necessitate consideration of a look back exercise).

- Breakdown of infection control procedures and or serious decontamination failures with actual or potential for cross infection.

4.10 The normal SI reporting process should be followed and a full systematic investigation using RCA must be undertaken and copy sent to the PCT and SHA, together with an action plan. The PCT will ensure ongoing monitoring of the action plan with the SHA ensuring that implementation is assured. Outcomes of actions are also monitored by the PCT through the Whole Systems HCAI group.

4.11 Epidemiological data from reported SIs will be shared with the Health Protection Agency (HPA) to allow further epidemiological studies to take place. Trusts may therefore be required to provide additional information in these circumstances.

4.12 The trust and commissioning PCT will manage the SI with advice and support from colleagues in the HPA. The SHA has an identified team to provide additional advice, support and guidance to both in the reporting and management of ongoing infections incidents. Current contact details are:

PCT

Assistant Director Health Protection **01707 369658**

Gill Goodlad (as at August 2010)

SHA

Infection Control Programme Manager **01223 597518**

Rosie Readman (as at August 2010) **07977 437404**

Clinical Quality and Patient Safety Team

01223 597567

(reporting of incidents)

4.13 **Root Cause Analyses on individual MRSA Bacteraemia should NOT be sent via the SI reporting process but sent directly to the Infection Control Programme Manager.**

Mental health services incidents including homicides involving service users (see Appendix D)

4.14 In June 2005 Department of Health (DH) issued new guidance on the independent investigations of serious patient safety incidents in mental health settings. This aimed to improve investigations and to help ensure a consistent approach across the NHS. It replaced paragraphs 33 –36 in HSG (94) 27 and (LASSL (94)4), concerning the conduct of independent inquiries into mental health services.

4.15 It is the responsibility of the SHA to commission independent investigations on behalf of commissioning PCTs and there are clear criteria that determine the requirements of an independent investigation: (**See Appendix E**)

- When a homicide has been committed by a person who is, or has been, under the care, i.e. subject to regular or enhanced care programme approach, of specialist mental health services in the six months prior to the event. All homicide cases will be designated as SI level 2.

- 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 or where the victim sustains life threatening injuries, 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 SHA determines that a serious patient safety incident warrants an independent investigation, for example if there is concern that an event may represent significant systemic service failure, such as a cluster of suicides.

4.16 The process needed for the three stages of the independent investigation process are:

1. Initial service management review: an internal trust review within 72 hours of the incident being known about in order to identify any necessary urgent action.

2. Internal NHS mental health trust investigation: using Root Cause Analysis (RCA) or a similar robust process to establish a chronology, identify underlying causes and what further action needs to be taken.

3. SHA independent investigation: Commissioned and conducted independently of the providers of care.

4.17 **Further information can also be sought from the NPSA guide on best practice http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/directivesguidance/mental-health/**

Safeguarding children

4.18 The requirements in relation to safeguarding children are set out in Working Together 2010. The SHA discharges its functions as set out below.

4.19 As part of Commissioning a Patient Led NHS the SHA ceased to be a member of all 10 Local Safeguarding Children's Boards but it will discharge its responsibilities in 3 key ways:

1. By holding PCTs to account for the delivery of their function and all other organisations from whom they commission, in relation to safeguarding children. The SHA would also use its regional partnerships and relationship with inspectorates to both support and ensure NHS organisations deliver their safeguarding children responsibilities.

2. Once an organisation providing NHS care has decided that a SI fits the East of England reporting criteria SI reporting mechanisms to the SHA are detailed in section 4, page 6. Where the SI is in relation to a child or young person under 18 then the relevant Local Safeguarding Children's Board (LSCB) should also be informed of the incident at the same time as the SHA is notified. The present contact details for the Hertfordshire Safeguarding Children Board Business Manager are:

   Hillary Griffiths, HSCB Business Manager
   County Hall
   Hertford
   Tel: 01992 555077
   07795 013577

3. Where the LSCB decides that a serious case review (SCR) is required, the SHA will ensure that the SI reporting mechanisms are used to report the initiation of a children's serious case review, reporting the scope and terms of reference of the review the SHA from the commissioners. This information will simultaneously be notified to the CQC by the commissioners and pending completion of the review may feed into the CQC regulatory process. Notifications should be sent within five working days of confirmation by the Local Safeguarding Children Board to proceed with the Serious Case Review and include the following information:

   a. Date(s) of incident

   b. Identifying code (notifications should not contain identifiable names or details).

   c. Age(s) of child(ren)

   d. Brief outline of case

   e. Terms of Reference for the review

f. Which health and/or social care partners were involved.

g. Date of approval to proceed by Local Safeguarding Children Board

h. Contact name and details should further information be required.

4.20 In NHS Hertfordshire the Designated Nurse is the lead responsible for notifying the CQC. The SHA require PCTs to submit a draft copy of the Health Overview Report (HOR) as set out in 'Working Together' 2010.

4.21 The PCT will receive feedback from the SHA within appropriate timescales to inform final report submissions. Feedback will also inform the PCTs performance management role, and the CQC may use the findings of SCRs to inform its processes for regulating NHS and independent sector provider organisations.

4.22 This SI policy incorporates best practice in investigations as part of any serious case review process and the coordination of action plans to be monitored by PCT commissioners. The Nursing and Quality directorate will assure that robust investigations are undertaken by NHS organisations and all actions implemented via the performance management of NHS organisations.

4.23 Details of the Herts SCR Policy and procedures to support this SI Policy are available at: http://www.hertssafeguarding.org.uk/adults/index.htm

Safeguarding adults

4.24 If a serious incident involves allegations of abuse or mistreatment of a vulnerable adult staff should consult the 'Hertfordshire inter-agency procedure for the protection of vulnerable adults' available at http://www.hertsdirect.org/infobase/docs/pdfstore/acs666part1.pdf

4.25 Contracts and Quality schedules with local health care provider organisations have been clearly established which clearly set out all provider organisations' obligations to meet the requirements of this policy. If a provider is uncertain about whether an incident is an SI they should discuss this with the lead nurse for adult safeguarding in NHS Hertfordshire on 07795646447.

Death in custody

4.26 All deaths in custody should be declared as an SI. Where deaths in custody occur the appropriate guidance should be followed. Guidance on clinical reviews undertaken in those circumstances and the responsibilities of the NHS are available on www.dh.gov.uk/socialcare (navigate to prison health) or from the

regional Health and Social Care in Criminal Justice Team, amanda.hawkins@eoe.nhs.uk or rob.jayne@eoe.nhs.uk. Draft Terms of Reference for clinical reviews have been developed and included at **(Appendix F.)**

Use of adult psychiatric wards for children aged 16 and under

4.27 In accordance with Department of Health Gateway letter 8390 of 29 June 2007 and in order to ensure compliance with the "age appropriate provision" legislative requirement under the Mental Health Act from April 2010 the SHA, via the PCT should be immediately notified when a child of 16 or under is placed on an adult ward, the notification should include how the child will be moved to appropriate accommodation within 48 hours and in the intervening time, how the ward and staffing have been made appropriate to the child's needs. For under 16's the SHA are required to notify the DH of all incidents providing details of the incident and the plans to move the child to a more appropriate setting.

4.28 Whilst there are occasions where it is appropriate to admit 16 and 17 years olds to adult Mental Health facilities, the SHA, via the PCT should be immediately notified of all incidents relating to 16 and 17 year olds placed on adult wards. The SHA will in each incident need to be assured that it is an appropriate placement (in line with best practice set out in the national service framework).

4.29 The SHA has agreed that the most effective way of alerting them if a provider has to place a child on an adult ward is to use the SI reporting mechanism and the EoE SI reporting form. This should be sent to the SHA and the PCT commissioner via the dedicated secure SI email address.

4.30 The notification must include the action being taken to ensure the ward and staffing are appropriate to the child's needs and the plan to ensure they are moved to a more appropriate setting within 48 hours. An update should be provided 48 hours after initial notification to demonstrate plans have been actioned.

Serious incidents related to clinical research

4.31 All clinical research needs to be approved via the National Research Ethics Service (NRES) and the network of local ethics committees and if necessary trust research and development committees before NHS patients and staff can be approached to be involved in research. If an incident occurs in relation to NHS patients or staff whereby harm has been caused or confidentiality has been breached or any other outcome which would constitute a serious incident, this should be reported using the organisation's serious incident process and the report should ultimately reach the PCT and SHA. In addition the incident should be reported to the relevant research body(ies).

Serious incidents related to National Screening Programmes

4.32 For serious incidents relating to national screening programmes staff should refer to the National Screening Committee's guidance on managing serious incidents. This guidance can be found at http://www.screening.nhs.uk/quality-assurance

4.33 The purpose of this guidance is to make explicit the requirements for national screening programme related serious incidents and to provide clarity and understanding for all staff providing NHS funded care. PCTs should also be informed of such SI's.

Medicines Management

4.34 For serious incidents relating to medicines management the Nursing and Quality team will seek the support of the Medicines Management team in reviewing all aspects of the incident.

5. Other responsibilities related to reporting SIs

5.1 This policy must not interfere with existing lines of accountability and does not replace the duty to inform the police and or other organisations or agencies where appropriate. Furthermore NHS organisations are encouraged to co-operate as fully as possible in investigations by other agencies, and should for example provide necessary documents as soon as appropriate. When such documents and records may be required, a photocopy should always be taken of anything disclosed.

5.2 In circumstances where a Police or HSE investigation is likely to run concurrent to a potential SI Investigation an incident co-ordination group should be established. This group should include representation from all NHS organisations involved in the incident, the Police and where required the Health and Safety Executive (HSE). At this group the need for an NHS investigation should be discussed with the Police and/or HSE and an agreement reached about how when this is to be conducted.

5.3 Further guidance can be obtained from the Department of Health publication "Memorandum of Understanding - Investigating Patient Safety Incidents, June 2004" and accompanying NHS guidance of November 2006 should be followed in conjunction with the relevant guidance.

5.4 Reporting managers must comply with the Caldicott principles of confidentiality when reporting SIs and must not refer to patients by name or by any other identifiable information. A reference number or identifier (not an NHS number) should be quoted as a reference on all correspondence to the PCT.

5.5 Reporting an incident to the PCT or the SHA does not remove any responsibility to comply with national guidance issued by the Department of Health or other organisations such as the NPSA.

5.6 Managers should be aware of Department of Health guidance that may exempt details of individual serious incident reports being made available to third parties, under either or both Sections 31(2) and Section 40 (2 & 3) of the Freedom of Information Act 2000.

5.7 When an incident or incidents are of such a serious nature that an external inquiry is required, it will need to be established in line with relevant national guidance for example HSG (94) 27 and associated amendment. The responsibility for commissioning an external inquiry depends on the nature of the incident. Such incidents are expected to be discussed with the SHA's clinical quality and patient safety team. Further details can be found in **Appendix E.**

6. Commissioning PCTs' Responsibilities and Expectations

6.1 Contracts and Quality Schedules with local healthcare provider organisations have been established which clearly set out all provider organisations' obligations to meet the requirements of this Policy. Through these commissioning and contractual arrangements and the quality monitoring systems within PCTs, we will ensure that:

- The originating provider informs the PCT of an SI via the SI reporting system to **Herts.SUI@nhs.net** using SI form **(Appendix G).**
- The PCT executive team is briefed on the details of each new serious incident received by utilising a SI Briefing Form template. (**Appendix H**).
- Investigation Reports are received to the set or otherwise agreed timescales and to require quality standards.
- SIs are monitored, reports and investigations scrutinised and appropriate actions are implemented by the reporting organisation according to best practice.
- Evidence of implementation is received following the completion of identified actions following the investigation of an SI and that improvement in practice is continually monitored via contract monitoring.
- The SHA is fully briefed on SIs within PCT commissioned services.
- Measures are in place in the provider organisation to manage

any potential press and media interest with briefings to the SHA communications team as required.

- Leadership and guidance is provided for independent contractors in undertaking investigations.

- The co-ordination of complex multiagency investigations/RCA is facilitated, by obtaining relevant documentation from other providers or independent contractors and arranging joint meetings.

- The dissemination of wider learning or national information on serious incidents takes place via PCT patient safety newsletters.

- Recommendations from independent investigations are implemented across the PCT and, where appropriate, across the wider NHS through all available mechanisms.

- SIs are closed in a timely manner using the SHA's closure form template (**Appendix I)** and advising provider organisations when incidents are closed formally.

- Overall figures on serious incidents being received, including Never Events, are reported to the Quality Assurance Committee and PCT Board prior to being publicly accessible.

- Regular thematic reviews of serious incidents are undertaken to identify trends and patterns across the PCT and ensure the wider implications and key learning points are disseminated across the PCT, and wider NHS

- Consistent close working with other stakeholders is undertaken to ensure that media messages and management reflect the perspective and needs of reporting & learning from serious incidents and their outcomes.

6.2 Local procedures have also been agreed with LSAB/LSCB that set out the arrangements for notification and management of serious case reviews, including action planning and learning from incidents.

6.3 The PCT will utilise the information received via the SI Process to assist in the undertaking of annual suicide audit and drug related death process for Hertfordshire. Information relating to Child Death SIs will also be used to inform the Child Death Overview Panel (CDOP).

7. Management of a serious incident

7.1 In all instances, the first priority for a provider organisation or independent contractor 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.

7.2 A safe environment should be re-established, all equipment or medication retained and isolated, and relevant documentation copied and secured to preserve evidence and facilitate investigation and learning. The organisation should give early consideration to the provision of information and support to patients, relatives and carers and staff involved in the incident, including information regarding support systems.

7.3 A useful checklist of actions to take following a serious incident can be found in **Appendix J.**

8. Reporting processes for Serious Incidents

8.1 Once an SI has occurred it should be reported within 2 working days using the East of England SI initial report form. **(See appendix F)** This notification should be completed by the relevant person within the service area involved, in consultation with the relevant patient safety or risk lead within the organisation. When completed all SI Notification should be submitted to: **Herts.SUI@nhs.net**

8.2 If not already included as part of the serious incident notification, the PCT will then forward a copy to the Clinical Quality and Patient Safety Team at the SHA via: **eoesha.SUI@nhs.net**

8.3 **The responsibility to declare a Serious Incident lies with the organisation that is first made aware of events.**

8.4 As part of this requirement there may be occasions for later agreement around who should investigate the incident should the event be identified by one provider but primarily involve another. The PCT will where necessary indicate who should undertake investigations where any disputes arise.

8.5 In addition to the PCT, all providers should ensure that when necessary the incident has also been reported to the relevant external agency.

a) Hertfordshire Safeguarding Children's Board if the serious incident involves a child.

b) If this serious incident involves allegations of abuse or mistreatment of a vulnerable adult staff should consult the 'Hertfordshire inter-agency procedure for the protection of vulnerable adults' http://www.hertsdirect.org/infobase/docs/pdfstore/acs666part1.pdf

c) Health and Safety Executive (HSE) are notified if the incident is reportable under RIDDOR.

d) Medicines and Healthcare products Regulatory Agency if the incident involves a medical device or adverse drug reaction is suspected.

e) Coroner is informed of any death within 24 hours of admission or any sudden unexplained death.

f) Counter Fraud and Security Management Service if the incident involves physical violence against a member of staff.

g) Local Health Protection Agency for East of England for any SIs which raise severe and widespread threats to public health.

8.6 In office hours, if an incident has very significant implications for the NHS in terms of clinical, managerial, media and reputation issues, direct contact should be made with a senior member of the PCTs Nursing and Quality Team. The commissioning PCT is then expected to contact the SHA Clinical Quality and Patient Safety team directly.

8.7 When the incident occurs out of office hours, the on-call PCT senior manager should be informed, who will discuss the incident with the on-call executive director.

8.8 In either case the PCT and SHA will agree whether the situation requires escalation and if so they will agree any action that needs to be taken with the relevant NHS organisation.

PCT Contact Number for SIs **01707 367231**

PCT Out of hours Duty Director **07909 913275**

SHA In hours: Clinical Quality and Patient Safety Team:

01223 597567

SHA Out of Hours: Senior Manager on call rota:

07699 732431

8.9 Further guidance on how to respond to SIs and initially co-ordinate potential investigations can be found in **Appendix K.**

8.10 Minimum reporting standards are:

- 2 working days for receipt of the SI form by the PCT.

- The PCT and SHA will acknowledge receipt of the SI within 2 working days. Grading will be agreed by the PCT and SHA with the provider, with advice from specialist sources where appropriate.

- In more serious cases a 3 working days or 72 Hour report (3 working days from the receipt of the incident at the PCT). The PCT will not ask for these 3 day updates as a regular occurrence but will do so when particularly significant cases have been reported. For an example template please see **Appendix L**. All Level 2 SI's will require a 72 hour report.

- Brief update in 7 working days, to identify any immediate actions taken as a result of the incident and or any additional relevant information that may have emerged during the trust's immediate investigation. An example template can be found in **Appendix M.** The report will be reviewed by the PCT with consideration being given for a further review of the grading and whether SI can be closed at this stage.

- Root cause analysis (or a similar recognised robust process to establish a chronology, identify underlying causes and what further action needs to be taken), with accompanying action plan within 45 working days. This may be extended on a case-by-case basis on mutual agreement between the provider and commissioner, where a delay is necessary for example whilst awaiting the results of criminal investigations or an inquest. A basic guide as to what should be incorporated within a 45 Day report is presented in **Appendix N.**

- For Level 2 graded Serious Incidents special dispensation may be given enabling NHS Providers to undertake more detailed RCA or Panel Review investigative processes. Deadlines for these investigations will be agreed at the start of each process and must be adhered to.

- An Action Plan is completed following the completion of the 45 Day RCA Investigation in order to ensure that recommendations can be effectively implemented. A standard Action Plan template is included in **Appendix O.**

- Once a completed action plan is received with any relevant evidence of implementation the PCT will complete a closure form which will be reviewed by the responsible Director. When closed an e-mail will be sent to confirm this to those providers involved.

8.11 At all stages of the process the Nursing and Quality team will review reports and provide feedback to support the SI process.

8.12 As of April 1 2010, as part of the new registration requirements arising from the Health and Social Care Act 2008, organisations are required to notify the CQC about events that indicate or may indicate risks to ongoing compliance with registration requirements, or that lead or may lead to changes in the details about the organisation in the CQC's register. Reports about serious incidents and deaths are defined in the CQC's guidance, *Essential Standards of Quality and*

Safety. Most of these requirements are met by reporting via the NPSA, and the NPSA will forward relevant information to the CQC.

8.13 It is therefore vital that Trusts also upload any serious incident onto the National Reporting and Learning System within 2 working days. Following completion of the initial report, further information should be inputted into the relevant electronic database (e.g. Datix) and re-uploaded to the NRLS.

9. Guidance on the grading of serious incidents

9.1 Once an SI Notification is received it will be clinically reviewed by the PCT in order to allocate a grading. The grading of an SI is central in identifying the level of investigation required and degree of monitoring/oversight by the SHA.

9.2 In circumstances where it may be unclear whether the event should be declared as a SI it will be allocated a Grade 0, which will then be reviewed following the completion of an initial investigation or receipt of other info.

9.3 For further guidance on the grading criteria please see **Appendix P.**

10. Problems reporting within timescale

10.1 If a report is unable to be completed within the expected time frame then the provider undertaking or leading the investigation needs to inform the designated PCT Patient Safety Manager or equivalent of reasons for the delay and an expected timescale for completion. Requests for extensions should be made in advance of set deadline dates. Reasons for such a delay may include:

- Police investigation/ Involvement
- Coroner involvement

10.2 Failure to meet reporting timescales may result in performance related penalties being incurred.

11. PCT Process for managing SIs

11.1 A flowchart documenting the PCTs standard operating process for managing all serious incidents received can be found in **Appendix Q.**

12. Specific Guidance for SIs that occur within the Commissioning PCT

12.1 All PCT staff should be aware of the SI policy and follow the flow chart in **Appendix R**. The manager who declared the SI Notification, guided by the Patient Safety Manager or equivalent, will ensure that a preliminary report is completed within 7 days to establish the facts of the incident. The preliminary report is sent to Herts.SUI@nhs.net and the Patient Safety Manager will liaise with the SHA.

12.2 A decision will then be made whether an internal investigation is required based on the severity of the incident, the scale of the incident, the ongoing risk, anticipated public interest and the opportunity for learning.

12.3 If required an internal investigation will then be allocated by the senior manager of the team involved who will nominate a responsible staff member to develop a full chronology of events, ensure that all appropriate actions have been taken and that any learning points have been identified. The allocated investigator and senior manager will produce a full investigation report within 45 days and this will be sent to the Patient Safety Manager or equivalent at Herts.SUI@nhs.net.

13. Specific Guidance for SIs that occur within independent contractors

13.1 Please see **Appendix S.**

13.2 Typically the process for SIs being declared by Independent contactors is similar to that of all NHS provider organisations, with an SI Notification being submitted by the practice manager or relevant clinician to the secure inbox. (Herts.SUI@nhs.net).

13.3 Once received the SI notification will be reviewed and discussed with the relevant primary care contract manager and primary care clinical governance lead. The contract manager will subsequently request the completion of a preliminary 7 Day Report by the practice or surgery involved. In certain circumstances a 72 hour report may be required. The Patient Safety team will inform the contractor if this is required on receipt of the SI notification.

13.4 If required a further RCA based investigation will then be undertaken by an investigator allocated by the primary care team (either within the PCT or practice involved depending on the sensitivities of the case) to develop a full chronology of events, ensure that all appropriate actions have been taken and that any learning points have been identified. The allocated investigator and relevant will produce a full investigation report within 45 days and this will be sent to the Patient Safety Manager or equivalent at Herts.SUI@nhs.net.

14. SIs that occur within private providers based in NHS Hertfordshire boundaries

14.1 A specific flowchart for SIs being reported by private providers hosted by NHS Hertfordshire can be found in **Appendix T.**

14.2 As part of the completion of SI Notifications private providers should always identify to which PCT the patient is a resident of, if different to NHS Hertfordshire.

15. SIs that occur in relation to the Ambulance Trust

15.1 Within the east of England, the lead commissioner for the East of England Ambulance Service NHS Trust is NHS Bedfordshire. The process for managing these SI's is outlined within a flowchart in **Appendix U**.

16. SIs that involve multiple services or occur across healthcare boundaries

16.1 Due to the broad range of NHS organisations and regional nature of healthcare provision, there are occasions when SIs need to be investigated which map the patient journey. For example, a patient may have started their care in a district general hospital, was transferred by ambulance to a regional centre, was discharged home but was unwell and presented to the GP. In such a scenario it may be necessary to investigate this incident with all the key stakeholders. This should be done in a co-operative manner and should be co-ordinated by the PCT whose services were primarily involved.

16.2 In situations relating to unexpected deaths or recent GP contact, GP reports may be requested by NHS Hertfordshire and shared with provider organisations involved. Further guidance on the requirement of this report can be found in **Appendix V.**

16.3 Typically the process of a co-ordinated approach will be facilitated by the undertaking of an SI co-ordination meeting which will be arranged and chaired by the PCT. All trusts involved will be expected to attend the meeting with completed chronologies detailing their involvement. Issues discussed at the meeting will be recorded utilising Serious Incident Co-ordination Meeting Actions Template **(Appendix W).**

16.4 As part of the outcome of the meeting, a lead provider organisation will be identified to primarily investigate the incident with

support and input being provided by those other trusts involved. The requirements around what support/information is required may be documented utilising **Appendix X.**

16.5 Where a serious incident crosses the boundary of two or more PCTs, the PCTs concerned will liaise to ensure all are notified, a lead PCT is identified and a timescale is agreed locally. The lead PCT will be identified based on the main geographical location and service area where the serious incident occurred or in certain circumstances the residential origin of the person(s) involved.

17. PCT Monitoring and Learning from SIs

17.1 The performance monitoring of the SIs and implementation of the policy are monitored by the following:

- The Clinical Quality Contract meetings with providers. The commissioners identify progress made, implementation of action plans and review trends and outcomes with the provider service.

- The Quality Assurance Committee is tasked with the performance monitoring and reviewing outcomes and trends of SIs. Issues highlighted are reported to the Clinical Executive Committee.

- The NHS Hertfordshire Board receives a bi-monthly update report on serious incidents as part of Part II briefings. In addition a dedicated serious incident section is incorporated within the Quality Report, presenting SI figures by each provider.

18. Training on Sis

18.1 It is the responsibility of all healthcare providers to ensure that a number of senior staff receive training in root cause analysis and investigating skills. This should include an up to date list of competent staff within the organisation familiar with the organisation's investigation policies and protocols who are also skilled in good practice root cause analysis methodologies and techniques. The identified team must have no conflicts of interest in the incident concerned and must be available, possibly at short notice, to undertake serious incident investigations.

18.2 There is guidance for root cause analysis online at http://www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/rootcauseanalysis/rca-investigation-report-tools/

18.3 All members of staff should have training in incident reporting and what actions they need to take at a local level if a SI occurs. Within the PCT, training on incident and SI reporting is given at corporate induction by the Nursing and Quality team.

19. References

National Patients Safety Agency (2010) – 'National Framework for Reporting and Learning from Serious Incidents Requiring Investigation'

SHA East of England (2010) 'Serious Untoward Incident Policy'

DOH (2004) Memorandum of Understanding, Investigating Patient Safety Incidents

National Patient Safety Agency (2009) 'Never Events Framework 2009/10'

http://www.npsa.nhs.uk/nrls/improvingpatientsafety/neverevents/the-core-list/wrongsitesurgery

http://www.npsa.nhs.uk/nrls/improvingpatientsafety/neverevents/the-core-list/retainedinstrumentpostoperation

http://www.npsa.nhs.uk/nrls/improvingpatientsafety/neverevents/the-core-list/wrongrouteadministrationofchemotherapy

http://www.npsa.nhs.uk/nrls/improvingpatientsafety/neverevents/the-core-list/inpatientsuiciderails

http://www.npsa.nhs.uk/nrls/improvingpatientsafety/neverevents/the-core-list/escapefromsecureperimeter

http://www.npsa.nhs.uk/nrls/improvingpatientsafety/neverevents/the-core-list/in-hospitalmaternaldeath

http://www.npsa.nhs.uk/nrls/improvingpatientsafety/neverevents/the-core-list/intravenousconcentratedpotassiumchloride

Working Together 2010

20. Related Polices and Documents

Incident Policy

Information Security Policy

Safeguarding Adults from Abuse Policy

Safeguarding Children through the Commissioning of Services Policy

Allegations and Suspicions of Child Abuse Against Staff

Appendix 1 – Equality Impact Assessment Stage 1 Screening

1. Policy	EIA Completion Details
Title: Serious Incidents Requiring Investigation ☑Proposed ☐ Existing Date of Completion: Sept 2010 Review Date: September 2012	Names & Titles of staff involved in completing the EIA: Catherine Pelley Deputy Director of Nursing and Quality

2. Details of the Policy. Who is likely to be affected by this policy?

☑ Staff ☑ Patients ☑ Public

3. Impact on Groups

	Probable impact on group?			High, Medium or Low	Please explain your answers
	Positive	Adverse	None		
Race, ethnicity, nationality, language etc.	☑	☐	☐	Low	Where SI investigations occur the impact of race may be considered as part of the overall analysis
Gender (inc. transgender)	☑	☐	☐	Low	Where SI investigations occur the impact of gender may be considered as part of the overall analysis
Disability, inc. learning difficulties, physical disability, sensory impairment etc.	☑	☐	☐	Low	Where SI investigations occur the impact of disability may be considered as part of the overall analysis
Sexual Orientation	☑	☐	☐	Low	Where SI investigations occur the impact of sexual orientation may be considered as part of the overall analysis
Religion or belief	☑	☐	☐	Low	Where SI investigations occur the impact of religion or belief may be considered as part of the overall analysis
Human Rights	☑	☐	☐	Low	Where SI investigations occur the impact of human rights may be considered as part of the overall analysis
Age	☑	☐	☐	Low	Where SI investigations occur the impact of age may be considered as part of the overall analysis
Other:	☐	☐	☐		
No impact on any of the groups above.	Please explain and provide evidence				

4. Which equality legislative Act applies to the policy?	
☐ Human Rights Act 1998 ☐ Sex Discrimination Act ☐ Race Relations Act ☐ Disability Discrimination Act ☐ Gender Recognition Act 2004 ☑ Mental Health Act 1983 ☐ Equality Act 2006 ☑ Mental Capacity Act 2005	☐ Age Equality Regulations 2006 ☐ Equal Pay Act ☐ Sexual Orientation Regulations 2003 ☐ Religion or Belief Regulations 2003 ☑ Health & Safety Regulations ☐ Part time Employees Regulations ☐ Civil Partnership Act 2004

5. How could the identified adverse effects be minimised or eradicated?
N/A

6. How is the effect of the policy on different Impact Groups going to be monitored?
Via the overall SI monitoring process

Appendix 2 – Privacy Impact Assessment Stage 1 Screening

1. Policy	PIA Completion Details
Title: Serious Incidents Requiring Investigation ☑ Proposed Date of Completion: ☐ Existing Sept 2010 Review Date: September 2012	Names & Titles of staff involved in completing the PIA: Catherine Pelley Deputy Director of Nursing and Quality

2. Details of the Policy. Who is likely to be affected by this policy?

☑Staff ☑ Patients ☑ Public

	Yes	No	Please explain your answers
Technology Does the policy apply new or additional information technologies that have the potential for privacy intrusion? (*Example: use of smartcards*)	☐	☑	
Identity By adhering to the policy content does it involve the use or re-use of existing identifiers, intrusive identification or authentication? (*Example: digital signatures, presentation of identity documents, biometrics etc.)*	☐	☑	The policy specifically indicates who to provide information that presumes patient confidentiality
By adhering to the policy content is there a risk of denying anonymity and de-identification or converting previously anonymous or de-identified data into identifiable formats?	☐	☑	
Multiple Organisations Does the policy affect multiple organisations? (*Example: joint working initiatives with other government departments or private sector organisations*)	☑	☐	The policy sets the context for all health services in Hertfordshire
Data By adhering to the policy is there likelihood that the data handling processes are changed? *(Example: this would include a more intensive processing of data than that which was originally expected)*	☐	☑	
If Yes to any of the above have the risks been assessed, can they be evidenced, has the policy content and its implications been understood and approved by the department?	**N/A**		

Appendix A

CONFIDENTIAL ENQUIRY INTO MATERNAL AND CHILD HEALTH SAVING MOTHERS' LIVES:

Reviewing maternal deaths to make motherhood safer 2003-2005. The Seventh Report of the Confidential Enquiries into Maternal Deaths in the United Kingdom December 2007.

Definitions of maternal mortality

The ninth and tenth revisions of the International Classification of Diseases, Injuries and Causes of Death, (ICD9/10) define a maternal death as "the death of a woman while pregnant or within 42 days of termination of pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes". This means that there was both a temporal and a causal link between pregnancy and the death. When the woman died she could have been pregnant at the time, that is, she died before delivery, or within the previous six weeks have had a pregnancy that ended in a live or stillbirth, a spontaneous or induced abortion or an ectopic pregnancy.

The pregnancy could have been of any gestational duration. In addition, this definition means the death was caused by the fact that the women was or had been pregnant. Either a complication of pregnancy or a condition aggravated by pregnancy or something that happened during the course of caring for the pregnant woman caused her death. In other words, if the woman had not been pregnant, she would not have died at that time. Maternal deaths are subdivided into further groups:

Direct maternal deaths are those resulting from conditions or complications or their management which are unique to pregnancy, occurring during the antenatal, intrapartum or postpartum period.

Indirect maternal deaths are those resulting from previously existing disease or disease that develops during pregnancy, not due to direct obstetric causes, but which was aggravated by physiologic effects of pregnancy. Examples of causes of *Indirect* deaths include epilepsy, diabetes, cardiac disease and, in the UK only, hormone dependent malignancies. The Enquiry also classifies most deaths from suicide as *indirect* deaths as they were usually due to puerperal mental illness although this is not recognised in the ICD coding of such deaths. The UK Enquiry assessors also classify some deaths from cancer in which the hormone dependant effects of the malignancy could have led to its progress being hastened or modified by pregnancy as Indirect although these also do not accord with international definitions. Only *Direct* and *Indirect* deaths are counted for statistical purposes as discussed later in the section on measuring maternal mortality rates.

ICD-10 also introduced two new terms related to maternal deaths. One of them is ***pregnancy related death***, defined as the death of a woman while pregnant or within 42 days of the end of her pregnancy, *irrespective* of cause.

These deaths include deaths from all causes, including accidental and incidental causes. Although the latter deaths, which would have occurred even if the woman had not been pregnant, are not considered true maternal deaths, they often contain valuable lessons for this Enquiry. For example they provide messages and recommendations about domestic abuse or the correct use of seat belts. From the assessments of these cases it is often possible to make important recommendations. The ICD coding classifies these cases as fortuitous maternal deaths. However, in the opinion of the UK assessors, the use of the term fortuitous could imply a happier event and this Report, as did the last, names these deaths as ***Coincidental***. The other new term introduced in ICD-10 is ***late*** maternal death, defined as the death of a woman from *Direct* or *Indirect* causes more than 42 days but less than one completed year after the end of the pregnancy. Identifying *late* maternal deaths enables lessons to be learnt from those deaths in which a woman had problems that began with her pregnancy, even if she survived for more than 42 days after its end. However, although this category has only been recently recognised in the ICD 10 codes, and then only for deaths from *Direct* or *Indirect* causes, the previous three UK Enquiry Reports had already included all *Late* deaths notified to the assessors (including *Coincidental* deaths) occurring up to one year after delivery or abortion, as does this.

Appendix B

REPORTING SERIOUS INCIDENTS (SIs) RELATING TO ACTUAL OR POTENTIAL BREACHES OF CONFIDENTIALITY INVOLVING PERSON IDENTIFIABLE DATA (PID), INCLUDING DATA LOSS. Annex B of DH Gateway Letter 9571 (29/2/08)

It is essential that all serious incidents that occur in the Trust are reported appropriately and handled effectively. This document covers the reporting arrangements and describes the actions that need to be taken in terms of communication and follow up when a serious incident occurs. Trusts should ensure that any existing policies for dealing with serious incidents are updated to reflect these arrangements.

Definition of a serious incident in relation to personal identifiable data

There is no simple definition of a serious incident. What may at first appear to be of minor importance may, on further investigation, be found to be serious and vice versa. 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.

Immediate response to serious incident

The Trust should have robust policies in place to ensure that appropriate senior staff are notified immediately of all incidents involving data loss or breaches of confidentiality. Where incidents occur out of hours, the Trust should have arrangements in place to ensure on-call directors or other nominated individuals are informed of the incident and take action to inform the appropriate contacts.

Assessing the severity of the incident

The immediate response to the incident and the escalation process for reporting and investigating this will vary according to the severity of the incident. Risk assessment methods commonly categorise incidents according to the likely consequences, with the most serious being categorised as a 5, e.g. an incident should be categorised at the highest level that applies when considering the characteristics and risks of the incident.

SI level 1			**SI level 2**		
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 e.g. celebrity involved	Damage to a team's reputation. Some local media interest that may not go public	Damage to a services reputation. Low key local media coverage.	Damage to an organisation's reputation. Local media coverage.	Damage to NHS reputation. National media coverage.
Minor breech of confidentiality. Only a single individual affected.	Potentially serious breach. Less than five people affected or risk assessed as low e.g. files were encrypted.	Serious potential breach and 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.

Informing patients

Consideration should always 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 identity theft it is strongly recommended that this is done

Appendix C

Potential, or Actual, Information Loss Briefing to PCTs and SHA

Organisation	
Date of incident	
Date of reporting	
Level of severity (DH levels)	
Summary of incident	
Where information was held	
Safeguards in place	
Number of individuals at risk	
Have patients been notified?	
Has the Information Commissioner been notified?	
Is the data loss in the public domain	
Action taken by organisation	

Please return this form to the Herts.SUI@nhs.net

The PCT will forward the form to eoesha.SUI@nhs.net

Appendix D

Homicides committed by patients in receipt of mental health services

Trust	Commissioner	SHA
Raise SI internally and report immediately via EOE SI Process.	Notification of SI received	Notification of SI received. SHA immediate briefing to Executive and communications team.
Trust undertakes rapid 72 hour service management review to assess risk to patients, public and staff. Immediate clinical or managerial actions taken where necessary as a result of 72 hour review.	PCT assesses risks of SI with trust and SHA	SHA designates Level 2 SI and reviews 72 hr report jointly with trust and PCT to ensure that any immediate action to safeguard other patients/public is taken
Trust continues to work/cooperate with police throughout investigation.		Consider whether to evoke memorandum of understanding during the SI process to ensure patient safety is maintained and to agree communication with perpetrator and victims' family
		SHA considers whether case meets/likely to meet criteria HSG (94) 27
Internal investigation completed as soon as possible (usually within 90 days).	PCT receives Trust final report of investigation.	SHA receives final trust report of internal investigation.
Changes to policy and/or practice to enhance patient safety implemented.	PCT monitors internal trust investigation and action plan jointly with SHA	SHA monitors internal trust investigation and action plan jointly with PCT
		At the end of any legal proceedings (or earlier if possible) and if criteria met, SHA commissions the independent investigation proportionate to findings of completed internal root cause analysis.

Appendix E

EXTERNAL INDEPENDENT INVESTIGATIONS

Where an incident is so serious that an independent investigation needs to be established, it should be done as soon as possible. It should take note of relevant guidance.

If the victim of a homicide or serious injury is a child, then the Local Safeguarding Children's Board (LSCB) will be involved. The SHA will need to be kept informed of the progress of the Investigation.

Where deaths in custody occur the appropriate guidance should be followed. Guidance on clinical reviews undertaken in those circumstances and the responsibilities of the NHS are available on www.dh.gov.uk/socialcare (navigate to prison health) or from the regional Health and Social Care Justice Team.

The national guidance contained in HSG (94) 27 paragraphs 33-36 updated June 2005 should be followed where incidents involve homicides and other serious incidents involving people who are mentally ill**.** Organisations must ensure they comply with the updated guidance.

In certain circumstances it may be appropriate to consider establishing a more wide ranging external investigation in addition to the trust's internal investigation. The following are examples:

- Where groups of patients have experienced similar adverse outcomes of care
- Where significant numbers of patients have been harmed or have died as a result of weakness in the way a service has operated.
- Where there is significant service dysfunction.
- Where root cause analysis, National Clinical Assessment Service (NCAS) or CQC involvement has highlighted wider issues of system failures, dysfunctional services or serious causes for concern.
- Where the incident is of great severity, complexity, involves large numbers of patients, or covers a long time period.
- Where there is evidence of high-risk activity beyond that of an individual practitioner.
- Where there is a pattern or theme of serious service failure.
- Where there is evidence of organisation failure beyond a single area or team.
- Where there is evidence of systems failure involving a number of agencies or organisations.
- Where there is a need for addressing issues of wider public confidence.
- Where there is scope for significant learning from the event and sharing that learning more widely across the whole health economy.

- At the request of an NHS organisation following their own internal investigation.

The final decision about what type of investigation is established will be influenced by a number of factors and contain an element of judgement. Ideally this will be agreed in partnership with commissioners and trust and after careful consideration of all available evidence.

The guiding principles of a review should be that it is:

- Objective
- Have expert input
- Credible
- Follows national guidance and legislation where this exists.

CONSTITUTION OF AN EXTERNAL INDEPENDENT INVESTIGATION

The constitution and membership of the panel should be proportionate to the extent and scale of the investigation.

Members of the panel should be independent of the organisation that is being investigated.

There must be Terms of Reference that make clear the remit of the investigation, to whom the investigating panel reports and by when.

The patient, family or patient groups should be consulted about the Terms of Reference, announcements to be made and advised about the processes being adopted for the investigation. This should always happen unless there are exceptional circumstances suggesting otherwise.

The investigation must have transparent and fair processes to take evidence and establish the facts.

A report of the investigation will be published, unless there are exceptional overriding and compelling reasons why this should not be the case.

When the NHS Trust, PCT or SHA identify a need for further action or enquiry it may consider referral to the Care Quality Commission for a special investigation or a statutory inquiry under the NHS Act 1977.

One of the major purposes of an investigation is to learn lessons and put that learning into practice. It is the responsibility of all NHS organisations to learn from these incidents and embed that learning within clinical practice and service delivery.

Appendix F

NHS Hertfordshire

DEATH IN CUSTODY – CLINICAL REVIEW

DRAFT TERMS OF REFERENCE

1. Aim of the clinical review

The aim of the clinical review into the death of patient **XX** is to consider the healthcare the deceased received whilst in The Mount Prison. An approach of HOW and WHY will be adopted, not WHO was to blame. The review will consider the following:

- How, when and where did the prisoner die?
- Is there any root cause(s) of the death?
- Was the clinical care equitable with the wider community?
- Are there any learning opportunities?
- Were local and national policies and procedures followed?
- Is there an opportunity to prevent future deaths in similar circumstances?
- Are there any examples of good practice?

2. Scope of the clinical review

Primary Care Trusts have commissioning responsibility for the primary healthcare services in all public prisons in England. The Secretary of State for Health has agreed that Primary Care Trusts will take the lead in investigating the clinical issues relating to deaths in custody. Therefore, the local Primary Care Trust, for all public prisons, has the lead responsibility for arranging an independent investigation of the clinical issues under their existing procedures and may be required to attend the inquest. The Prisons and Probation Ombudsman in partnership with the DH and the NPSA have produced guidance on clinical reviews which form the basis of these Terms of Reference.

The Ombudsman's investigation includes examining the clinical issues relevant to each death in custody – such deaths are regarded by the National Patient Safety Agency (NPSA) as a serious incident (SI). In the case of deaths in public prisons and immigration facilities, the Ombudsman will ask

the local Primary Care Trust to review the clinical care provided, including whether referrals to secondary healthcare were made appropriately. Prior to the clinical review, the PCT will inform the NPSA of the SI. The clinical reviewer will be independent of the prison's healthcare service. The reviewer will conduct joint interviews with the Ombudsman's investigator.

A clinical review is required regardless of whether an internal Serious Incident (SI) investigation is being carried out. The SI investigation process should continue and not be delayed by the clinical review process.

The PCT has identified a clinical reviewer and in agreement with the reviewer will be establishing a review panel to review the clinical care provided to **XX**.

The review will:

- Examine the provision of clinical care and treatment, including risk assessment and risk management.
- Examine, to the extent necessary, the secondary care provided.
- Provide a chronology of the health and social care events leading up to the incident.
- Identify any care or service delivery failures along with the factors that contributed to these problems.
- Examine whether care provided to ***XX*** was in line with agreed policy practice and clinical guidelines.
- Identify any root cause(s) that inform the identification of learning opportunities to be included in the action plan.
- Make timely, clear and sustainable recommendations for the health community and the prison service.
- Provide explanations and insight for the relatives of the deceased.
- Identify any areas of good practice.
- Identify if care provided was equitable with care available in the community.

3. Clinical Review Panel

The core membership of the NHS Hertfordshire Clinical Review Panel is:

- Deputy Director of Nursing and Quality (Chair)
- Clinical Reviewer
- PCT Deputy Medical Director

- IMB Representatives from HMP The Mount
- Prison Health Commissioner
- Prescribing Adviser
- PPO representation
- Primary Care Clinical Governance Lead
- Representative from prison healthcare provider (independent of the prison healthcare service)
- Representatives from secondary care

Other clinical specialists/advisors may be co-opted as required.

The Clinical Reviewer identified will then make contact with the Ombudsman. The clinical review will be carried out within 6 weeks (as per Ombudsman Policy).

Any urgent issues requiring immediate remedial actions will be brought to the attention of the chair of the panel, key stakeholders and providers as soon as possible.

Papers will be circulated 1 week prior to the meeting of the Clinical Review Panel. All information collected will be presented to the meeting which will contribute to the draft report by asking for clarification, challenging findings, requesting further detail, providing peer support etc. The Clinical Review Panel meeting will be minuted and circulated to all panel members and the clinical reviewer. The Chair of the clinical review panel will report to the Prison Partnership Board

The Clinical Reviewer will send the final draft clinical review to the panel chair and Prison Health Commissioner for final sign off, who may refer it to the Panel for agreement before returning it to the Ombudsman. When agreed the Prison Health commissioner will send the final report to the Ombudsman, copying to the following:

- Panel Members
- PCT Lead Director for the HMP The Mount
- Chief Operating Officer prison healthcare provider and other relevant Trust Directors and Chief Executives as agreed by the panel

The Ombudsman prepares the full report, incorporating the NHS Hertfordshire clinical review, and sends draft to NHS Hertfordshire and Prison Governor for comments.

The Prison Health Commissioner sends a copy of the full draft report to:

- Clinical Reviewer
- Panel Members
- Director of Public Health
- Chief Operating Officer HCHS and other relevant Trust Directors and Chief Executives as agreed by the panel

Any comments or amendments are returned to the Ombudsman within the requested timescale

The Ombudsman prepares the final report and sends to NHS Hertfordshire. The Prison Health Commissioner is responsible for developing a commissioning action plan and provider action plans will be monitored through contracting and quality management processes.

June 2010

Appendix G

STRICTLY CONFIDENTIAL

East of England NHS
Strategic Health Authority

REVISED FORM AUGUST 2010

1.	Your Local Organisation SI Code		
2.	Date of this report		
3.	Name of Organisation		
3a.	Name of Commissioner		
4.	NPSA Category		
5.	Your Name and Contact details	Name	
		Job Title	
		Tel No	
		SecureEmail	
6.	Name and Contact details for Correspondence	Name	
		Job Title/role	
		Tel No	
		Secure Email	

7.	Date of Incident		(dd/mm/yyyy)

8.	Incident Category				

			Person 1.		Person 2.
9.	Details of Patient or other person(s) involved	Reference Code			
		Age (years)		Age (Months)	
		Gender			

10.	Outcome in terms of patient, other persons, staff or service failure		
		Other, please specify	

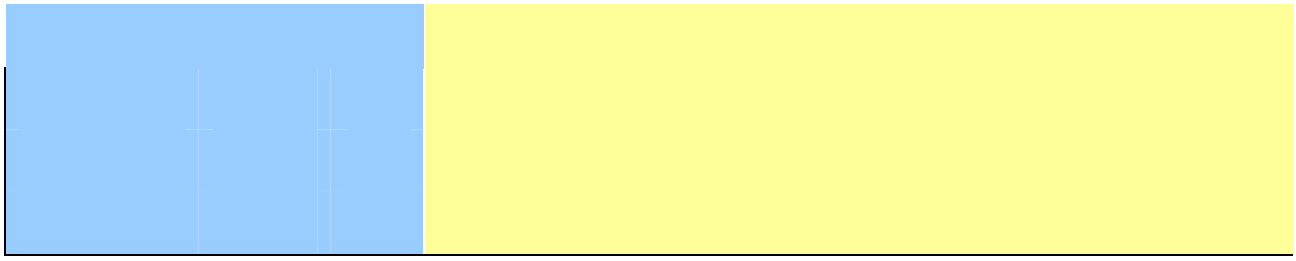
11.	Where did the incident occur? Eg. site, ward, in the home, etc	Location	
		Speciality	

12.	Staff Involved (designation only)	

STRICTLY CONFIDENTIAL

13.	Summary details of incident/issue: give a factual account, incl. a description of any medical devices, equipment and/or any medicines involved, and time of day if relevant. If a data loss, incl. how many individuals are involved, if they have been notified, any safeguards in place around the data, DH level of severity. **PLEASE NOTE THIS FIELD IS LIMITED TO 1000 CHARACTERS OF TEXT**. If you have more information, please attach an additional Word document.	
14.	Other information not in the public domain.	

15.	Immediate Action Taken	
16.	Legal Advice Taken?	
17.	Has, or will information on this incident be reported to any other agency/body (specify e.g. Police, Information Commissioner, etc)	
18.	Information about actual or likely media interest (local or national) and/or political interest or involvement (MP's, Ministers, etc)	
19.	Lines to take. (Include local and suggested national lines if applicable). *YOUR COMMUNICATIONS MANAGER should complete this section or provide you advice.*	



Save this form and send it as an attachment via **Secure** email to your **PCT Commissioner and to the SHA** at: eoesha.SUI@nhs.net

Appendix H

SI BRIEFING FORM

Initial report received from and site		**Date received**	_ _ / _ _ / _ _
SUI Ref		**Date of report**	_ _ / _ _ / _ _
SHA Ref		**Date of incident**	_ _ / _ _ / _ _
Score		**CEO Advised**	
SHA Form completed		**Date sent to SHA**	_ _ / _ _ / _ _
Service Area or Commissioned Service			
Lead Director identified			
Brief summary of incident			
Comms team advised **Yes / No**	_ _ / _ _ / _ _	**Communications Lead**	
SUI reviewed by			
Additional information requested from provider			
Additional action taken by PCT			
Other agencies to be included in SUI investigation			

Appendix I

SERIOUS INCIDENT CLOSURE FORM

EAST OF ENGLAND SHA

Commissioning PCT	
Trust	
SHA reference	
PCT reference	
Trust code	
Incident Date	
One line summary of incident	
Investigation completed?	
Has an action plan with deadlines and responsible person identifiable been provided?	
Have all actions been implemented?	
If any haven't, which and why not?	
Please state any future monitoring arrangements.	
Summary of key findings.	
Key lessons learnt.	
Date SUI closed by PCT.	
Date closed by SHA.	

Additional information ie Coroners report, requests from NPSA.	
Monitoring by PCT	

Signed off by:

Designation:

Date:

Organisation:

Reviewed by:

Appendix J

Immediate action following an incident by manager at the scene of an SI

1. Can the patient safety incident be investigated using existing NHS procedures developed by the Department of Health and NPSA	Yes	No
2. Does the incident need to be reported by the service to the PCT or other health related organisations?	Yes	No
3. Has the NHS organisation informed the organisations with an analytical or advisory function, e.g. NPSA?	Yes	No
4. Has the NHS organisation sought advice from Clinical Governance, Governance Unit or Health and Safety or the Care Quality Commission?	Yes	No
5. Has the NHS organisation considered whether the incident needs to be reported to the police and / or the HSE?	Yes	No
6. Has the NHS organisation's risk manager or equivalent made early, informal contact with the police and HSE to discuss concerns or take advice about further action?	Yes	No
7. Does the unexpected death, major injury or patient safety incident need to be reported to the HSE under RIDDOR?	Yes	No
8. Has reporting of the patient safety incident to the HSE been discussed with Clinical Governance or Health and Safety?	Yes	No
9. Has the service manager or member of Clinical Governance/ Governance Unit preserved all relevant evidence e.g. photocopied documents and safeguarded the scene?	Yes	No
10. Has clinical governance, Governance Unit or Health and Safety assisted the senior manager/clinician in assessing evidence?	Yes	No
11. Has a record been made regarding the scene of the incident, e.g. have photographs of the scene been taken?	Yes	No
12 Has Clinical Governance or Governance Unit or service manager protected the evidence by packaging and preserving it?	Yes	No

Supporting staff and relatives

1. Has the appropriate and timely (immediate and ongoing) support been made available to family and NHS staff involved, including professional counselling and appropriate referral to occupational health?	Yes	No
2. Have the staff been encouraged to contact their professional association and union representative?	Yes	No
3. Has legal advice been provided through the professional association or union or by the organisation in the event of them being called as a witness?	Yes	No
4. Has the organisation's communications unit and the communications team from the PCT been briefed and help line established (if applicable)	Yes	No
5. Has the NHS organisation ensured that the family and patient have been informed before the media?	Yes	No

Appendix K

The investigation team should discuss the following

What should be discussed	What to consider
Nature of the incident(s)	➢ What has happened, when and how? ➢ Who is involved?
Reasons for meeting, including an explanation from the organisation responsible for calling the meeting	➢ Why has the meeting been called? ➢ Are other parties involved e.g. relatives, the coroner?
NHS actions to date, including the outcome of any internal or external investigation or root cause analysis	➢ What has the service done to date? ➢ Are written reports available?
Public safety concerns	➢ Does the matter raise such concerns? ➢ If so, what are they?
Safety of NHS systems and the need for continuity of patient care	➢ Is there a need for remedial action and/ or further investigation by the NHS? ➢ Does the matter need to be reported to another investigative body e.g. MHRA?
The extent of further immediate NHS investigations and how these may need to be constrained in subject matter or format by the needs and requirements of the police and/ or HSE	➢ Is patient safety at risk ➢ If so, what has been done to minimize the risk?
Role and responsibilities of the police and/ or HSE and next steps to be taken (except where this would jeopardise any police/HSE investigations or subsequent legal proceedings)	➢ Each organisation should describe what it needs to do next and how it will fit – or conflict – with what others propose to do.
Other statutory responsibilities	➢ Do the organisations have other statutory responsibilities they should consider e.g. the

	need to involve the Local Safeguarding Children Board in a case concerning a child?
Need to inform professional regulatory bodies e.g. General Medical Council, General Dental Council, Nursing and Midwifery Council	➢ Does the individual(s) need to be reported? ➢ Who will do this? ➢ Should they be excluded? (see NPSA Incident Decision Tree)
Securing and preserving evidence	➢ Has this been done? ➢ By whom? ➢ What has been preserved? ➢ Where is it?
Sharing information	➢ What information is available? ➢ What can be shared? ➢ Is consent needed? ➢ To keep patient and relatives informed
Need of and support to patients, relatives, contractors and NHS staff	➢ How are these to be met? ➢ By whom?
Information to other interested parties e.g. the coroner	➢ Who else needs to know? ➢ What can they be told?
Handling communications / media	➢ Is the incident likely to attract the attention of the media? ➢ What will be said in response? ➢ Who will say it and in what circumstances?
Future handling and coordination, including the appointment of a liaison officer from each organisation	➢ Who from each organisation is to act as point of contact and lead?

Appendix L

Report (Example 72 Hour Report)

ORGANISATION

SI (Trust REF)

SHA ref --------

72hr report: Submitted -- -- --

Background

Summary

Immediate action taken

Next steps / proposed actions for further investigation

Report signed off by: _____(name)

_____ (role)

Appendix M

Report (Example 7 day)

7 Day Report Template

This report should be completed using the principles of Root Cause Analysis. The report will seek to investigate the initial facts as found within 7 Days of the incident determining reasons as to why the incident occurred and immediate actions necessary to reduce the likelihood of the incident recurring.

Service User Profile					
Name:		Date of Birth:		NHS Number:	
Reason for accessing service:		Primary Diagnosis		MCA Status (If applicable)	
Directorate:		Service:		Unit/Team:	

Incident Overview					
Trust Severity Grading:		Type/Category of event:		Risk score :	
Date of Incident:		Time of Incident:		Date Incident Reported as an SUI	

Summary of Incident
Brief description of Incident (what/when/how)

Initial understanding of possible contributory factors (why)

Initial Analysis

Please consider factors relating to the care and treatment of the service user, taking in to account potential problems/deficiencies initially identified: For Instance

- What exactly was the level of involvement of services
- Was there a failure to adhere to/apply any Trust policies
- Was the risk assessment and management of the individual involved in the incident appropriate and robust? When was the last review or assessment – had frequent reviews been undertaken?
- Were adequate treatment and equipment arrangements in place?
- Was there adequate communication between the service user, their carers and the Trust, health professionals and external agencies (if applicable)?
- How compliant was the service user with their treatment plan?

In addition to the above considerations please also highlight any good practice identified at this stage

Immediate Actions taken/to be taken		
Has the immediate risk been assessed for impact and likelihood of recurrence?		
Yes ☐ No ☐		
If Yes, what measures if any have been put in place to minimise risk of reoccurrence?		
Measure/Action	Who is Responsible for Action	Completed (Please Mark)
		☐
		☐
		☐
		☐

Incident Report completed by:					
Name:		Designation		Date	
Telephone:		E-mail		Base	
Please confirm that the manager commissioning the investigation has accepted this report as final					
Final Report:	*YES/NO*	Name of Manager:		Date:	

RETURN YOUR COMPLETED REPORT TO: Nursing and Quality Directorate, Charter House, Welwyn Garden City

OR EMAIL TO: Herts.SUI@nhs.net

Appendix N

45 DAY REPORT GUIDANCE

Quick reference guide	Type your investigation report in this column
Cover page • Organisation name and / or logo • Title or *Brief* outline of incident • Incident date • Incident number • Author(s) • Report date • Page numbers • Document version • Computer File Path	
Contents page	**CONTENTS** 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
Executive summary A one page summary of the main report presented succinctly under the following headings:-	**EXECUTIVE SUMMARY** **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** **Arrangements for Sharing Learning**

Main Report

Incident description and consequences

- Concise incident description

- Incident date
- Incident type
- Healthcare speciality involved
- Actual effect on patient and / or service
- Actual severity of incident

Pre-investigation risk assessment

Assess the realistic likelihood and severity of recurrence, using your organisation's Risk Matrix

Background and context to the incident

A brief description of the service type, service size, clinical team, care type, treatment provided etc.

Terms of reference - Outline :-

- Specific problems to be addressed
- Who commissioned the report
- Investigation lead and team
- Aims, Objectives and Outputs (see examples opposite)
- Scope, boundaries and collaborations
- Administration arrangements (accountability, resources, monitoring)
- Timescales

Investigation team

Names, Roles, Qualifications, Dept.'s

Scope and level of investigation

- State level of investigation (NPSA -1.Concise; 2.Compre.; 3.Independent)
- Describe the start and end points
- List services & orgs involved

NB: for Level 3 'Independent' Investigations 'scope' could be included under Terms of Reference

Investigation type (i.e. Single / Aggregation / Multi-incident)**, process, and methods used**

- Gathering information e.g. *Interviews*
- Incident Mapping e.g. *Tabular timeline*
- Identifying Care and service delivery problems e.g. *Change analysis*
- Identifying contributory factors & root causes e.g. *Fishbones*
- Generating solutions e.g. *Barrier analysis*

Involvement and support of patient and relatives

MAIN REPORT

Incident description and consequences

Example only (please delete and add your own findings)

A lady with asthma sustained brain damage following IV administration of a drug to which she was known to be allergic.

Incident date:
Incident type:
Specialty:
Effect on patient:
Severity level:

Pre-investigation risk assessment

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

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 Refer (anonymously) to involvement of staff in the investigation, and to formal & informal support provided to those involved and not involved in the incident.	**Involvement and support provided for staff involved**
Information and evidence gathered 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)	**Information and evidence gathered** **Example only (please delete and add your own findings)** The patient's clinical records 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
Chronology of events For complex cases any summary timeline included in the report should be a summary	**Chronology of events** See table below
Detection of incident Note at which point in the patient's 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	**Detection of incident** Select from the list on the left Add additional information
Notable practice Points in the incident or investigation process where care and/or practice had an important positive impact and may provide valuable learning opportunities. (e.g. Exemplar practice, involvement of the patient, staff openness etc)	**Notable practice** **Example only (please delete and add your own findings)** 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.
Care and service delivery problems 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 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) 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	**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

and EFFECT on the patient. **Lessons learned** (numbered) 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.	**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 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 Describe who (e.g. patients, relatives and staff involved) will be informed of the outcome of the investigation and how	**Distribution list**
Appendices Include key explanatory documents. e.g. Tabular timeline, Cause + effect chart, Acknowledgements to patients, family, staff or experts etc.	**Appendices**

Author	**Job title**	**Date**

Appendix O
ACTION PLAN TEMPLATE

No	Recommendation	Action	Priority **1. Low**(Green) **2. Medium** (Amber) **3.High** (Red)	Lead Responsibility	Agreed Date	Comments/ Progress	Completion date

Appendix P

SI GRADING

Grade 0

Action required

Notification only it is unclear if a serious incident has occurred.

The provider organisation must update the PCT and SHA with further information within three working days of a grade 0 incident being notified.

If within three working days it is found not to be a serious incident, it can be downgraded with the agreement of the accountable SHA and PCT.

If a serious incident has occurred it will be regraded as a grade 1 or 2

Grade 1

Action required

Commissioning PCTs will monitor the case and report findings, recommendations and associated action plans to the SHA.

SHA will monitor progress on a quarterly basis with PCT unless earlier discussion is required or the serious incident is re-graded.

Monitoring required
Local monitoring

- The PCT and/or SHA will close the incident when it is satisfied the investigation, recommendations and action plan are satisfactory, and local monitoring arrangements are in place and working efficiently.
- Publish incident details within Annual Reports

Timescales: up to **45 working days or nine weeks** from the date the incident is notified to the PCT and SHA.

Examples of cases

- Mental Health – deaths in the community
- HCAI outbreaks
- Avoidable or unexplained death
- Mental health – attempted suicides as inpatients
- Ambulance services missing target for arrival resulting in death or severe harm to patient
- Data loss and information security (DH Criteria level 2, see Information Resource)
- Grade 3 pressure ulcer develops
- Poor discharge planning causes harm to patient
- Research and clinical trials

See Information Resource Tool

www.nrls.npsa.nhs.uk/patientsafetydirect

Grade 2

Action required

Case will be monitored by the SHA/PCT/local authority in conjunction with the provider organisation.

The SHA will review findings, recommendations and associated action plans.

For Never Events, the commissioning PCT will be obliged to monitor overall numbers and actions and report these in its annual reporting arrangements.

Monitoring required
SHA/PCT monitoring

- Incidents leading to an independent investigation or inquiry or those considered high risk will continue to be monitored by the SHA/PCT or Local Authority until evidence is provided that each action point has been implemented. Incidents involving adult or child abuse are referred to local safeguarding arrangements.
- Publish quarterly reports.

Timescales: for independent investigations allow up to **26 weeks/six months** for completion of investigation. Extensions can be granted on an individual case-by-case basis by the SHA/PCT.

Examples of cases

- Maternal deaths.
- Inpatient suicides (including following absconsion).
- Child protection.
- Adult safeguarding
- Data loss and information security (DH Criteria level 3-5).
- Never Events.
- Accusation of physical misconduct or harm is made.
- Homicides following recent contact with mental health services*.

See Information Resource Tool

* Mental Health incidents should refer to DH guidance: Independent investigation of adverse events in mental health services

Appendix Q

PCT PROCESS TO MANAGING A SERIOUS INCIDENT

PCT receives SI Notification – Clinical review of SI. Distributes to relevant Senior Managers/Contract Leads & advises Communications Team. **PCT provisionally sets grading for SI.** Enters onto SI Log. Creates new case folder within SUI Folder of N:Drive. If necessary, advice sought from other senior colleagues within Nursing and Quality Directorate and Public Health to confirm SI and its grading.

↓

SHA informed and confirms grading level of severity with PCT.

↓

Severity and circumstances of SI examined *by PCT to reach one of the below grading levels*

Level 0	**Level 1**	**Level 2**
SI process undertaken subject to further info	SI overseen and monitored by PCTs with advice of SHA if necessary	Joint monitoring and management of SI process by SHA and PCTs

↓

If required; contact made with Healthcare organisation concerned to seek assurance that immediate action has been taken to mitigate risk arising from the incident which will be covered in the initial report.

↓

For All SUIs - Requirement of update report within 7 working days. Update scrutinised by PCT and/or SHA. **Reminder e-mail sent if required and SUI Log updated**

For Level 2 SIs - Interim report required within 72 hours. Report reviewed clinically with feedback as necessary to provide

↓

Once 7 Day Report received, SI is scrutinised by PCT. For Mental Health SIs, once 7 day report received, report forwarded initially to JCT for their review. JCT feedback subsequently received within three days. Virtual Group of Patient Safety Manager, Quality Improvement Manager, Head of Patient Experience & Safety and Patient Experience Manager to review each report **within 7 working Days** – then feedback to Patient Safety Manager and provider. Report may also be cascaded to contact lead for info. **Log updated** If Level 1 SI or further info revealed, decision made as to whether 45 Day Report required.

↓

If Yes
45 Day/Further Report Required, contact to be made with Trust confirming Report requirements and confirmation of expected completion date. **Log updated**

If No
Further Report not needed, **Log updated** and Action Plan to be completed if required. If not, SI may be closed with notification being sent to contract lead.

↓

Completion of investigation within 45 working days or any other agreed timescale (Dependent on criminal investigations etc) **Reminder e-mail sent if required**. **Log updated**

↓

Once received, report to be scrutinised by PCTs and SHA for robustness of investigation and action plan. For Mental Health SIs, once 45 day report received, report forwarded initially to JCT for their review. JCT feedback subsequently received within 3 days. **Deputy Director Nursing and Quality, and allocated Public Health Doctor for the reporting Healthcare Organisation, to review report within 10 working days.** Report may be cascaded to relevant Contract Leads. **Action Plan requested.**

Action Plan completed by Healthcare Orgs and submitted to PCT*, with monitoring by PCT and SHA as outlined below.*
If actions relate to PCT – agree such actions and monitoring, plus allocate suitable lead

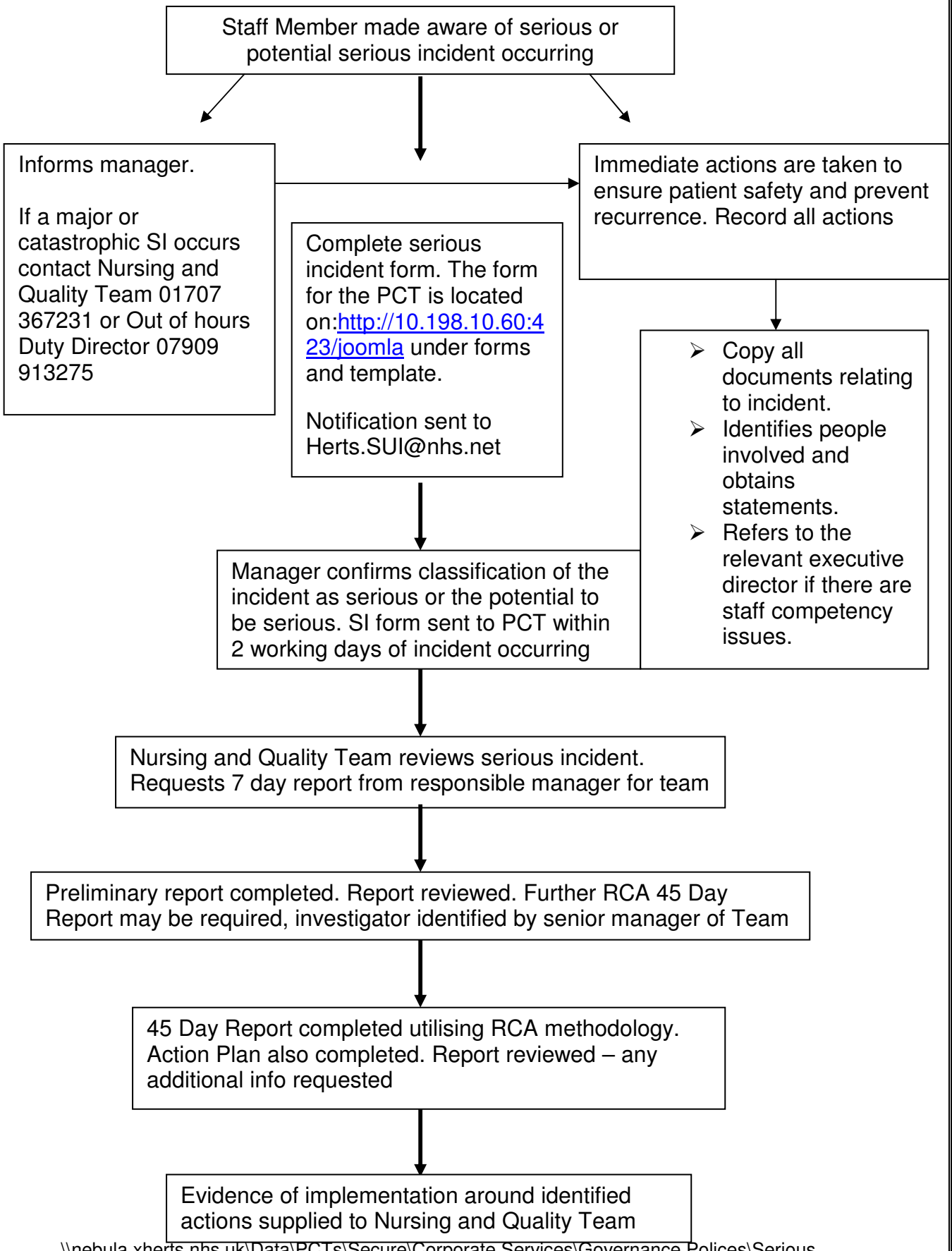
Level 1 Action Plan PCT monitors with overview by SHA	Level 2 Action Plan - PCTs monitor, with SHA requiring assurance

Evidence of implementation requested prior to closure. **For Mental Health, SI forwarded to JCT to confirm their agreement to close**. **Action Plans circulated to contract leads with evidence of implementation to be reviewed at contract leads meeting.** When evidence received, SI reviewed for possible closure by Quality Improvement Manager, Head of Patient Experience & Safety and Patient Experience Manager. **SI Closure Form completed by Quality Improvement Manager and signed off by Dir. responsible** Closure template is distributed to Contract Leads, SHA (appendix H) and to Services reporting the SUI. **Log updated**

- Learning from SI is shared across Healthcare Orgs and Contract/Commissioning Leads
- Regular monthly briefing to be distributed to Responsible Directors, Contract Leads and Public Health Consultants for assurance purposes
- Monthly meeting held with Director of Commissioning
- Outcome of SIs and Never Events are reported to the PCT Board, via quarterly reports.

Appendix R

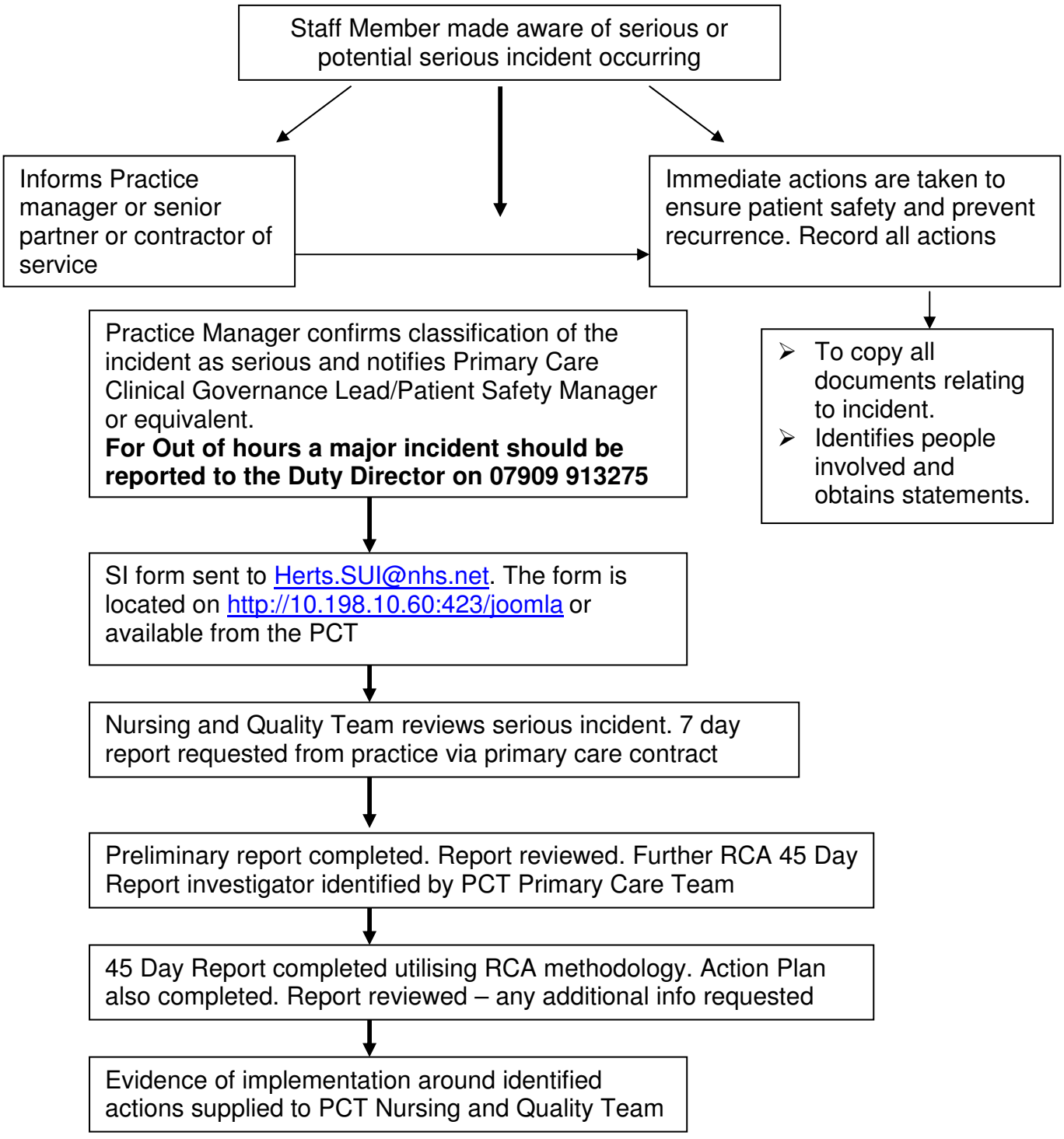
PCT COMMISSIONING STAFF REPORTING A SERIOUS INCIDENT



Appendix S

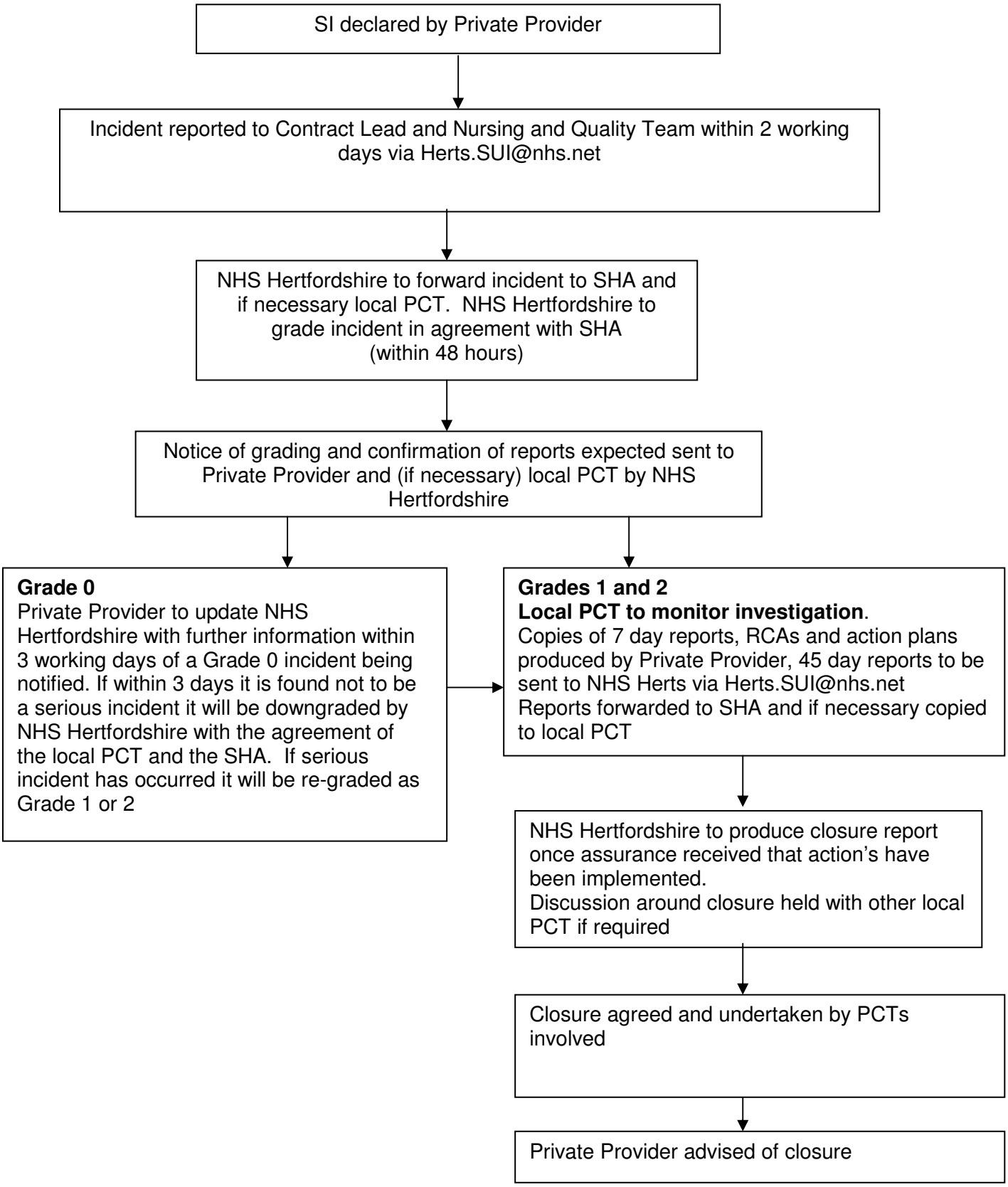
INDEPENDENT CONTRACTORS (GENERAL PRACTITIONERS, DENTISTS, PHARMACISTS AND OPTOMETRISTS)

Independent contractors are required to report serious incidents such as patient death to the Hertfordshire PCT. Please contact the Patient Safety Manager or equivalent (01707 367231) or Primary Care Commissioning Lead Clinical Governance (01707 369623 or 369637) for any assistance



Appendix T

FLOWCHART SHOWING REPORTING OF SERIOUS INCIDENTS (SIs) BY PRIVATE PROVIDERS



Appendix U

NHS Bedfordshire

FLOWCHART SHOWING REPORTING OF SERIOUS INCIDENTS (SIs) BY EAST OF ENGLAND AMBULANCE TRUST

SI declared by Ambulance Trust

↓

Incident reported to Head of Clinical Governance, NHS Bedfordshire (Lead Commissioners) via nhs net email address within 2 working days Sui.bedfordshire@nhs.net

↓

NHS Bedfordshire to forward incident to SHA and local PCT. NHS Bedfordshire to grade incident in agreement with SHA (within 24 hours)

↓

Notice of grading and confirmation of reports expected sent to Ambulance Trust and local PCT by NHS Bedfordshire

↓

Grade 0
EEAST to update NHS Bedfordshire with further information within 3 working days of a Grade 0 incident being notified. If within 3 days it is found not to be a serious incident it will be downgraded by NHS Bedfordshire with the agreement of the local PCT and the SHA. If serious incident has occurred it will be re-graded as Grade 1 or 2

→

Grades 1 and 2
Local PCT to monitor investigation.
Copies of 7 day reports, RCAs and action plans produced by EEAST to be sent to local PCT and copied to NHS Bedfordshire.

↓

Local PCT's to produce closure report once assurance received that actions implemented. Closure report to be sent to NHS Bedfordshire and copied to SHA

↓

NHS Bedfordshire in conjunction with SHA to agree closure. NHS Bedfordshire to confirm back to local PCT any issues

↓

EEAST advised of closure

Appendix V

GP REPORT GUIDANCE

In circumstances where further information is required regarding the clinical history of a patient involved in a serious incident, a GP report will be requested by the PCT. This information is often required to look at any long-standing health issues which may have had an impact on the nature of the serious incident and its outcomes. For instance a serious incident reported by a mental health trust relating to an unexpected death may often require a GP report to look at any potential physical health causes.

Once complete any GP Report will be shared with the lead provider investigating the incident, so as to fully inform their investigative process.

The below Questions and Answers should assist to clarify the requirements of these reports

Who should complete the Report if multiply GPs had seen patient?

When requested the report will be directed to the patient's named GP within their care records. If this named GP has not seen the patient concerned, it may be passed to a GP colleague who has undertaken most contact.

In circumstances whereby the named GP had maintained regular contact with the patient but had not seen them on the last appointment a joint report, with multiple input is acceptable.

What should the GP Report look like/cover?

The report should not take the form of a letter, but rather be specifically set out to address and incorporate the following details:

- Number of years/months patient was known to practice
- Summary of health complaints/conditions
- General summary of patient contact with Practice including a chronology and timeline
- Staff involved in contacts with patient
- Specific details around nature of last contact
- Analysis of their involvement with the patient
- Details around other services/healthcare providers offering treatment to patient
- Any conclusions or recommendations

What is the timescale for completing the report?

Once requested by the PCT, the report will need to be completed and submitted by secure e-mail (via NHS Net) within 3 working days

Does the report need to anonymised?

The report itself should not refer to the name of the patient, in order to comply with the Caldicott principles of confidentiality when dealing with serious incidents.

NHS Hertfordshire

Appendix W

SERIOUS INCIDENT CO-ORDINATION MEETING ACTIONS TEMPLATE

ISSUE RAISED	RESPONSE	OUSTANDING ACTION	RESPONSIBLE PERSON	TIMESCALE FOR REPONSE

Appendix X

NHS HERTFORDSHIRE

SYSTEM WIDE REVIEW OF A SERIOUS INCIDENT

INCIDENT REFERENCE:

LEAD ORGANISATION:

KEY STEPS IN INCIDENT	INFORMATION REQUIRED	INFORMATION SOURCE	LEAD	TIMESCALES