SERIOUS INCIDENT POLICY AND PROCEDURE

CONTENTS

CIRCULATED TO: Public Health Senior Team, Commissioners of Public Health Services; providers of public health services via the Public Health contract; ESCC communications and press contracts and purchasing unit.

Providers should report a SI to the Commissioner of the service and the Public Health Business Manager. ESCC contact details are listed below.

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Business Manager - Manages the SI Procedure and Local Service Agreements

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For urgent notification of incidents out of hours, contact the Duty Emergency Planning Officer, contact via WELbeing (Lifeline on Tel: 01323 644422, Fax: 01323 636398) who will contact the Director of Public Health or nominated deputy. Please indicate nature of incident and provide contact details for your call to be returned by Public Health.

Introduction and Purpose

Proper management of Serious Incidents (SI) is vital for promoting patient and client safety. East Sussex County Council (ESCC) is keen to promote learning from incidents and encourages this by fostering open and honest learning cultures among commissioned providers.

This document sets out:

- the procedure for the management of SIs
- the reporting mechanisms, key decision points and the procedures to follow in relation to a SI for Providers of services in reporting an incident and conducting a Root Cause Analysis, and Commissioners of services in managing the decision as to whether to close an incident report.

Providers of Public Health Services commissioned by ESCC are contractually required to have a designated post holder and deputising post with responsibility for managing SIs.

The reporting and management of incidents involving ESCC employees under the County Council procedures for reporting incidents and accidents at work are not within the scope of the procedure.

1. Definition

A SI relates to the service of the provider and may involve one or more patients, carers, visitors, staff, members of the public, contractors or another person to whom the organisation owes a duty of care, premises, property, other assets, information or any other aspect of the organisation. Examples include:

- avoidable death;
- unexpected patient death on premises in unusual or suspicious circumstances;
- serious harm 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 services, for example, actual or potential loss of personal /organisational information, damage to property, reputation or the environment, or IT failure;
- allegations of abuse, neglect or sexual assault;
- One of the core set of 'Never Events[1]';
- serious damage to property e.g. through flood, fire or criminal activity;
- outbreak of significant Health Care Associated Infection where there are two or more epidemiologically linked cases of the same organism, e.g. Clostridium difficile. Outbreaks of minor self limiting illnesses do not need to be reported as SIs unless there is a significant impact on service provision or a significant impact on an individual patient;
- chemical, biological, radiological or nuclear incidents (CBRN incidents);
- large scale theft, fraud, large confidentiality breaches or major litigation;
- suspension of health professional because of concerns about professional conduct, practice or criminal activity;

[1] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215206/dh_132352.pdf

- marked trend or pattern of events causing concern for the organisation which is leading to further internal investigation;
- any event which is classified as the highest level of the organisation's incident grading process and requires a significant level of internal investigation or inquiry; and
- any loss or breach of confidentially where person/patient or service user's is/are identified. This can be paper documents, paper files, or electronic data which is person identifiable.

2. Responsibilities and obligations

The contractual obligation of provider organisations to report SIs is contained within the appropriate schedule of their standard ESCC contract. All providers of public health services commissioned by ESCC should consider this procedure as contractually binding and ensure any internal procedures/policies are compatible with it.

Providers of Public Health Services commissioned by ESCC are contractually required to have a designated post holder and deputising post with responsibility for reporting an SI. The Provider is responsible for ensuring the safety of patients whilst on their premises and/or under the care of their staff and departments and/or throughout the discharge process. The commissioner expects that they have robust risk management systems in place including incident reporting and learning, and risk assessment. It is expected that all provider organisations will manage incidents in accordance with the National Patient Safety 'being open' guidance[2].

Commissioners of public health services are responsible for having a process in place to receive reports of SIs from providers. The Commissioner is responsible for ensuring that the Provider fully understands and is able to comply with the SI Policy. The Commissioner of the service will be responsible for leading or delegating relevant actions for SI management referred to within this policy. The Commissioner of the service is responsible for reviewing Root Cause Analysis reports from providers and making a decision as to whether to submit to the Public Health Senior Team to close the incident.

3. Accountability and Governance

The Director of Public Health is accountable for developing, implementing and monitoring the systems and processes for reporting, investigation and management of SIs within public health services commissioned by ESCC. The Public Health Senior Team has the responsibility for reviewing and approving SI reports and agreeing closure of incidents (see Appendix 1 for Public Health Senior Team Terms of Reference). The Commissioner will produce reports when appropriate to meet external requirements for SI reporting.

The Commissioner is responsible for liaising with the provider risk management team and ensuring the appropriate level of investigation takes place, including any reference to the ESCC policy statement: Anti Fraud and Corruption Strategy (July 2012). The ESCC Communications lead is responsible for managing media interest, defining, and mitigating any reputational risk to ESCC. The Public Health Business Manager will summarise key issues each financial year and identify any trends.

[2] http://www.nrls.npsa.nhs.uk/resources/collections/being-open/?entryid45=65077

4. Reporting a Serious Incident

How to report an incident

Providers should report a SI to the Commissioner of the service, and the Public Health Business Manager. ESCC contact details are listed on the front page.

Reporting stages and timescales

Providers should use the SI Reporting Form at Appendix 2 to record the details of an incident. The key reporting stages and expected timescales are set out at Appendix 3 together with the obligations of both the Provider and the Commissioner.

Grading an incident

As part of completion of SI Reporting Form, the incident must be graded into one of the following six categories (details of which are included at Appendix 4):

1. Near Miss,
2. Grade 0,
3. Grade 1,
4. Grade 2,
5. a Never Event, or
6. Fraud.

Any doubts that the Provider may have about thresholds of reporting should be discussed with the Commissioner of the service. There are specific requirements for managing SI under particular circumstances. The Commissioner will review all SIs grades within two working days of receipt of the SI reporting form, using the grading system, changing the initial grade if required.

All SIs graded as Grade Two will require an update after 72 hours after the first report to the commissioner. The update will be completed on the SI Reporting Form and sent to the Commissioner and the Public Health Business Manager.

SIs reported from a third party: if a possible SI under the responsibility of the provider is reported to ESCC from a different source than the provider organisation, then the Commissioner of the service will contact the identified provider and request investigation of the incident and a decision on SI reporting. If the commissioner has reason to believe the provider organisation had knowledge of the SI beforehand but failed to report the incident, the Commissioner will record this as a possible breach of contract.

SIs involving more than one Provider: if an SI involves a number of providers and those providers are unable to agree on the organisation responsible for reporting on the SI Reporting Form, the commissioner will assign a lead organisation on the available evidence. Failure of that organisation to report on the SI Reporting Form and lead the investigation will be considered a possible breach of contract.

Events of media interest that are not SIs: If events cause media interest or have the potential to cause media interest but do not meet with the SI definition, then the provider need only report the event via phone or email to the appropriate Commissioner and the Public Health Business Manager. In these cases, an SI Reporting Form should not be submitted and the commissioner in consultation with the ESCC Communications lead will decide on any further action.

Other requirements

The commissioner and Public Health Business Manager will be responsible for monitoring the SI investigation and may request additional information from the provider and or higher levels of investigation, up to an external review. If the commissioner feels an external investigation is required, a request must be made to the Contract Holder. The Director of Public Health is accountable for authorising any external investigation.

Reporting a possible SI to an external body other than ESCC does not remove the need to report the incident to the commissioner and the Public Health Business Manager and complete the SI reporting process.

Any SI reported to the commissioner involving a patient under the age of 18 will be forwarded to the ESCC child protection leads. This does not in any way override provider organisations' responsibilities in regard to the reporting of child protection/safeguarding children issues.

The reporting of an SI does not remove the provider organisation's responsibility for contacting any external bodies that need to be informed of the SI, including adult and child safeguarding. The Provider shall work with ESCC to safeguard adults at risk of abuse by undertaking the responsibilities for staff reporting incidents of suspected adult abuse in relation to SI reporting. The Provider will also comply at all times with the Sussex Multi-Agency Policy and Procedures for Safeguarding Adults at Risk and undertake reporting as agreed in respect of this policy. The Provider will continue to work with the Commissioner and Local Authorities to harmonise the Safeguarding Adults at Risk and SI processes and to ensure that adult safeguarding is informed by the SI investigations and that the outcomes of these investigations are shared where necessary. Similarly, the Provider will work with the Commissioner to ensure harmonisation of the safeguarding children processes with SI process. The provider will comply at all times with the East Sussex Child Protection and Safeguarding Procedures, including the safeguarding of adults at risk.

Any SIs reported to the commissioner involving information governance breaches will be reported to the ESCC Information Governance Lead. The Provider will forward to the appropriate professional lead any SI that identifies possible professional misconduct or professional negligence by a registered health care professional. The commissioner and the Public Health Business Manager will ensure compliance with timescales for SI and Root Cause Analysis (RCA) reporting.

The commissioner may require the Provider to:

- produce the Provider SI policy within five working days of the request;
- produce an action plan within ten operational days of a request to do so; and/or
- submit further reports within ten operational days of a request to do so; and/or
- attend meetings with regard to implementation of the action plan within ten operational days of a request to do so.

5. SI Closure

At the point the provider organisation has completed investigation it should update the SI Reporting Form with the date the investigation was completed. The full investigation report should be sent electronically and securely to the commissioner and the Public Health Business Manager within the timescale related to the grade of the SI (as shown in Appendix 3). All RCA reports and action plans should be submitted according to the format in Appendix 5. The report should not contain person or patient identifiable information. If there is concern that a patient, staff member or member of the public may be able to be identified from the report, the provider must arrange and confirm with the Commissioner how to send the report to a secure email account.

The Public Health Senior Team will decide whether to close a SI reported by a Provider. The Commissioner of the service will present the investigation report and recommendation for closure to the Public Health Senior Team for consideration. The Provider of the service will be notified of the decision by the Commissioner of the service.

If the provider organisation is unable to provide the full investigation report within the timeframes in Appendix 3, a request for an extension should be made to the commissioner explaining the reasons. Requests for extensions will be granted for any delay in the investigation that is outside of the provider organisation's control. Examples include:

- Police investigation
- Safeguarding investigation
- Awaiting statements or reports from individuals not employed by the Provider organisation
- Awaiting external investigation reports
- Extensive investigation required (Example: reviewing 100+ patient records)

Extensions will not be granted for the following:

- Delay in reporting of incidents
- Staff annual leave
- Lack of available investigators

The Commissioner or Public Health Business manager will inform the provider of its decision to close or keep open the SI case within 20 working days of receipt of an RCA report.

Appendix 1

Terms of Reference when considering a Serious Incident Public Health Senior Team

Membership

The group must consist of a minimum of the Director of Public Health, a Public Health Consultant and two other members of the Team unrelated to the Serious Incident (SI) and management of the SI to be quorate.

No member of the Team should be involved in the Root Cause Analysis (RCA) of any incident being assessed for closure, as this will be classed as a conflict of interest.

Overall purpose

The purpose of this group will be to agree whether to close an SI on the basis of the Root Cause Analysis submitted by the provider and presented by the Commissioner.

Submission and Standard Documentation

No SI will be considered for closure unless a full RCA report has been submitted with accompanying action plan and evidence of compliance with appropriate provider level scrutiny.

All RCA reports and action plans should be submitted in accordance with the report structure shown in Appendix 5. Required information includes:

- Evidence of Being open guidelines followed
- Clear and robust Investigation process and RCA methodology followed
- Root Causes and service/care delivery issues identified
- Learning identified for each Root Cause and significant service/care delivery issue
- Action plan that covers all identified learning, including responsible individuals (By Post) and timescales
- Evidence that the investigation and report has been considered by the provider governance processes
- Action plans that identify Responsible and Accountable persons and monitoring arrangements.

Reporting arrangements

The decision to close or keep open the SI will be communicated to the provider by email and supported by a meeting with the provider if the provider requests this. Any trends noted from SI closures including, root causes, lessons learn and submission times and quality of RCA reports will be included in the SI review process and the development of an audit process.

Frequency of meetings

Meetings will take place based on the occurrence and status of SIs.

Appendix 2

Serious Incident (SI) Reporting Form

Please remember you have a duty of confidentiality to patients and staff. Try to record your information in a factual and objective way.

Reporting Organisation

Contracted service	
Organisation	
Date	
Lead contact	
Job Title	
Tel. No	
Email	

Incident Overview

Status	(e.g. first report or update)
Date/time of Incident	
Site/location of Incident	

What happened?

Actual incident or near-miss	
Type of incident	

Type of Incident:	
Allegation against Provider staff	*Delayed Diagnosis*
Allegation against Provider staff (Fraud)	*Deliberate self-harm by patient / client*
Adult Safeguarding issue	*Drug Incident (general)*
Assault by patient / client	*Equipment Failure*
Assault (unknown assailant)	*Failure to obtain consent*
Attempted homicide by patient / client	*Fire*
Bogus health worker	*Health and Safety*
Chemical Incident	*Infection / communicable disease issue*
Closure / suspension of service	*Homicide by patient/client*
Child Safeguarding issues	*Security threat*
Child Serious Injury	*Suicide by patient / client*
Child Death	*Unexpected death*
Confidential Information Leak	*Other*

Description of what happened	
Immediate action taken	

Is anyone affected by the incident – staff, patients, visitors, members of the public? YES/NO (delete as appropriate). If Yes, complete the sections below:

General details of those affected

How many people are affected?	
Age of person / people affected	
Gender of person / people affected	

Risk assessment

Apparent outcome of incident	
Likelihood of recurrence/further impacts	

Closure

RCA Report submission date	
Date closed	

External reporting

Is there media interest?	
Has there been reporting to external agencies (e.g. police, Safeguarding)?	(see next page for external reporting requirements)

External reporting requirements

Other Commissioners: should be informed by the Commissioner within three working days of receipt of the SI Report when any person, premises or property involved in a Serious Incident (SI) is linked to them or of interest to them in understanding the whole picture of a provider organisation's safety record. For example, the commissioner may inform the Commissioning Support Unit (CSU) of a SI where a provider has contracts both with public health and with other services commissioned through the CSU.

Public Health England Health Protection Agency: should be informed immediately by Public Health where a SI is associated with adverse affect upon the health and wellbeing of the public, e.g., infections, diseases, chemicals, radiation hazards, etc.

Care Quality Commission: should be informed by the provider of any SI associated with serious failings (actual or alleged) which may have a negative impact on the safety of patients, clinical effectiveness or responsiveness to patients.

Police: should be informed immediately by the provider (and Crime Number Recorded) when it is perceived that a SI may have involved foul play, flagrant or wilful negligence or malicious intent, acts of violence to any person/s, premises. If the police are involved, they will guide the organisation as to the parameters of the local investigation under the Memorandum of Understanding of the Department of Health.

Fire/Ambulance/Other Emergency Services: should be requested by the provider immediately when required.

Social Services: should be informed by the provider immediately when it is perceived that a SI may have involved persons under the care of Social Services, or where persons are put at risk as a result of a SI and may require the assistance of Social Services (with respect to Caldicott Principles and on a strictly need to know basis).

Medicines & Healthcare Products Regulatory Agency: should be informed by the Provider immediately when it is perceived that a SI may be the result of a Medical Device fault, failure or user error or an adverse drug or blood product reaction is suspected (please refer to the Medicines Policy).

Health and Safety Executive: should be informed immediately when it is perceived that a SI is reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) or may be the result of non-compliance with Health & Safety Legislation.

Area Child Protection Committee and area Child Protection Lead: should be informed immediately by the commissioner when it is perceived that a child or children (under 18 years of age) are involved in or are victims of an SI (with respect to Caldicott Principles and on a strictly need to know basis). Where the incident involves the death of a child the anonymised report of the investigation should additionally be sent to the Area Child Protection Committee and a Child Protection Alert raised. Where persons involved in an incident lack capacity under the definition of the Mental Capacity Act 2007, the Act must be considered.

Safeguarding Adults Board (SAB) adult safeguarding policy and procedures should be applied by raising an alert and relevant NHS Adult Protection Lead should be informed immediately by the commissioner when it is perceived that an adult or adults (over 18 years of age) are involved in or are victims of a SI (with respect to Caldicott Principles and on a strictly need to know basis). Where the SI involves the death of an adult the anonymised report of the investigation should additionally be sent to the SAB's Safeguarding Investigation Manager. Where persons involved in an incident lack capacity under the definition of the Mental Capacity Act 2007, the Act must be considered.

Legal Advisers: The provider should inform its legal advisors immediately when it is perceived that a SI may give rise to legal proceedings.

Estates: Should be informed by the provider immediately when it is perceived that a SI may be related to Estates & Facilities.

Professional Regulatory Bodies/Medical Defence Organisation: Health Professionals involved in a SI should be advised by the provider to inform their Professional Regulatory Bodies/Medical Defence Organisation, e.g. General Medical Council, Nursing and Midwifery Council, etc, immediately when it is perceived that a SI may give rise to legal proceedings. Under these circumstances, Legal Advisers can provide valuable information and advice, along with union representation.

Trading Standards: Should be informed immediately by the provider when it is perceived that a SI may be the result of a product (whether failure or user error) falling outside of the remit of the MHRA.

Relevant Counter Fraud and Security Management Services: Should be informed immediately by the provider if any SIs are associated with fraud or security.

Care Quality Commission: Should be notified by the provider where a SI indicates a breach of the National Care Standards.

Appendix 3a

Reporting stages and timescales	Due	Insert date
Stage 1	**Immediately**	**xx/xxx/xx**
Provider to: – Email relevant commissioner and Public Health Business Manager and give a brief summary of the incident. – Collect as much specific detail as possible, but do not delay reporting to wait for all details.		
Stage 2:	**On the same or nearest working day**	**xx/xxx/xx**
Provider to: – Update the relevant commissioner and the Public Health Business Manager in terms of any actions taken. – Report the incident to the providers own communications team and determine any actions needed on contacting external organisations.		
Commissioner to: – Determine actions needed within ESCC in terms of communications – Determine any actions needed on contacting external organisations / Safeguarding – Determine, with the DPH or PH Consultant, in the case of an infectious disease whether PHE's (Health Protection) recording criteria (see Appendix 3b) are met. – Update Provider in terms of any actions taken.		
Stage 3:	**Within the next two working days**	**xx/xxx/xx**
Provider to: – If the immediate report was a Grade Zero, recommend to Public Health how it should be re-graded. – Send SI Reporting Form by e-mail to relevant commissioner and Public Health Business Manager and start internal investigation procedures		
Commissioner to: – Inform named Public Health Pharmaceutical Advice and Support and seek advice if it appears from the provider SI report that issues of prescribing or dispensing of medicines are involved. – Review grading of the SI (consider closure of incident if initial report is Zero) – Exchange information with Provider on communications/ media role and what has been reported to external organisations – Inform the relevant Clinical Commissioning Group – Determine actions needed within ESCC in terms of communications – Determine any further actions needed on contacting external organisations / Safeguarding – Determine, with the Director of Public Health or Public Health Consultant whether additional clinical opinion is required in the investigation of the SI		
Stage 4:	**Within 45 working days for Grade 1 and 60 working days for Grade 2**	**xx/xxx/xx**
Provider to: – Conduct Root Cause Analysis (RCA) – Update commissioner and Public Health Business Manager if required – Meet commissioner and Public Health Business Manager if requested – Submit RCA report to commissioner and Public Health Business Manager – Update SI Reporting Form		
Stage 5:	**Within next 20 working days**	**xx/xxx/xx**
Commissioner to: – Extend Stage 4 until evidence gathering is complete in cases reported to external organisations / Safeguarding. – Inform Provider of decision to close or keep open the SUI case by electronic letter.		

Appendix 3b

Public Health England (Health Protection) Recording Criteria

Single case report with significant public health or media implications including:

- Serious infection associated with identified link to environmental source, e.g. Legionella associated with a water source.
- Exposure of particularly vulnerable population to infective case, e.g. TB in a teacher/HCW, BBV in HCW, E coli O157 in nursery child, rubella in HCW, typhoid in food handler, CJD in blood donor, etc.
- Death from disease of public health interest, e.g. meningococcus, E coli O157, vCJD, etc.
- Case of serious and rare infection with public health implications, e.g. Diphtheria, VHF, polio, botulism, necrotising fasciitis, non-compliant TB case, CJD in blood recipient, etc.
- Any case leading to creation of Incident Control Team.
- Late diagnosis of HIV with CD4 count under 350 cells/mmol blood

Does not include**:** Routine response to single cases of GI infection, meningitis, measles, mumps, rubella, TB, HAV, HBV, HCV, Legionella (unless identified risk factors in UK), etc. Community outbreak of infection.

Community outbreak of infection including:

- General population.
- Community settings (nursing home, residential home, school, workplace, etc.),
- Defined cohorts (e.g. wedding party).

Does not include**:** Family outbreak unless community implications or rare and serious disease.

Community cluster of infection including:

- Increase in meningococcus, E coli O157, Legionella, HBV, rare Salmonella, STI, HIV, vCJD etc. requiring investigation or advice.

Does not include: Local/regional contribution to investigating national increases (unless a focus is definable locally), or family clusters.

Significant hospital health protection incident including:

- Health protection incident leading to ward closure, look back exercise, Outbreak Control Team meeting or Serious Incident (SI) report to SHA.
- Failure of decontamination.

Does not include: Simple needlestick injury or routine single cases of HCAI.

Notable community SI related to Health Protection including:

- Failure of immunisation service provision (wrong vaccine, failure of cold-chain, etc.),
- Inadequate decontamination in primary care.

Does not include**:** Simple needlestick injury

Significant chemical/environmental incident including:

- Acute events in which there is, or could be, exposure of public to chemical hazard (includes response to unknown hazard),
- Chronic exposure to local hazard requirement local/regional HPA input/advice
- Water or food contamination leading.

Does not include: Local advice on national problems/incidents, or IPPC applications.

Significant radiation incident including:

- Acute events in which there is, or could be, exposure of public to radiation or nuclear hazard
- Chronic exposure to local hazard (power station, radon in local environment) requiring local/ regional Public Health England (Health protection) input/advice.

Does not include: Local advice on national problems/incidents

Any case/incident/exposure likely to lead to media interest including:

- White powder incidents,
- Interest from politicians,
- Community unhappiness with response.

Any incident involving significant workload for Public Health England (Health Protection) staff including:

- Incidents with limited public health implications (e.g. scabies or head lice) if they require visits or repeated need for advice
- Use of public health law or multi-agency response to non-compliant cases (e.g. HIV case continuing to put others at risk)
- Identification of false positives/negatives in laboratory testing equipment.

Any incident with an important lesson for Public Health England (Health Protection) of its partners

Appendix 4

Grading a Serious Incident situation

Grade	Guidance
Near Miss	A Near Miss is an unplanned event that did not result in injury, illness or damage, but had the potential to do so. The Provider should use the SI Reporting Form to describe the Near Miss along with any immediate actions to reduce risk and prevent re-occurrence.
Grade Zero	Grade Zero means that it is unclear if a serious incident (SI) has occurred. A Grade Zero SI must be reported and the Provider must update the commissioner and the Public Health Business Manager with further information within two working days of a grade Zero incident being notified. If within three working days it is found not to be an SI, it can be closed with the agreement of the Director of Public Health. If an SI has occurred it will be re-graded as a grade One or Two.
Grade One	The following incidents will be classed as grade one SIs: • Health Care Associated Infection (see advice in Appendix 3b) • Avoidable/unexplained death • Data loss and information security breaches The provider will conduct an Investigation Root Cause Analysis (RCA) and provide a report of the outcome of this analysis by 45 working days/9 weeks from the date the incident is notified to the commissioner and Public Health Business Manager.
Grade Two	The following incidents are classed as grade Two SIs: • Child protection/Adult protection • Accusation of physical misconduct or harm • All Never events[3] The provider will complete a Comprehensive Investigation (RCA level 2 investigation) (as above) or Independent Investigation (RCA level 3 Investigation) required. For Independent Investigations allow up to 26 weeks/6 months for the provider to submit to the commissioner a report of the investigation. Extensions may be granted on an individual case-by-case basis by an appropriate regional or national body / organisation.
Never Events	Never Events are defined by the Department of Health and their scope is updated yearly. Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. All Never Events must without exception be reported as SIs.
Fraud	Including incidents where the NHS Counter Fraud Services are involved and there is suspicion of large scale theft or any incident that might give rise to criminal charges, notification on to the SI Reporting Form should only take place once FIRM EVIDENCE HAS BEEN PROVIDED and there is a risk of public disclosure. Management and prevention of fraud must adhere to ESCC Fraud Policy and Anti-Fraud and Corruption Strategy.
Data breach	For confidential information loss and breaches of confidentiality involving personal identifiable details refer to 'A Checklist for Reporting, Managing and Investigating Information Governance Serious Untoward Incidents' which was issued by NHS Connecting for Health in January 2009[4].

[3] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215206/dh_132352.pdf
[4] http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/security/risk/suichecklist.pdf

Appendix 5

Root Cause Analysis (RCA) Template

When incidents happen, it is important that. Root Cause Analysis investigation is a well recognised way to ensure that lessons are learned to prevent the same incident occurring elsewhere. A helpful guide to completing an RCA report is available at http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/.

Cover page

- Organisation name and / or logo
- Title or Brief outline of incident
- Incident date and number and date of report date
- Author(s)
- Document version/file path

Contents page

- 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

- 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 and recommendations
- Arrangements for Sharing Learning

Incident description and consequences

- Concise incidence description
- Incident date
- Incident type
- Speciality involved
- Actual effect on patient and / or service
- Actual severity of incident

Pre-investigation risk assessment

- Background and context to the incident,
- A brief description of the service type, service size, clinical team, care type, treatment provided etc.
- An Assessment of the realistic likelihood and severity of recurrence, using your organisation's Risk Matrix.

Terms of reference

- 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

As an example, the Terms of Reference may be to look for improvements rather than to apportion blame or to establish the facts of what happened and the impacts; whether failings occurred in care or treatment; how recurrence may be reduced or eliminated and to formulate recommendations and an action plan.

Investigation team

Names, Roles, Qualifications, Department, Organisation

Scope and level of investigation

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

- 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).
- Family liaison person appointed, information given on sources of independent support

Involvement and support for staff involved

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

Information and evidence gathered

- A summary of relevant local and national policy / guidance in place at the time of the incident, and any other data sources used
- Any relevant content from management information or patient clinical records (anonymous)
- Any interviews conducted – with staff or patients relatives for example
- Information derived from any visits to the location of the incident

Chronology of events

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

Detection of incident

Note at which point in the service to the patient the error was identified, and by which process (e.g. by an IT system or by a face-to-face assessment).

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.

Root Cause Analysis: Care and service delivery problems

A themed list of the key problem points.

Root Cause Analysis - 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)

Root causes (numbered)

These are the most fundamental underlying factors contributing to the incident that can be addressed. There should be a clear link, by analysis, between root CAUSE and EFFECT on the patient.

Lessons learned (numbered)

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

Recommendations

Numbered and referenced, recommendations should be directly linked to root causes and lessons learned.

Arrangements for shared learning

Describe how learning has been or will be shared with staff and other organisations.

Distribution list

Describe who (e.g. patients, relatives and staff involved) will be informed of the outcome of the investigation and how.

Appendices

Include key explanatory documents. Acknowledgements to patients, family, staff or experts etc.