NHS
Cannock Chase
Clinical Commissioning Group

NHS
Stafford and Surrounds
Clinical Commissioning Group

Serious Incident Reporting and Management Policy

Agreed at Cannock Chase Governing Body

Date: 6th March 2014

Signature:

Designation: Chair

Review: 28 Feb 2015

Agreed at Stafford & Surrounds Governing Body

Date: 15th April 2014

Signature:

Designation: Chair

Review: 28 Feb 2015

Purpose of the policy

This policy describes the overarching process for ensuring that serious incidents are promptly reported and managed.

Document Control Sheet

Title:	Serious Incident Reporting and Management Policy		
Electronic File Name:	Electronic version held by Janinne Lake		
Placement in Organisational Structure:	Quality, Nursing and Safety		
Consultation with stakeholders:	Consultation with relevant CCG staff		
Equality Impact Assessment:	Completed		
Approval Level:	Joint Quality Committee		
Dissemination Date:		**Implementation Date:**	
Method of Dissemination:	By email to relevant staff and placed on the CCG website		

Document Control				
Version No	Draft Issued	Page(s)	Author	Draft approved
1	12 November 2013	20	J Lake (based on a Policy written for Herefordshire CCG)	12th November 2013
2	15th November 2013	20	J Lake	15th November 2013
3	17th December 2013	22	J Lake – addition of updated references to IG Guidance issued June 2013.	17th December 2013
4	14TH February 2014	22	J Lake/K Roberts – updated IG and grammatical change to paragraph 6.11 NHS 111	14TH February 2014
5	18th February 2014	22	L Tolley/K Roberts updated SCCG to SAS/CC CCG and some minor grammatical changes	18th February 2014
6	26th February 2014	22	L Tolley/K Roberts updated SCCG to SAS/CC CCG and some minor grammatical changes	26th February 2014
7	1st April 2014		L Tolley/K Roberts updated SCCG to SAS/CC CCG and some minor grammatical changes	1st April 2014

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Executive Summary

Serious incidents requiring investigation in healthcare are rare, but when they do occur, everyone must make sure that there are systematic measures in place to respond to them. These measures must protect patients and ensure that robust investigations are carried out, which result in organisations learning from serious incidents to minimise the risk of the incident happening again. When an incident occurs it must be reported to all relevant bodies.

This policy establishes a clear approach to the handling of an incident defined as a serious incident (SI). It contains the minimum reporting requirements expected by Stafford & Surrounds and Cannock Chase Clinical Commissioning Group in line with the process laid out in the National Patient Safety Agency (2010) framework for Reporting and Learning from Serious Incidents Requiring Investigation and updated in NHS England Serious Incident Reporting Framework. (March 2013)

Underpinning this process is a system of good governance that promotes a culture of openness and an attitude that facilitates learning from all incidents. This should include prompt reporting, appropriate and robust investigation, action planning, learning and follow-up, and where necessary communications management.

This policy and procedure contains serious incident reporting criteria to guide organisations and supports their own internal serious incident policies, but where there are any doubts about thresholds of reporting these should be discussed with the quality and patient safety lead at the Stafford & Surrounds and Cannock Chase Clinical Commissioning Group or Staffordshire & Lancashire Commissioning Support Unit (S&LCSU), who provide the SI Management function on behalf of Staffordshire & Surrounds and Cannock Chase CCG.

1.0 Introduction

1.1 This policy is based on the NHS England Serious Incident Reporting Framework published in March 2013 (Appendix 8). Organisations providing NHS funded care in England are required to demonstrate accountability for effective governance and learning following a Serious Incident or Never Event. Serious incidents in healthcare are relatively uncommon, but when they occur the National Health Service (NHS) has a responsibility to ensure there are systematic measures in place for safeguarding people, property, NHS resource and reputation. This includes the responsibility to learn from these incidents to minimise the risk of reoccurrence (NPSA, 2010).

1.2 The revised SI Framework contains guidance in relation to the requirements of the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2010 and CQC Essential Standards on Quality and Safety, particularly in relation to reporting serious incidents; contractual terms in relation to reporting serious incidents, including reporting to commissioners of services;

guidance on reporting, disclosing, investigating and responding to serious incidents; duties under the Health and Social Care Act 2012 to continuously improve the quality of services; reporting requirements in relation to other bodies such as the NHS Trust Development Authority, Police, Health and Safety Executive, local Safeguarding Boards, Monitor, Coroners and others.

2.0 The purpose of this policy

2.1 The NPSA (and subsequently NHS England) have provided a clear framework to ensure consistency across the reporting and the management of SIs. The purpose of this policy is to outline the overarching governance arrangements for the management of Serious Incidents and/or Never Events and ensure that patient safety and other reportable incidents are appropriately managed within commissioned and contracted NHS services in order to address the concerns of the patients and promote public confidence. The policy describes the requirements for Serious Incidents and Never Events reporting and management.

2.2 Promoting safety by reducing error is a key priority for the NHS, particularly since the publication of '*An Organisations with a memory'* (Department of Health, 2000) which emphasises the importance of learning from adverse events.

2.3 Staffordshire & Surrounds and Cannock Chase Clinical Commissioning Group (SAS/CC CCG) is committed to the commissioning of high quality care and services and the achievement of a high standard of health, safety and welfare at work for all its employees and others visiting, engaged in or affected by its activities and services.

2.4 This policy supports openness, trust, continuous learning and service improvement from SI's reporting, monitoring and learning from incidents.

2.5 SAS/CC CCG makes explicit in its contracts with all providers its expectations regarding serious incident reporting and management, the indicators and the process for performance management.

2.6 The role of SAS/CC CCG in dealing with Serious Incidents is to ensure that:

1. Serious incidents are thoroughly investigated
2. Action is taken where necessary, to improve clinical quality and patient safety

3. Lessons are learned in order to minimise the risk of similar incidents occurring in the future and that learning is shared across the wider health community
4. Commission independent investigations where appropriate

3.0 The scope of this policy

3.1 This policy is designed to help providers take appropriate steps in the best interests of their service users, staff and the NHS as a whole. It contains the minimum reporting requirements expected by SAS/CC CCG. This policy does not replace the duty to inform other relevant authorities relating to serious incidents as required.

3.2 All SAS/CC CCG Staff

The policy applies to anyone working on official CCG business either as a directly employee member of staff, subcontractor, volunteer, those providing services under Service Level Agreements, agency, back staff, locum etc. whether or not they are working on SAS/CC CCG owned premises at the time.

3.3. Commissioned Services (Providers of NHS care)

This policy does not apply to commissioned services including independent contractors, who are expected to have their own arrangements in place for recording and monitoring of incidents. This is in line with Health & Safety legislation, the NPSA and requirements of relevant regulatory bodies. Where regulated activities take place, registration with the Care Quality Commission and compliance with Essential Standards of Quality and Safety are required.

However this policy does outline the requirements for providers to report serious incidents to SAS/CC CCG/S&LCSU which are explicit in all contracts and the responsibilities of SAS/CC CCG in relation to this.

3.4 Independent Contractors (GPs/Pharmacists/Dentists/Optometrists);

Independent contractors and managers of contracted services must notify the Shropshire & Staffordshire Area Team of:

1. All serious incidents in line with the Serious Incident Framework
2. All significant trends incident trends and adverse events
3. All significant incidents with noteworthy learning opportunities for other independent contractors
4. Any serious incident that in the reasonable opinion of the contractor affects or is likely to affect the contractor's performance of its obligations as outlined in the contract for the service.
5. Any death of a patient on GP premises

4.0 Definitions

4.1 Serious Incident

Serious incidents requiring investigation were defined by the NPSA's 2010 *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*. In summary, this definition describes a serious incident as an incident that occurred during NHS funded healthcare (including in the community), which resulted in one or more of the following;

- unexpected or avoidable death or severe harm of one or more patients, staff or members of the public;
- a never event - all never events are defined as serious incidents although not all never events necessarily result in severe harm or death. (See *Never Events Framework* i);

- a scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;
- allegations, or incidents, of physical abuse and sexual assault or abuse; and/or
- loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

4.2 Examples of categories and incidents that should be reported are included in the NPSA (2010) National Reporting & Learning Service Information Resource to Support the Reporting of Serious Incidents (Appendix 2). This resource is not exhaustive and other categories of incidents may fall within the definition of a serious incident. Where there are any doubts about reporting an incident then guidance should be sought from the relevant quality/patient safety lead at SAS/CC CCG or S&LCSU.

4.3 As a minimum, patient safety incidents leading to unexpected death or severe harm should be investigated to identify root causes and enable improvement action to be taken to prevent recurrence. The definition of SIs 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 on-going healthcare. All serious patient safety incidents should be reported to the NPSA, and to notifiable partner organisations, as detailed in the information resource that supports this policy (Appendix 2).

4.4 'Never Event'

Never Events are *"serious, largely preventable, patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers (DOH, 2012). Never events are patient safety incidents that are preventable because:*

- *There is guidance that explains what the care or treatment should be;*
- *There is guidance to explain how risks and harm can be prevented;*
- *There has been adequate notice and support to put systems in place to prevent them from happening."*

4.5 Details of the categories of Never Events, as defined by the Department of Health and NPSA, are reviewed and published annually on the Department of Health website. The list of current Never Events can be found appendix 3, with an update of the never event policy framework in appendix 4.

4.6 Fair Blame statement

SAS/CC CCG recognises that most incidents occur as a result of an accumulation of a number of factors and events all conspiring together, as opposed to individuals and is committed to a 'fair blame' culture. Staff should be encouraged to report incidents without fear of disciplinary action in a culture of learning and fair blame. Fear of disciplinary action may defer staff from reporting a serious incident. However, there are instances where the SAS/CC CCG recognise that an incident may occur which is clearly due to deliberate or non- compliance of following policies and procedures, in those circumstances the individual will be held to account.

4.7 Being Open Statement

SAS/CC CCG is committed to a culture of openness and accountability and encourages openness and honesty in accordance with the NPSA's framework for effective communication with patients and/or their carers 'Being Open Framework (2009) and works to the principles set out within this document (appendix 1). The duty of candour is explicitly stated in contracts with providers.

5 Accountabilities

5.1 Accountabilities to patients and carers

The principal accountability of all providers of NHS-funded care and commissioners is to patients and their families/carers. The first consideration following a serious incident is that the patient must be cared for, their (and other patients') health and welfare secured and further risk mitigated. Patients must be fully involved in the response to the serious incident.

Where a patient has died or suffered serious harm, their family/carers must be similarly cared for and involved. Consideration must be given to their needs first. That means prioritising further treatment they may require, including offering treatment at an alternative provider if appropriate, and at all times showing compassion and understanding, even if simply making regular contact to keep them informed of the progress of investigations or action plan implementation.

5.2 Accountabilities to commissioners

Providers are accountable via contracts to their commissioners (either CCGs or the NHS England Area Team). CCGs are accountable to the NHS England Area Team, which is in turn accountable to Government and Parliament.

The key organisational accountability for serious incident management is from the provider in which the incident took place to the commissioner of the care. This may for example be from an acute or community hospital to a CCG or to the NHS England Area Team (for specialised services), from a mental health trust to a CCG, or from a primary care provider to the NHS England Area Team. Where the commissioner is the NHS England Area Team, the relationship is likely to be with Shropshire & Staffordshire Area Team.

Where a provider has multiple commissioners, it may not be immediately obvious who the appropriate commissioner for serious incident management is. Appendix D provides advice on identifying the appropriate commissioner.

Where more than one provider is involved in a serious incident, the relevant commissioners should take a decision with those providers on who will act as the lead provider and who will act as the coordinating commissioner for the purposes of reporting; investigation and incident management (see Appendix D). This should be a collaborative decision, supported by the NHS England Area Team if necessary.

CCGs are responsible (via S&LCSU) for reporting SIs on STEIS that occur in Nursing Homes, based on the CCG area in which the Nursing Home is sited. RCA investigations regarding nursing homes are currently conducted by the Quality Improvement Lead or other CCG nominated person. The monitoring and management is via the S&LCSU Head of Governance & Compliance with any closure agreed by the CCG.

The NHS England Area Team will support CCGs to ensure they have the right systems and capability to hold providers to account for their response to serious incidents.

Where serious incidents originate in or involve the actions of commissioning organisations or the NTDA, they are accountable for their response to the serious incident according to the principles in this document.

5.3 Accountability to NHS Trust Development Authority

NHS trusts (as opposed to foundation trusts) are accountable to the NTDA, which is in turn accountable to the Secretary of State for Health. The NTDA will support NHS trusts in ensuring they have effective systems and processes in place to report, investigate and respond to serious incidents in line with national policy and best practice. It will work in partnership with the relevant commissioner, but it is the commissioner who is responsible for holding trusts to account for their responses to serious incidents.

5.4 Accountability to Care Quality Commission and Monitor

Most healthcare providers have to register with CQC and most providers of NHS-funded care have to be licensed by Monitor. The regulators will use the details of incident reports to monitor organisations' compliance with essential standards of quality and safety and their licence terms.

CQC-registered organisations are required to notify CQC about events that indicate or may indicate risks to compliance with registration requirements, or that lead or may lead to changes in the details about the organisation in CQC's register. They are required to report serious incidents as defined in CQC's guidance, *Essential Standards of Quality and Safety*. Most of these requirements are met by reporting via the National Reporting and Learning System (NRLS), who will forward relevant information to CQC. The exception is for independent sector providers and primary medical service providers who must report serious incidents directly to CQC. They can also report to the NRLS.

6.0 Serious Incident Reporting Process

6.1 This policy is intended to compliment, and not replace, the robust incident reporting systems which are already in place within NHS organisations. This policy also does not replace the duty to inform other authorities of Serious Incidents, for example the Police, Social Services, Local Safeguarding Boards for Children and Adults. In such circumstances this serious incident policy and procedure should be followed as well as specific national guidance. A flow chart is attached (Appendix 2) which briefly explains the SI reporting process.

6.2 When an incident is of such a serious nature that an external enquiry is required, it will need to be established in line with relevant national guidance. The responsibility for commissioning an external inquiry depends on the nature of the incident. Such incidents will require discussion with the appropriate patient safety SAS/CC CCG Executive Lead or deputy and NHS England Area Team – Shropshire & Staffordshire - Medical Director or Director of Nursing prior to establishing the enquiry.

6.3 When an organisation identifies an incident which is assessed as meeting the definition of a serious incident, that organisation should contact the relevant senior quality lead to discuss the details and grading of the incident. Organisations are then required to report the incident via the Strategic Executive Information System (STEIS) within two working days of the incident occurring or being classified as a SI, or at the earliest point thereafter with an explanation for any delay.

6.4 Electronic notification will be made from STEIS to inform delegated key personnel at the Shropshire & Staffordshire Area Team. The Risk Team at S&L CSU will also be automatically notified when a new SI is logged on STEIS, in addition to the direct email or initial proforma report from the reporting organisation.

6.5 For any SI that occurs outside of normal office hours 08:30 – 17:30 (Monday – Friday, excluding Bank Holidays) providers should initially alert their own Directors/Senior Management via the providers own on-call system. It will be the decision of the Provider Director on-call whether to escalate the matter to the CCG on-call Director, dependant on severity of incident and whether media attention is expected, or wait until the next working day. SAS/CC CCG Director on-call will make the decision on whether to alert Shropshire & Staffordshire Area Team via the on-call system.

6.6 If more than one organisation is involved in a SI, the organisation that is responsible for the care of the patient at the time of the incident will report the SI. Independent practitioners should contact the Area Team for any such SI queries. Other providers of NHS-funded care (e.g. Nursing Homes) should contact the SAS/CC CCG/S&LCSU to discuss reporting requirements and the CCG/S&LCSU will arrange for a Lead Investigator to be appointed

where necessary.

6.7 Where potential media interest exists, SAS/CC CCG will prepare a media response based on the available information, this will be shared with Shropshire & Staffordshire Area Team to ensure any necessary media management is proportionate and well managed.

6.8 Information Governance Incidents

Information Governance incidents that fulfil the criteria of being an SI must be handled in accordance with the process detailed in the Health & Social Care Information Centre/Department of Health (1st June 2013) Checklist Guidance for reporting, managing and investigating information governance serious incidents requiring investigation(appendix 3).

Information should also be recorded on the IG Incident Reporting Tool (see Appendix 9 for detail). The Information Governance Incident Reporting Tool is an online product hosted on the secure Information Governance Toolkit website.
It is the Department of Health (DH) and Information Commissioner's Office (ICO) agreed solution for reporting personal data security breaches. The severity of the incident will be determined by the scale (numbers of data subjects affected) and sensitivity factors selected. If the outcome in terms of the severity of the incident is IG SIRI level 2 (reportable) an email notification will be sent to the HSCIC External IG Delivery Team, DH, ICO and escalated to other regulators, as appropriate. If the outcome is IG SIRI level 0 or 1 no notifications will be sent.

The immediate response to the incident and the escalation process for reporting and investigating this will vary according to the severity of the incident. See Appendix 3 Annex A for fuller details of how to assess the severity. All incidents rated as 1-5 are to follow the SI process and the following additional information should be provided in each case:

Date, time and location of the incident.

- Breach Type (definitions and examples of these can be found in Annex C).
- Details of local incident management arrangements.
- Confirmation that appropriate and documented incident management procedures are being followed and that disciplinary action will be invoked, where appropriate, following the investigation.
- Description of what happened.
- Theft, accidental loss, inappropriate disclosure, procedural failure etc.
- The number of patients/service users/staff (individual data subjects) involved.
- The number of records involved.
- The format of the records (paper or digital).
- If digital format, whether encrypted or not.
- The type of record, breach or data involved and sensitivity.
- Whether the IG SIRI is in the public domain.
- Whether the media (press etc.) are involved or there is a potential for media interest.
- Whether the IG SIRI could damage the reputation of an individual, a work-team, an organisation or the Health or Adult Social Care sector.
- Whether there are legal implications to be considered.
- Initial assessment of the severity level of the IG SIRI (see Annex A for further detail on how this is calculated).
- Whether the following have been notified (formally or informally):
    - Data subjects
    - Caldicott Guardian

- Senior Information Risk Owner
- Chief Executive
- Accountable Officer
- Police, Counter Fraud Services, etc.

- Immediate action taken, including whether any staff have been suspended pending the results of the investigation.

The IG SIRI category is determined by the context, scale and sensitivity. Every incident can be categorised as level:

1. Confirmed IG SIRI but no need to report to ICO, DH and other central bodies.
2. Confirmed IG SIRI that must be reported to ICO, DH and other central bodies.

A further category of IG SIRI is also possible and should be used in incident closure where it is determined that it was a near miss or the incident is found to have been mistakenly reported:

Near miss/non-event

Where an IG SIRI has found not to have occurred or severity is reduced due to fortunate events which were not part of pre-planned controls this should be recorded as a “near miss” to enable lessons learned activities to take place and appropriate recording of the event.

Step 1 Establish the scale of the incident. If this is not known it will be necessary to estimate the maximum potential scale point.

Baseline Scale		
0	Information about less than 10 individuals	
1	Information about 11-50 individuals	
1	Information about 51-100 individuals	
2	Information about 101-300 individuals	
2	Information about 301 – 500 individuals	
2	Information about 501 – 1,000 individuals	
3	Information about 1,001 – 5,000 individuals	
3	Information about 5,001 – 10,000 individuals	
3	Information about 10,001 – 100,000 individuals	
3	Information about 100,001 + individuals	

Step 2: Identify which sensitivity characteristics may apply and the baseline scale point will adjust accordingly.

Low: For each of the following factors reduce the baseline score by 1
No clinical data at risk
Limited demographic data at risk e.g.address not included, name not included
Security controls/difficulty to access data partially mitigates risk
Medium: The following factors have no effect on baseline score
Basic demographic data at risk e.g. equivalent to telephone directory
Limited clinical information at risk e.g. clinic attendance, ward handover sheet
High: For each of the following factors increase the baseline score by 1
Detailed clinical information at risk e.g. case notes
Particularly sensitive information at risk e.g. HIV, STD, Mental Health, Children
One or more previous incidents of a similar type in past 12 months

Failure to securely encrypt mobile technology or other obvious security failing
Celebrity involved or other newsworthy aspects or media interest
A complaint has been made to the Information Commissioner
Individuals affected are likely to suffer significant distress or embarrassment
Individuals affected have been placed at risk of physical harm
Individuals affected may suffer significant detriment e.g. financial loss
Incident has incurred or risked incurring a clinical untoward incident

Step 3 - Final Score

Final Score	Level of SIRI
1 or less	Level 1 IG SIRI (Not Reportable)
2 or more	Level 2 IG SIRI (Reportable)

6.9 All staff dealing with SI information must comply with Caldicott Principles, Data Protection and Information Governance requirements. Particular attention must be paid to confidentiality, sensitivity and person identifiable information – apart from the name of the reporter and the file holder within STEIS all other reports and correspondence should not contain any patient or staff identifiable information. The SI will be given a unique identifier which should be quoted as a reference during all associated correspondence, final RCA and Action Plan, see appendix 4 for guidance on submission to STEIS.

6.10 National Screening Programme Incidents

Guidance for any serious incident classified as a screening incident relating to the national programmes can be found in appendix 5

6.11 NHS 111

Stafford and Surrounds CCG as Lead Commissioner for Staffordshire for this service will be responsible for monitoring of NHS 111 Sis through the NHS 111 governance route with Sandwell and West Birmingham CCG However, they will be required to inform “associate” CCGs of any SIs that involve their patients. A flow chart is included in Appendix 10.

6.12 Out of Hours (OOH) Providers

CCGs will be responsible for logging and monitoring any SIs on behalf of the OOH in respect of patients for whom they commission services. S&LCSU will log the details on STEIS but the investigation will be the responsibility of the CCG. The flow chart at Appendix 10 will reflect this.

6.13 Initial Review

Following notification of a SI SAS/CC CCG/S&LCSU will liaise with the reporting organisation to request any additional information/clarify details, confirm the appropriate level of investigation, terms of reference and reports required. An entry will be made onto STEIS to this effect. In addition to ensuring entry onto STEIS conforms to the minimum dataset, S&LCSU will also ensure that their internal database is updated to enable the production of reports and monitoring on behalf of SAS/CC CCG.

6.14 Where a SI has been initially graded as a ‘0’ S&LCSU will challenge this as part of the three working day update. Except in exceptional circumstances, it is expected that these incidents are either re-graded or closed as part of the update.

6.15 In high profile cases or where serious harm has occurred then, dependent upon available information, a 72-hour Update Brief (appendix 6) will be created by SAS/CC CCG/S&LCSU

guided by the former NHS Midlands & East 'Key Questions – Prompt Cards', following which an Executive Brief will be issued to the Shropshire & Staffordshire Area Team Reporting organisations will be expected to respond to the 72-hour update within the deadline providing additional relevant information that may have emerged during the reporting organisation initial scoping. The types of incidents that may require a 72 hour brief can be found at appendix 7.

6.16 All actions and correspondence taken by SAS/CC CCG/S&LCSU will be recorded on STEIS within the AT/CCG 'Correspondence' or Comments field. The name and title of the person adding the detail should be recorded against the comments.

7.0 Serious Incident Investigation Process

7.1 The reporting organisation is responsible for ensuring that all SI are investigated and documented. Investigations should follow the NPSA's best practice on conducting investigations using root cause analysis (RCA) methodologies. The principles of RCA will be applied to all investigations, but the scale, scope and timescales of investigation will be appropriate to the incident. (see page 35/36 of Appendix 8)

7.2 Where a SI involves a child, young person or vulnerable adult consideration must be given to raising an alert as a safeguarding concern and local safeguarding processes initiated and followed by the reporting organisations Safeguarding Team (refer to SAS/CC CCG safeguarding policy).

7.3 The timescale of the investigation, including notification to SAS/CC CCG, in normal circumstances will not exceed the deadline defined on page 38, appendix 1, and should be completed within the terms of the agreed contract. However, if the reporting organisation faces unavoidable delays in its investigation of a SI then SAS/CC CCG should be notified of the reason for the delay, the anticipated delay period and a new reporting timescale will be negotiated on a case by case basis. If these unavoidable delays are due to an external party, e.g. police investigation the provider should notify SAS/CC CCG of the reason for the delay immediately and where appropriate a "Clock-stop" will be put in place (refer to Section 7.7).

7.4 If, at any time during a SI investigation, it becomes apparent that the incident does not constitute a SI it can be downgraded by formal notification, including reasons for downgrading, and agreement with SAS/CC CCG /S&LCSU. At this point the SI will be removed from STEIS and the S&LCSU database noted accordingly.

7.5 Assurance will be sought by SAS/CC CCG that action plans resulting from a SI investigation are completed within appropriate timescales. Therefore evidence demonstrating that actions have been completed will be requested by SAS/CC CCG/S&LCSU as part of their contract monitoring processes. Providers must reference in action plans how shared learning will be implemented both in the specialty involved and across the wider organisation.

7.6 Involving patients and their families in investigations into serious incidents

The level of patient/family involvement depends on the nature of the incident and the patient or family's wishes to be involved. Provider organisations should have a 'being open' policy in place for staff to follow the principles laid out within that document. The provider will be required to make it explicit in the RCA's its compliance with the duty of candour.

7.7 Stop the Clock

It is acknowledged that whilst every effort should be made to ensure that all SI investigations

are completed in a timely manner, in accordance with the National Framework, there are instances when this is impossible due to circumstances which are beyond the immediate control of the reporting organisation. Such delays may be caused by:

- Awaiting outcomes of court proceedings;
- Awaiting Coroner Inquests;
- Awaiting forensic post-mortem findings;
- Awaiting Toxicology results;
- Awaiting completion of an external review;
- In direct response to a Police request under Memorandum of Understanding.

In such cases discussion between the organisation undertaking the investigation and SAS/CC CCG/S&LCSU are required with the rationale for the request to stop the clock. It is the decision of SAS/CC CCG/S&LCSU whether or not a SI meets the criteria for a 'stop the clock'. This rationale will be reported on STEIS

7.8 In order to ensure robust governance SAS/CC CCG will monitor/review Clock-stop agreements at the regular SI Review Group meetings. In cases where such delays are evident it is essential that a clear entry is made onto STEIS by the provider to explain the rationale for the delay.

7.9 Process for restarting the clock

In order to ensure that RCA investigations progress in a timely manner, once the outcome of the recorded delay is known e.g. outcome of court proceedings, post mortem findings, the provider and SAS/CC CCG/S&LCSU will discuss the removal of the clock-stop and agree a timeframe for completion of the RCA investigation. This date will then become the timeframe for closure of that incident and an entry made on STEIS by S&LCSU. This timeframe whilst negotiated with the provider will be required to be a realistic yet prompt timeframe in order to ensure timely closure of the incident.

7.10 Process for Closure and Sign-Off

Where a SI investigation has been completed and a full investigation report received from the provider including an action plan, SAS/CC CCG to initially determine whether an incident has met the appropriate quality level to be closed. On receipt of the RCA, SAS/CC CCG/S&LCSU will review and where appropriate ask for expert/specialist advice to ensure the investigation and actions are appropriate. RCAs will be reviewed at the regular SI Review meetings, but may also be reviewed outside of this arrangement if closure deadlines fall between meetings. The decision will be recorded at the next meeting to allow an audit trail of outcomes.

7.11 In the circumstances where the report is deemed unsatisfactory and extra assurance or information is required this will be sought from the reporting organisation, within two working days of the review meeting, and the SI will remain open until the extra information/feedback is received (a timescale of 10 days for a response is given). STEIS will be updated to reflect the request for extra information.

7.12 Where the SI investigation report is deemed by SAS/CC CCG to be complete and details of the findings/lessons learned/actions have been entered onto STEIS by the provider the incident will be authorised for closure and referred to the S&LCSU for action. Closure will only be actioned by the S&LCSU where STEIS has been updated with the RCA outcome including recommendations; actions; lessons learnt; how shared across the organisation and notable practice. Where there has been a death of the patient, the actual cause of death should be recorded on STEIS.

7.13 Where the SI is a Grade 2 SI, closure cannot be effected until evidence is supplied by the provider that all actions have been implemented.

7.14 If the reported SI is either a Never Event or a Homicide, a copy of the full investigation report and associated action plan will be shared with Staffordshire & Shropshire Area Team upon closure. **N.B.** Homicide closures cannot take place until such time as a decision has been taken as to whether or not an Independent Inquiry should be commissioned, in accordance with Department of Health guidance. In cases where an Independent Inquiry is commissioned by NHS England Area Team the case should not be closed on STEIS until this is fully completed.

7.15 Where an incident occurs within an organisation in the Staffordshire and Surrounds and Cannock Chase area, but involves a patient from an external CCG area, this information should be relayed to the S&LCSU Risk Manager to enable the home CCG to be informed.

8.0 Monitoring of Serious Incidents

8.1 SAS/CC CCG is committed to improvement in quality and safety in commissioned services. A systematic approach to the analysis of patient safety intelligence has been developed which supports the commissioning of safe services.

8.2 The role of SAS/CC CCG in the monitoring of serious incidents is to ensure that they are properly investigated, action is being taken to improve patient safety and that lessons are learned in order to minimise the risk of similar incidents occurring in the future.

8.3 Clinical Quality Review Group (CQRG)

Shropshire CCG makes explicit reference within its contracts to its expectation regarding incident reporting and management. To ensure continuous improvement in serious incident management SAS/CC CCG has a range of key performance indicators built into provider contracts which it uses for monitoring purposes. The CQRG held with providers monitor the provider's SI performance and highlight any concerns in relation to trends, robustness of actions and lack of assurance with regard to quality and safety. Lessons learnt from incidents are also shared via this forum.

8.4 SAS/CC CCG SI Review Meeting

The SI Review Meeting is held jointly with Staffordshire and Surrounds and Cannock Chase CCG on a regular basis. The chair is the Director of Nursing for Staffordshire and Surrounds and Cannock Chase CCG or the Executive Lead Nurse for Staffordshire and Surrounds and Cannock Chase and is a sub-group of Staffordshire and Surrounds and Cannock Chase CCG Governing Body. Its purpose is to receive and review regular reports on Serious Incidents and Never Events across all NHS commissioned providers. This committee has the delegated authority from the Staffordshire and Surrounds and Cannock Chase CCG Governing Body to formally 'sign off' the closure of serious incidents investigations.

8.5 Dissemination of Shared Learning

One of the key aims of the serious incident reporting and learning process is to reduce the risk of recurrence, both where the original incident occurred and elsewhere in the NHS. The timely and appropriate dissemination of learning following a serious incident is core to achieving this and to ensure that lessons are embedded in practice (NPSA, 2010). Lessons learnt from incidents are shared through a variety of ways. Lessons learnt are shared through reporting to SAS/CC CCG QPR meeting, to the CCG Governing Body. Lessons are also shared via bulletins, presentations and via prescribing newsletters.

Where information lessons identified can/should be shared with other organisations to share learning these will be identified by the S&LCSU/SAS/CC CCG and included in the S&LCSU Quarterly Risk Bulletin/Newsletter which will be distributed to Commissioners and commissioned services by the S&LCSU Risk Team.

8.6 Shropshire & Staffordshire Area Team Monitoring of Serious Incidents

Oversight of serious incident management by the Shropshire & Staffordshire Area Team will be proportionate to the circumstances at the time and will be undertaken primarily through Quality Surveillance Groups (QSGs) in relation to the providers within their relevant geographical area. The Area Team, CCGs, CQC and NTDA should fully exploit the opportunities for sharing information about serious incidents in relevant providers with partner organisations that make up the relevant local and regional QSGs.

Where systems are functioning well, oversight activities via QSGs (or elsewhere) will be limited. In these circumstances, QSGs will support providers and commissioners, review routine data, help to disseminate relevant learning and information, and resolve individual issues escalated to them, for example with more complex serious incident cases. .

9.0 Roles and Responsibilities for the reporting and management of serious incidents within SAS/CC CCG

- Overall accountability sits with the Director of Quality and Safety.
- Overall day to day management sits with the S&LCSU Head of Governance & Compliance. This role has delegated responsibility for the management of the serious incident reporting system, including notifications to reviewing and performance monitoring, acting as a liaison between the Commissioner and provider organisations. The Head of Governance & Compliance has responsibility for the monitoring, closure, downgrading and extraction of information from STEIS and will provide the nominated leads with information on individual SIs as they are reported. A weekly report is also distributed to nominated CCG Leads, along with a monthly report showing detail and graphs to enable trends to be highlighted.

10.0 Acknowledgement of evolving organisational process

10.1 This policy is an overarching policy relating to the current local process for reporting and the management of incidents defined as serious incidents. In view of the recent organisational changes and the partnership working with the commissioning support unit this policy will be reviewed in April 2014 to update any process changes.

11.0 References and relevant documents

Department of Health (2012) The “Never Events” List 2012/13 Update; [Online] Never events list update for 2012/13 | Department of Health

Department of Health; (2012) Update of Never Events Policy Framework [Online] Updated never events policy framework and data published | Department of Health

Department of Health (2009) Checklist for Reporting, Managing & Investigating Information Governance Serious Untoward Incidents [online] Checklist for reporting, managing and investigating information governance serious untoward incidents: Department of Health - Publications

Department of Health (2008) Health and Social Act [Online] Health and Social Care Act 2008

Department of Health (2000) An organisation with a memory [Online] An organisation with a memory : Department of Health - Publications

Memorandum of Understanding (2006) Investigating Patient Safety Incidents (unexpected death or serious untoward harm); Department of Health; Association of Chief Police Officers; Health and

Safety Executive. [Online]; Memorandum of understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm : Department of Health - Publications

National Patient Safety Agency (2009) Information Resource to Support the Reporting of Serious Incidents 2009/2010

National Patient Safety Agency (2010) National framework for Reporting and Learning from Serious Incidents Requiring Investigation [Online] National framework for reporting and learning from serious incidents requiring investigation

Equality Impact Assessment

This policy has been screened to ensure that there is no discrimination on the basis of race, colour, nationality, ethnic or national origins, religious beliefs gender, marital status, age, sexual orientation or disability.

12.0 Appendices

Appendix 1
Being Open Framework (2009)

Being_Open_Framework_WEB_Revised[1].

Appendix 2
Local serious incident flowchart

Flow chart.docx

Appendix 3
Information Governance SI checklist 2013

Information governance serious ir

Appendix 4
Guidance on SI management and STEIS

Guidance on SI management and STE

Appendix 5
Managing Serious Incidents in the English NHS National Screening Programmes

Managing_Serious_Incidents_in_National_

Appendix 6
72 hour brief template

72 hour Brief 2012 - blank CSU.docx

Appendix 7
Category of VSI (very serious incidents that may require 72 hour brief)

SHA_Very_Serious_I
ncidents_Category_C

Appendix 8
NHS England Serious Incident Reporting Framework (2013)

serious incident
framework 2013.pdf

Appendix 9
IG Incident Reporting Tool (2013)
https://nww.igt.hscic.gov.uk/resources/IG%20Incident%20Reporting%20Tool%20User%20Guide.pdf

Appendix 10
NHS 111/Out of Hours GP service Provider SI Reporting Flow Chart DRAFT

NHS 111 Draft
Process 9.pptx

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Version No.:	Version 7
Approval Date:	20/02/14
Review Date:	28/02/15