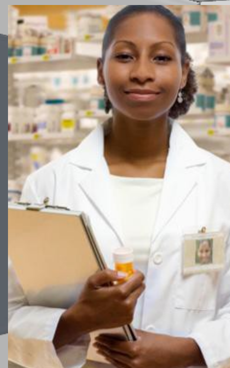
NHS England

HOW TO:

Report a Serious Incident Requiring Investigation (SIRI) or a Significant Event (SEA) to the Surrey and Sussex Area Team

Quality & Safety Team, Nursing Directorate



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1. INTRODUCTION AND BACKGROUND

This '*How to'* guide has been prepared primarily to support the reporting of Serious Incidents Requiring Investigation by Primary Care organisations (General Practice, Dentistry, Community Pharmacy and Optometry) to the Surrey and Sussex Area Team. It gives an overview of the definitions of Serious Incidents Requiring Investigation, and gives some categories and examples of incidents that should be notified to the Area Team. Within the guide there are links to national bodies and further associated guidance as appropriate. The guidance is not exhaustive and other categories of incidents may fall within the definition of a serious incident.

This process may also be used to support the reporting of Significant Events for learning and sharing purposes.

In March 2010, the National Patient Safety Agency published the National framework for Reporting and Learning from Serious Incidents Requiring Investigation. http://www.nrls.npsa.nhs.uk/resources/?entryid45=75173. This framework details how all organisations providing NHS funded care should, report, investigate and monitor serious incidents. The National Framework has been subsequently updated by NHS England Serious Incident Framework 2013 to take into consideration the new NHS architecture and should be read in conjunction with the National Framework.
http://www.england.nhs.uk/ourwork/patientsafety/

2. WHY REPORT? – The purpose of the serious incident reporting and learning process

Serious incidents Requiring Investigation (SIRIs) 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.

The purpose of the serious incident reporting and learning process is:

- To demonstrate assurance of good governance and safety for the most serious incidents;
- To facilitate the wide sharing of learning arising from serious incidents, locally, regionally, and nationally where appropriate;

- To help prevent reoccurrence where the incident occurred and reduce the chance of a similar incident happening elsewhere;
- To support health service improvement by providing information, guidance and recommendations to support health care managers in directing resources where they are most needed to improve quality and safety.

The organisation where the SIRI occurred has overall responsibility for the investigation and implementation of subsequent action plans. Lead commissioners are responsible for monitoring the management of SIRIs reported by providers of NHS funded care. Where a SIRI spans more than one NHS provider or organisation the local commissioners will work together to facilitate a multi-agency review.

As the commissioner of Primary Care, the Surrey and Sussex Area Team has a responsibility to ensure that the systems and processes for reporting and learning from SIRIs are robust and in place.

3. HOW DOES THIS FIT WITH OTHER REPORTING PROCESSES AND SYSTEMS?

This reporting system is not intended to replace current local or other national reporting systems. Organisations should continue to comply with their own local significant event or other reporting systems including reporting to the National Reporting and Learning System (NRLS) and other statutory bodies and regulators such as the CQC, MHRA, HSE, IG etc. However, where a SIRI is identified then the processes described in this '*How to'* guide should also be followed with the subsequent investigation process following national guidance as set out in the National Framework and will be overseen by the Area Team as commissioner.

There is a programme of work underway which aims to bring the nationally required incident reporting systems together but until that time SIRIs are required to be reported by all organisations providing NHS funded care to the STrategic Executive Information System (STEIS). Primary Care organisations do not have direct access to the STEIS system and therefore SIRIs will be reported on their behalf by the Area Team. Our form has been developed to provide the mandatory information required to complete the STEIS form using a few fields as possible so as to ease completion.

The Area Team is mindful of adding to burden and wherever possible duplication of work should be avoided. If the reporting organisation has a local form or reporting system that captures the level of detail set out in the Area Team reporting form (attached at Appendix 1), and can easily be copied to the Area Team then this will be accepted in place of the Area Team form. However it should be noted that for Serious Incidents the information must wherever possible reach the Area Team within 48 hours. If your organisation believes it can provide the information in a different format in a timely way then please contact the Area Team, quality and safety team to discuss. The team will do everything they can to support and ease completion.

4. 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.

For communicating with patients and their families following a SIRI recommended actions are provided in the NPSA Being Open Guidance. www.nrls.npsa.nhs.uk/beingopen

The Complaints Team and/or the Quality and Safety Team at the Area Team will also provide guidance if required.

5. SUPPORTING STAFF

When something goes wrong all staff should have the confidence to be open; focusing on the 'what', 'how' and 'why', rather than necessarily 'who'. Responses should be supportive of individuals, proportionate and robust. The investigation process should focus on the learning that is to be gained from the incident.

6. WHAT TO REPORT (some definitions)

A Serious Incident Requiring Investigation (SIRI) also known as a Serious Untoward Incident or Serious Incident) may be 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;
- A scenario that prevents or threatens to prevent a provider organisations 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;
- Adverse media coverage or public concern about the organisation or the wider NHS;
- 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). A full list of Never Events can be found at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213046/never-events-policy-framework-update-to-policy.pdf.

Where an incident is identified by one organisation but appears to be the responsibility of another organisation this is still an incident and should be reported and responded to by the organisation where the incident occurred provided they are identifiable. The discovering organisation does not have to report the incident themselves but should endeavour to inform the originating organisation or seek guidance from the Area Team.

SIRIs are graded in accordance with the National Framework, as Grade 1 or Grade 2. See Appendix 3 for further details.

Significant Events – This process has been put in place primarily to support SIRI reporting in accordance with the National Framework. However it is recognised that the sharing of Significant Events whilst not meeting SIRI criteria, may also be a valuable means of sharing learning and

capturing themes and trends. This may be particular ly beneficial where systems fall down between NHS provider organisations.

7. HOW TO REPORT

Where a SIRI/ SEA occurs or is suspected to have occurred the Surrey and Sussex *Serious Incident Notification Form* (a copy of which is attached to this guide as Appendix 1) should be completed within **48 hours for a SIRI** of first acknowledgement of the incident and emailed to kategorman@nhs.net.

Completion of this form does not constitute an admission of liability of any kind.

A local root cause analysis or significant event type investigation should be undertaken within 45 or 60 working days from the date reported to the STEIS system. This timeframe is subject to the Grade of the incident (see National Framework for grading). Guidance on grading will be provided by the area team once the incident report has been received, a further explanation of grading can be found at Appendix 3.

8. WHAT HAPPENS NEXT

The Quality and Safety Team will acknowledge receipt of the form and check for completion of all relevant fields. The incident will be reviewed to ensure it meets the criteria for a SIRI following which the Quality and Safety Team will raise a STEIS alert notification on behalf of the reporting organisation.

The incident will be graded in accordance with the National Framework and brought forward date for completion of the local investigation will be set.

The Quality and Safety Team will liaise with the reporting organisation with regard to next steps; this may include:

- Providing advice and guidance with regard to local investigation processes;
- Contacting any other local organisations who may be involved or be required to take part or provide advice during the investigation process;
- Escalating any potential for further harm and mitigating risks to other patients;

The form will also be shared with the relevant specialist within the primary care contracting team.

Where SEAs have been shared the Quality and Safety Team will provide any advice or support locally as per the above and capture themes and trends.

The reporting organisation should commence their local Serious Incident investigation or Significant Event Audit.

9. THE INVESTIGATION PROCESS

The principles of Root Cause Analysis (RCA) or robust Significant Event Audit (SEA) and relevant NPSA guidance (www.nrls.npsa.nhs.uk/resources) should be applied to all NHS investigations.

The purpose of a serious incident investigation is to establish:

- What happened (chronology/timeline of events);

- Who or what it happened to (the people or property involved); When it happened;
- Where it happened;
- How it happened (what went wrong/problem identification, as well as identifying good practice);
- Why it happened (what underlying, contributory or deep-rooted factors caused things to go wrong);
- Identify good practice and lessons learned;
- Clearly state what recommendations for action are needed that should address the root causes identified and which, when implemented will remove or significantly reduce the chance of the same incident happening again.

The reporting organisation should complete its internal investigation, applying the principles and structure set out above. The final investigation should be shared with the Quality and Safety Team. The Quality and Safety Team will provide support with the local investigation if requested.

On receipt of the final investigation report (for SIRIs should be 45 or 60 days from the date the incident was reported) the Quality and Safety Team will seek assurance from the provider organisation that a robust action plan is in place to address the recommendations. Such action plan should have a clear time frame with the responsible person for each action identified and a trajectory for implementation.

Once the Quality and Safety Team are satisfied with the final report for SIRIs the Area Team will update the STEIS system with the final outcome of the investigation process, adding a summary of root causes and lessons learned and once assured close the incident form on the STEIS system. For SEAs the Area Team will capture the key learning points.

10. CALDICOTT, DATA PROTECTION AND INFORMATION GOVERNANCE

When reporting serious incidents, providers must comply with Caldicott, data protection and information governance requirements.

With the exception of details of the reporting organisation and reporter, information provided should not refer to individuals by name or give other identifiable information, and should "restrict access to patient information within each organisation by enforcing strict need to know principles".

In any circumstance where it may be necessary to identify an individual, the serious incident lead in the provider organisation must contact the senior member of the Commissioning Area Team to discuss the incident and provide more detailed information.

11. SHARING THE LEARNING

There will be opportunities for sharing learning from incidents across the Surrey and Sussex area and wider where national learning is identified.

The Quality and Safety Team will produce regular themes and trends from SIRIs and SEAs and share these back with provider organisations.

GLOSSARY OF TERMS

National Framework for Reporting and Learning from Serious Incidents Requiring Investigation - Published in 2009 by the National Patient Safety Agency.
A National framework for reporting and management of serious incidents for investigation (previously known as Serious Untoward Incidents/SUIs) occurring in the NHS and those parts of the independent sector that provide NHS services in England.

Strategic Executive Information System (STEIS) – STEIS allows users to report and view (depending on access rights) Serious Untoward Incidents. The module enables electronic logging, tracking and reporting.

Serious Incident Requiring Investigation (SIRI) Serious Untoward Incident, Serious Incident – *(detailed in paragraph 6 "what to report" of this guide)*

Significant Event Audit - A process in which individual episodes (when there has been a significant occurrence either beneficial or deleterious) are analysed in a systematic and detailed way to ascertain what can be learnt about the overall quality of care, and to indicate any changes that might lead to future improvements.

Patient Safety Incident - Any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare.

Never event–a serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented by healthcare providers

Root Cause Analysis – A systematic process whereby the factors that contributed to an incident are identified. As an investigation technique for patient safety incidents, it also looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which an incident happened.

AVAILABLE RESOURCES

The resources below are all available to provide support in the reporting and learning from serious incidents

National Patient Safety Agency. *Seven Steps to Patient Safety.* 2004. http://www.nrls.npsa.nhs.uk/resources/?entryid45=59787&q=0%c2%acseven+steps +to+patient+safety%c2%ac

Department of Health. *The never events policy framework*. October 2012. *http://www.dh.gov.uk/health/2012/10/never-events/*

National Patient Safety Agency. *Being open: communicating patient safety incidents with patients, their families and carers.* NPSA. 2009. http://www.nrls.npsa.nhs.uk/resources

National Patient Safety Agency. *National Framework for Reporting and Learning from SIRIs.* 2010. http://www.nrls.npsa.nhs.uk/resources/?entryid45=75173

National Patient Safety Agency – *Significant Event Audit – Guidance for Primary Care Teams.* NPSA 2008. www.npsa.nhs.uk/nrls http://www.rcgp.org.uk/clinical-and-research/clinical-resources/clinical-audit/~/media/Files/CIRC/SEA/SEA%20Pilot%20amended%20docs%2024%20sept/NPSA_Quick_Guide_to_SEA.ashx

National Patient Safety Agency. *Three Levels of RCA Investigation - Guidance.* 2008. www.npsa.nhs.uk/rca

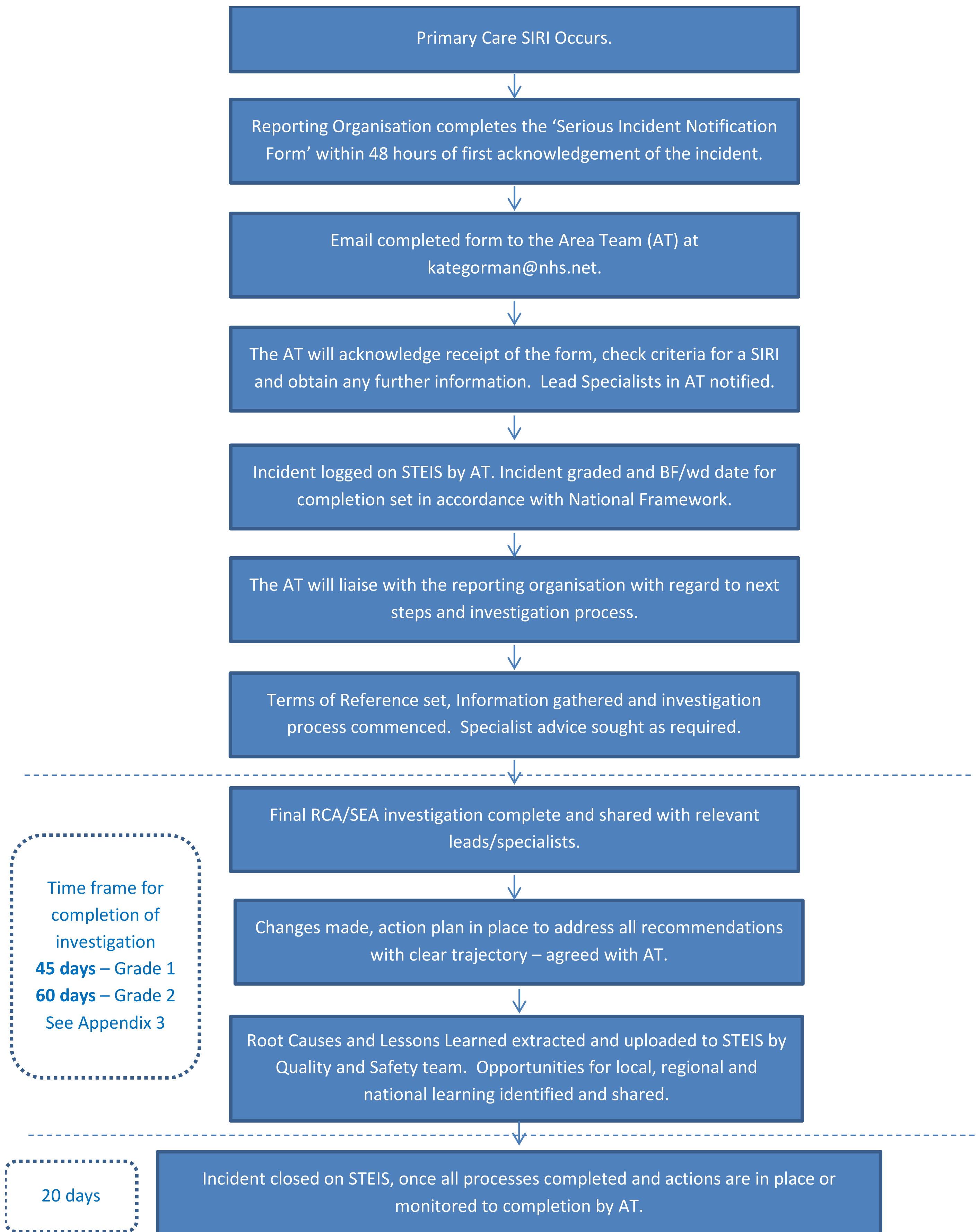
Health and Social Care Information Centre. *Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation* – June 2013. https://www.igt.hscic.gov.uk/help.aspx?

NHS Comms Link. http://nhscommslink.ning.comhttp://nhscommslink.ning.com/page/crisis-management

Care Quality Commission. *Essential standards of quality and safety*. CQC. 2010. www.cqc.org.uk

NHS Connecting for Health. Checklist for Reporting, Managing and Investigating Information Governance Serious Untoward Incidents 2010. http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/links/suichecklist.pdf

Appendix 2 – Primary Care SIRI Reporting Flowchart



Appendix 3 – Grading (based on the grades as set out in the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation)

Grade 0 - Action required

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

The provider organisation must update the Area Team with further information within three working days of a grade 0 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 Area Team. If a serious incident has occurred it will be re-graded as a grade 1 or 2.

Grade 1 – Investigation should be completed within 45 working days from the date the incident was notified. (Short report – see RCA toolkit)

Area Teams will monitor the investigation process, ensuring that the incident is investigated applying robust methodologies with a fully completed action plan with clear trajectory to address any recommendations falling out of root causes and lessons

Grade 2 - Investigation should be completed within 60 working days from the date the incident was notified. (More detailed report – see RCA toolkit)

Area Teams will monitor the investigation process, ensuring that the incident is investigated applying robust methodologies with a fully completed action plan with clear trajectory to address any recommendations falling out of root causes and lessons

***Examples* of a Grade 1 incident**

- Adverse incident affecting business continuity,
  Avoidable or unexplained death,
- Grade 3 or 4 pressure ulcer, Health
  Care Associated Infection,
- Inappropriate treatment or treatment delay resulting in a requirement for further intervention or treatment or permanent harm,
- Information governance or confidential information loss or breach,
  Medication error (not falling within the current Never Event list), Poor
  discharge planning causing harm to patient,
- Serious damage to property including fire flood or explosion, loss of IT,
  Serious health and safety incident,
- Suicide, attempted suicide or self-harming behaviour.

***Example*s of a Grade 2 incident**

- Accusation of physical misconduct or harm by a health or non-health care professional providing treatment or care.
- Homicide following recent contact with mental health services or domestic homicide (90 day investigation),
- Never Event,
- Safeguarding vulnerable adult or child,

It should be noted the above list has been provided as an example and is not intended to be exclusive to only those types referred to above.

NHS England

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