

Serious Incident Policy

SCCG

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1 Introduction

The following Policy identifies the process and arrangements for the reporting and management of Serious Incidents (SI's) for staff within the CCG and services commissioned by NHS Southend CCG (known hereafter as CCG).

2 Purpose

- 2.1 The purpose of this policy is to ensure that staff and commissioned services understand and ensure that serious incidents are investigated appropriately and learning is shared in accordance with the National Framework for Serious Incidents published in March 2015.
- 2.2 There is an expectation that all staff groups who work within the CCG will adhere to policy guidance.
- 2.3 Compliance with the requirements for reporting and managing incidents and SI's will be included within the monitoring of quality contracts.
- 2.4 All services commissioned by the CCG will be required to identify as part of the contract the process in place to declare and manage serious incidents aligned to the principles within the policy.
- 2.5 General Practice and Independent providers who are contracted by the CCG will be requested to follow the serious incident framework (2015) in line with the national contract.
- 2.6 The Framework seeks to support the NHS to ensure that robust systems are in place for reporting, investigating and responding to serious incidents so that lessons are learned and appropriate action taken to prevent future harm.
- 2.7 The Framework is split into three parts;

Part One: Definitions and Thresholds - sets out what a serious incident is and how serious incidents are identified. This section also outlines how the Framework must be applied in various settings.

Part Two: Underpinning Principles - outlines the principles for managing serious incidents. It also clarifies the roles and responsibilities in relation to serious incident management, makes reference to legal and regulatory requirements and signposts to tools and resources.

Part Three: Serious Incident Management Process - outlines the process for conducting investigations into serious incidents in the NHS for the purposes of learning to prevent recurrence. It covers the process from setting up an investigation team to closure of the serious incident investigation.

It provides information on timescales, signposts tools and resources that support good practice and provides an assurance Framework for investigations.
- 2.8 The Framework aims to facilitate learning by promoting a fair, open, and just culture that

abandons blame as a tool and promotes the belief that 'incidents cannot simply be linked to the actions of the individual healthcare staff involved but rather the system in which the individuals were working. Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring'.

- 2.9 It is recognised that serious incidents that require investigation extend beyond those which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

3. Definitions and Thresholds

3.1 What is a serious incident?

- 3.1.1 In broad terms, serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.
- 3.1.2 The occurrence of a serious incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.
- 3.1.3 There is no definitive list of events/incidents that constitute a serious incident and lists should not be created locally as this can lead to inconsistent or inappropriate management of incidents. Where lists are created there is a tendency to not appropriately investigate things that are not on the list even when they should be investigated, and equally a tendency to undertake full investigations of incidents where that may not be warranted simply because they seem to fit a description of an incident on a list.

3.2 Serious Harm

3.2.1 Serious Incidents in the NHS include:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in the unexpected or avoidable death of one or more people by:
 - Suicide/ self-inflicted death
 - homicide by a person in recent receipt of mental health services
- Unexpected or avoidable injury to one or more people that has resulted in:
 - Serious harm;
- Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent serious harm or death of the service user
- Actual or alleged abuse (outlined below) where Healthcare did not take appropriate

action/ intervention to safeguard against such abuse occurring:

- Sexual abuse
 - Physical or psychological ill-treatment
 - Acts of omission which constitute neglect
 - Exploitation
 - Financial or material abuse
 - Discriminative and Organisational abuse
 - Self-neglect
 - Domestic abuse
 - Human trafficking
 - Modern day slavery
- Abuse that occurred during the provision of NHS-funded care including abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry (section 42 Care Act) or other externally led investigation
 - Where delivery of NHS funded care caused/contributed towards the incident.
 - Severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS funded care)
 - Chronic pain (continuous long term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery)
 - Psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days)

3.3 Assessing whether an incident is a serious incident

- 3.3.1 In many cases it will be immediately clear that a serious incident has occurred and further investigation will be required to discover what exactly went wrong, how it went wrong (from a human factors and systems-based approach) and what may be done to address the weakness to prevent the incident from happening again.
- 3.3.2 Whilst a serious outcome (such as the death of a patient who was not expected to die or where someone requires on going/long term treatment due to unforeseen and unexpected consequences of health intervention) can provide a trigger for identifying serious incidents, outcome alone is not always enough to delineate what counts as a serious incident. The NHS strives to achieve the very best outcomes but this may not always be achievable. Upsetting outcomes are not always the result of error/ acts and/ or omissions in care. Equally some incidents, such as those which require activation of a major incident plan for example, may not reveal omissions in care or service delivery and may not have been preventable in the given circumstances. However, this should be established through thorough investigation and action to mitigate future risks should be determined.
- 3.3.3 Where it is not clear whether or not an incident fulfils the definition of a serious incident, providers and commissioners must engage in open and honest discussions to agree the appropriate and proportionate response. It may be unclear initially whether any weaknesses in a system or process (including acts or omissions in care).
- 3.3.4 Can a 'near miss' be a serious incident?
 It may be appropriate for a 'near miss' to be classed as a serious incident because the outcome of an incident does not always reflect the potential severity of harm that could be

caused should the incident (or a similar incident) occur again. Deciding whether or not a 'near miss' should be classified as a serious incident should therefore be based on an assessment of risk that considers:

- 3.3.5 The likelihood of the incident occurring again if current systems/process remains unchanged and the potential for harm to staff, patients, and the organisation should the incident occur again.
- 3.3.6 This does not mean that every 'near miss' should be reported as a serious incident but where there is a significant existing risk of system failure and serious harm, the serious incident process should be used to understand and mitigate that risk.

3.4 How are serious incidents identified?

- 3.4.1 As described above, serious incidents are often triggered by events leading to serious outcomes for patients, staff and/or the organisation involved. They may be identified through various routes including, but not limited to, the following:
- Incidents identified during the provision of healthcare by a provider e.g. patient safety incidents or serious/distressing/catastrophic outcomes for those involved;
 - Allegations made against or concerns expressed about a provider by a patient or third party;
 - Initiation of other investigations for example: Serious Case Reviews (SCRs), Safeguarding Adult Reviews (SARs), Safeguarding Adults Enquires (Section 42 Care Act) Domestic Homicide Reviews (DHRs) and Death in Custody Investigations (led by the Prison Probation Ombudsman) NB: whilst such circumstances may identify serious incidents in the provision of healthcare this is not always the case and SIs should only be declared where the definition above is fulfilled (see Part One; section 1 and 1.1. for further details);
 - Information shared at Quality Surveillance Group meetings;
 - Complaints;
 - Whistle blowing;
 - Prevention of Future Death Reports issued by the Coroner.
- 3.4.2 If an incident is identified by an organisation that is not involved in the delivery of care in which the incident occurred, then that organisation must take action to ensure that the relevant provider(s) and commissioner(s) are informed to ensure the incident is reported, investigated and learned from to prevent future risk of reoccurrence. Where the identifying organisation is another provider it must raise concerns with its commissioner, who can assist in the necessary correspondence between other organisations as required.
- 3.4.3 Serious incidents identified (or alleged) through the complaints route, or any other mechanism, must be treated in line with the principles in this Framework to ensure that it is investigated and responded to appropriately. If the investigation reveals that there were no weaknesses/problems within health's intervention which either caused or contributed to the incident in question, the incident can be downgraded.

4 Risk management and prioritisation

- 4.1 Managing, investigating and learning from serious incidents in healthcare requires a considerable amount of time and resource. Care must be taken to ensure there is an

appropriate balance between the resources applied to the reporting and investigation of individual incidents and the resources applied to implementing and embedding learning to prevent recurrence. The former is of little use if the latter is not given sufficient time and attention.

4.2 Prioritising

- 4.2.1 Organisations should have processes in place to identify incidents that indicate the most significant opportunities for learning and prevention of future harm. This is not achieved by having prescribed lists of incidents that count as serious incidents. For example, blanket reporting rules that require every grade 3 and 4 pressure ulcer, every fall or every health care acquired infection to be treated as serious incidents can lead to debilitating processes which do not effectively support learning.

4.3 Opportunities for investing time in learning

- 4.3.1 The multi-incident investigation root cause analysis (RCA) model provides a useful tool for thoroughly investigating reoccurring problems of a similar nature (for example, a cluster of falls or pressure ulcers in a similar setting or amongst similar groups of patients) in order to identify the common problems (the what?), contributing factors (the how?) and root causes (the why?). This allows one comprehensive action plan to be developed and monitored and, if used effectively, moves the focus from repeated investigation to learning and improvement.
- 4.3.2 Where an organisation has identified a wide-spread risk and has undertaken (or is undertaking) a multi-incident investigation and can show evidence of this and the improvements being made, then this can be used as a way of managing and responding to other similar incidents within an appropriate timeframe. This means that if another similar incident occurs before the agreed target date for the implementing of preventative actions/improvement plans, a separate investigation may not be required. Instead consideration should be given to whether resources could be better used on.

4.4 Framework application and interfaces with other sectors

- 4.4.1 This Framework applies to serious incidents which occur in all services providing NHS funded care, including independent providers where NHS funded services are delivered. The infrastructure within each healthcare setting will largely determine how the Framework is applied in practice. It is acknowledged that some providers, particularly small providers, may be less well equipped to manage serious incidents in line with the principles and processes outlined in this Framework. Where this is the case commissioners and providers must work together to identify where there are gaps in resources, capacity, accessibility and expertise. Arrangements for supporting providers should be agreed on a local basis. Whilst commissioners should offer support where there is capacity to do so, providers are ultimately responsible for undertaking and managing investigations and consequently incur the cost for this process. This includes paying for independent investigations of the care the provider delivered and for undertaking its own internal investigations.
- 4.4.2 The principles and processes outlined in this Framework are relevant for the majority of serious incidents that occur in healthcare. However, there are occasions (outlined below) where the processes described in this Framework will coincide with other procedures. In such circumstances, co-operation and collaborative working between partner agencies is essential for minimising duplication, uncertainty and/or confusion relating to the investigation process.

Ideally, only one investigation should be undertaken (by a team comprising representatives of relevant agencies) to meet the needs/requirements of all parties. However, in practice this can be difficult to achieve. Investigations may have different aims/ purposes and this may inhibit joint investigations. Where this is the case efforts must be made to ensure duplication of effort is minimised.

- 4.4.3 Wherever possible, serious incident investigations should continue alongside criminal proceedings but this should be considered in discussion with the police. In exceptional cases (i.e. following a formal request by police, Coroner or judge) the investigation may be put on hold and this should be discussed with those involved.

5 Responsibilities

5.1 Commissioners of NHS- funded care

- 5.1.1 Commissioners are responsible for securing a comprehensive service within available resources, to meet the needs of their local population. They must commission 'regulated activities' from providers that are registered with the Care Quality Commission (CQC) and should contract with the provider to deliver continuously improving quality care.
- 5.1.2 They must assure themselves of the quality of services they have commissioned, and should hold providers to account for their responses to serious incidents. Commissioner's need to quality assure the robustness of their providers' serious incident investigations and the action plan implementation. Commissioners do this by evaluating investigations and gaining assurance that the processes and outcomes of investigations include identification and implementation of improvements that will prevent recurrence of serious incidents.
- 5.1.3 Commissioning Support Units (CSUs) assist some Clinical Commissioning Groups (CCG's) in some of the practical aspects of their role, for example, by ensuring there is timely reporting of serious incidents by the provider and quality assuring the robustness of the serious incident investigation undertaken by the provider. Delegating activity to the CSU does not remove a CCG's overall accountability for this activity.
- 5.1.4 Commissioners should use the details of serious incident investigation reports, together with other information and intelligence achieved via day to day interactions with providers to inform actions that continuously improve services (where this is required). Commissioners must establish mechanisms for sharing intelligence with relevant regulatory and partner organisations.
- 5.1.5 Commissioning organisations have a responsibility to work together to determine how best to manage oversight of serious incidents in all the services they commission, particularly where multiple commissioners commission services from the same provider and/or where commissioning teams may be geographically remote. Commissioners should establish a RASCI ('Responsible, Accountable, Supporting, Consulted, Informed,') model for the management of serious incidents in their commissioned services
- 5.1.6 A 'lead commissioner' role should be agreed in relation to serious incident management in providers with multiple commissioners in order to provide a clear communication channel between the provider and commissioning system.

- 5.1.7 As previously described, commissioners will typically manage serious incidents by overseeing investigations that are actually led and resourced by the provider(s) of care in which the serious incident occurred. However, in complex situations where multiple providers are involved or where the provider requires support with the investigation, commissioners may need to take a more hands-on approach to the investigation process itself.
- 5.1.7 Commissioners should develop and agree procedures for managing concerns raised to them in relation to the management of the investigation process. They should take responsibility for communicating clearly and effectively with those raising concerns through a single person and ensure issues are effectively resolved.
- 5.1.8 Commissioners also need access to resources/expertise and access to competent independent investigators to support investigations in which they have an obligation to assist (for example PPO investigations require the input of clinical reviewers to support the investigation of death in prison custody), or where they recognise an independent investigation may be required.
- 5.1.9 Commissioners must also have procedures for managing serious incidents within their own organisations including mechanisms to support the quality assurance and closure of investigations reports. They must also have procedures to support their providers in reporting serious incidents onto the STEIS system where this is required.

5.2 NHS England and NHS Improvement

- 5.2.1 NHS England has a direct commissioning role as well as a role in leading and enabling the commissioning system. As part of the latter role, NHS England maintains oversight and surveillance of serious incident management within NHS-funded care and assures that CCGs have systems in place to appropriately manage serious incidents in the care they commission. They are responsible for reviewing trends, analysing quality and identifying issues of concern. They have a responsibility for providing the wider system with intelligence gained through their role as direct commissioners and leaders of the commissioning system. NHS England must maintain mechanisms to support this function, including exploiting opportunities provided by their involvement and participation in local and regional Quality Surveillance Groups.
- 5.2.2 In certain circumstances (for example with many incidents relating to mental health homicide, see Appendix 1) NHS England may be required to lead a local, regional or national response (including the commissioning of an independent incident investigation) depending on the circumstances of the case.

5.3 Care Quality Commission (CQC)

- 5.3.1 The CQC makes authoritative judgements on the quality of health and care services, according to whether they are safe, effective, caring, responsive and well-led. The chief inspectors rate the quality of providers accordingly, and clearly identify where failures need to be addressed. They have a role in encouraging improvement and may use the details of incident reports, investigations and action plans to monitor organisations' compliance with essential standards of quality and safety, to assess risks to quality and to respond accordingly.
- 5.3.2 The CQC works closely with commissioners and providers to gather intelligence and information as part of their pre-inspection process. The Health and Social Care Act sets specific requirements for registered organisations in relation to the type of incidents that must be

reported to them. Further details are published online:

<http://www.cqc.org.uk/organisations-we-regulate/registered-services/notifications>.

5.4 CCG Roles and Responsibilities

5.4.1 Accountable Officer (AO)

The Accountable Officer has overall responsibility for ensuring compliance with the Health & Safety at Work Act 1974, associated legislation and Department of Health requirements, Therefore the AO must ensure that this policy is implemented within the CCG

5.4.2 Chief Nurse (CN)

The Chief Nurse has executive level responsibility and Governing Body level responsibility to ensure that the CCG has management and accountability structures to ensure that commissioned providers deliver safe and effective services in accordance with statutory, national and local guidance.

The Chief Nurse also ensures that there are procedures in place to ensure that all commissioned services have comprehensive policies and procedures in place should there be a need to raise a serious incident.

The Chief Nurse also provides formal sign off of all serious incidents or Never Events.

5.4.3 Caldicott Guardian (CCG)

The Chief Nurse is the CCG Chief Nurse and is responsible for ensuring that patient identifiable information is used appropriately during the incident reporting process.

5.4.4 Quality Finance and Performance Committee

Serious Incidents are reported to the Quality, Finance and Performance Committee. Any concerns raised in relation to this are discussed and action plans are considered.

5.4.5 The Patient Safety Meeting

This meeting ensures that all open open serious incidents are reviewed and discussed. Formal sign off of significant incidents also occurs at this meeting.

5.4.6 Senior Manager On-Call

Has responsibility to assess the urgency of matters relating to incidents reported out of hours and to co-ordinate an appropriate response; this may link with procedures for emergency planning.

5.4.7 Senior Information Risk Owner (SIRO)

The SIRO takes ownership of the organisations' information risks policy and acts as advocate for information risk to the Governing Body by providing written advice on the content of the Annual Governance Statement. This includes oversight of both the organisation's information

security incident reporting and response arrangements. (The SIRO role is generally assigned to the Chief Finance Officer).

5.4.8 **Governing Body (GB)**

The GB will seek assurance from the Quality, Finance and Performance Committee on all serious incidents, it is the Governing Body's role to challenge and seek assurances that lessons are learned and any actions resulting from the serious incident review are actioned and embedded within appropriate organisations in a timely manner.

5.4.9 **Quality Team**

The team are responsible for writing, implementing and monitoring the effectiveness of this policy. With the aim of the policy to provide guidance to staff both within the CCG or within a provider organisation.

The Team will also ensure that the designated email box and the SI database are managed appropriately.

Designated members of the team will participate in the Patient Safety Meeting whereby the sign off of open serious incidents will be discussed and signed off.

5.4.10 **All Staff**

Any staff who suspect a serious incident has occurred should refer to the serious incident flow chart (see Appendix 1) and follow the outlined process.

6. **Policy**

6.1 **What Constitutes a Serious Incident?**

In accordance with the SI Framework (2015), there is no definitive list of events/incidents that constitute a SI and lists should not be created. Every incident must be considered on a case by-case basis using the description below and reported to the CCG.

6.2 Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:

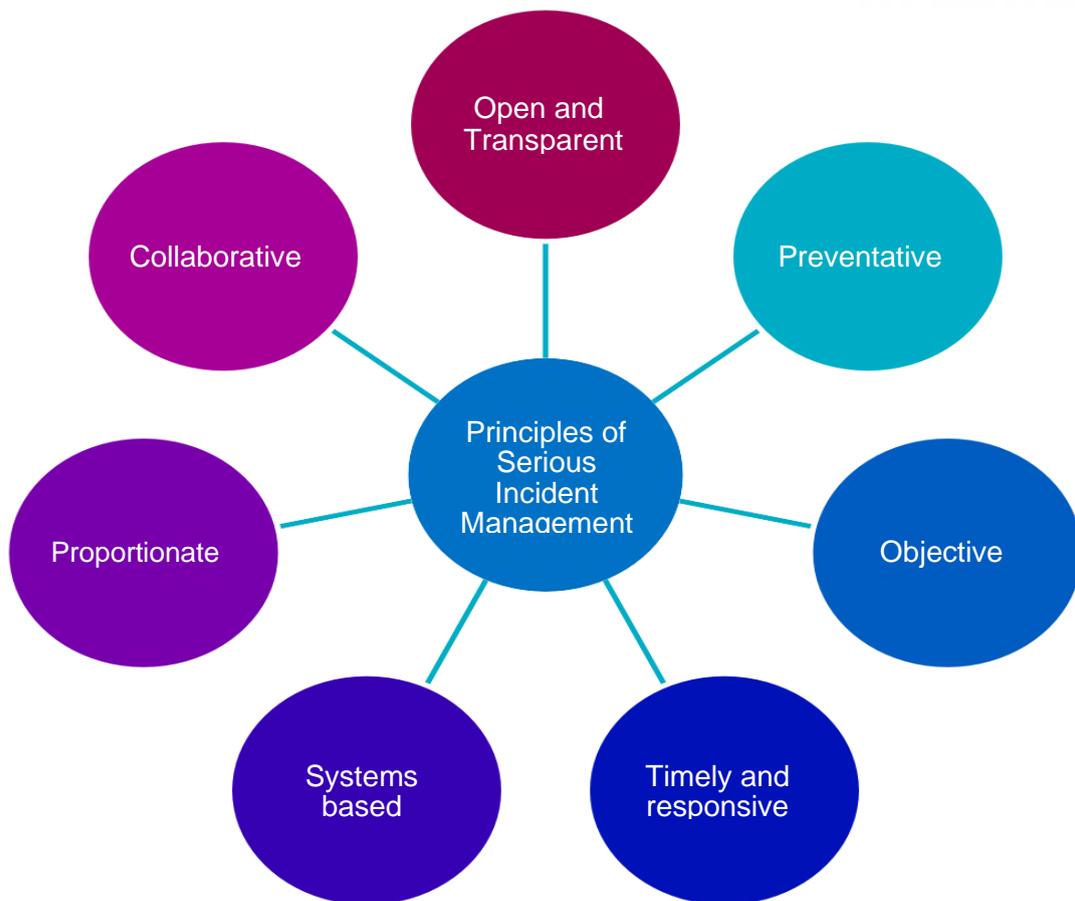
- Unexpected or avoidable death of one or more people. This includes suicide/self-inflicted death and homicide by a person in receipt of mental health care within the recent past
- Unexpected or avoidable injury to one or more people that has resulted in serious harm;
- Unexpected or avoidable injury to one or more people that has required further treatment by a healthcare professional to prevent death or serious harm;
- Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and

organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where healthcare did not take appropriate action/intervention to safeguard against such abuse occurring or where abuse occurred during the provision of NHS-funded care.

- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services (full details are provided in the SI Framework);
 - Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation;
 - A Never Event – all Never Events are defined as SI's although not all Never Events result in serious harm or death. The Never Event framework is reviewed annually. The CCG is required to monitor the occurrence of Never Events within the services they commission and publically report on them on an annual basis.
- 6.3 Excluded from this definition are adverse outcomes (complications) reasonably associated with routine NHS activity such as major surgical procedures or radiotherapy treatment. As a minimum patient safety incidents leading to unexpected death or severe harm should be investigated to identify root causes and enable action to be taken to prevent recurrence; this should include human factors principles.

7. Key Principles in the Management of SI's

- 7.1 The NHS Framework endorses the application of 7 key principles in the management of all SI's. Outlined below are the 7 key principles:



8. Reporting of Serious Incidents

8.1 Providers

8.1.1 All providers are required to enter SI's on STEIS (Strategic Executive Information System) within two working days of the incident being identified. Once the SI has been reported on STEIS an automated email will be sent to the relevant Commissioner to notify and provide a unique identifier number.

8.1.2 The NHS England SI framework indicates that an update should be sent to the relevant commissioning CCG within 3 working days of reporting the incident. This is to provide more detail to the CCG with regards to immediate action taken and Duty of Candour.

8.2 Accountability

8.2.1 The primary responsibility in relation to serious incidents is from the provider of the care to the people who are affected and/or their families/carers.

8.2.2 The key organisational accountability for serious incident management is from the provider in which the incident took place to the commissioner of the care in which the incident took place. Given this line of accountability, it follows that serious incidents must be reported to the organisation that commissioned the care in which the serious incident occurred.

8.3 Involvement of multiple commissioners

8.3.1 In a complex commissioning landscape where multiple commissioners may commission services from multiple providers spanning local and regional geographical boundaries, this model (i.e. where providers report incidents to the commissioner holding the contract who then assumes responsibility for overseeing the response to the serious incident) is not always practicable so a more flexible approach is required. Commissioners must work collaboratively to agree how best to manage serious incidents for their services.

8.3.2 In all cases, a RASCI (Responsible, Accountable, Supporting, Consulted, and Informed) model should be agreed in relation to management of serious incidents. This will ensure that it is clear who is responsible for leading oversight of the investigation, where the accountability ultimately resides and who should be consulted and/or informed as part of the process. This allows the 'accountable commissioner', i.e. the commissioner holding the contract to clearly delegate responsibility for management of serious incident investigations to an appropriate alternative commissioning body, if that makes sense. It should be noted that this does not remove the overall accountability of the commissioner who holds the relevant contract.

8.3.3 The RASCI model supports the identification of a single 'lead commissioner' with responsibility for managing oversight of serious incidents within a particular provider. This means that a provider reports and engages with one single commissioning organisation who can then liaise with other commissioners as required. This approach is particularly useful where the 'accountable' commissioner is geographically remote from the provider (and therefore removed from other local systems and intelligence networks) and/or where multiple commissioners' commission services from the same provider. It facilitates continuity in the management of serious incidents, removes ambiguity and therefore the risk of serious incidents being overlooked and reduces the likelihood of duplication where there is confusion regarding accountability and/or responsibility and general management of the serious incident process.

8.4 Involvement of multiple providers

8.4.1 Often more than one organisation is involved in the care and service delivery in which a serious incident has occurred. The organisation that identifies the serious incident is responsible for recognising the need to alert other providers, commissioners and partner organisations as required in order to initiate discussions about subsequent action.

8.4.2 All organisations and agencies involved should work together to undertake one single investigation wherever this is possible and appropriate.

- 8.4.3 Commissioners should help to facilitate discussions relating to who is the most appropriate organisation to take responsibility for co-ordinating the investigation process. Commissioners themselves should provide support in complex circumstances. Where no one provider organisation is best placed to assume responsibility for co-ordinating an investigation, the commissioner may lead this process.
- 8.4.4 Often in complex circumstances separate investigations are completed by the different provider organisations. Where this is the case organisations (providers and commissioners and external partners as required) must agree to consider cross boundary issues i.e. the gaps in the services that may lead to problems in care. The contributing factors and root causes of any problems identified must be fully explored in order to develop effective solutions to prevent recurrence. Those responsible for coordinating the investigation must ensure this takes place. This activity should culminate in the development of a single investigation report. Development, implementation and monitoring of subsequent action plans by the relevant organisations must be undertaken in line with guidance outlined in part three of this Framework.
- 8.4.5 This policy must not interfere with existing lines of accountability and does not replace the duty to inform the police and/or other agencies/organisations where appropriate. A no harm/near miss event in relation to any of the above should also be recorded by NHS provider organisations and potential aggregated trends and clusters analysed using root cause analysis. Any emerging trends, which constitute a significant risk in any of the above categories, should be reported using this policy.
- 8.4.6 All providers must be aware of their responsibility for reporting to the CQC in relation to serious incidents. From April 2010, as part of the new registration requirements arising from the Health and Social Care Act 2008, organisations are required to notify the Care Quality Commission (CQC) about events that indicate or may indicate risks to on-going compliance with registration requirements, or that lead or may lead to changes in the details about the organisation in the CQC's register.

8.4.7 NHS Southend CCG or Co-Commissioned Services

When a serious incident occurs within the CCG or any co-commissioned services, in the first instance, immediate action must be taken to minimise and prevent further harm. The incident should be reported to the Chief Nurse or if out of hours the Executive on Call.

Relevant staff should complete the reporting template (Appendix D) and send to the NHS Southend CCG secure mailbox (sccg.si@nhs.net) within 2 working days of the incident being identified for the Quality Team to enter on the STEIS System.

- 8.4.8 An investigating officer will be identified who must then follow the reporting schedule outlined in Appendix B.
- 8.4.9. All reports must be completed by the deadline and sent to CCG secure mailbox: sccg.si@nhs.net

8.4.10 Advise on completing full RCAs can be accessed via the NPSA website
<http://www.nrls.npsa.nhs.uk/resources/?entryid45=59847>

8.5 Grading of Si's

8.5.1 The NHS England Framework no longer requires incidents to be graded 0 – 2; this has been replaced with a single grade. All incidents meeting the threshold of an SI must be investigated and reviewed according to the principles set out in the framework.

8.6 De-escalation of Si's

8.6.1 If, after initial investigation, it is evidenced that the incident does not meet the criteria for an SI, then a formal withdrawal request must be sent to the CCG's secure mailbox for consideration. The CCG will consider the rationale for the retraction and if considered appropriate the SI will be retracted from STEIS.

8.7 Types of Investigation

8.7.1 All SI's will vary in nature, severity and complexity and therefore vary on a case-by- case basis. The level of response should be dependent on and proportionate to the circumstances of each specific incident.

Level	Type	Detail
Level 1	Concise internal investigation	Suited to less complex incidents which can be managed at a local level
Level 2	Comprehensive internal investigation	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators.
Level 3	Independent Investigation	Required when the integrity of the investigation is likely to be challenged or if a number of organisation's are involved.

8.8 Final Report Requirements

8.8.1 The CCG promotes the use of the former National Patient Safety Template for completing investigations, However will accept an organisations template as long as the domains within this templates meets the serious incident framework guidance (2015).

8.8.2 Staff conducting investigations should be trained in RCA methodology and final reports should describe causative factors and recommendations to prevent recurrence.

- 8.8.3 The investigation should be completed and a final report and action plan submitted within 60 working days of the incident being reported.
- 8.8.4 If there is likelihood that the report will not be completed within the 60 day timeframe, an extension request must be submitted to the CCG. All requests for extensions must be made in writing via the SI box and are considered on a case by case basis by the CCG. Extensions will only be granted for justifiable circumstances i.e. inquest, safeguarding investigations and criminal proceedings or similar. They will not be granted for internal governance approval, work pressures or planned annual leave by the investigator.
- 8.8.5 Any request should be made at least 7 working days prior to the original date the 60 day report was due. Level 1 and 2 investigations (concise and comprehensive) must be completed within 60 working dates and Level 3 investigations (independent) completed within 6 months from the date the investigation is commissioned.
- 8.8.6 Action plans must be submitted with the final report. Actions must be; clear, with responsible persons, timeframes and plans to monitor and review, including follow-up audits to gain assurance that the learning has been implemented and changes embedded into practice.

9. Monitoring and Closure Of Incidents

- 9.0.1 It is expected that each provider organisation has a formal committee accountable to its Trust Board that has responsibility for monitoring and managing SI's.
- 9.0.2 Final reports for SI's will be reviewed by designated members of the Quality Team to determine if all aspects of the incident have been adequately investigated. The CCG will provide feedback to the provider within 20 working days. The CCG may request additional information or evidence that actions have taken place as additional assurance.
- 9.0.3 The final report will be reviewed at the Patient Safety Meeting and if the CCG is assured that the investigation and action plan are robust the SI will be closed on STEIS. However, identified actions will be monitored through local monitoring systems until all actions have been implemented and appropriate evidence, where appropriate, has been received.
- 9.0.4 Any escalations in terms of breaches in timeframes will be escalated to the Chief Nurse and reported at the Quality Finance and Performance Committee within the Quality Report and further decision on escalating to Governing Body will be at the discretion of the committee members and Chair.

9.1 Dissemination of Lessons Learnt

- 9.1.1 All NHS organisations with a responsibility for notifying or receiving details of SI's have a responsibility for seeking assurance that the lessons learnt are embedded back into the organisation and disseminated as appropriate.

NHSE Framework 2015 Application and Interfaces with Other Organisations or CCGs

9.1.2 The principles and processes outlined in the framework are relevant for the majority of serious incidents that occur in healthcare. However, there are occasions (outlined below) where the processes described in the framework will coincide with other procedures.

9.1.3 In such circumstances, co-operation and collaborative working between partner agencies is essential for minimising duplication, uncertainty and/or confusion relating to the investigation process. Ideally, only one investigation should be undertaken (by a team comprising representatives of relevant agencies) to meet the needs/requirements of all parties. However, in practice this can be difficult to achieve. Investigations may have different aims/ purposes and this may inhibit joint investigations. Where this is the case efforts must be made to ensure duplication of effort is minimised.

9.2 Maternal Deaths

9.2.1 A maternal death is defined as any death of a woman, which occurs during or within one year of pregnancy, childbirth, miscarriage or termination, from any cause related to or aggravated by the pregnancy or its management. The death may occur in any setting, including acute or primary care. A maternal death must be notified by the clinician aware of the death in accordance with the regional maternal death guidelines as well as the local serious incident reporting process.

9.3 Healthcare Associated Infections (HCAs)

9.3.1 The categories for reporting include:

- Outbreaks of healthcare associated infections (this includes the presumed transmission within a hospital and causes significant morbidity/mortality and/or impacts significantly on activity, including ward or facility closure.
- Infected healthcare workers (incidents which necessitate consideration of a 'look back' exercise)
- Breakdown of infection control procedures/serious decontamination failures with actual or potential for cross infection.
- Methicillin-resistant Staphylococcus Aureus (MRSA) Bacteraemia and deaths due to Clostridium Difficile (C.Diff).

9.3.2 Epidemiological data from reported SI's will be shared with the Health Protection Agency to allow for further studies to take place. Organisations may therefore be required to provide additional information in these circumstances.

9.4 Homicide by Patients in Receipt of Mental Health Care

9.4.1 Where patients in receipt of mental health services commit a homicide, NHS England will

consider, and, if appropriate commission an investigation.

9.5 Safeguarding Adults and Children

9.5.1 It is important that all safeguarding issues relating to children or adults are reported immediately via the local multi-agency safeguarding procedures (Southend, Essex & Thurrock (SET) Safeguarding and Child Protection Procedures and Adult Safeguarding Guidance. They will then go through the appropriate investigation process. However, to ensure learning in healthcare settings, there is a requirement to report safeguarding issues as serious incidents in the following circumstances:

- Allegations of abuse against a provider organisation e.g. member(s) of staff deliberately harming a patient; staff member behaving inappropriately with a patient or client; evidence of neglect
- Abuse identified by an employee requiring referral to safeguarding process, which is then escalated to a Safeguarding Children Practice Review, Safeguarding Adult Review or Domestic Homicide review

9.6 Serious Case Reviews

9.6.1 The CCG's Head of Safeguarding will be included in the distribution for any SI's related to safeguarding issues.

9.6.2 Any serious incident that has been escalated to a SCR (this includes Safeguarding Children Practice Review, Safeguarding Adult Review or Domestic Homicide Reviews), need not have a separate root cause analysis carried out, the SCR reporting process will be followed. However, a 'stop clock' will need to be requested as the timescales for a serious incident will be dictated by the SCR timescales.

9.6.3 Any lessons learned or recommendations from a SCR relating to healthcare should be monitored by the CCG's Safeguarding and Quality Teams.

9.6.4 Providers who are requested to provide Individual Management Reviews (IMR's) are not routinely required to report as a serious incident. However, if internal omissions or failures are identified within the IMR or Overview Reports, these should be escalated to a serious incident.

9.7 Child Death

9.7.1 The Child Death Overview Panel is responsible for reviewing the deaths of any child normally resident in Southend, Essex and Thurrock local authority areas, whether from natural, unnatural, known or unknown causes, at home, in hospital or in the community.

9.7.2 Any agency becoming aware of:

- a child death occurring in Essex

- A death of a normally resident Essex child occurring elsewhere should make a notification to the Child Death Review Manager in line with Southend, Essex and Thurrock Procedure for Responding to Deaths in Childhood

Advice can be sought from the CCG Safeguarding Team

9.8 Use of adult psychiatric wards for children aged 17 years and under

9.8.1 This is no longer classified as a serious incident but mental health providers are required to ensure that for each child or young person under the age of 18 who is placed on an adult ward for the provision of mental health services that a consultation with an experienced Emotional Wellbeing and Mental Health Services (EWMHS) Clinician, who has agreed the placement.

9.8.2 That the respective commissioned at the CCG has been notified within 24 hours of the placement starting.

9.9 Incidents Involving Coroners

9.9.1 All unexpected/avoidable deaths should be reported to the HM Coroner. These would include maternal deaths, stillbirths and neonatal deaths. The Coroner may request an inquest/criminal investigation.

9.9.2 If the Coroner writes to an organisation under the Coroner's Investigation Regulations 2013 Schedule 5 Regulation 28 (Prevention of Future Death Notice) then it is likely that the death should be investigated as an SI as there is a suggestion that acts or omissions contributed to the patient's death by the organisation. The commissioner of the service must be informed of all inquests and any subsequent learning or Regulation 28 letter.

9.10 Incidents involving National Screening Programmes

9.10.1 There are explicit requirements for national screening programme related serious incidents and guidance is available from the UK National Screening portal <http://www.screening.nhs.uk>

9.11 Death in Custody

9.11.1 When a death in custody occurs the appropriate guidance should be followed and reported to the relevant commissioning organisation.

9.11.2 Guidance on clinical reviews undertaken in those circumstances, and the responsibilities of the NHS, is available from the Regional Health and Social Care in Criminal Justice Team.

9.12 Incidents involving work-related deaths

9.12.1 Incidents involving work-related deaths should follow the Work Related Deaths Protocol and the agreed protocol between the Health & Safety Executive (HSE), the Police, the Crown

Prosecution Service and the British Transport Police. This deals with incidents where following a death evidence indicates that a serious criminal offence other than a health and safety offence may have been committed.

9.13 Information Security Incidents

9.13.1 Breaches of confidentiality involving person identifiable data and cyber information governance breaches should be reported to the CCG's Head of Information Governance in accordance with the Health and Social Care Information Centre (HSCIC) Checklist guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation.

9.13.2 Any breaches identified within the CCG would be raised as an SI and follow the usual process alongside that undertaken by the Information Governance Team.

9.13.3 The immediate response to the incident and the escalation process for reporting and investigating this will vary according to the severity of the incident.

9.13.4 Definition of an IG cyber breach:

- hacking
- denial of service
- malicious internal damage
- spoof website
- cyber bullying
- phishing emails
- social media platform
- website defacement

9.13.5 Organisations should report all breaches to the Head of Information Governance who will be responsible for notifying the Information Commissioners Office (ICO) and Department of Health (DH) of any level 2 breaches via the IG toolkit incident reporting tool.

9.13.6 All serious incidents involving data losses and breaches of confidentiality should be published in the annual reports of all NHS organisations.

9.14 Incidents Involving Multiple Provider Organisations

9.14.1 If an incident involves two or more providers the most appropriate organisation will report on STEIS and co-ordinate the investigation to ensure an agreed list of recommendations is formulated into an action plan.

9.14.2 Each organisation is expected to co-operate in the investigation process.

9.14.3 The relevant CCG will support the lead organisation to ensure adherence by all providers to the SI process.

9.15 Serious Incidents reported within Primary Care

9.15.1 The CCG has delegated commissioning in relation to Primary Care services and therefore, Primary Care Providers are to report any serious incidents to the dedicated mailbox managed by the CCG.

9.15.2 The Quality Team can provide support and advice.

9.16 Communication with the Media

9.16.1 During normal office hours all enquiries from the press or media are to be referred, in the first instance, to the Communications and Engagement Manager or equivalent.

9.16.2 If approached by the media, CCG staff should initially not answer any questions on behalf of the CCG and should instead confirm that a member of the Communications Team will get back to them, as soon as possible.

9.16.3 A brief summary of the enquiry along with contact details should be taken and given to the Communications and Engagement Manager or equivalent for action.

9.16.4 The CCG's Head of Communications will be made aware of any serious incidents that are likely to be of interest to the media.

9.16.5 The Head of Communications, in conjunction with the CCG's Executive Officers will be responsible for the management of any communication with the media.

9.17 Freedom of Information (FOI)

9.17.1 The FOI Act 2000 provides public access to information held by public authorities. It does this in two ways: public authorities are obliged to publish certain information about their activities; and, members of the public are entitled to request information from public authorities.

9.17.2 All healthcare organisations should be aware that information relating to SIs including information held on national systems, local databases, internal reports, investigation reports and related documents could be subject to disclosure under the Freedom of Information Act

9.17.3 Any requests for such information should follow the CCG's FOI Policy

10. MONITORING COMPLIANCE

10.1 Providers

10.1.1 Specific Serious Incident Key Performance Indicators (KPI) for Provider organisations are monitored through the Clinical Quality Review Group meetings on a monthly basis.

10.2 CCG Staff

10.2.1 The process will be monitored through the Quality Team and reported to the Quality, Finance and Performance Committee. Any escalations will be reported to the Governing Body at the discretion of the Committee members and the Chair.

10.3 Dissemination of Policy

10.3.1 The ratified Policy will be available within the CCG shared drive.

11. STAFF TRAINING

11.1 Compliance with CCG staff training would be monitored by the Education Facilitator within Corporate Services.

11.2 Training for staff will be provided on an annual basis by way of face to face training.

12. ARRANGEMENTS FOR REVIEW OF POLICY

12.1 This policy will be reviewed no less frequently than every three years. An earlier review will be carried out in the event of any relevant changes in legislation, national or local policy/guidance.

13. RELATED POLICIES

- Safeguarding Adults Policy
- Safeguarding Children’s Policy
- Freedom of Information Policy
- Health & Safety Policy
- Complaints Policy
- Disciplinary Policy
- Information Governance Policy

14. List of Stakeholders Consulted

Name	Designation
Lin Teasdale	Patient Safety Manager
Sharon Connell	Head of Safeguarding

15. Equality Impact Assessment

15.1 NHS Southend CCG is committed to carrying out a systematic review of all its existing and proposed policies to determine whether there are any equality implications.

15.2 This policy has been assessed using NHS Southend CCG's Equality Impact Assessment and identified as having the following impact upon equality and diversity issues.

Age	Disability	Gender	Race	Sexuality	Religion	Human Rights	Total Points	Impact
0	0	0	0	0	0	0	0	Low

16. Version Control

Version	Date Issued	Author	Comments
1	May	Lucy Moss - HR	New Policy
2	August 2019	Lorraine Coyle Deputy Chief Nurse	Review and refresh

17. REFERENCES

National SI Framework – March 2015

<https://improvement.nhs.uk/documents/920/serious-incident-framwrk.pdf>

NHSE SI Framework – frequently asked questions March 2016_

<https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2016/03/serious-incident-framwrk-fags-mar16.pdf>

Never Events Policy and Framework – January 2018_

<https://improvement.nhs.uk/resources/never-events-policy-and-framework/>

Duty of Candour – CQC Regulation 20 – March 2015_

http://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final_.pdf

Reporting maternal deaths_

<https://www.mbrace.ox.ac.uk/>

Southend, Essex & Thurrock (SET) Guidance for Adults_

http://www.safeguardingsouthend.co.uk/pdfs/SET_Safeguarding_Adults_Guidelines_2015.pdf

Southend, Essex & Thurrock (SET) Guidance for Children_

<http://www.escb.co.uk/Portals/67/Documents/Local%20Practices/SET%20Procedures%202015%20-%20Version%20%20August%202015.pdf>

Child Death Review Process

<http://www.escb.co.uk/en-gb/workingwithchildren/childdeathreviews.aspx>

Coroners Investigation Regulations 2013

<https://www.judiciary.gov.uk/related-offices-and-bodies/office-chief-coroner/pfd-reports/>

Regional Health and Social Care in Criminal Justice

Team <https://www.england.nhs.uk/commissioning/health-just/>

Work Related Deaths Protocol (HSE)_

<http://www.hse.gov.uk/enforce/wrdp/>

(HSCIC) Checklist guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation_

<https://www.igt.hscic.gov.uk/resources/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf>

Freedom of information Act 2000

<https://ico.org.uk/for-organisations/guide-to-freedom-of-information/what-is-the-foi-act/>

RCA Investigation Resources_

www.npsa.nhs.uk/rca

APPENDIX ONE

Flow Chart Serious Incident Process

Serious incident is identified.

Notify CCG via sccg.si@nhs.net and complete subsequent 3 day report on the template provided.

Complete 3 day report and return to sccg.si@nhs.net.

Quality Team review the 3 day report and will request a full 60 day comprehensive investigation to be completed if necessary.

Completed 60 day report returned to sccg.si@nhs.net. Quality Team will review for sign off.

Within 20 days SI report and action plan is reviewed at the Patient Safety Meeting and CCG will email back either further recommendations/closure.

Serious incident referrer closes off on their System. If no access to STIES CCG will do on behalf of referrer

APPENDIX TWO National SI Framework – March 2015

<https://improvement.nhs.uk/documents/920/serious-incident-framwrk.pdf>

Part Three: The Serious Incident Management Process

1. Overview of the Serious Incident Management Process

