

Corporate	CCG CO18: Serious Incident & Management Policy
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V3.5	01 March 2022	01 July 2022 (or in line with Integrated Care board establishment)

Prepared By:	Senior Clinical Quality Officer, NECS
Consultation Process:	Head of Governance, North Tyneside CCG

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Document History

Version	Date	Significant Changes
1	28/02/2013	First issue
2	December 2015	Revised SI Framework & Never Event April 2015
3	07/10/2016	Updated to reflect changes to screening guidance and to reflect the checklist guidance for information governance and cyber security serious incidents. Also to include responsibilities of the NTCCG SI panel.
3.1	January 2017	Review date extended to comply with CCG request of 3 yearly reviews (unless amendments to legislation etc).
3.2	October 2017	Updated to reflect CCG responsibilities for closing SIs through the SI Panel process and to reflect updated guidance on managing screening incidents
3.3	November 2020	Extension request. No further update to legislation.
3.4	September 2021	Updated to reflect Just Culture Guidance
3.5	March 2022	Extended pending ICB establishment

Equality Impact Assessment

Date	Issues
December 2015	See section 9 of this document

POLICY VALIDITY STATEMENT

This policy is due for review on the latest date shown above. After this date, policy and process documents may become invalid.

Policy users should ensure that they are consulting the currently valid version of the documentation.

ACCESSIBLE INFORMATION STANDARDS

If you require this document in an alternative format, such as easy read, large text, braille or an alternative language please contact NECSU.comms@nhs.net

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1. Introduction

The Clinical Commissioning Groups (CCGs) aspire to the highest standards of corporate behaviour and clinical competence, to ensure that safe, fair and equitable procedures are applied to all organisational transactions, including relationships with patients their carers, public, staff, stakeholders and the use of public resources. In order to provide clear and consistent guidance, the CCGs will develop documents to fulfil all statutory, organisational and best practice requirements and support the principles of equal opportunity for all.

The NHS treats over one million patients every single day. The vast majority of patients receive high standards of care however incidents do occur and it is important they are reported and managed effectively.

The CCGs as Commissioners, seek to assure that all services which may be commissioned meet nationally identified standards and this is managed through the local contracting process. Compliance with Serious Incident (SI) and Never Event (NE) reporting is a standard clause in all contracts and service level agreements as part of a quality schedule.

The role of the CCGs as Commissioners is to gain assurance that incidents are properly investigated, that action is taken to improve clinical quality, and that lessons are learnt in order to minimise the risk of similar incidents occurring in the future. It is intended that intelligence gained from SIs will be used to influence quality and patient safety standards for care pathway development, service specifications and contract monitoring.

The revised policy is intended to reflect the responsibilities and actions for dealing with SIs and NEs and the tools available.

It outlines the process and procedures to ensure that SIs and NEs are identified, investigated and learned from as set out in the Serious Incident Framework 2015/16 and Never Event Framework 2018. This revised Framework replaces the Serious Incident Framework and Never Event Framework published in January 2018.

1.1 Status

This policy is a corporate policy and outlines the Serious Incident (SI) Policy for North Tyneside CCG.

1.2 Purpose and Scope

1.2.1 The purpose of this policy is to identify what is meant by a SI or NE and to describe the role of the CCGs when a SI or NE occurs across a number of organisations.

This policy aims to ensure that the CCGs as Commissioners comply with current legislation as well as current national guidance, NHS England and requirements with regard to accident/incident reporting generally, but in particular reporting, notifying, managing and investigating SIs and NEs.

1.2.2 This policy applies to all employees of the CCGs and is recommended to independent contractors e.g. GPs, Dental Practitioners, Optometrists and Pharmacists.

1.2.3 All NHS providers including Independent Healthcare Sector providers, where NHS services are commissioned, need to comply with the CCGs' reporting requirements within this policy, (which are set out in the relevant contract), and reflects the Serious Incident Framework 2015 and Never Events Framework 2018.

1.3 **Policy Statement**

It is the duty of each NHS body to establish and keep in place arrangements for the purpose of monitoring and improving the quality of healthcare provided by and for that body. The CCGs as commissioners of services are committed to this policy and the implementation of a consistent approach to the implementation of robust arrangements for the management of SIs and NEs.

2. **Definitions and Terms**

The following definitions and terms are used in this policy document:

2.1 **Definition of a Serious Incident and Never Event**

2.1.1 An incident is a single distinct event or circumstance that occurs within the organisation which leads to an outcome that was unintended, unplanned or unexpected.

2.1.2 NHS England has produced an information resource to support the reporting and management of serious incidents which can be found in The SI Framework and supporting appendices (Appendix 1).

2.1.3 Whilst the definition of a SI is quite broad, the following criteria outline the type of incidents which should be included:

1. Unexpected or avoidable death of one or more people. This includes:
 - Suicide/self-inflicted death
 - Homicide by a person in receipt of mental health care within the recent past
2. Unexpected or avoidable injury to one or more people that has resulted in serious harm.

3. Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
 - The death of the service user
 - Serious harm
 - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment or acts of omissions which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery.
4. Never Events - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. Further information can be found at: <https://www.england.nhs.uk/publication/never-events/>
5. 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, including (but not limited to) the following:

Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues (see Appendix 4 for further information);

- Property damage
 - Security breach/concern
 - Incidents in population-wide healthcare activities such as screening or immunisation programmes where the potential for harm may extend to a large population;
 - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
 - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/unit closure or suspension of services); or
 - Activation of Major Incident Plan (by provider, commissioner or relevant agency)
6. Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

2.2 Working with other Organisations/Sectors

2.2.1 *Deaths in Custody*

- People in custody, including those detained under the Mental Health Act (1983) or those detained under the police and justice system, are owed a duty of care by relevant authorities. The obligation on the authorities to account for the treatment of an individual is particularly stringent when that individual dies.
- Any death in custody will be referred to the Prison and Probation Ombudsman (PPO) or the Independent Police Complaints Commission (IPCC) who are responsible for carrying out the relevant investigations. Healthcare providers must fully support these investigations where required to do so.
- In NHS Mental Health services, providers must ensure that any death of a patient detained under the Mental Health Act (1983) is reported to CQC without delay. However providers are responsible for ensuring that there is an appropriate investigation into the death of a patient detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies. In circumstances where the cause of the death is unknown and/or where there is reason to believe the death may have been avoidable or unexpected then the death must be reported to the provider's commissioner(s) as an SI and investigated appropriately.

2.2.2 *Serious Case Reviews and Safeguarding Adult Reviews*

- The Local Authority via the Local Safeguarding Children Board or Local Safeguarding Adult Board (LSCB, LSAB as applicable) has a statutory duty to investigate certain types of safeguarding incidents/concerns.
- Healthcare providers must contribute towards safeguarding reviews as required to do so by the Local Safeguarding Board, where it is indicated that a serious incident within healthcare has occurred.
- The interface between the serious incident process and local safeguarding policies must therefore be articulated in the local multi-agency safeguarding policy and protocol.

2.2.3 *Domestic Homicide Reviews*

- Where a Domestic Homicide is identified by the police, the Community Safety Partnership (CSP) will consider the case meets criteria for Domestic Homicide Review (DHR)

2.2.4 *Homicide by patients in receipt of mental health care*

- Where patients in receipt of mental health services commit a homicide, NHS England will consider and, if appropriate, commission an investigation. This process will be overseen by NHS England's Regional investigation teams.

2.2.5 *Serious Incidents in National Screening Programmes*

2.2.5.1 There are a number of immunisation or screening programmes which require a broader approach to handling incidents.

2.2.5.2 The Screening Quality Assurance Service is responsible for surveillance and trend analysis of all screening incidents. It will ensure that the lessons learned from incidents are collated and disseminated nationally.

2.2.5.3 Screening SIs are often very complex, multi-faceted incidents that require robust coordination and oversight by Screening and Immunisation Teams working within Sub-regions and specialist input from Public Health England's Screening Quality Assurance Service.

2.2.5.4 Further details on the management of incidents within the screening programme are available in "Managing Safety Incidents in NHS Screening Programme" in appendix 3.

2.2.5.5 For SIs linked to national screening programmes (e.g. ante natal and child health screening, retinal screening etc.) the Regional Screening Lead will provide advice to local organisations and will inform the national coordinating bodies as appropriate.

2.2.5.6 Flow chart for managing screening incidents can be found in Appendix 3

2.3 Additional guidance for personal data related (Information Governance) SIs

2.3.1 There is no simple definition of an information governance serious incident. The scope of an Information Governance Serious Incident may include:

- A breach of one of the principles of the Data Protection Act and/or the Common Law Duty of Confidentiality.
- Unlawful disclosure or misuse of confidential data, recording or sharing of inaccurate data, information security breaches and inappropriate invasion of people's privacy.
- Personal data breaches which could lead to identity fraud or have other significant impact on individuals.

2.3.2 There are many possible definitions of what a cyber incident is, for the purposes of reporting the definition is anything that could (or has) compromised information assets within Cyberspace. “Cyberspace is an interactive domain made up of digital networks that is used to store, modify and communicate information. It includes the internet, but also the other information systems that support a businesses, infrastructure and services.” These types of incidents could include:

- Denial of Service attacks
- Phishing emails
- Social Media Disclosures
- Web site defacement
- Malicious Internal damage
- Spoof website
- Cyber Bullying

2.3.3 The Health and Social Care Centre (HSCIC) has provided additional guidance for how SIs relating to information governance and cyber security should be dealt with and a hyperlink to the guidance is included in Appendix 4.

2.4 Serious Incidents involving controlled drugs.

2.4.1 SIs that involves controlled drugs must also be notified to the North of England Commissioning Support Medicines Optimisation Team.

3. Reporting and Management of Serious Incidents

3.1 Independent Healthcare sector

3.1.1 The Independent Healthcare Sector (IHS) should be subject to contractual obligations for the reporting of SIs. The CCG should ensure that appropriate reporting arrangements are in place with the IHS in relation to SIs (Appendix 8).

3.1.2 The commissioning CCG should ensure that IHS SIs are reported via StEIS and investigated appropriately.

3.2 Guidance for Commissioned Services/Providers

3.2.1 Each NHS Trust/organisation must nominate a single point of contact or lead officer for managing all SIs.

3.2.2 Organisations should ensure that mechanisms are in place to report all incidents meeting the criteria.

3.2.3 The SI lead officer must report a SI through StEIS within 2 working days of Identification of the SI, completing all relevant sections. At this stage it is important that any immediate learning is included in this report.

- 3.2.4 If appropriate, the SI lead officer must liaise with the organisations communications team who will liaise directly NHS England Communications team.
- 3.2.5 The organisation must then provide a 72 hour report, which should be sent to NECS as the responsible delegate for CCGs. The report should include more information regarding the event, immediate learning and how the RCA will be conducted.
- 3.2.6 Under the Data Protection Act (1998) organisations need to be open and transparent with regards to investigation processes, unless there are specific exceptions. Arrangements may need to be put in place to support patients and family members through the investigation process and sharing of the outcomes of investigations. The appointment of a Family Liaison Officer may be appropriate.
- 3.2.7 If an incident spans organisational boundaries, **it is the responsibility of the organisation where the incident took place** to formally report it through StEIS. All other additional organisations involved must contribute and fully cooperate with the process in line with the agreed timescales. Where there is doubt about who should report the incident then clarity must be sought through the North of England Commissioning Support (NECS) Clinical Quality Team.
- 3.2.8 If an incident involves more than one NHS organisation a decision will be made (mutually agreed) as to which is the lead investigating organisation. Where an incident involves the independent sector or contracted services, it is the role of the commissioning CCG to lead. The Responsible, Accountable, Supporting, Consulted, Informed (RASCI) model should be completed in order to assign accountability.
- 3.2.9 This guidance must not interfere with existing lines of accountability and does not replace the duty to inform the police and/or other organisations or agencies where appropriate. Further guidance can be obtained from the Department of Health publication *Memorandum of Understanding: Investigating Patient Safety Incidents* June 2004 and accompanying NHS guidance of December 2006. The need to involve outside agencies should not impede the retrieval of immediate learning.
- 3.2.10 Incidents which have impacted or have had potential to impact on children and/or vulnerable adults must be investigated in conjunction with the identified safeguarding lead and in accordance with related guidance.
- 3.2.11 Where an incident is subject to the involvement of a coroner, an independent inquiry, serious case review or any safeguarding issues, this should be highlighted clearly within the StEIS report as this may affect closure date.

3.2.12 Organisations should undertake investigation procedures / root cause analysis (RCA) as per organisation policy and submit to the responsible body within the agreed timescales. An example for the contents of a report and action plan can be found in **Appendix 5**. To ensure confidentiality all reports submitted to the CCGs or North of England Commissioning Support Clinical Quality Team should be anonymous and sent via the agreed StEIS NHS-net account. NECS will conduct a quality assurance check on all RCAs on behalf of the relevant CCG in order to ensure the 20 day deadline is met.

3.3 Independent Contractors

3.3.1 Once an SI is identified, in a CCG commissioned service, the Independent Contractors Procedure for the Reporting and Management of Serious Incidents should be followed, or where applicable NHS England should be notified. This is explicit in Appendix 7.

3.3.2 Where an SI raises professional concerns about a GP CCG local arrangements for assuring high standards of professional performance should be invoked, where this is applicable or NHS England notified.

3.3.3 Independent Contractors should have systems in place to ensure that staff are supported appropriately following the identification of a SI.

3.4 NHS Providers

3.4.1 Once an SI is identified, the Providers' Procedure for the Reporting and Management of Serious Incidents should be followed (Appendix 7).

3.4.2 Providers should have systems in place to ensure that staff are supported appropriately following identification of a SI

3.5 Independent Healthcare Sector Providers

3.5.1 Once an SI is identified, the Procedure for the Reporting and Management of Independent Healthcare Sector Serious Incidents should be followed (Appendix 8).

3.6 Staff Involved in Serious Incidents

3.6.1 Serious incidents can be distressing for those involved.

3.6.2 The Director, Assistant Director or appropriate Manager should ensure that staff are supported at all stages of a SI with reference to CCG HR policies.

3.6.3 The Director, Assistant Director or appropriate Manager are responsible for ensuring that a de-briefing session occurs at an appropriate stage following a SI.

3.6.4 If, during the course of a SI investigation, it becomes apparent that a member of staff may be subject to a disciplinary hearing, appropriate advice and support should be taken via Human Resources and the relevant policy followed.

3.7 Information for Education and Training Organisations

3.7.1 In the event an incident involves a student or trainee, the relevant academic institution will be notified by the NHS Trust/CCG as appropriate.

3.7.2.1 Where a SI concerns the commissioning or provision of medical or dental education or training, or a medical or dental trainee or trainees, there will be appropriate communication between the CCG and NHSE.

3.8 CCG Management and Closure of Serious Incidents

3.8.1 The CCG is responsible for quality assuring the robustness of its providers' serious incident investigations and the action plan implementation undertaken by their providers.

3.8.2 The CCG is responsible for 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.

3.8.3 In order to achieve this, the CCG has established the Serious Incident Closure Panel and the terms of reference can be found in Appendix 9.

4. Duties and Responsibilities

Council of Practices	Have delegated responsibility to the governing body (GB) for setting the strategic context in which organisational process documents are developed, and for establishing a scheme of governance for the formal review and approval of such documents.
Chief Officer	<p>The Chief Officer has overall responsibility for the strategic direction and operational management, including ensuring that CCG process documents comply with all legal, statutory and good practice guidance requirements.</p> <p>The Chief Officer has responsibility for ensuring that the CCG has the necessary management systems in place to enable the effective management and implementation of all risk management and governance policies and delegates the responsibility for the management of SIs to the Executive Lead for Patient Safety and Safeguarding.</p>

Executive Director of Nursing	<p>The Executive Director of Nursing has overall responsibility for ensuring:</p> <ul style="list-style-type: none"> • The incident management process is robust and adhered to. • Incidents are maintained and managed in timely manner. • Staff have the necessary training required to implement the policy. • Mechanisms are in place within the organisation for regular reporting and monitoring of incident themes and lesson learned. • Confirm to NECS Clinical Quality Team that incidents can be marked as fully completed.
Executive Director of Nursing	<p>The Executive Director of Nursing has overall responsibility for ensuring the necessary management systems are in place for the effective implementation of serious incident reporting for the CCG and delegates management of SIs and reporting to the NECS Clinical Quality Manager.</p>
NTCCG SI Panel	<p>The Panel will provide assurance to the Quality and Safety Committee that the CCG has relevant mechanisms and governance processes in place to consider and monitor serious incident investigations. The panel will also provide assurance via regular thematic reviews undertaken to extract learning and support the development of organisational memory and continuous improvement with regard to patient safety in the CCG's commissioned services. The SI Panel ensure an annual SI report is presented to the Quality and Safety Committee.</p>
Line Managers	<p>The service leads have the responsibility:</p> <ul style="list-style-type: none"> • To support their directors and staff to maintain the incident policy and to manage individual incidents in accordance with policy. • To work closely with the Executive Director of Nursing to ensure a transparent and consistent approach to incident management across the CCG in partnership with key stakeholders. <p>All line managers and supervisory staff are responsible for the adherence and monitoring compliance within this policy.</p> <p>Managers have responsibility for promoting the policy directly with their staff and, where appropriate, taking Directorate responsibility for the co-ordination of investigations in support of the Executive Lead for Patient Safety and Safeguarding</p>

<p>All staff</p>	<p>All staff, including temporary and agency staff, are responsible for:</p> <ul style="list-style-type: none"> • Compliance with relevant process documents. Failure to comply may result in disciplinary action being taken. • Co-operating with the development and implementation of policies and procedures as part of their normal duties and responsibilities. • Identify the need for a change in policy or procedure as a result of becoming aware of changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising their line manager. • Attending training/awareness sessions when provided.
<p>North of England Commissioning Support (NECS) Clinical Quality Manager</p>	<p>The NECS Clinical Quality Manager will</p> <ul style="list-style-type: none"> • Consider if a serious incident falls into the category of a StEIS reportable SI and report accordingly. • Review clinical quality incidents reported by the CCG. • Review clinical quality incidents reported by providers • Provide clinical quality incident reports as requested.
<p>North of England Commissioning Support (NECS) Senior Medicines Optimisation Pharmacist</p>	<p>The NECS Senior Medicines Optimisation Pharmacist has Responsibility for ensuring that all SIs in relation to controlled drugs are investigated appropriately and liaison with the Controlled Drugs Local Intelligence Network (LIN).</p>
<p>North of England Commissioning Support (NECS) Senior Governance Officer</p>	<p>NECS Senior Governance Officer will:</p> <ul style="list-style-type: none"> • Provide incident management support and advice. • Produce CCG reported incident reports as requested. • Identify trends, lessons learned and themes in incident reporting in order to identify any issues of concern for the CCG. • Provide training and assistance to the CCG in incident reporting and management in the SIRMS system. • Manage the administration of the SIRMS database. • Undertake an incident investigation in conjunction with CCG managers if required e.g. health and safety and IG incidents.
<p>North of England Commissioning Support (NECS) Information Governance Lead</p>	<p>NECS Information Governance Lead has the responsibility to:</p> <ul style="list-style-type: none"> • Provide information governance support to staff in the organisation. • Co-ordinate different areas of information governance and to ensure progress against key standards and requirements. • In collaboration with IT, develop, implement and monitor information security across the organisation. • Support the CCG in evidence collation, upload and publicise the IG Toolkit.

All Independent Contractors (e.g. GPs, Dental Practitioners, Optometrists and Pharmacists)	This policy is recommended to all independent contractors, where NHS services are commissioned by the CCG, for implementation appropriately and working across the health economy in learning and improving care for our patients and services.
All NHS provider organisations and Independent Healthcare Sector (IHS) providers	All NHS provider organisations and Independent Healthcare Sector providers providing NHS commissioned services are responsible for ensuring that their own SI policy reflects the reporting arrangements for NHS provider organisations and Independent Healthcare Sector organisations within this policy.

5. Implementation

- 5.1 This policy will be available to all staff for use in the circumstances described on the title page.
- 5.2 CCG directors and managers are responsible for ensuring that relevant staff within the CCG have read and understood this document and are competent to carry out their duties in accordance with the procedures described.
- 5.3 The implementation of the detail of this policy is aligned into the full roll-out, development and implementation of the incident module of the SIRMS across the CCG, NECS and their Council Members.
- 5.4 This policy is reviewed at regular intervals to ensure that the implementation of the processes contained in the policy are in line with the practical experience of users of the SIRMS.

6. Training Implications

- 6.1 The Sponsoring Director will ensure that the necessary training or education needs and methods required to implement the policy are identified and resourced or built into the delivery planning process. This may include identification of external training providers or development of an internal training process.
- 6.2 The level of training required in incident reporting and management varies depending on the level and responsibility of the individual employee.
- 6.3 The training required to comply with this policy is key to the successful implementation of the policy and embedding a culture of incident reporting and management in the organisation. Through a training and education programme, staff will have the opportunity to develop more detailed knowledge and appreciation of the role of incident reporting and management. Training and education will be offered through a rolling programme of incident reporting and management training.

7. Fair Blame

The CCG is committed to a policy of 'fair blame'. In particular formal disciplinary procedures will only be invoked following an incident where:

- there are repeat occurrences involving the same person where their actions are considered to contribute towards the incident
- there has been a failure to report an incident in which a member of staff was either involved or about which they were aware (failure to comply with organisation's policy and procedure)
- in line with the organisation and/or professional regulatory body, the action causing the incident is removed from acceptable practice or standards, or where
- there is proven malice or intent

Fair blame means that the organisation:

- operates its incident reporting policy in a culture of openness and transparency which fulfils the requirements for integrated governance
- adopts a systematic approach to an incident when it is reported and does not rush to judge or 'blame' without understanding the facts surrounding it
- encourages incident reporting in the spirit of wanting to learn from things that go wrong and improve services as a result

7.1 Support for staff, and others

When an incident is reported it can be a stressful time for anyone involved, whether they are members of staff, a patient directly involved or a witness to the incident. They all need to know that they are going to be treated fairly and that lessons will be learned and action taken to prevent the incident happening again.

7.2 A Just Culture Guide

In March 2018 NHS Improvement published 'A just culture guide' which replaced the NPSA incident decision tree. The fair treatment of staff supports a culture of fairness, openness and learning in the NHS by making staff feel confident to speak up when things go wrong, rather than fearing blame. Supporting staff to be open about mistakes allows valuable lessons to be learnt so the same errors can be prevented from being repeated. The guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely.

it asks a series of questions that help clarify whether there truly something is specific about an individual that needs support or management versus whether the issue is wider, in which case singling out the individual is often unfair and counter-productive. it helps reduce the role of unconscious bias when making

decisions and will help ensure all individuals are consistently treated equally and fairly no matter what their staff group, profession or background.

The guide should not be used routinely. It should only be used when there is already suspicion that a member of staff requires some support or management to work safely, or as part of an individual practitioner performance/case investigation. Remember, you have moved into individual practitioner performance investigation when it is suggested a single individual needs support to work safely (including training, supervision, reflective practice, or disciplinary action), as opposed to where a whole cohort of staff has been identified, which would be examined as part of a safety investigation. The guide does not replace the need for patient safety investigation and should not be used as a routine or integral part of a patient safety investigation. This is because the aim of those investigations is system learning and improvement. As a result, decisions on avoidability, blame, or the management of individual staff are excluded from safety investigations to limit the adverse effect this can have on opportunities for system learning and improvement.

8 Documentation

8.1 Other related policy documents

8.1.1 *Legislation and statutory requirements:*

- Serious Incident Framework (March 2015)
- Revised Never Events Policy and Framework (January 2018)
- Health and Social Care Information Centre; Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation

8.2 Best practice recommendations

Managing Safety Incidents in NHS Screening Programmes (2015)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/472611/Managing_Safety_Incidents_in_National_Screening_Programmes_gateway_291015.pdf

9. Monitoring, Review and Archiving

9.1 Monitoring

The Governing Body will agree a method for monitoring the dissemination and implementation of this policy. Monitoring information will be recorded in the policy database.

The Head of Quality and Patient Safety will ensure that each policy document is reviewed in accordance with the timescale specified at the time of approval. No policy or procedure will remain operational for a period exceeding three years without a review taking place.

9.2 Review

9.2.1 The Governing Body will ensure that this policy document is reviewed in accordance with the timescale specified at the time of approval. No policy or procedure will remain operational for a period exceeding three years without a review taking place.

9.2.2 Staff who become aware of any change which may affect a policy should advise their line manager as soon as possible. The governing body will then consider the need to review the policy or procedure outside of the agreed timescale for revision.

9.2.3 For ease of reference for reviewers or approval bodies, changes should be noted in the 'document history' table on the front page of this document.

NB: If the review consists of a change to an appendix or procedure document, approval may be given by the sponsor director and a revised document may be issued. Review to the main body of the policy must always follow the original approval process.

9.3 Archiving

The Governing Body will ensure that archived copies of superseded policy documents are retained in accordance with Records Management: NHS Code of Practice for Health and Social Care 2016.

10. Equality Analysis

Initial Screening Assessment (STEP 1)

As a public body organisation we need to ensure that all our current and proposed strategies, policies, services and functions, have given proper consideration to equality, diversity and inclusion, do not aid barriers to access or generate discrimination against any protected groups under the Equality Act 2010 (Age, Disability, Gender Reassignment, Pregnancy and Maternity, Race, Religion/Belief, Sex, Sexual Orientation, Marriage and Civil Partnership).

This screening determines relevance for all new and revised strategies, policies, projects, service reviews and functions.

Completed at the earliest opportunity it will help to determine:

- The relevance of proposals and decisions to equality, diversity, cohesion and integration.
- Whether or not equality and diversity is being/has already been considered for due regard to the Equality Act 2010 and the Public Sector Equality Duty (PSED).
- Whether or not it is necessary to carry out a full Equality Impact Assessment.

Name(s) and role(s) of person completing this assessment:

Name: Sandra Ross

Job Title: Senior Clinical Quality Officer

Organisation: North of England Commissioning Support Unit (NECS)

Title of the service/project or policy: Serious Incident Management Policy

Is this a;

Strategy / Policy X **Service Review** **Project**

Other N/a

What are the aim(s) and objectives of the service, project or policy:

This policy aims to ensure that the CCGs as Commissioners comply with current legislation as well as current national guidance, NHS England and requirements with regard to accident/incident reporting generally, but in particular reporting, notifying, managing and investigating SIs and NEs.

Who will the project/service /policy / decision impact?

(Consider the actual and potential impact)

- **Staff** x
- **Service User / Patients**
- **Other Public Sector Organisations**
- **Voluntary / Community groups / Trade Unions**
- **Others, please specify** [Click here to enter text.](#)

Questions	Yes	No
Could there be an existing or potential negative impact on any of the protected characteristic groups?	<input type="checkbox"/>	X
Has there been or likely to be any staff/patient/public concerns?	<input type="checkbox"/>	X
Could this piece of work affect how our services, commissioning or procurement activities are organised, provided, located and by whom?	<input type="checkbox"/>	X
Could this piece of work affect the workforce or employment practices?	<input type="checkbox"/>	X
Does the piece of work involve or have a negative impact on: <ul style="list-style-type: none"> Eliminating unlawful discrimination, victimisation and harassment Advancing quality of opportunity Fostering good relations between protected and non-protected groups in either the workforce or community 	<input type="checkbox"/>	X

If you have answered no to the above and conclude that there will not be a detrimental impact on any equality group caused by the proposed policy/project/service change, please state how you have reached that conclusion below:

No detrimental impact identified.

If you have answered yes to any of the above, please now complete the 'STEP 2 Equality Impact Assessment' document

Accessible Information Standard	Yes	No
Please acknowledge you have considered the requirements of the Accessible Information Standard when communicating with staff and patients. https://www.england.nhs.uk/wp-content/uploads/2017/10/accessible-info-standard-overview-2017-18.pdf	x	<input type="checkbox"/>
If any of the above have not been implemented, please state the reason: Not applicable.		

Governance, ownership and approval

Please state here who has approved the actions and outcomes of the screening		
Name	Job title	Date
Quality and Safety Committee	Approval	December 2015

Publishing

This screening document will act as evidence that due regard to the Equality Act 2010 and the Public Sector Equality Duty (PSED) has been given.

If you are not completing 'STEP 2 - Equality Impact Assessment' this screening document will need to be approved and published alongside your documentation.

Appendix 1

SERIOUS INCIDENT FRAMEWORK 2015/16 AND FREQUENTLY ASKED QUESTIONS

<http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framwrk-upd.pdf>

<http://www.england.nhs.uk/wp-content/uploads/2015/03/serious-incident-framwrk-15-16-faqs-fin.pdf>

[Revised Never Event Policy & Framework 2015/16, Never Events list & Frequently asked questions](#)

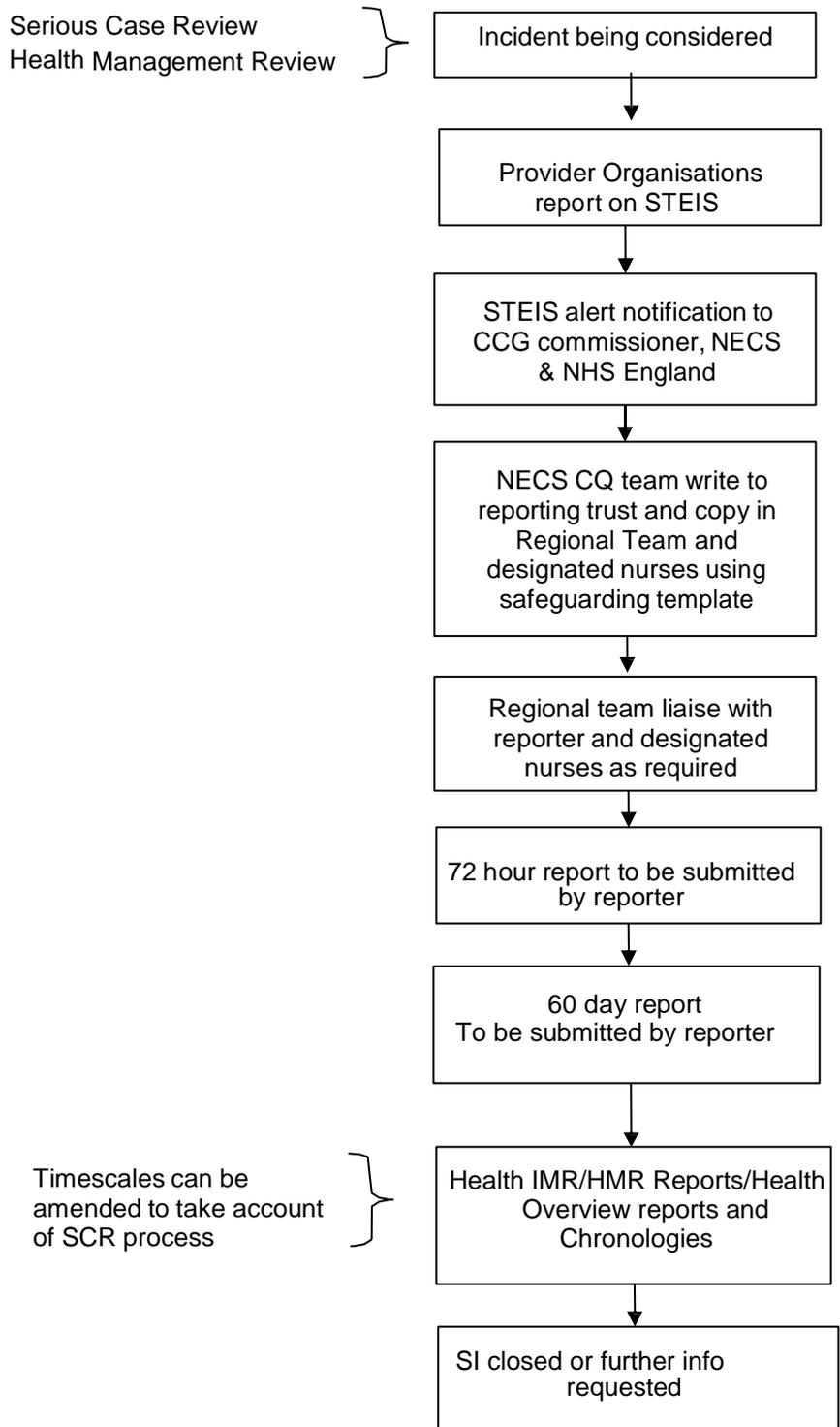
<https://www.england.nhs.uk/wp-content/uploads/2020/11/Revised-Never-Events-policy-and-framework-FINAL.pdf>

<https://www.england.nhs.uk/wp-content/uploads/2020/11/Never-Events-list-2018-FINAL-v7.pdf>

<https://www.england.nhs.uk/wp-content/uploads/2020/11/Recommendations-from-NPSA-alerts-that-remain-relevant-to-NEs-FINAL.pdf>

Appendix 2

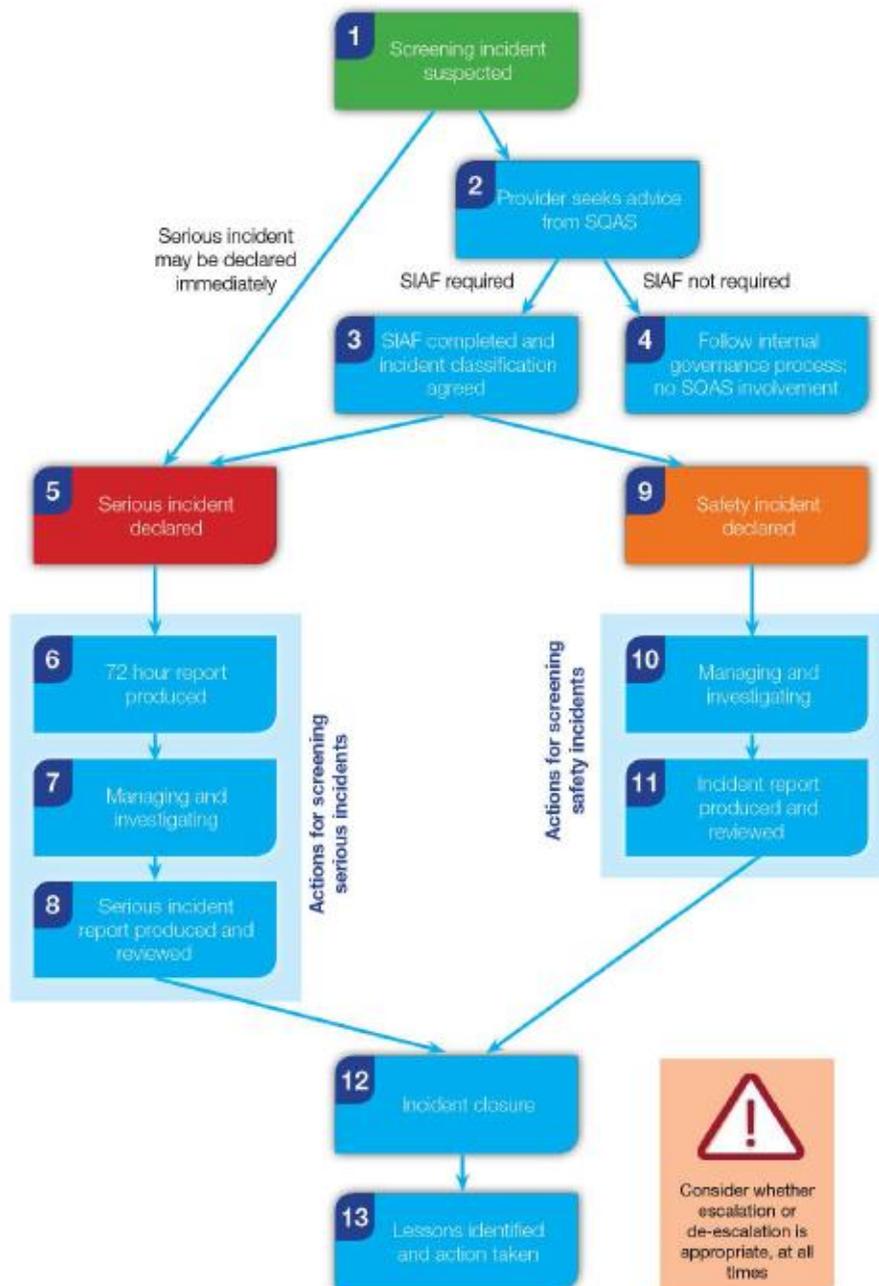
PROCEDURE FOR THE REPORTING AND MANAGEMENT OF SAFEGUARDING CHILDREN/ADULTS INCIDENTS



Appendix 3

REPORTING AND MANAGING SCREENING INCIDENTS

Further details on the management of incidents within the screening programme are available in [Managing Safety Incidents in NHS Screening Programmes](#)



Appendix 4

CHECKLIST GUIDANCE FOR REPORTING, MANAGING AND INVESTIGATING INFORMATION GOVERNANCE AND CYBER SECURITY SERIOUS INCIDENTS REQUIRING INVESTIGATION

It is essential that all Information Governance Serious Incidents Requiring Investigation (IG SIRIs) which occur in Health, Public Health and Adult Social Care services are reported appropriately and handled effectively.

The purpose of this guidance is to support Health, Public Health and Adult Social Care service commissioners, providers, suppliers and staff in ensuring that

- the management of SIRIs conforms to the processes and procedures set out for managing all Serious Incidents Requiring Investigation;
- there is a consistent approach to evaluating IG SIRIs and Cyber SIRIs;
- early reports of SIRIs are sufficient to decide appropriate escalation, notification and communication to interested parties;
- appropriate action is taken to prevent damage to patients, staff and the reputation of Healthcare, Public Health or Adult Social Care;
- all aspects of an SIRI are fully explored and 'lessons learned' are identified and communicated; and
- appropriate corrective action is taken to prevent recurrence in line with the open data transparency strategy.
- Caldicott 2 recommendations (accepted by the Government) are addressed.
- Transparent reporting of incidents
- Contractual obligations are adhered to with regards to managing, investigating and reporting SIRIs in a standardised and consistent manner, including reporting to Commissioners.

The checklist guidance should be embedded within local processes and procedures and the full guidance can be accessed at

<https://www.igt.hscic.gov.uk/resources/HSCIC-SIRIReportingandchecklistGuidance.pdf>

Appendix 5

EXAMPLE TEMPLATE

Guidance on Serious Incident Report and Action Plan

The report into Serious Incidents and the associated action plan should cover the following minimum information. Further work is under way with local organisations to develop and agree a common template

Report

- Introduction
- Constitution and investigation procedure
- Membership of the investigation team
- Terms of reference
- Background information
- Chronology
- Findings – to be identified against each of the terms of reference
- Conclusions
- Root cause(s)
- Lessons learnt
- Recommendations

Action Plan

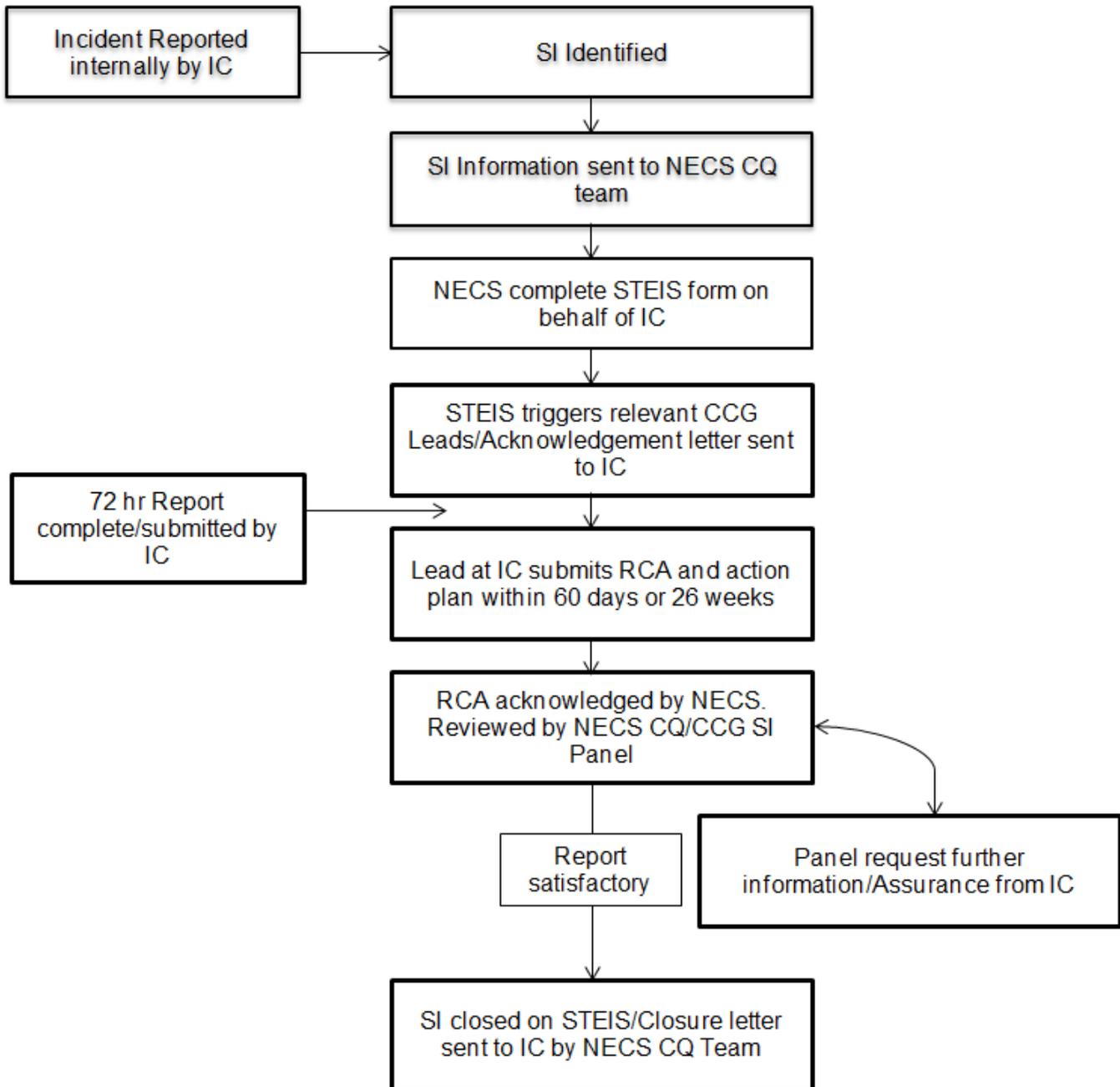
- Clearly set out which fall from the recommendations
- What needs to happen to achieve the outcome
- Identified title of who is responsible for the action
- Specific timescales on-going except where incorporated in to the Trust's everyday business for example the organisations annual programme of audit.

Root cause analysis tools to assist organisations in their investigations can be found at:

<http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/>

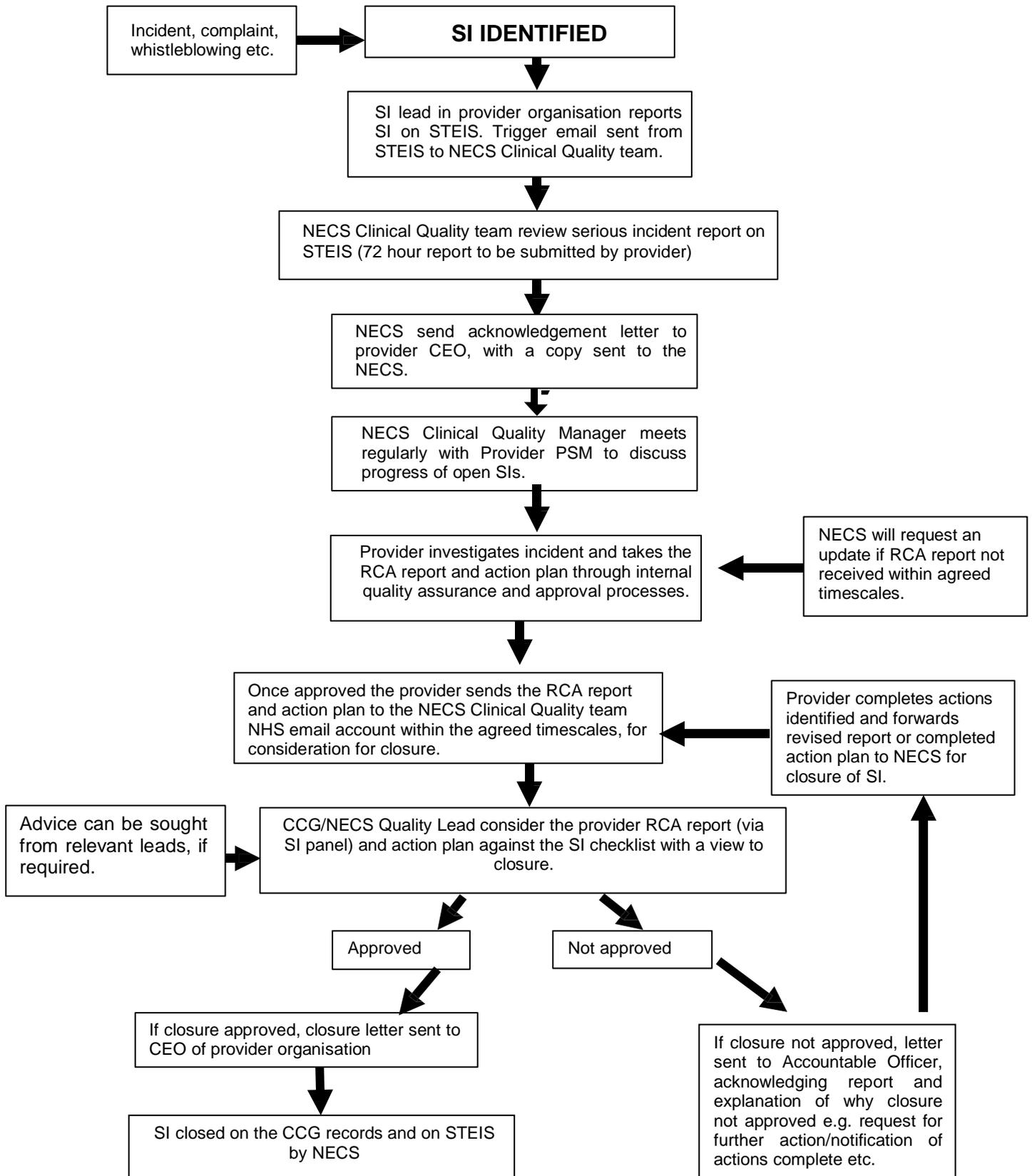
Appendix 6

PROCEDURE FOR THE REPORTING AND MANAGEMENT OF INDEPENDENT CONTACTOR/COMMISSIONED SERVICE SIs ONLY



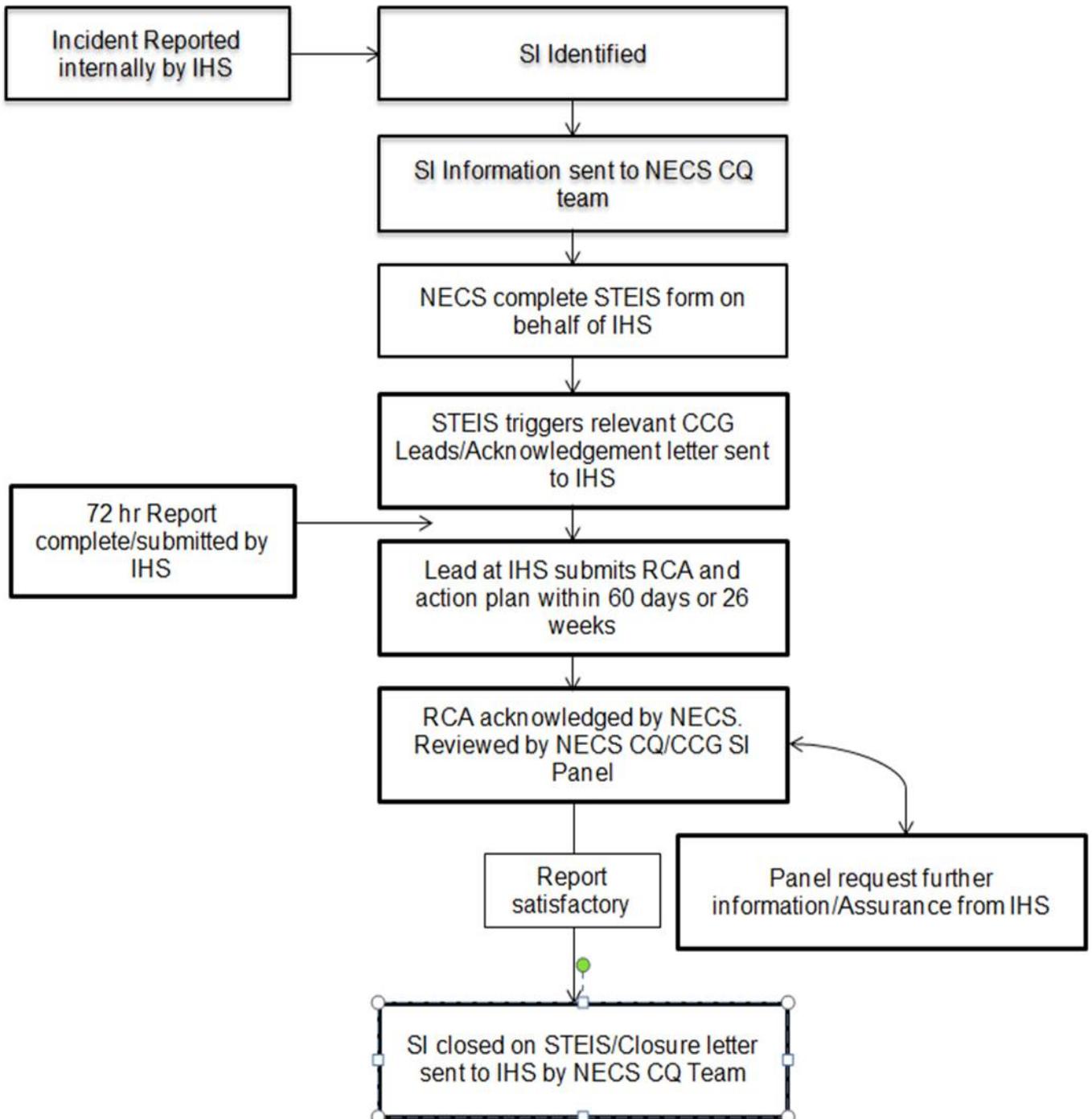
Appendix 7

PROCEDURE FOR THE REPORTING AND MANAGEMENT OF NHS PROVIDER SIs ONLY



Appendix 8

PROCEDURE FOR THE REPORTING AND MANAGEMENT OF SERIOUS INCIDENTS INDEPENDENT HEALTHCARE SECTOR (IHS) PROVIDERS



Appendix 9

NHS North Tyneside Clinical Commissioning Group

Serious Incident (SI) Closedown Panel - Terms of Reference

1. Introduction

The Serious Incident (SI) panel (the Panel) is established as a sub - committee of the Quality and Safety Committee of NHS North Tyneside Clinical Commissioning Group (NTCCG). This is in accordance with the Serious Incident Framework (March 2015) published by NHS England.

These terms of reference set out the membership, remit, responsibilities and reporting arrangements of the panel and shall have effect as if incorporated into the CCG constitution and standing orders.

2. Principal function

The Panel will provide assurance to the Quality and Safety Committee that the CCG has relevant mechanisms and governance processes in place to consider and monitor serious incident investigations. The panel will also provide assurance via regular thematic reviews undertaken to extract learning and support the development of organisational memory and continuous improvement with regard to patient safety in the CCG's commissioned services.

2.1 Links to Safeguarding

The Panel will escalate any identified children or adult safeguarding concerns, as appropriate, to local safeguarding boards/community safety partnership/arrangements for consideration as SCR/SAR/DHR. Feedback to the panel relating to safeguarding will be provided by the Head of Safeguarding: Designated Nurse Safeguarding Children.

3. Membership

The membership of the panel will consist of:

- NTCCG Director of Quality and Patient Safety (Chair)
- NTCCG Head of Safeguarding: Designated Nurse Safeguarding Children
- NTCCG Designated Nurse Looked After Children
- Trainee GP aligned to NTCCG
- North of England Commissioning Support representative(s)

There is an open invitation extended to:

- NTCCG Medical Director
- NTCCG Executive Director of Nursing & Chief Operating Officer

There is a standing invitation to all CCG Clinical Directors and provider organisation staff, to attend all or part of Panel meetings to provide advice or support particular discussion.

The Chair has responsibility to ensure that the Panel obtains appropriate advice in the exercising of its functions. At least two Panel members should be CCG representatives **and** clinically qualified.

4. Administrative and secretarial support

NECS will provide administrative and secretarial services to the Panel and shall ensure that notes of the meeting are taken and provide appropriate support to the Chair and Panel members.

5. Frequency of meetings

Meetings will be held the last Thursday of each month from 09.30 until 11.30 at NTCCG headquarters. Where a panel is stood down due to inability of members to attend, a lack of cases to consider or other reasonable circumstances, the Panel must meet the following month to ensure continuity of assurance.

In exceptional circumstances, and where agreed in advance by the Chair, members of the Panel or others invited to attend may participate in meetings by telephone, by the use of video conferencing facilities and/or webcam where such facilities are available. Participation in a meeting in any of these manners shall be deemed to constitute presence in person at the meeting.

If the number of serious incidents requiring review proves to be more than the Panel are able to consider within the time available, a virtual Panel may be convened.

6. Agendas and papers

The agenda for meetings of the committee will be agreed by the Panel Chair in consultation with the NECS representative.

The agenda and papers for meetings of the Panel will be distributed at least 5 working days in advance of the meeting. Items for the agenda should be notified to the Chair 10 days in advance of each meeting. The setting of agendas for, and minutes of, each meeting should identify where discussion should rightly be recorded as being of a confidential or commercially sensitive nature. Papers will be provided by the North of England Commissioning Support team.

7. Quorum and decision making

The quorum will be two CCG members both of who must be clinical and one member of NECS. Generally it is expected that decisions will be reached by consensus.

8. Remit and responsibilities of the Panel

The Panel will:

8.1 Make recommendations to the Quality and Safety Committee on the robustness of the process regarding the management of serious incidents reported.

8.2 Specifically, the duties and functions of the Panel is to provide advice and make recommendation to the Quality and Safety Committee on the appropriate actions the CCG should take regarding the reporting and management of serious incidents reported by the CCG's commissioned services, this includes:

- to ensure investigations into the root causes of serious incidents are of good quality underpinned by clear terms of reference;
- to ensure investigations demonstrate the application of robust investigative methodologies with resultant recommendations which link back to the findings;
- to continue to monitor incidents until the provider gives evidence that each action point has been implemented;
- recommend closure of incidents when they are satisfied with the investigation, recommendations and action plans that have been submitted;
- to ensure learning is embedded and demonstrated through regular thematic reviews;
- investigations are quality assured to ensure they are robust and that they demonstrate the use of recognised principles of investigation such as root cause analysis (RCA) or significant event audit (SEA).
- monitor providers compliance with national time-scales in relation to:
 - reporting serious incidents to the CCG and their recording on the StEIS incident reporting system
 - the submission of investigation reports

The panel will inform the Quality and Safety Committee of significant non-compliance and action taken to address the problem.

The Panel will also advise and make recommendation to the Quality and Safety Committee regarding trends and themes arising from the reporting of serious incidents.

9. Reporting arrangements

The Panel reports to the CCG's Quality and Safety Committee. The Panel will provide a quarterly SI report to the Quality and Safety Committee, as well as minutes of the meetings and updates on closure of SIs and lessons learned via the Integrated Governance report. The Quality and Safety Committee will hold the Panel to account for the delivery of its remit and responsibilities.

10. Policy and best practice

The Panel will apply best practice in its decision making, and in particular it will:

- comply with the Serious Incident Framework (March 2015) NHS England;
- seek independent advice where appropriate to ensure equity and fairness;
- ensure that decisions are based on clear and transparent criteria

- comply with the CCG's policy and procedures for the declaration of interests

The Panel will have full authority to commission any reports or surveys it deems necessary to help it fulfil its obligations.

11. Conduct of the Panel

All members of the panel and participants in its meetings will comply with the Standards of Business Conduct for NHS Staff, the NHS Code of Conduct, NHS Code of Confidentiality and the CCG's Policy on Standards of Business Conduct and Declarations of Interest which incorporate the Nolan Principles.

12. Date of review

The Panel will review its performance, membership and these terms of reference at least once per financial year. It will make recommendations for any resulting changes to these terms of reference to the Quality and Safety Committee for approval.

No changes to these Terms of Reference will be effective unless and until they are approved by the Quality and Safety Committee.

Approved by Quality & Safety Committee:	3 October 2017
Approved by Quality & Safety Committee:	2 October 2018
Approved by Quality & Safety Committee:	4 June 2019
Approved by Quality & Safety Committee:	14 January 2020
Approved by Quality & Safety Committee:	1 September 2020

Review Due September 2023 NTGB(P)/19/179 (Oct 2019)

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this just culture guide, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- A just culture guide is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- A just culture guide can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- A just culture guide does not replace HR advice and should be used in conjunction with organisational policy.
- The guide can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - Q1. deliberate harm test

1a. Was there any intention to cause harm?

Yes

Recommendation: Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual.

END HERE

No go to next question - Q2. health test

2a. Are there indications of substance abuse?

Yes

Recommendation: Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier.

END HERE

2b. Are there indications of physical ill health?

Yes

Recommendation: Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier.

END HERE

2c. Are there indications of mental ill health?

Yes

Recommendation: Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier.

END HERE

If No to all go to next question - Q3. foresight test

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

If No to any

Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

END HERE

If Yes to all go to next question - Q4. substitution test

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?

If Yes to any

Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

END HERE

If No to all go to next question - Q5. mitigating circumstances

5a. Were there any significant mitigating circumstances?

Yes

Recommendation: Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

END HERE

If No

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

END HERE

improvement.nhs.uk

Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

Supported by:



NHS England and NHS Improvement

