Northern, Eastern and Western Devon Clinical Commissioning Group

Serious Incident Requiring Investigation Policy

Author(s): Leanne Dowds, Senior Complaints & Risk Manager	**Contact Details:** Leanne.dowds@nhs.net	
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Document Change History:		
Version	**Date**	**Comments (i.e. reviewed/amended/approved)**
V1.2	05/08/2015	18.7 added to the policy, agreed by SIRO Lead
V1.3	06/08/2015	Executive summary added. Appendix A (MOU) removed 24.2 added to the policy
V1.4	18/02/2016	Appendix A up-dated and included Reviewed and approved at Executive Committee
V1.5	12/04/2016	Appendix C - Duty of Candour: • Introduction changed to include the details and the date of the Health & Social Care Act and that it is a statutory requirement. • Author Sue Moreton removed • Date removed • Review date of approved documents changed (2 years from approved)
V1.6	04/05/2016	Paragraph added (1.4) to include new statutory patient safety function.
V1.7	29/03/2018	• Amended – Included front pages, Policy information, document change history and information regarding quality, diversity and human rights. • Amended introduction, removal of changes from new framework published in 2015 • Amended review date • Section 11 Amended with reference to the new never event guidance • Section 11 amended to make reference to 'extension agreed' rather than 'stop the clock' • Section 15 amended to make reference to initial

		report rather than 72 hour report • Removal of appendixes

NHS Northern, Eastern and Western Devon Clinical Commissioning Group (NEW Devon CCG) promote equality, diversity and human rights and is committed to ensuring that all people and communities it serves have access to the services we provide. In exercising the duty to address health inequalities, the CCG has made every effort to ensure this policy does not discriminate, directly or indirectly, against patients, employees, contractors or visitors sharing protected characteristics of: age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion and belief; sex (gender); sexual orientation or those protected under the Health and Social Care Act 2012 and Human Rights legislation.

All CCG policies can be provided in large print or Braille formats; translations on request; language line interpreter services are available; and website users can use contrast, text sizing and audio tools if required. For any other assistance, please contact the CCG at on 01392 205205.

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1. Introduction

1.1 The purpose of this policy is to provide a consistent interpretation of the 2015 NHS England Serious Incident Framework (SIF), ensuring the management of Serious Incidents Requiring Investigation (SIRI) is clearly defined, embedded and understood by all organisations commissioned by the NHS Northern, Eastern & Western Devon Clinical Commissioning Group to provide NHS funded care.

1.2 The 2015 NHS England Serious Incident Framework builds on and replaces the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation issued by the National Patient Safety Agency (NPSA, March 2010) and NHS England's Serious Incident Framework (March 2013). The revised framework became effective from 01 April 2015.

1.3 It replaces the NPSA Independent investigation of serious patient safety incidents in mental health services, Good Practice Guide (2008).

1.4 This policy outlines the process and procedures to ensure that SIRI are identified correctly, investigated thoroughly and, most importantly, learned from to prevent the likelihood of similar incidents happening again.

1.5 This policy is designed to inform staff providing and commissioning NHS funded services in England who may be involved in identifying, investigating or managing a serious incident. It is relevant to all NHS-funded care in the primary, community, secondary and tertiary sectors including private sector organisations providing NHS-funded services.

1.6 This policy does not replace the duty of all registered organisations to report serious incidents to the Care Quality Commission (CQC).

2. Information governance

2.1 Organisations must comply with the Data Protection Act, Caldicott principles and information governance requirements when sharing information relating to a SIRI. Any information governance breach or incident in relation to patient safety and quality will also be reported in line with our information governance policies and requirements by Health & Social Care Information Centre (HSCIC).

2.2 There should be no person identifiable information within the information shared. Reports should be anonymised using only initials where appropriate when referring to individuals.

2.3 Other regulatory, statutory, advisory and professional bodies should be informed about serious incidents depending on the nature and circumstances of the incident and reports must clearly state that relevant bodies have been informed.

2.4 In some circumstances, where a SIRI or multiple SIRI raises profound concerns about the quality of care being provided, organisations should consider calling a risk summit, which provides a mechanism for key stakeholders in the health economy to come together to collectively share and review information.

2.5 All serious incidents which meet the definition for a patient safety incident should also be reported by the provider separately to the NRLS for national learning.

3. Application of the SIRI policy

3.1 This policy applies to serious incidents which occur in all services providing NHS funded care, including independent providers where NHS funded services are delivered.

3.2 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 policy. Where this is the case it is the responsibility of the provider to liaise with the Safety Systems Team to identify where there are gaps in resources, capacity, accessibility and expertise.

3.3 Whilst the Safety Systems Team may offer support, 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.

3.4 The primary responsibility in relation to serious incidents sits with the provider of the care to the people who are affected and/or their families/careers. The key organisational accountability for serious incident management sits with 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.

4. Management of the SIRI process

4.1 The accountability and responsibility for Serious Incidents Requiring Investigation sits with the NEW Devon CCG Chief Nursing Officer, Nursing and Quality Directorate. The NEW Devon CCG Safety Systems Team will manage and monitor the SIRI process on behalf of the NEW Devon CCG.

4.2 The Safety Systems Team is responsible for the receipt of notification from the Strategic Executive Information System (StEIS), the national database used to report all Serious Incidents, StEIS notifications, serious incident reports from providers and all enquiries and communication relating to the SIRI process.

4.3 The NEW Devon CCG has identified leads within the Patient Safety and Quality and Safeguarding Teams to support the SIRI process at a locality level, liaising closely with providers and the Safety Systems Team.

4.4 If 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.

4.5 All organisations and agencies involved should work together to undertake one single investigation wherever this is possible and appropriate. A [1]memorandum of understanding (MOU) is being agreed to support this process.

4.6 The Safety Systems Team within the NEW Devon CCG will facilitate discussions relating to who is the most appropriate organisation to take responsibility for co-ordinating the investigation process.

4.7 The Safety Systems Team within the NEW Devon CCG will provide support in complex circumstances where no one provider organisation is best placed to assume responsibility for co-ordinating an investigation.

5. Duty of Candour

5.1 The Duty of Candour is now a statutory requirement for all organisations since from the 01 April 2015 and is included in the NHS Standard Contract 2014/15 Service conditions, SC35 Duty of Candour page 33 to 35, it applies to all reportable Patient Safety incidents that occur or are suspected to have occurred.

5.2 The CQC has put in place a requirement for healthcare providers to be open with patients and apologise when things go wrong. This duty applies to all registered providers of both NHS and independent healthcare bodies, as well as providers of social care from 01 April 2015. The organisational duty of candour does not apply to individuals, but organisations providing healthcare will be expected to implement the new duty throughout their organisation by making sure that staff understand the duty and are appropriately trained.

5.3 Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 intends to make sure that providers are open and transparent in relation to care and treatment with people who use their services. It also sets out some specific requirements that providers must follow when things go wrong with care or treatment, including informing people about the incident, providing reasonable support, giving truthful information and apologizing when things go wrong. The CQC can prosecute for a breach of parts 20(2)a and 20(3) of this regulation.

5.4 The NEW Devon CCG will seek assurance from its providers that the Duty of Candour is being applied, and will expect this to be demonstrated in the final investigation report as part of the criteria before agreeing to close an incident on StEIS.

5.5 There is a requirement for all organisations to complete the Duty of Candour section within StEIS when reporting a serious incident, detailing what steps have been taken to include, inform and support those affected by the serious incident. It is also expected that all Root Cause Analysis (RCA) reports demonstrate that the Duty of Candour has been applied. The NEW Devon CCG has provided guidance on Duty of Candour, which is available if requested.

[1] https://www.newdevonccg.nhs.uk/information-for-patients/serious-incidents-100161

6. Providers of NHS funded care

6.1 The executive leadership within a provider organisation is ultimately responsible for the quality of care that is provided by that organisation. Serious incident management is a critical component of corporate and clinical governance, and providers are responsible for arranging and resourcing investigations and must ensure robust systems are in place for recognising, reporting, investigating and responding to serious incidents. The principles and processes associated with robust serious incident management must be endorsed within an organisation's Incident Reporting and Management Policy or similar titled policy.

7. Non NHS providers of NHS funded care

7.1 Smaller organisations that are not NHS organisations are expected to comply with this and other related policies and that all serious incidents, even those not directly attributed to NHS funded patients, are reported to the CCG as outlined in this policy.

7.2 In the case of non NHS funded patient incidents, agreement will be reached with the Chief Nursing Officer as to the level of investigation and reporting.

8. Commissioners of NHS funded care

8.1 The NEW Devon CCG must provide assurance of the quality of services they have commissioned, and should hold providers to account for their responses to serious incidents. This means the CCG will quality assure the robustness of their providers' serious incident investigations and the action plan implementation undertaken by their providers. This will be enabled 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.

8.2 It is expected that the NEW Devon CCG will 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.

9. SIRI communication

9.1 Communication for serious incidents between reporting organisations and the NEW Devon CCG will be carried out initially by the Safety Systems Team and Chief Nursing Officer on behalf of the NEW Devon CCG.

9.2 The Safety Systems Team will be the main contact for all communication in relation to:

- Initial cascade of information following a StEIS notification of an incident being raised.

- Requests for information.
    - Submission of completed reports;
    - Communication regarding the NEW Devon CCG SIRI review process;
    - Request for further information following review of an incident;
    - Receipt of Rule 28 letter and response letters;
    - Update of information to reporting organisations;
    - Closure of serious incidents;

9.3 Communication may be escalated through the Chief Nursing Officer or a designated deputy.

9.4 Any concerns, including extended delays in provider reporting and completion of serious incidents will be escalated formally through the provider Quality and Performance meetings as necessary.

10. SIRI definitions

10.1 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.

10.2 In broad terms, serious incidents are events in healthcare 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.

10.3 Serious Incidents include acts or omissions in care that result in;

- Unexpected or avoidable death;
- Unexpected or avoidable injury resulting in serious harm;
    - including those where the injury required treatment to prevent death or serious harm;
- Abuse;
- Never Events;
- Incidents that prevent (or threaten to prevent) an organisation's ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in healthcare services;

10.4 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;

10.5 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.

10.6 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.

10.7 Investigations carried out under this policy are conducted for the purposes of learning to prevent recurrence. They are not inquiries into how a person died (where applicable) as this is a matter for Coroners.

10.8 Where it is not clear whether or not an incident fulfils the definition of a serious incident the provider should seek timely clarification from the Safety Systems Team.

11. Never events

11.1 Never Events are defined as serious incidents that can be prevented as guidance or safety recommendations are provided at a national level of which should be implemented by all healthcare providers. See Never Events Policy and Framework for the national definition and further information;[2]

11.2 It is expected that Never Events or potential Never Event declarations will be made verbally and followed up by email to the Chief Nursing Officer or their Deputy in their absence and confirmed via StEIS within 48 hours after the incident has been identified.

11.3 Any delays in the notification to the NEW Devon CCG will need to be explained by the Provider and with clear justification. If an incident occurs out of hours, the NEW Devon CCG on-call Director will be informed verbally and confirmation in writing provided, copied to the Chief Nursing Officer.

12. Reporting a SIRI

12.1 Serious incidents must be reported by the provider to the commissioner without delay and no later than 2 working days after a serious incident is identified.

12.2 Incidents falling into any of the serious incident categories listed below should be reported immediately on identification to the NEW Devon CCG. This should be done by telephone as well as electronically:

- Never Events or potential Never Events;
- Incidents which activate the NHS Trust or Commissioner Major Incident Plan;
- Incidents which will be of significant public concern;
- Incidents which will give rise to significant media interest or will be of significance to other agencies such as the police or other external agencies;
- Incidents that may cause serious disruption in services;

[2] Never Events arise from failure of strong systemic protective barriers which can be defined as successful, reliable and comprehensive safeguards or remedies e.g. a uniquely designed connector to prevent administration of a medicine via the incorrect route - for which the importance, rationale and good practice use should be known to, fully understood by, and robustly sustained throughout the system from suppliers, procurers, requisitioners, training units, and front line staff alike. See the Never Events Policy and Framework available online at: https://improvement.nhs.uk/resources/never-events-policy-and-framework/

12.3 It is expected that for such incident declarations will be made verbally and followed up by email to the Chief Nursing Officer or their Deputy in their absence and confirmed via StEIS within 48 hours after the incident has occurred.

12.4 Any delays in the notification to the NEW Devon CCG will need to be explained by the Provider and with clear justification. If an incident occurs out of hours, the NEW Devon CCG on-call Director will be informed verbally and confirmation in writing provided, copied to the Chief Nursing Officer.

12.5 Reporting a serious incident must be done by recording the incident on StEIS, ensuring the form does not contain any patient or staff identifiable information.

12.6 This will include immediate actions taken outlining consideration of safeguarding to provide assurance to the NEW Devon CCG that actions are in place to mitigate recurrence and to identify any safeguarding actions taken. Where full details are not completed the NEW Devon CCG may ask for further information to be submitted to ensure the safety of the individuals affected.

12.7 The organisation where the incident occurred has overall responsibility for the investigation of the incident including the final RCA report, the immediate dissemination of learning and implementation of subsequent action plans.

12.8 Where the NEW Devon CCG is an associate Commissioner, there may be responsibility for co-reviewing the SIRI.

12.9 Where a serious incident relates to a patient who is undergoing treatment that is commissioned by the NHS Southwest Specialist Commissioning Group (SCG), both the SCG and the NEW Devon CCG will be notified of the incident by the provider through StEIS. Reports will then be received by both organisations to review, to advise and to make comment as appropriate.

12.10 If it is identified that the serious incident does not meet the threshold for reporting onto StEIS then the incident can be removed. A request with a clear explanation of why the incident does not meet the threshold and a copy of the initial investigation should be submitted to the Safety Systems Team. The request will then be reviewed and a decision made by the Chief Nursing Officer.

13. Providers without access to StEIS

13.1 The Serious Incident Policy remains the same for Providers without direct access to StEIS and the Safety Systems Team will coordinate the reporting and uploading functions to StEIS on their behalf. Providers must ensure all information shared with the Safety Systems Team is via secure means.

13.2 The Provider retains responsibility for investigating and reporting serious incidents.

13.3 For Providers of Social Care where people will have health need e.g. residential homes, community providers will add the incident to StEIS with the original provider undertake the investigation.

13.4 For providers of nursing care where people are in receipt of health funding including:
- Funded Nursing Care;
- NHS Continuing Health Care;
- Section 117.

13.5 The Safety Systems team will add the incident to StEIS.

14. Agreeing the level/type of investigation

14.1 All incidents meeting the threshold of a serious incident must be investigated and reviewed according to principles set out in the Framework.

14.2 The nature, severity and complexity of serious incidents vary on a case-by-case basis and therefore the level of response should be dependent on and proportionate to the circumstances of each specific incident.

14.3 The appropriate level of investigation should be proposed by the provider as informed by the initial review. Incidents graded as Level 1 and 2 require the investigation and final report to be submitted to the NEW Devon CCG within 60 working days. Level 3 incidents, will require an independent investigation and have 6 months from the date the investigation is commissioned.

- **Level 1 - Concise internal investigation**
  - Suited to less complex incidents which can be managed by individuals or a small group 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 where applicable

- **Level 3 - Independent investigation**
  - Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved

14.4 The investigations team and, where applicable, other stakeholders will use the information obtained through the initial review to inform the level of investigation and the level of investigation may need to be reviewed and changed as new information or evidence emerges as part of the investigation process.

14.5 If it is identified that an incident does not meet the SIRI reporting criteria, the incident can be removed from StEIS. A request in writing via email to the Safety Systems Team is required setting out the reasons for deletion, this will then be forwarded to the executive lead for serious incidents.

15. Follow up information (initial report)

15.1 An initial report should be undertaken and submitted to the NEW Devon CCG within 3 working days of the incident being identified.
The aim of the initial review is to:

- Identify and provide assurance that any necessary immediate action to ensure the safety of staff, patients and the public is in place;
- Assess the incident in more detail (and to confirm if the incident does still meet the criteria for a serious incident and does therefore require a full investigation); and
- Propose the appropriate level of investigation;

15.2 The information submitted as part of the initial review should be reviewed by the appropriate stakeholders and the investigation team (once in operation) in order to inform the subsequent investigation.

15.3 The reporting organisation should ensure the initial report is provided within 3 working days to the Safety Systems Team.

16. Alerting the system: Escalation and information sharing

16.1 Where a serious incident indicates an issue/problem that has (or may have) significant implications for the wider healthcare system, or where an incident may cause widespread public concern, the relevant commissioner (i.e. lead commissioner receiving the initial notification) must consider the need to share information throughout the system i.e. with NHS England Sub-regions and Regions and other partner agencies as required and under the guidance of the Caldicott Guardian.

16.2 This is a judgement call depending on the nature of the incident, although the scale of the incident and likelihood of national media attention will be a significant factor in deciding to share information.

17. SIRI identified as 'extension agreed'

17.1 Reporting organisations may experience a delay to the investigation that is beyond their control and in these circumstances they can request an 'extension' to be allocated by the CCG. This will be agreed on incidents where the investigation cannot continue or is likely to be delayed due to other ongoing investigations

17.2 Where an incident has had an 'extension' agreed, where possible (with exception of ongoing police investigations and Children's death overview panel) the investigation should continue to ensure lessons learnt and actions are implemented in a timely way with the expectation that the report submission may be delayed.

17.3 Incidents that involve a death or that have been agreed as an 'extension agreed' should continue to be investigated where possible and the investigation report submitted within the usual timeframe. The incident will be noted as 'extension

agreed' on StEIS until the outcome of, for example, the coroner's inquest, is known. Once the reporting organisation is informed of the Coroners verdict, this should be forwarded to the NEW Devon CCG allowing for the incident to be reviewed with the new information and closed on StEIS in the usual way. Following closure further monitoring of actions may need to take place.

17.4 All requests for 'extensions' must be made in writing via email to the Safety Systems Team with either the initial report or the completed RCA investigation report.

17.5 It is expected that incidents allocated with an 'extension' status will continue to be monitored by the reporting organisation and updates provided to NEW Devon CCG on a regular basis. (Every 5 weeks).

17.6 When a SIRI has an agreed 'extension agreed' it is important that any immediately identified actions, (including those recorded on the initial report) are implemented in line with the agreed timescales, to ensure mitigation of any further risk to individuals.

17.7 The NEW Devon CCG may ask for assurance that immediate actions have been implemented. (With the exception of incidents where taking further action may compromise external investigations such as criminal enquiry).

18. Final RCA report

18.1 The reporting organisation's investigation will be undertaken using best practice methodologies such as RCA reporting. Adopting a standardised style and approach will enable both the reporting organisation and the reviewer to more easily assess the quality and robustness of the report and extract themes and trends for future learning.

18.2 The report should:

- Be fully anonymised;
- Have an executive summary, index and contents page and clear headings;
- Contain an Action Plan;
- Include the title of the document and state whether it is a draft or the final version;
- Disclose only relevant confidential personal information for which consent has been obtained, or if patient confidentiality should be overridden in the public interest. This should however be considered by the Caldicott Guardian and where required confirmed by legal advice;
- Include evidence and details of the methodology used for an investigation (for example timelines/cause and effect charts, brainstorming/brain writing, nominal group technique, use of a contributory factor framework and fishbone diagrams, five whys and barrier analysis);
- Identify root causes and recommendations;
- Ensure that conclusions are evidenced and reasoned, and that recommendations are implementable;
- Include a description of how patients/victims and families have been engaged in the process and how the duty of candour has been applied;
- Include a description of the support provided to patients/victims/families and staff following the incident.

18.3 All organisations have a responsibility to ensure that staffs are treated fairly and with consistency. Where a serious incident raises concerns in relation to individual staff culpability or competence, these concerns should be managed in accordance with local Human Resources (HR) procedures.

18.4 Where an incident involves more than one organisation the investigation will involve representatives from all organisations involved in the pathway e.g. the ambulance service, primary or acute care, children's services, mental health providers, out of hour's services and care homes.

18.5 The NEW Devon CCG will only lead an investigation by exception or where the SIRI is deemed to be extremely complex.

18.6 Once a satisfactory final report and time-bound action plan has been received and all relevant entries on StEIS have been completed by the provider, the incident will be reviewed independently by two designated clinical reviewers in the NEW Devon CCG to ensure all assurance has been received that mitigated risk of reoccurrence of the incident.

18.7 When it is deemed that there is [3]confidential information that is relevant to the final RCA report, then the report must be restricted to those with specific authority to view the data i.e. only an employee with a legitimate business/clinical need to review the information will be permitted to see it.

18.8 Once the NEW Devon CCG has agreed to closure the incident will be closed on StEIS by the NEW Devon CCG or NHS England for incidents raised by the NEW Devon CCG.

18.9 On completion of the RCA investigation, the reporting organisation will also update StEIS with root causes and lessons learnt in the respective fields on the StEIS form.

19. Closure of SIRI

19.1 Closure of SIRI will take place once two clinical reviewers have independently reviewed the final reports and action plans and both parties are in agreement that the information submitted by the providers is complete. Specifically that the remedial actions to be taken will eliminate or minimise recurrence of the incident.

19.2 The review process will ensure that sufficient assurance has been given by the provider in relation to the investigation; that there is clear identification of root causes and lessons learned including recommendations and actions to be taken.

19.3 Where an agreement between reviewers cannot be made regarding closure or where the SIRI is deemed very complex, a third reviewer will be nominated to mediate.

[3] Further details on confidential information is within NEW Devon CCG Information Security Policy and the NHS NEW Devon CCG – Code of confidentiality policy

19.4 All reviews of SIRI reports should be completed within 10 working days ensuring that feedback can be given to the provider within the outlined 20 working days.

19.5 A request to the provider will be made if further assurance is required, of which the provider is asked to respond with the additional information within 5 working days of receiving the request.

19.6 Closure will be agreed by all organisations before confirmation is given to the reporting organisation. The incident will then be closed on StEIS. SIRIs may be closed before all actions detailed in the action plan are completed provided that assurance is received of implementation and on-going monitoring.

19.7 The exception to this is any incidents where a Level 3 investigation has taken place. In these cases, the NEW Devon CCG and the Area Team will continue to monitor the action plan and only close the incident once assurance has been received that all action points have been completed.

19.8 Where a patient lives within the geographical area of another CCG, the final RCA report will be shared by the lead commissioner allowing for comments to be made prior to closure of the serious incident. This will ensure that each CCG is sighted on outcomes for patients within their CCG populations. This will be relevant for all commissioned organisations including care homes, NHS providers and independent providers.

19.9 For SIRIs that are reported by the NEW Devon CCG the investigation process will be the same as for the providers and will be reported to NHS England who will monitor the process and agree when the SIRI can be closed.

20. Action plan

20.1 NHS England recommends use of the NPSA Action Plan template, however the minimum requirements for an action plan include the following:

- Action plans must be formulated by those who have responsibility for implementation, delivery and financial aspects of any actions (not an investigator who has nothing to do with the service although clearly their recommendations must inform the action plan);

- Every recommendation must have a clearly articulated action or actions that follow logically from the findings of the investigation;

- Actions should be designed and targeted to significantly reduce the risk of recurrence of the incident. It must target the weaknesses in the system (i.e. the 'root causes' /most significant influencing factors) which resulted in the lapses/acts/omissions in care and treatment identified as causing or contributing towards the incident;

- A responsible person (job title only) must be identified for implementation of each action point;

- There are clear deadlines for completion of actions;
- There must be a description of the form of evidence that will be available to confirm completion and also to demonstrate the impact implementation has had on reducing the risk of recurrence;

20.2 A SMART approach to action planning is essential. That is, the actions should be: Specific, Measurable, Attainable, Relevant and Time-bound.

20.3 To ensure that the most effective actions/solutions are taken forward, it is recommended that an option appraisal of the potential actions/solutions is undertaken before the final action plan is developed and agreed

21. Assurance of action plans

21.1 It is the responsibility of the NEW Devon CCG to be assured that all actions plans are completed within the timeframes set within the investigation report, with any persistent delays in completing actions being escalated and formally noted by the commissioner to the relevant provider Quality and Performance meeting.

21.2 Once the incident has been closed on STEIS, the Safety Systems Team will extract the details of the action plan for assurance purposes. Assurance and evidence that the actions have been completed will be sought from the provider. This evidence will be noted against the action plan and progress or completion noted. Assurance may also be sought to demonstrate that following completion of actions, the learning is embedded with the practice of the provider organisation.

21.3 For Incidents where STC has been agreed the provisional action plan will be used to provide assurance for those actions that can be carried out while the clock is paused.

21.4 The CCG will not hold the evidence provided; however assurance will be noted on the action plan follow up system by the Patient Safety and Quality Team.

22. Dissemination of learning

22.1 The NEW Devon CCG has a responsibility to ensure that when a serious incident occurs, there are systematic measures in place for safeguarding individuals, property, NHS resources and reputation, for understanding why the event occurred and ultimately to ensure steps are taken to reduce the chance of a similar incident happening again.

22.2 Provider organisations will have systems in place to ensure that learning is disseminated within their organisation and to consider who, outside of the immediate incident and organisation, may benefit from the learning arising from the investigation report.

22.3 The NEW Devon CCG will ensure that it has processes in place to share learning from all serious incidents across commissioned organisations within the local area and nationally where appropriate.

23. Safeguarding adults and children

23.1 There will be instances of SIRI reportable incidents meeting the thresholds of a Section 42 Safeguarding Enquiry under the Care Act 2014; where a Local Authority will require the NEW Devon CCG to undertake an enquiry to determine if an adult at risk with care and support needs is experiencing or is at risk of abuse occurring within an NHS provider service.

23.2 Safeguarding Adults incorporates measures to reduce the likelihood of abuse and neglect occurring as well as ensuring effective systems are in place to protect 'adults at risk' where abuse and neglect has occurred or is suspected to have occurred.

23.3 The Safeguarding Team has identified leads within the Safeguarding Children's and Adults Team to support the SIRI process; liaising closely with Local Authorities, providers and the Safety Systems Team.

23.4 The Safeguarding Team are always available for advice and guidance to all staff within the New Devon CCG including Commissioners, Contract Managers, Patient advice and Liaison Teams as well as the Safety Systems Team when clarity is needed regarding any SIRIs where a safeguarding concern is unclear or equally if a safeguarding concern is likely to require reporting on STEIS.

23.5 Where the Safeguarding Team has identified that a safeguarding alert is likely to meet the threshold for a SIRI; the team will inform the provider that they should consider raising a SIRI on STEIS and the Safeguarding Team will escalatethe incident to the Chief Nursing Officer and the Safety Systems Team.

23.6 Any incidents where abuse of children or adults is suspected the Safety Systems Team will inform the team immediately who will advise if a referral is needed to the local Authority via the Multi Agency Safeguarding Hub (MASH) for children or direct to the Local Authority for Adults.

23.7 The 72 Hour report will then be shared with the Safeguarding Team for an opinion, who will ensure an adequate safeguarding protection plan is in place.

23.8 Where a SIRI case also meets the threshold for a safeguarding enquiry the SIRI investigation will also form the section 42 enquiry. There is no requirement to undertake a separate investigation.

23.9 The same 60 day threshold will apply except where a STC is required. Where a SIRI/safeguarding enquiry is a police led investigation this will always take precedence.

23.10 The provider will not be able to commence the SIRI investigation until the police deem this appropriate. A request for a STC will be made to the Chief Nursing Officer by the provider and supported by the Safeguarding Team.

23.11 In these cases the Safeguarding Team will ensure the Safety Systems Team is kept up to date with the progress of the enquiry with a removal of STC as soon as possible. The Safeguarding Team will respond to a request from the Safety Systems Team to review any SIRI's/safeguarding incidents providing their view in line with the policy.

23.12 For further information regarding Safeguarding please refer to the Safeguarding Children's and Adult's Policy.

24. SIRI analysis and feedback

24.1 Quarterly reports will be included in the Quality report which is submitted to Quality Committee to include Data on open and closed Serious Incidents, Key Performance Indicators of the review process and trend analysis of Serious Incidents reported by Providers.

24.2 NEW Devon CCG will meet every quarter to review a selection of serious incidents. Within SIRI Panel, a deep dive analysis will be undertaken to review the decisions made throughout the investigation and in particular the review process. NEW Devon CCG welcome's attendees from NHS England and their neighbouring CCG's to ensure learning is shared.