



**Somerset**  
**Clinical Commissioning Group**

**PROCESS FOR REPORTING AND LEARNING FROM  
SERIOUS INCIDENTS (SI)**

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# PROCESS FOR REPORTING AND LEARNING FROM SERIOUS INCIDENTS (SI)

## CONTENTS

|  | Page |
|--|------|
| <b>CONTENTS</b>  |      |
| VERSION CONTROL .....  | i    |
| IMPACT ASSESSMENT .....  | ii   |
| 1 INTRODUCTION .....   | 1    |
| 2 DEFINITION OF A SERIOUS INCIDENT .....   | 2    |
| 3 REPORTING PROCESS FOR SERIOUS INCIDENTS .....  | 5    |
| 4 INVESTIGATING SERIOUS INCIDENTS .....  | 9    |
| 5 SERIOUS INCIDENT FRAMEWORK APPLICATION,<br>INTERFACE WITH OTHER CARE SECTORS AND<br>REGULATORS .....                         | 13   |
| 6 ROLES AND RESPONSIBILITIES .....   | 19   |
| 7 RESPONSIBILITIES OF THE COMMISSIONER .....   | 20   |
| 8 MONITORING AND COMPLIANCE .....  | 23   |
| 9 BLACK ALERT STATUS – ESCALATION FRAMEWORK .....  | 26   |
| 10 MEMORANDUM OF UNDERSTANDING: INVESTIGATING<br>PATIENT SAFETY INCIDENTS, INCLUDING UNEXPECTED<br>DEATH OR SERIOUS HARM ..... | 26   |
| 11 DISSEMINATION OF LEARNING.....  | 28   |
| 12 RELEVANT PUBLICATIONS.....  | 28   |

## APPENDICES

|              |  |    |
|--------------|--|----|
| APPENDIX 1   | Out of Hours Reporting and Media Relations .....   | 30 |
| APPENDIX 2   | Serious Incident (SI) 72 hour report template.....   | 32 |
| APPENDIX 3   | Specialised Services.....  | 34 |
| APPENDIX 4   | Services Commissioned by Public Health England<br>and Local Authority Public<br>Health.....    | 36 |
| APPENDIX 5   | NHS England Overview of Incident Management<br>Process .....                                   | 37 |
| APPENDIX 5a  | NHS England 12 Hour Trolley Wait Flowchart.....  | 38 |
| APPENDIX 6   | Incident and Risk Rating matrix.....   | 39 |
| APPENDIX 7   | Communication template .....   | 41 |
| APPENDIX 8   | Serious Incidents – Contact details.....   | 42 |
| APPENDIX 9   | Adult Safeguarding Process flowchart .....   | 43 |
| APPENDIX 10  | Somerset LSCB: Learning and Improvement Sub-<br>Group Serious Incident Notification Form ..... | 44 |
| APPENDIX 11  | Child Safeguarding Process flowchart .....   | 46 |
| APPENDIX 12  | Flowchart for the Management of Mental Health<br>Homicide Incidents .....                      | 47 |
| APPENDIX 13  | Root Cause Analysis (RCA) Investigation Report.....  | 49 |
| APPENDIX 13a | Being Open and Duty of Candour template.....   | 52 |
| APPENDIX 14  | Independent Contractor Pathway in respect of<br>Commissioned Services.....                     | 53 |
| APPENDIX 15  | Serious Incidents / Patient Safety Incidents for<br>Nursing Homes.....                         | 54 |
| APPENDIX 16  | Equality Monitoring form.....  | 56 |

## PROCESS FOR REPORTING AND LEARNING FROM SERIOUS INCIDENTS

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|     |                 |  |
|-----|-----------------|--|
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**CONFIRMATION OF EQUALITY IMPACT ASSESSMENT FOR THE  
COMMISSIONER DOCUMENTS/POLICIES/STRATEGIES AND SERVICE  
REVIEWS**

Main aim of the document:

This document sets out the commissioner's policy for the Reporting and Learning from Serious Incidents (SI's).

Outcome of the Equality Impact Assessment Process:

Neutral impact identified

If relevant, outcome of the full impact assessment:

Actions taken and planned as a result of the equality impact assessment, with details of action plan with timescales/review dates as applicable:

Review of Policy in two years (2018)

Groups/individuals consulted with as part of the impact assessment:

The commissioner staff



## PROCESS FOR REPORTING AND LEARNING FROM SERIOUS INCIDENTS (SIs)

### 1 INTRODUCTION

- 1.1 This policy sets out the arrangements by which organisations that provide NHS funded healthcare, commissioned by Somerset Clinical Commissioning Group (CCG) will report, investigate and evidence learning from Serious Incidents (SIs).
- 1.2 This policy follows the Serious Incident Framework and the Revised Never Events Policy and Framework published by NHS England on 27 March 2015. The approach endorses the seven key principles set out in the Serious Incident Framework ('Part two: underpinning principles' provides further detail) for the management of all serious incidents to be:
- Open and transparent
  - Preventative
  - Objective
  - Timely and responsive
  - Systems based
  - Proportionate
  - Collaborative
- 1.3 Promoting patient safety by reducing harm or error has been a key priority for the NHS since the publication of 'An Organisation with a Memory' (Department of Health, 2000) and 'A Promise to Learn a Commitment to Act: Improving the Safety of Patients in England' (National Advisory Group on the Safety of Patients in England, 2013) which emphasises the need for the NHS to put patient safety above all other aims and to foster a culture of continuous learning, transparency and the involvement of patients and their families in safety activities.
- 1.4 The NHS England Area Team is required to receive notification of all SIs from all NHS trusts and commissioned services within its boundary. In addition, the reporting of SIs to Clinical Commissioning Groups is a requirement of the national contract for NHS funded providers, together with a statutory 'Duty of Candour'.
- 1.5 Somerset CCG is required to receive notification of all SIs from NHS trusts and providers, where the CCG is the lead commissioner, in accordance with the requirements of the National Department of Health Contract for NHS providers of healthcare.
- 1.6 This Policy should be read in conjunction with the following Somerset CCG policy documents:
- Risk Management Strategy and Policy
  - Complaints Policy

- Safeguarding Assurance Policies
- Health and Social Care System Wide Escalation Framework, December 2015

## **2 DEFINITION OF A SERIOUS INCIDENT(SI)**

2.1 Serious incidents in healthcare are rare, but it is acknowledged that systems and processes have weaknesses and that errors will inevitably happen. But a good organisation will recognise harm and the potential for harm and will undertake swift, thoughtful and practical action in response, without inappropriately blaming individuals.

2.2 As defined in the NHS England Serious Incident Framework, SIs in the NHS 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.

2.3 There is no definitive list of events/incidents that constitute a SI and the Framework states that lists should not be created locally, as this can lead to inconsistent or inappropriate management of incidents. Instead, the Framework sets out the circumstances in which a SI must be declared. These include:

- acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
  - unexpected or avoidable death of one or more people. This includes:
    - suicide/self-inflicted death
    - homicide by a person in receipt of mental health care within the recent past (6 months)
  - unexpected or avoidable injury to one or more people that has resulted in serious harm;
  - unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
    - the death of the service user; or
    - serious harm
  - actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
    - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or

- where abuse occurred during the provision of NHS-funded care

(This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry (SAE) or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident (see Part One; sections 1.3 and 1.5 for further information).

- 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
  - property damage
  - security breach/concern
  - incidents in population-wide healthcare activities like screening and 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)
  - activation of Major Incident Plan (by provider, commissioner or relevant agency)
- major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation
- a Never Event – all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death (see NHS England Revised Never Events Policy and Framework, published 27 March 2015)

## **Never Events**

- 2.4 Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.

2.5 The list of core Never Events which should be reported are updated by NHS England on an annual basis. For the latest list and further guidance, please refer to the NHS England website at <https://www.england.nhs.uk/patientsafety/never-events/>

2.6 Never Events must be reported to the commissioner and investigated in line with the Serious Incident Framework and the process as outlined above.

### **Notification**

2.7 Where there are any doubts about the reporting of a SI, the Director of Quality, Safety and Governance, their Deputy, or the Head of Patient Safety and Governance should be contacted for advice during working hours.

2.8 From 1 April 2010, as part of the registration requirements arising from the Health and Social Care Act 2008, NHS providers are required to notify the Care Quality Commission (CQC) about events that indicate, or may indicate risks to ongoing compliance with registration requirements, or that lead, or may lead to changes in the details about the organisation in the CQC register. Reports about SIs and deaths are defined in the CQC's 'Guidance for Providers on meeting the Regulations', March 2015. For CQC registered providers, most of these requirements can be met by reporting via the NRLS, who will forward relevant information to the CQC.

2.9 In certain instances, there will also be a need to inform other agencies in accordance with national guidance such as the Medicines and Healthcare Products Regulatory Agency (MHRA) in the case of medicines equipment failure, the Counter Fraud and Security Management Service (CFSMS) in the case of fraud and violence towards staff and the Health and Safety Executive where incidents involve harm to staff or harm as a result of the impact of the environment to care to patients. NHS Foundation Trusts are also required to report specific incidents to Monitor, as the regulator.

2.10 The 2012 Liaison Agreement between the Health and Safety Executive (HSE) and the Care Quality Commission (CQC) was reviewed and published as a Memorandum of Understanding (MOU) between CQC, HSE and local authorities in England. This MOU applies to both health and adult social care in England and came into effect on 1 April 2015 to reflect the new enforcement powers granted to the Care Quality Commission (CQC) by the Regulated Activities Regulations 2014.

2.11 The MoU outlines the respective responsibilities of CQC, HSE and local authorities when dealing with health and safety incidents in the health and adult social care sectors, and the principles that will be applied where specific exceptions to these general arrangements may be justified. It also describes the principles for effective liaison and for sharing information more generally. Further information can be found at [http://www.cqc.org.uk/sites/default/files/20150210\\_mou\\_between\\_cqc\\_hs\\_e\\_las\\_in\\_england\\_final.pdf](http://www.cqc.org.uk/sites/default/files/20150210_mou_between_cqc_hs_e_las_in_england_final.pdf)

### **3 REPORTING PROCESS FOR SERIOUS INCIDENTS**

- 3.1 The organisation where the SI has occurred, or is identified, has overall responsibility for reporting the incident and for the investigation and implementation of subsequent action plans. The lead commissioner is responsible for agreeing the arrangements for the investigation and for monitoring the management of the SI reported by providers of NHS funded care.

#### **Delegation of responsibility from the ‘accountable’ commissioner to another commissioner**

- 3.2 The NHS England Serious Incident Framework acknowledges that NHS commissioning arrangements are often complex, with the potential for a number of commissioners to be commissioning services from multiple providers over local and regional geographical boundaries. The Framework recognises that the provider must report the SI to the lead commissioner but they may also report to the commissioner holding the contract (the ‘accountable’ commissioner) for the particular incident. In these circumstances it may be appropriate for the accountable commissioner to be responsible for managing the SI. In these circumstances, it is expected that the lead commissioner for the provider will have overall responsibility for the management of the incident, and a flexible approach will be adopted so that commissioners will work collaboratively together to agree how best to manage the SI.

#### **Responsible, Accountable, Supporting, Consulted, Informed (RASCI) Model**

- 3.3 The RASCI model provides an approach for the identification of a lead commissioner with responsibility for managing a SI investigation that allows the lead commissioner holding the contract to delegate responsibility for this to an associate commissioner, where appropriate, and when agreed. In those circumstances, the associate commissioner is then the single point of contact for the provider and has responsibility for co-ordination of the investigation and liaising with other commissioners, as appropriate.
- 3.4 Where appropriate, a RASCI assessment will be completed by Somerset CCG, with the assistance of the provider, when the 72 hour report is submitted (see section 3.14 to 3.16 below).
- 3.5 Where there are a number of providers and agencies involved in the SI, the RASCI also helps to identify, from the beginning of the investigation process, a lead investigator, where appropriate, and the other organisations/providers who should contribute to the investigation or be informed of the investigation. It is expected that the lead investigator takes responsibility for contacting and involving any other service that needs to contribute to the investigation. In some cases, the commissioner may be best placed to request other services contribute to the investigation process.

- 3.6 It is expected that multiple providers should work together to undertake a single investigation, where this is possible and appropriate. However, when separate investigations are necessary, the multiple providers should work together and consider cross boundary issues and fully explore the root causes and contributory factors, with co-ordination by the lead commissioner. It is the responsibility of the lead investigator to produce a single investigation report. (See section 2.1 and 2.2 of the NHS England Serious Framework for more information on the management of SI investigations involving multiple providers/agencies and the RASCI model).
- 3.7 For SIs reported by a provider whereby Somerset CCG is the lead commissioner, a lead investigator will be identified when agreeing the Terms of Reference for the investigation. This would usually be the provider who has reported the incident on STEIS.
- 3.8 Somerset CCG expects to be notified of SIs or suspected SIs as soon as possible. This can be in the form of an e-mail or by telephone call to the Director of Quality, Safety and Governance (or appropriate deputy). This applies particularly in the event of an incident that has resulted in serious harm to the patient and where immediate action may be required to prevent further incidents, or where there may be media interest.
- 3.9 SI's should be reported on the Strategic Executive Information System (STEIS) as soon as possible, or at least within two working days of the organisation identifying the SI. In the majority of cases, the date of the incident occurring is the same as the date in which the reporting organisation identifies the incident. In some cases, the date that the organisation identifies the incident may differ from the actual incident date. An example of this is when an incident comes to light, following a retrospective case note review or complaint. In these cases, the date of when the organisation identified the incident becomes the incident date for monitoring purposes. The commissioner will make the final decision on which date applies, in consultation with the reporting organisation.
- 3.10 When an organisation does not have access to the Strategic Executive Information System (STEIS), for example independent providers and Treatment Centres, the commissioner will input the details of the SI and sign off the report on STEIS. In these cases, oversight of the reporting and investigation process detailed in this Policy remains the same as for other providers.
- 3.11 Where there is an unavoidable delay in investigating an incident, NHS providers should update STEIS and inform the Somerset CCG Quality, Safety and Governance Team as the commissioner, at the earliest opportunity.
- 3.12 During out-of-hours periods, the senior manager or director on-call in the NHS trust will be responsible for the reporting of any SIs to the Somerset

CCG director on-call, as lead commissioner. Further details are provided in Appendix 1.

### **Immediate action following reporting of a SI**

3.13 The following action should be taken following an SI being reported.

#### **Initial review (72 hour report)**

3.14 An initial review (characteristically termed a '72 hour review') should be undertaken for all incidents and submitted to the lead commissioner (a template is provided at Appendix 2). This should be completed within three 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)
- propose the appropriate level of investigation (see section 4.2 below)
- ensure the 'Duty of Candour' obligations have been initiated (see section 3.17 below)

3.15 The information submitted to Somerset CCG as part of the initial review should be reviewed by all appropriate stakeholders and the Director of Quality, Safety and Governance, in order to inform the level of investigation required.

3.16 On receipt of the initial review (72 hour report), Somerset CCG will, in most cases, arrange a meeting or telephone call with the provider to agree the Terms of Reference for the investigation. This will include the involvement of any other providers, agencies or persons to be involved in the investigation, identified through the use of the RASCI model.

### **Duty of Candour (Communicating with patients, families and carers)**

3.17 The Being Open principle is now underpinned by a statutory requirement, Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) 2014, which places a Duty of Candour on providers to advise patients and / or their family of a serious incident, to apologise and offer them the opportunity to be advised of the outcome. Further information can be found at:

[http://www.cqc.org.uk/sites/default/files/20150327\\_duty\\_of\\_candour\\_guidance\\_final.pdf](http://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf)

3.18 This ensures that health care providers operate in an open and transparent way when certain incidents occur in relation to the care and treatment provided to people using the service.

3.19 Providers must, within 10 operational days after reporting a SI, notify the relevant person and/or their family/carer that the incident has occurred/or is suspected to have occurred and that an investigation will be conducted. The relevant person/family/carer should be invited to contribute and/or ask any questions they would like the investigation to cover. Somerset CCG expects the provider to:

- provide an apology
- understand and include vital information on events from the perspective of the relevant person/family/carer
- have ongoing discussions with the patient/family/carer to ensure that the investigation will consider their concerns and perspectives, so the report conclusions and recommendations are understandable, using language which is clear and non-technical
- involve the relevant person/family/carer in the process of learning and the action plan which will result from the investigation

3.20 Where statutory instruments deem contact with the patient / relatives may not be indicated, for example in safeguarding incidents or where a criminal investigation is in progress, the statutory instrument should be adhered to following discussion with the relevant agencies (see section 5 for more information).

3.21 When logging incidents on STEIS, the Duty of Candour field must confirm that the patient / family have been informed and the extent of planned involvement of the patient / family in the investigation.

### **Notification of SIs involving specialist commissioning patients**

3.22 For SIs that involve a service commissioned by NHS England specialist commissioning, these need to be identified separately on STEIS, by the inclusion of an entry in the 'comments/further action required' field of "SpecComm". In these incidents, the CCG will ascertain who needs to be involved in the investigation by obtaining the relevant RASCI template from NHS England and will invite them to be involved in the setting of the Terms of Reference and review of the investigation report. A list of specialised services for Somerset providers is provided at Appendix 3.

### **SIs for services commissioned by Public Health**

3.23 For SIs in services commissioned by Public Health England and the Somerset County Council Public Health Team, Somerset CCG will lead and co-ordinate the arrangements for the management and monitoring of the investigation where the CCG is the lead commissioner of the NHS provider. The Public Health Team will lead and co-ordinate the arrangements for the management and monitoring of the investigation where Somerset County Council is the lead commissioner of the NHS provider. An initial telecon will take place, at which the Terms of Reference for the investigation will be agreed. When public health are identified as taking the lead, representatives from the CCG will be invited to review and comment on the final investigation report and when the

CCG is the lead, public health will be invited to review and comment on the final investigation report. A list of services commissioned by Public Health England and the Somerset County Council Public Health Team are attached as Appendix 4.

### **Information Governance (IG) SIs**

- 3.24 SIs involving the disclosure of confidential information constitute a breach of the Data Protection Act and a patient's rights under the NHS Constitution. Information breaches should be assessed and where appropriate, reported through the IG Toolkit, as set out in the Health and Social Care Information Centre 'Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation, version 5.1, May 2015'. As there is no link between the IG toolkit and the Strategic Executive Information System (STEIS), IG level 2 incidents will also need to be reported on STEIS.

### **Confidentiality**

- 3.25 It should be noted that, in the interests of confidentiality, all reports should contain anonymised information. The content of any report relating to SIs should not contain the names of practitioners, patients or information, which could lead to the identification of practitioners or patients. Investigation reports may be disclosable under the Freedom of Information Act 2000.
- 3.26 Where Somerset CCG or NHS England Area Team consider the SI to be of a nature where patient (and practitioner) identifiable information may be required in order to protect patient safety, the Trust may be asked to release this information in line with Caldicott principles and agreement with the relevant Trust and CCG Caldicott Guardian
- 3.27 If a patient is transferred to the care of another healthcare organisation and clinical staff report that the patient may have previously been involved in a SI in the originating organisation, the incident should be reported by the receiving organisation. The receiving organisation should advise their Lead Commissioner, who may negotiate transfer of the incident and responsibility for investigation to the originating organisation, once 72 hour reports have been received and the nature of the incident established. An example of this may be the identification of a suspected safeguarding incident.

## **4 INVESTIGATING SERIOUS INCIDENTS (SI)**

- 4.1 NHS England's overview of the incident management process by Somerset CCG is provided at Appendix 5 and 5a.

## Levels of investigation and timescales

4.2 The nature, severity and complexity of SIs 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. The appropriate level of investigation should be informed by an initial review of the 72 hour report (see section 3.14 above) and consideration using the risk matrix (Appendix 6). There are three levels of investigation, as shown in the table below:

| Level   | Application  | Product/<br>outcome  | Owner   | Timescale for<br>completion   |
|---|--|--|---|---|
| Level 1<br><b>Concise<br/>internal<br/>investigation</b>  | Suited to less complex incidents which can be managed by individuals or a small group at a local level   | Concise / compact investigation report which includes the essentials of a credible investigation | Provider organisation (Trust Chief Executive / relevant deputy) in which the incident occurred, providing principles for objectivity are upheld   | Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner<br><br>All internal investigation reports should be supported by a clear investigation action plan |
| Level 2<br><b>Comprehensive<br/>internal<br/>investigation</b><br><br>(this includes those with an independent element or full independent investigations commission by the provider) | Suited to complex issues which should be managed by a multi-disciplinary team involving experts and / or specialist investigators where applicable | Comprehensive investigation report including all elements of credible investigation              | Provider organisation (Trust Chief Executive / relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity |   |

|   |   |  |  |   |
|---|---|--|--|---|
| <p>Level 3<br/><b>Independent investigation</b></p> | <p>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 the organisation or the capacity / capability of the available individuals and / or number of organisations involved.</p> <p>This will be required for all mental health homicides.</p> | <p>Comprehensive investigation report including all elements of a credible investigation</p> | <p>The investigator and <b>all</b> members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated</p> | <p>6 months from the date the investigation is commissioned</p> |
|---|---|--|--|---|

### **Timescales for completion of investigations**

4.3 Timescales for the completion of investigations will be in line with the NHS England Serious Incident Framework as follows:

- for level 1 and level 2 investigations - 60 days
- for cases that require an independent investigation (such as mental health homicides) (level 3 investigations) - 26 weeks from the date the investigation is commissioned, will be given

4.4 Exceptions to the above timescales can be agreed with the commissioner in exceptional circumstances. Further details are provided in section 7.10 and 7.11 below.

## **Communication between Provider Organisations**

- 4.5 When there is an SI involving more than one provider, it is essential that there is robust communication between these organisations. Somerset CCG has developed a communication template, to share patient details and contact details (Appendix 7). Contact details for all local NHS providers are listed in Appendix 8.

## **Submission of Final Report, Quality Assurance and Closure**

- 4.6 SI investigation reports and action plans must be submitted to Somerset CCG within 60 days (unless otherwise agreed) or 26 weeks where an independent investigation is required (further guidance on the format and content of the investigation report and action plan is provided in section 4.4 of the NHS England Serious Incident Framework).
- 4.7 Somerset CCG will acknowledge receipt by e-mail and undertake a quality assurance review of the report within 10 calendar days (an alternative timescale may be agreed, when appropriate). Where multiple commissioners are involved and Somerset CCG has been identified as the lead commissioner through the RASCI process (see section 3.3), the CCG will share the investigation report and action plan with the other commissioners and invite them to participate in the quality assurance process.
- 4.8 In order to close a SI on STEIS, the commissioner will require a robust investigation report, generated following a full root cause analysis, to include root causes, lessons learned and a time bounded action plan. The action points need to address each lesson learnt and associated recommendations with timescales and named lead for implementation. This will provide assurance to the commissioner of actions to be taken to improve patient safety and enable sharing of lessons learned. Somerset CCG will identify key themes across the health community of the improvements made within Trusts, as a result of investigations.
- 4.9 SIs can be closed on STEIS before all the identified actions have been completed, such as where actions cannot be completed immediately. Where this is agreed, providers should have robust arrangements in place to ensure that implementation of outstanding actions are regularly reviewed. SIs can be re-opened when deemed necessary if actions have not been fully completed or additional concerns are raised with the CCG through the Clinical Quality Review meetings.
- 4.10 Publication of SI investigation reports and action plans is considered best practice. Somerset CCG fully supports the principles of openness and transparency and will work with and support all NHS providers to enable them to publish anonymised SIs for the purposes of learning.

## 5 **SERIOUS INCIDENT FRAMEWORK APPLICATION, INTERFACE WITH OTHER CARE SECTORS AND REGULATORS**

5.1 The NHS England Serious Incident Framework applies to SIs which occur in all services providing NHS funded care, including independent providers. The Framework recognises that sometimes processes will coincide with other procedures and in such circumstances, co-operation and collaboration between different agencies is essential to reduce duplication and confusion. Ideally, only one investigation should be undertaken. Wherever possible, SI investigations should continue alongside criminal proceedings, serious case reviews and domestic homicide reviews.

### **Safeguarding Adults - What it is and Why it Matters**

5.2 Safeguarding means protecting an adult's right to live in safety, free from abuse and neglect. It is about people and organisations working together to prevent and stop both the risks and experience of abuse or neglect, while at the same time making sure that the adult's wellbeing is promoted including, where appropriate, having regard to their views, wishes, feelings and beliefs in deciding on any action.

5.3 Safeguarding adults is everyone's business. The Care Act (2014)<sup>1</sup> puts in place a framework and duties for adult safeguarding. The safeguarding duties apply to an adult who:

- has needs for care and support (whether or not the local authority is meeting any of those needs)
- is experiencing, or at risk of, abuse or neglect
- as a result of those care and support needs is unable to protect themselves from either the risk of, or the experience of abuse or neglect

5.4 Making safeguarding personal is a key element of the Care Act (2014). It means that safeguarding should be person-led and outcome-focused, engaging the person about how best to respond to their safeguarding situation in a way that enhances involvement, choice and control as well as improving quality of life, wellbeing and safety.

### **Safeguarding Adults Principles**

5.5 The following six principles apply to all sectors and settings, the principles should inform the ways in which professionals and other staff work with adults:

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<sup>1</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/315993/Care-Act-Guidance.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/315993/Care-Act-Guidance.pdf)

- 1 – Empowerment
- 2 – Protection
- 3 – Prevention
- 4 – Proportionality
- 5 – Partnerships
- 6 – Accountability

### **Duties in Respect of Safeguarding for NHS Providers and Commissioners**

- 5.6 This is now a statutory duty for all agencies to work in partnership to ensure the best outcome for the adult when there are safeguarding concerns. The Care Act (2014) states that all NHS organisations have a duty to cooperate with the local authority around safeguarding matters and the local authority must co-operate with its partners. If a local authority reasonably suspects an adult who meets the criteria is, or is at risk of, being abused or neglected, then they must make enquiries, or cause others to do so. The purpose of the enquiries is to enable the local authority to decide what (if any) action is needed to help and protect the adult.
- 5.7 Each local authority must set up a Safeguarding Adults Board (SAB) which must include the local authority, the CCG, and the Police. The main objective of a SAB is to assure itself that local safeguarding arrangements and partners act to help and protect adults in its area who meet the criteria. Somerset CCG is a member of the Somerset SAB.
- 5.8 The SAB must carry out safeguarding adults reviews (SARs). A SAR is required when an adult in the SAB area dies as a result of abuse or neglect, whether known or suspected, and there is concern that partner agencies could have worked more effectively to protect the adult. SABs must also arrange a SAR if an adult in its area has not died, but the SAB knows or suspects that the adult has experienced serious abuse or neglect.
- 5.9 The purpose of a SAR is to determine what the relevant agencies and individuals involved could have done differently that could have prevented harm or death. This is so that lessons can be learned from the case and those lessons applied to future cases to prevent similar harm occurring again.

### **Somerset Safeguarding Adult Board and Somerset Clinical Commissioning Group; Serious Incidents, Information Sharing and Safeguarding**

- 5.10 All agencies in Somerset have a statutory duty to cooperate with the local authority in relation to safeguarding adults. Somerset CCG and all health providers must ensure that information about abuse or potential abuse is shared with the local authority safeguarding teams.

- 5.11 Somerset CCG and all organisations must have arrangements in place which clearly sets out the processes and the principles for sharing information between each other, with other professionals and the SAB. These arrangements must be in line with the information sharing agreement that has been agreed by Somerset SAB.
- 5.12 These principles apply to any information that arises from a serious incident as defined in the NHS England Serious Incident Framework that may indicate an individual is, or is at risk of, being abused or neglected.
- 5.13 In the Somerset CCG area, information relating to a SI or SIs, where there are safeguarding concerns, will be shared between providers/commissioners and the local authority safeguarding teams, via the safeguarding referral number or e-mail address stated in The Somerset Safeguarding Adults Multi Agency Policy<sup>2</sup>.
- 5.14 When the responsible local authority is one outside of Somerset, the responsible local authority will be approached by the provider/commissioner to determine the route for information sharing.

#### **Interface between Safeguarding Enquiries/Safeguarding Adults Reviews (SAR) and Serious Incidents**

- 5.15 All NHS organisations have a duty to co-operate with the local authority in the exercise of their functions relevant to care and support to protect adults. It remains the responsibility of every NHS funded organisation and each individual working in that organisation to ensure that the duties of safeguarding adults are holistically, consistently and conscientiously applied with the well-being of adults at the heart of what we do. A SI may also require a safeguarding enquiry or safeguarding adults review under the Care Act (2014).
- 5.16 As part of the monitoring arrangements, Somerset CCG and all providers will review all serious incidents to consider if there are safeguarding concerns and whether a referral should be made to the safeguarding team for a safeguarding enquiry or to Somerset SAB for a SAR. Any referrals will be in accordance with the Somerset Safeguarding Adults Policy<sup>2</sup> and the Local Information Sharing Agreement approved by the Somerset SAB.
- 5.17 When a potential serious incident is identified through a safeguarding adults enquiry or a safeguarding adults review, Somerset CCG or the relevant provider will only report a SI where the definition in the National Framework for Serious Incidents is fulfilled. That is, where there has been a significant failure of health systems or care that has contributed to the abuse of an adult at risk.

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<sup>2</sup> <http://www.somerset.gov.uk/adult-social-care/safeguarding/safeguarding-information-for-providers/>

- 5.18 In addition to the provider's obligations under the Somerset Safeguarding Adult's Multi Agency Policy, any serious adult safeguarding incidents that occur will be reported to the Executive lead for Safeguarding Adults at Risk, the Director of Quality, Safety and Governance in Somerset CCG.
- 5.19 Providers remain responsible for taking the appropriate action/intervention to safeguard people where abuse has occurred, or where there is a risk of abuse occurring during the provision of NHS funded care. Somerset CCG and all providers will co-operate fully in all SARs that are initiated by the Somerset SAB and will ensure that the learning from serious case reviews are implemented.
- 5.20 Healthcare providers must contribute towards safeguarding enquiries and reviews as required by Somerset SAB and the Care Act (2014). If, as part of any SAR or enquiry, it becomes apparent that a SI has occurred, then the provider must make the necessary declaration and record the information on STEIS.

### **Management of Serious Incident and SARS investigations**

- 5.21 Whilst the local authority will lead the management and co-ordination of the investigation for SARs and initiate safeguarding enquiries, where a SI has occurred, Somerset CCG will require assurance from healthcare providers that appropriate measures will be made to protect individuals and minimise the risk of further harm or recurrence as per the Serious Incident Framework, where the incident involves a failure in health systems or care.
- 5.22 Where there is an interface between a SI and a safeguarding enquiry or safeguarding adults review, providers and commissioners will liaise regularly with the local authority to co-ordinate a multi-agency approach to any investigation. This liaison should have the aim of reducing duplication. This should be achieved through alignment of the Terms of Reference for investigations for SIs and SARS, and ensuring the investigation processes are complementary and do not duplicate. It will be necessary for the agreed investigation process to ensure that all aspects of the SI investigation process are included, to provide assurance to Somerset CCG that measures are in place to protect the individual and reduce the likelihood of reoccurrence.
- 5.23 Commissioners and providers should also refer to the Somerset Safeguarding Adults Policy and the Serious Care Reviews/ Safeguarding Adults Reviews Policy, which also describe the interface between the two processes.
- 5.24 Any learning that is identified through the SI process that relates to safeguarding adults will be shared with Somerset SAB through the learning and development sub group. Details of the Adult Safeguarding process can be found at Appendix 9.

## Safeguarding Children

- 5.25 Health Commissioners and NHS Trusts have a statutory duty to safeguard and promote the welfare of children (Children Act 2004). As part of that duty commissioners must ensure that all NHS Providers have arrangements in place to identify, report, and investigate safeguarding incidents, as well as implement and manage any remedial action required in situations where it is believed that an incident has occurred that could have adversely affected the health or welfare of a child. This also includes 'near misses'.
- 5.26 When a safeguarding incident has occurred, there should be consideration of whether there has been a failure of healthcare or ongoing care that has contributed to harm of the child or young person and therefore consideration of whether this should be reported as an SI on the STEIS system. There should also be consideration of whether a referral should be made to the Somerset Safeguarding Children's Board to raise a safeguarding alert, or to request a multi agency case review or a serious case review. All referrals should be made in accordance with Somerset Safeguarding Children Board (SSCB) Serious Incidents Notification Protocol, dated October 2015. This protocol outlines the incidents and circumstances that must be notified and the incidents and circumstances that could be notified. The Serious Incident Notification Form can be found at Appendix 10. Details of the Child Safeguarding process can be found at Appendix 11. All referrals for safeguarding incidents to the Somerset Safeguarding Children's Board should also be notified to the lead commissioner.
- 5.27 A number of Safeguarding SIs may also meet the criteria, outlined within Working Together (2015) statutory guidance for a Serious Case Review (SCR). It is the decision of the SSCB as to whether or not a SCR will be commissioned. Any child protection incident for a child or young person in care, or is subject to a SCR is a notifiable incident to OFSTED. There should also be consideration as to whether it meets the threshold for a safeguarding SI and reporting on the STEIS System.
- 5.28 A referral should be made to the Learning and Improvement sub group for SIs where it is considered that a serious case review should also be considered where:
- abuse or neglect of a child is known or suspected; and either
    - the child has died; OR
    - the child has been seriously harmed and there is cause for concern as to the way in which the authority, their Board partners or other relevant persons have worked together to safeguard the child
  - when a child dies in custody:
    - in police custody
    - on remand or following sentencing

- in a Young Offender Institution
  - in a secure training centre or a secure children's home
  - or where the child was detained under the Mental Health Act 2005 or where a child aged 16 or 17 was the subject of a deprivation of liberty order under the Mental Capacity Act 2005
- cases where a child died by suspected suicide and abuse or neglect is known or suspected

5.29 All referrals to the SSCB Learning and Improvement Sub-Group for consideration of an SCR should be discussed with the CCG and with the designated professionals, who will make the referral. Where the SSCB decides to commission a SCR, the CCG, as the lead commissioner, will be informed and will co-ordinate the arrangements for the health contribution from providers to the SCR and ensure that the SCR process aligns with the SI investigation process. Under these circumstances 'Stop the Clock' will be applied to the investigation timescale while the serious case review is completed.

5.30 Under the Children Act, 2004, Local Safeguarding Children Boards are responsible for reviewing all child deaths. All NHS Providers and partner agencies have a duty to report all child deaths to the SSCB Child Death Overview Panel. Where NHS providers consider that there has been a less than satisfactory outcome for a child as a result of a failure or omission of health care, providers should consider whether the child death should also be reported as an SI on the STEIS system.

### **Domestic Homicide Reviews (DHR)**

5.31 A domestic homicide is identified by the police, usually in partnership with the Community Safety Partnership (CSP), with whom the overall responsibility lies for establishing a review of the case.

5.32 The chair of the CSP holds responsibility for establishing whether a homicide is to be subject of a DHR by applying the definition set out in paragraph 5 of the Multi-agency Statutory Guidance for the Conduct of Domestic Homicide Reviews (applicable to all notifications from 1 August 2013). This decision should be taken in consultation with local partners with an understanding of the dynamics of domestic violence and abuse. This will assist in identifying those best placed to sit on the Review Panel for that particular homicide. This may also establish the existence of any other ongoing reviews, such as a child or adult Serious Case Review (SCR) or Mental Health Investigation (MHI), which will need to be considered as part of the decision to undertake a DHR.

5.33 Somerset CCG will review the initial findings from the Domestic Homicide Review process to establish whether there has been a failure of health services to protect the victim from harm and whether or not this incident constitutes an SI. Where an SI is reported, the SI investigation process should support the overall NHS contribution to the Domestic Homicide Review.

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

- 5.34 Homicides committed by those in receipt of mental health care have devastating consequences for the family of the victim(s), patients and their families and a profound impact for all parties involved. The process for external review of all mental health homicides is led and overseen by NHS England's regional investigation team to ensure an appropriate approach is undertaken when responding to mental healthcare related homicides.
- 5.35 NHS England's regional investigation team will consider an independent investigation of mental healthcare related homicides when a homicide has been committed by a person who is, or has been, subject to a care programme approach, or is under the care of specialist mental health services, in the past 6 months prior to the event (see NHS England Serious Incident Framework 'Appendix 1: Regional Investigation Teams: Investigation of homicide by those in receipt of mental health care' for more information). A flowchart for the management of mental health homicide incidents is provided at Appendix 12.
- 5.36 In the first instance, the CCG will agree the arrangements for the NHS trust SI investigation using root cause analysis (RCA) as set out in section 4 above. Once the trust internal investigation report and action plan has been completed and quality assured by the CCG, this will be submitted to the NHS England Regional Team for review and to inform commissioning of the external homicide review investigation.
- 5.37 Independent investigations should follow Department of Health guidance published in HSG (94) 27, *Guidance on the discharge of mentally disordered people and their continuing care in the community*, and the updated paragraphs 33-36 issued in June 2005.

## **6 ROLES AND RESPONSIBILITIES**

- 6.1 The NHS has a responsibility to ensure that when a serious incident does happen, there are systematic measures in place for:
- safeguarding people, property, the service's resources and its reputation
  - understanding why the event occurred
  - ensuring that steps are taken to reduce the chance of a similar incident happening again
  - reporting to other bodies, where necessary
  - sharing the learning with other NHS organisations and providers of NHS-funded care

## **7 RESPONSIBILITIES OF THE COMMISSIONER**

7.1 The commissioner is responsible for ensuring that the following SI arrangements are in place:

- processes for reporting the event to other local agencies, such as the Police, local authority and other NHS trusts, when required
- clear requirements for responding to SIs are specified, agreed and included within contracts with all providers of NHS care
- that procedures and relevant skills and resources are in place in Somerset CCG to receive and appropriately manage and monitor follow up of SIs
- obtain assurance that actions plans have been implemented within the planned timescales through the contractual Clinical Quality Review Meeting process
- in addition to suitably qualified and experienced commissioning staff, there is access to independent investigators and experienced clinical advisors to provide specialist clinical advice in the management and oversight of investigations and to undertake investigations, when required and in exceptional circumstances
- local procedures are agreed with SSAB/SSCB, that set out the arrangements for notification and management of SIs that may constitute a serious case review, including action planning and learning from incidents
- arrangements are in place to be satisfied that providers are operating an open and just culture where staff are encouraged to report incidents without fear of inappropriate or unjust blame and where patients are informed and involved in investigations when they have been affected by an incident
- quality assure investigations, including internal investigations, to ensure they are robust and demonstrate use of recognised principles such as root cause analysis or Significant Event Audit
- ensure timely and transparent closure of serious incidents underpinned by effective communication with providers

7.2 Somerset CCG is responsible for ensuring that there are effective arrangements in place, for dealing with major incidents in accordance with the Civil Contingencies Act 2004, the Health and Social Care Act 2012, the management of infectious disease outbreaks in line with NHS Act 2006, section 72 and infection control (Health Service Guidance 93, 56). The commissioner has the responsibility of assuring the quality of commissioned services and ensuring that these arrangements are in

place in all NHS providers. When significant or major incidents are declared, they are also required to be reported under the NHS England Serious Incident Framework if they 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, It is usual for major incidents to be declared by the South West Ambulance NHS Foundation Trust. Therefore in line with this policy, where the incident should be reported by the provider where the incident occurred, it will usually be the ambulance trust that will report major incidents onto the STEIS system.

- 7.3 The responsibility for ensuring that major outbreaks and incidents are appropriately managed lies with Public Health England and NHS England respectively. These organisations will be responsible for notifying national, regional and the local health and multi-agency partners, where appropriate.
- 7.4 In the event of an actual, or possible, terrorist threat, the Ambulance Service will be notified by Police and will act as the gateway to health. They will notify Public Health England and NHS England who will activate locally agreed major incident notification cascades. Public Health England will also work closely with the Police and fire and rescue service, on any health risks posed by suspect packages that might contain a biological or chemical substance/hazard. The requirements for health organisations is set out in the NHS England Emergency Preparedness, Resilience and Response Framework (November 2015) and the Avon and Somerset Local Health Resilience Partnership Health Community Response Plan (v 2.2), November 2015.
- 7.5 All SIs that involve controlled drugs must be reported to the NHS England Area Team Accountable Officer, who will oversee the arrangements for investigation of the incident and manage the shared learning through the Local Network for Accountable Officers for controlled drugs.

### **Management of Serious Incidents**

- 7.6 If a SI has occurred within a commissioned service the Somerset CCG Quality, Safety and Governance Team will ensure that an appropriate process is followed to ensure that a full investigation is undertaken using root cause analysis techniques, lessons learned are identified and recommendations for improvement made. The CCG Patient Safety Team will ensure that the relevant directors, clinical leads and commissioning managers are informed when SIs are reported and that appropriate specialist clinical expertise is engaged to oversee the management of each SI investigation. This will ensure that the necessary action has been taken and lessons learned are shared across the Somerset health and care community. Details of the steps taken to discharge Duty of Candour must also be provided. The commissioner will review and monitor action plans from commissioned services through the Patient Safety and Quality Assurance Committee. An example root cause analysis investigation report template and Duty of Candour is provided at Appendix 13 and 13a.

7.7 If a SI occurs within a service commissioned from an Independent Care Contractor, NHS England is the lead commissioner for primary medical services, primary care dental services, pharmacy and optometry service. The CCG will support NHS England in ensuring a full investigation is undertaken where this relates to an incident in a CCG commissioned service. The CCG will ensure the investigation is led by the appropriate professional lead for the service and supported by the Quality, Safety and Governance Team. Investigations involving general practice will be led by a GP Patient Safety Lead. The pathway for the investigation process for independent care contractors can be found at Appendix 14. Investigations involving nursing homes will be led by a member of the Quality, Safety and Governance Team. Further details on the management of SIs occurring in nursing homes is provided at Appendix 15.

### **Management of Investigations for Never Events and External Independent Reviews**

7.8 The arrangements for monitoring and managing Never Events and External Independent Reviews will involve Somerset CCG agreeing Terms of Reference for the investigation with the Trust and regular telephone monitoring calls will be held to oversee the management of the investigation and to ensure immediate and on-going assurance of patient safety.

### **Standards for Management of SIs**

7.9 The commissioner will monitor the time taken to complete a SI investigation on the STEIS system, from the date the incident is notified, in line with the National Framework as follows:

- within 60 days
- for cases that require an independent investigation (such as mental health homicides), within 26 weeks from the date the investigation is commissioned

7.10 On rare occasions exceptions to the above timescales can be agreed with the commissioner. These will be considered when there are specific circumstances that will impact on the usual timescales, such as the outcome of an inquest is still awaited or where the family have not been available for interview, but wish to participate in the investigation process, or where the case is subject to a serious case review, or safeguarding adult's review. The reason for the extension must be recorded on STEIS in the further information section.

7.11 A request can be made to the commissioner 'to stop the clock' on investigations involving the Police, or other external agency, where this prevents the SI investigation proceeding, or where an incident is subject to an external review and it is known that the investigation will exceed the reporting timeframes. These requests must be made to the commissioner for approval.

## **8 MONITORING AND COMPLIANCE**

- 8.1 In order to comply with the requirements of the NHS England Serious Incident Framework, providers and commissioners should monitor trends in SI reporting and review these collectively. This trend analysis should include not only a quantitative report, but also a qualitative analysis of those incidents, where root causes and lessons learned have been identified.
- 8.2 Feedback from staff utilising the policy when a SI occurs will be sought and the policy amended as necessary.
- 8.3 The Patient Safety and Quality Assurance Committee for Somerset CCG has responsibility for monitoring the management and follow up of SIs, implementation of action plans and identification of themes and trends and reports to the Governance Committee. The commissioner will monitor the performance of all NHS providers in managing SIs through quarterly reports on the status of all incidents on STEIS to the Patient Safety and Quality Assurance Committee.
- 8.4 The Quality, Safety and Governance Team will evaluate the quality of all investigation reports at its Serious Incident Review Meeting and ensure that these are robust, include the lessons learned and have recommendations that feed into a 'SMART' action plan. Where there are further recommendations raised at the Serious Incident Review Meeting, this will be feed back to the Trust, for inclusion in the report.
- 8.5 The commissioner will monitor the implementation of all action plans from SIs through the Clinical Quality Review Meetings with NHS providers. All action plans arising from external independent investigations of SIs will be monitored through Patient Safety and Quality Assurance Committee.
- 8.6 The commissioner will report on performance in managing SIs and Never Events, trends in incident reporting, and key themes from lessons learned on a quarterly basis to the CCG Governance Committee and in the CCG Annual Report. Never events and incidents that have led to an independent investigation, or that are considered to be high risk, will also be reported to the Governing Body in the quarterly Clinical Quality Review report.
- 8.7 Somerset CCG is committed to providing equal access to healthcare services, to all members of the community. To achieve this, gathering equality and diversity information is essential to help ensure that we deliver the most effective and appropriate healthcare. Attached at Appendix 16 are the nine protected characteristics which, where possible, should be included and considered in all root cause analysis investigation reports.

## Rapid Response Review

- 8.8 A rapid response review provides commissioners with a means by which they can carry out a structured and purposeful visit to a trust, or other provider, as part of monitoring the quality of care being delivered, where significant patient safety concerns have been identified about a clinical service. The process can also be used where issues have been raised that could potentially impact adversely on an aspect of the quality of care, including patient safety and/or experience.
- 8.9 A rapid response review may be considered where there have been a cluster of SIs or failings that may lead to the requirements of a rapid responsive review.
- 8.10 A rapid response review would usually be commissioned in discussion with NHS England through the Quality Surveillance Group and in discussion with NHS Improvement and the CQC. *Reference: National Quality Board – How to: Organise and Run a Rapid Responsive Review: 2013/14, February 2013*

## Risk Summits

- 8.11 Quality Surveillance Groups (QSG) were established following recommendations from the National Quality Board<sup>3</sup> to bring together commissioners, regulators and other agencies, such as Healthwatch, involved in the provision of health and care services across a local area. Somerset CCG belongs to the Bristol, North Somerset, Somerset and South Gloucestershire QSG. The QSG meets every 2 months to review the membership's collective intelligence about services. It provides the opportunity to highlight and discuss early warning signs of the risk of poor quality, as well as opportunities to co-ordinate actions to ensure improvement. The QSG may, as a result of ongoing enhanced QSG surveillance concerns, call a Risk Summit.
- 8.12 A risk summit provides a mechanism for key stakeholders to come together collectively to share and review information when a serious concern about the quality of care has been raised. Risk summits enable NHS organisations and associated supervisory bodies to:
- give specific, focused consideration to the concern raised, sharing information and intelligence among each other and with the service provider in question
  - facilitate rapid, collective judgements to be taken about quality within the provider organisation in question
  - agree any actions that might be needed as a result of the risks identified

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<sup>3</sup> Quality in the New Health System: Maintaining and Improving Quality from April 2013

- 8.13 A risk summit is a meeting of high-level leaders, called to shape a programme of action. It is focused on sharing information willingly to help achieve a consensus about the situation under scrutiny and the actions required to mitigate the identified risks. Normally the risk summit will be held and the agreed actions will then be followed up at a further risk summit with the NHS England Area Team so that stakeholders can be satisfied that matters under review can be safely handed over to routine operational management systems, which is the ultimate goal.
- 8.14 Potential triggers for when a risk summit might be requested by Somerset CCG with NHS England include:
- the Care Quality Commission issues a warning notice(s)/applies material conditions on a provider/ or serves notice to withdraw registration
  - serious failings in the provision of care, such that patients are at imminent or immediate risk:
    - quality, patient safety / experience metrics causing alarm
    - clinical services poorly performing, missing targets and the serious incidents / never event profile suggests / confirms there to be an unsafe or failing service
    - serious and sustained safety breaches indicative of a more systemic quality failure within a single provider or across a health and social care system
    - death of a patient(s) which is unexpected and avoidable and which raises specific alarms about clinical practice
    - significant safeguarding breaches and breakdown in systems which compromise the protection of vulnerable adults and children (statutory and other formal processes apply)
  - soft intelligence, which when triangulated against the quantitative data, including trend analysis, clearly identifies a serious problem
  - patients / carers speak out at a level beyond that which would be expected to be addressed by the provider and local commissioners
  - Monitor raises serious concerns about the governance and/or leadership of a Foundation Trust
  - one or more of the professional regulators raises concerns about the appropriateness of trainees /students remaining on clinical placements in a provider and are considering / intend withdrawing them
  - an independent report, such as a Royal College report, raises serious concerns about patient safety which cannot be managed locally through routine service improvement

*Reference: National Quality Board – How to: Organise and Run a Rapid Responsive Review: 2013/14, February 2013*

## **9 BLACK ALERT STATUS – ESCALATION FRAMEWORK**

- 9.1 A framework has been designed for managers and clinicians involved in managing capacity and patient throughput at a time of excess demand on NHS emergency and acute care services. The document provides a practical working reference tool for all parties, thereby aiding co-ordination, communication and implementation of the appropriate duties in each organisation. *Reference – NHS England (South) Surge Management Framework, August 2015*
- 9.2 When significant or major incidents are declared, they are required to also be reported under the NHS England Serious Incident Framework if they 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, In these circumstances, the incident would be reported onto the STEIS system by the provider where the major incident is declared.

## **10 MEMORANDUM OF UNDERSTANDING: INVESTIGATING PATIENT SAFETY INCIDENTS INCLUDING UNEXPECTED DEATH OR SERIOUS UNTOWARD HARM**

- 10.1 In November 2006 the Department of Health published practical advice for the NHS about what to do when faced with a patient safety incident that may require investigation by the Police and/or Health and Safety Executive ('Guidelines for the NHS: In support of the Memorandum of Understanding – Investigating Patient Safety Incidents Involving Unexpected Death or Serious Untoward Harm'). The MOU has now been withdrawn. However, it is acknowledged that much of the content is still relevant for conducting investigations in healthcare settings and has been included in a guide produced by the National Police Chiefs' Council (NPCC) Homicide Working Group 'An SIO's Guide to Investigating Unexpected Death and Serious Harm in Healthcare Settings – Revised 2015 (v10.3). In keeping with the original MOU the text of this guidance refers in the main to the NHS however, many of the principles are applicable to incidents in other settings, including in the independent healthcare sector and nursing and residential care homes.
- 10.2 It will sometimes be immediately obvious that the Police and/or the Health and Safety Executive should be contacted, but in other cases, the need may not come to light until the organisation, coroner or other body, such as the Medicines and Healthcare Products Regulatory Agency has carried out its own investigations. The decision to report an incident to the Police should be made at a sufficiently senior level, for example, by either the chief executive, or another executive director of the relevant NHS provider or independent provider. The NHS should refer cases to the Police only when any or all of the following circumstances apply:

- evidence or suspicion that the actions leading to harm (including acts of omission) were reckless, grossly negligent or wilfully neglectful
  - evidence or suspicion that harm/adverse consequences were intended
- 10.3 Once such a decision has been taken, representatives of the organisation, Police and, where appropriate Health and Safety Executive, should arrange an initial meeting. The meeting of this 'Incident Coordination Group' should be called, as soon as practicable, following the referral and, in any case, the group should meet within five working days of the referral. All three organisations are entitled to call an Incident Co-ordination Group meeting. The responsibility for organising the meeting will be agreed between the participating investigation bodies, the CCG and where appropriate, the provider.
- 10.4 The Police, and/or the Health and Safety Executive may also call an Incident Co-ordination Group meeting, in response to a complaint, referral from a coroner, or in response to other concerns.
- 10.5 Until the first meeting of the Incident Co-ordination Group, the service provider should continue to deal with concerns about patient safety, but not undertake any activity that may compromise any subsequent investigations conducted by the Police and/or the Health and Safety Executive and the Care Quality Commission (CQC). If in doubt about this matter, the organisation should seek legal advice and consult the Police, the Health and Safety Executive, the CQC, or where appropriate, other investigating bodies.
- 10.6 It is also critical that, for these incidents, any relevant physical, scientific and documentary evidence that may be required by external agencies, including the Police, is secured and preserved.
- 10.7 Some patient safety incidents may result in the Police, and/or the Health and Safety Executive and the CQC investigating possible offences by individual employees and/or the employer. This is set out in a Memorandum of Understanding between the CQC, the Health and Safety Executive and the police. Investigation of the NHS employer will normally involve the Health and Safety Executive. This is because the Police and regulators have primary responsibility for enforcing legislation relating to the legal requirements and obligations on service providers and employers. In such cases, it may not be appropriate for those who may be investigated, or could be defendants in a criminal case, to be members of the Incident Co-ordination Group. When this issue arises, it should normally be discussed, at the outset, by the agencies involved, and if necessary, the Strategic Health Authority should take on the role of liaising with the Police and Health and Safety Executive, on behalf of the Trust.

## **11 DISSEMINATION OF LEARNING**

### **Responsibilities of Providers**

- 11.1 In order to ensure steps are taken to reduce the chance of a similar incident happening again, it is expected that providers will disseminate any learning identified within their own organisation and other services involved in the incident. These arrangements will be overseen by Somerset CCG with each NHS provider through the quarterly Clinical Quality Review Meetings.

### **Responsibilities of the CCG**

- 11.2 Somerset CCG has processes in place to review incidents by theme and provider and to share learning more widely within the local health community through the SafetyNet Newsletter, the quarterly Clinical Quality Review Meetings, other appropriate stakeholder groups and the quarterly Clinical Quality Review Meeting reports to the CCG Governing Body.

## **12 RELEVANT PUBLICATIONS**

NHS England Serious Incident Framework, March 2015

National Quality Board – How to: Organise and Run a Rapid Responsive Review: 2013/14, February 2013

National Quality Board – How to Organise and Run a Risk Summit (second edition), December 2014

National Quality Board - Quality in the New Health System: Maintaining and Improving Quality from April 2013

NHS England Revised Never Events Policy and Framework, March 2015

NHS England Emergency Preparedness, Resilience and Response Framework (November 2015)

Avon and Somerset Local Health Resilience Partnership Health Community Response Plan (v 2.2), November 2015  
Care Quality Commission: Guidance for providers in meeting the regulations – Health and Social Care Act 2008 (Regulated Activities) Regulations 2014; Care Quality Commission (Registration) Regulations 2009, March 2015

Managing Safety Incidents in NHS Screening Programmes, October 2015

Health and Social Care Information Centre, Checklist Guidance for Reporting, Managing and Investigation Information Governance and Cyber Security Serious Incidents Requiring Investigation, Version 5.1, May 2015

Department of Health, Care and Support Statutory Guidance - Issued under the Care Act 2014, dated June 2014

Somerset County Council, Safeguarding information for providers,  
<http://www.somerset.gov.uk/adult-social-care/safeguarding/safeguarding-information-for-providers/>

Civil Contingencies Act 2004

Health and Social Care Act 2012

**April 2016**