

# COVENTRY AND RUGBY CLINICAL COMMISSIONING GROUP

## Serious Incident Policy

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## **1. Introduction**

This policy is intended to support Coventry and Rugby Clinical Commissioning Group's (CRCCG's) commitment to ensure that patients receive the best quality of care delivered through services which are safe, clinically effective and patient centred.

CRCCG recognises that within the complex environment of healthcare, things will sometimes go wrong. Therefore the NHS has a duty to ensure that systematic measures are in place to respond to incidents in order to safeguard people, property, resources and reputation.

The role of the CCG is to gain assurance from its provider organisations that serious incident investigations are robust and that improvements that will prevent recurrence of serious incidents are implemented. In line with the CCGs clinical governance framework the CCG will triangulate information from serious incident reports with other intelligence to inform actions that continuously improve services. The CCG will share intelligence with relevant regulatory and partner organisations through locally established mechanisms.

In line with the NHS England Serious Incidents Framework (March 2015) CRCCG will be informed of any Serious Incidents that have occurred within any of its commissioned services as listed below:

- University Hospitals Coventry and Warwickshire (UHCW)
- Coventry and Warwickshire Partnership Trust (CWPT)
- Independent and Private Providers, commissioned to provide NHS services for the CCGs population, including NHS commissioned placements and service provision in nursing homes
- Any other provider of NHS commissioned services affecting the patient population of CRCCG (e.g. South Warwickshire Foundation Trust or George Eliot Hospital)

This document reflects national policies in relation to serious incidents including:

- Serious Incident Framework – NHS England (March 2015)
- Never Events Framework and Policy NHS England (March 2015)
- Statutory Duty of Candour

## **2. Purpose**

The purpose of this policy is to outline the overarching governance arrangements for Serious Incidents and Never Events, and to describe the process for reporting and management. This will ensure that incidents are appropriately managed within commissioned and contracted services. The responsibility of individuals in this process is explained in section 6.

The policy is intended to compliment and not replace the robust incident reporting systems which are already in place within NHS organisations. Providers should read this policy in context with other policies they have in place to ensure compliance with

the Health and Social Care Act (2012) and local arrangements for ensuring staff, patients, carers and relatives receive support following a serious incident.

This policy does not replace the duty to inform other authorities of Serious Incidents, for example the Police, Social Services or Local Safeguarding Boards for Children and Adults, where appropriate. Other regulatory, statutory, advisory and professional bodies (listed in appendix 2 of the NHSE Serious Incident Framework) should be informed about serious incidents depending on the nature and circumstances of the incident. All serious incidents which meet the definition for a patient safety incident should also be reported separately to the NRLS for national learning.

### **3. Scope of Policy**

This policy aims to ensure that:

- all members, staff and/or employees working for or on behalf of the CCG are aware of their duties when reporting, investigating or managing incidents.
- providers of commissioned services report serious incidents in a timely manner, respond appropriately and learn from incidents
- CRCCG has an open and honest approach to provider incidents affecting patients, relatives and carers; and a commitment to sharing lessons learned
- lessons learned from incidents and trends are fully acted upon by commissioned providers and shared across the wider health economy

### **4. Definitions**

#### Serious Incident

The definition below sets out circumstances in which a serious incident must be declared. Every incident must be considered on a case-by-case basis using the description below. Inevitably, there will be borderline cases that will require open and honest discussion between the CCG and the provider to agree the appropriate and proportionate response.

Serious Incidents in the NHS 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 caused or contributed to by weaknesses in care/service delivery (including lapses/acts and/or omission). This includes suicide/self-inflicted death; and homicide by a person in receipt of mental health care within the recent past. This includes those in receipt of care within the last 6 months but this is a guide and each case should be considered individually;
  - 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.
- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. (See Never Events Policy and Framework for the national definition and 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 (MCA), Deprivation of Liberty Safeguards (DOLS);
  - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/unit closure or suspension of services); or
  - Activation of Major Incident Plan (by provider, commissioner or relevant agency)
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

#### Death due to natural causes

A death which occurs as a direct result of the natural course of the patient's illness or underlying condition where this was managed in accordance with best practice would not be classified as a serious incident.

#### Near Miss

It may be appropriate for a 'near miss' to be classified as a serious incident because the outcome of an incident does not always reflect the potential severity of harm that could be caused should the incident (or a similar incident) occur again. Deciding whether or not a 'near miss' should be classified as a serious incident should therefore be based on an assessment of risk that considers:

- The likelihood of the incident occurring again if current systems/process remain unchanged; and

- The potential for harm to staff, patients, and the organisation should the incident occur again.

This does not mean that every 'near miss' should be reported as a serious incident but, where there is a significant existing risk of system failure and serious harm, the serious incident process should be used to understand and mitigate that risk.

## **5. Roles and Responsibilities**

The roles and responsibilities of NHS England, commissioners and providers are clearly outlined in the NSHE Serious Incident Framework 2015.

### NHS England

NHS England has a direct commissioning role as well as a role in leading and enabling the commissioning system. As part of the latter role, NHS England maintains oversight and surveillance of serious incident management within NHS-funded care and assures that CCGs have systems in place to appropriately manage serious incidents in the care they commission. They are responsible for reviewing trends, analysing quality and identifying issues of concern. They have a responsibility for providing the wider system with intelligence gained through their role as direct commissioners and leaders of the commissioning system.

### CRCCG

The role of the CCG is to assure the quality of commissioned services and to hold providers to account for their responses to serious incidents. This includes:

- ensuring there is timely reporting of serious incidents by providers and feedback from the CCG
- engaging in open and honest discussion with providers
- gaining assurance 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
- evaluating and quality assuring the robustness of their providers' serious incident investigations
- managing concerns raised in relation to the management of the investigation process
- agreeing a mechanism with providers to ensure that action plan implementation is undertaken and robust monitoring the implementation of long term actions
- triangulating serious incident data with other intelligence achieved via day to day interactions with providers to inform actions that continuously improve services
- Liaising with the local authority safeguarding lead to ensure that there is a coherent multi-agency approach to investigating and responding to safeguarding concerns
- complying with the statutory obligations and requirements of health services in relation to domestic homicide reviews
- facilitating joint investigations between providers as appropriate

- establishing mechanisms for sharing intelligence with relevant regulatory and partner organisations
- sharing information with members of their local NHSE Quality Surveillance Group (QSG) serious incident investigation reports to support openness and transparency
- ensuring that serious incident trend data informs quality reviews and commissioning decisions

#### Provider organisations

The CCG requires commissioned providers to meet the requirements outlined in the NHSE Serious Incident Framework. The leadership at a provider organisation is ultimately responsible for the quality of care that is provided by that organisation. The principles and processes associated with robust serious incident management must be endorsed within an organisation's Incident Reporting and Management Policy.

## **6. Accountabilities**

#### Accountable Officer

Overall accountability within the CCG lies with the Accountable Officer who has responsibility for ensuring that the CCG has the necessary processes and procedures in place to support the effective management of implementation of all risk management and governance policies. In CRCCG responsibility for the management of serious incidents is formally delegated to the Chief Nurse.

#### Chief Nurse

The Chief Nurse has been designated by the Accountable Officer as the managerial lead for patient safety and safeguarding. The Chief Nurse has executive responsibility for ensuring that the necessary management systems are in place for the effective implementation of serious incident reporting for commissioned services and independent contracts.

#### Governing Body Secondary Care Doctor

The Secondary Care doctor has been designated as the Lead Executive for patient safety and provides support to the Chief Nurse.

#### Lead Nurse for Patient Safety and Experience

The Lead Nurse for Patient Safety and Experience is responsible for the clinical leadership, coordination and operational management of the serious incident reporting process, ensuring there is a consistent and robust approach in line with policy. Specific responsibility will include:

- Acting as a point of contact for provider organisations to report any serious incidents/Never Events via Serious Incident telephone
- Overview of the management of incident notifications
- Authority to make decisions regarding any withdrawal or extension requests received from provider organisations
- Responsibility for sign off and closure of incidents
- Attendance at provider Serious Incident Group meetings
- Submission of regular patient safety reports to the Clinical Quality and Governance Committee



- identification and analysis of themes and trends from serious incidents, RCA reports and action plans.
- ensuring the local policies and procedures reflect national guidance

#### Commissioning Support Unit (CSU) Patient Safety Team

The CSU Patient Safety Team is responsible for administration of incident reporting systems (SOR and STEIS) and management of associated databases, including:

- notifying the CCG of any incidents reported on SOR and STEIS and any investigation updates/reports submitted by provider organisations
- maintenance and administration of the SOR database and additional local databases
- creating and updating serious incident records on SOR and STEIS for providers that cannot access the database (i.e. care homes)
- producing a monthly overview report of serious incident data
- extracting additional data and reports in line with CRCCG requirements

#### CRCCG Quality and Nursing Team

The Quality and Nursing Team support the Lead Nurse for Patient Safety and Experience in delivery of the Serious Incident Policy and process requirements e.g. by reviewing Root Cause Analysis reports.

#### CRCCG Contract Managers

Contract Managers will ensure that explicit reference to Serious Incident management and reporting is included in contracts with all commissioned provider services including the process for performance management.

#### CRCCG Communications Team

The CCG communications team will prepare briefings in relation to serious incidents as required.

## **7. Interfaces with Other Sectors**

In certain circumstances the serious incident process will coincide with other procedures. In order to minimise duplication and confusion, CRCCG will work collaboratively with partner agencies. Ideally, only one investigation should be undertaken to meet the needs/requirements of all parties. However, where investigations have different aims and purposes, joint investigations may not be possible but efforts should be made to ensure duplication of effort is minimised.

#### Serious Case Reviews (SCR) and Safeguarding Adult Reviews (SAR)

Healthcare providers must contribute towards safeguarding reviews and enquiries as required to do so by the Local Safeguarding Board. Where it is indicated that a serious incident has occurred, this must be reported. Whilst the Local Authority will lead SCRs, SARs and initiate Safeguarding Enquiries, the CCG must be able to gain assurance that, if a problem is identified, appropriate measures will be undertaken to protect individuals that remain at risk and ultimately to identify the contributory factors and the fundamental issues to minimise the risk of further harm and/or recurrence.

The interface between the serious incident process and the local safeguarding adult procedures is outlined in the West Midlands Adult Safeguarding Multiagency Policy and

Procedure.

The arrangements for interagency working in respect of safeguarding children are outlined in the Safeguarding Children Boards' Policies and Procedures for both Coventry and Warwickshire. The Chief Nurse is a member of both Coventry and Warwickshire Safeguarding Children's Boards and liaises regularly with the Local Authority Safeguarding Executive Leads.

## **8. Reporting of Serious Incidents**

Serious incidents must be reported by the provider to the commissioner without delay and no later than 2 working days after the incident is identified, or at the earliest point thereafter with an explanation for any delay. A serious incident must be reported by recording the incident on the NHS serious incident management system (STEIS or its successor system) and the local Serious Incident Online Reporting Database (SORD). Where providers are unable to access STEIS (e.g. nursing homes) the provider should submit a serious incident form to the CSU who will enter the incident onto STEIS and SORD and report to the CCG on the provider's behalf. The serious incident report must not contain any patient or staff names and the description should be clear and concise.

Incidents falling into any of the categories below should be reported immediately to the relevant commissioner by telephone as well as electronically:

- 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, the local health protection unit (Public Health England) or other external agencies

Out-of-hours, the local on-call management procedures must be followed.

### Safeguarding Incidents

The Serious Incident Framework requires that incidents involving actual or alleged abuse to be reported as serious incidents where:

- healthcare did not take appropriate action/intervention to safeguard against such abuse occurring.  
(This may include failure to take a complete history, gather information from which to base care plan/treatment, assess mental capacity and/or seek consent to treatment; or share information when to do so would be in the best interest of the client in an effort to prevent further abuse by a third party and/or to follow policy on safer recruitment)
- the abuse occurred during the provision of NHS-funded care.

Abuse includes:

- sexual abuse, physical or psychological ill-treatment
- acts of omission which constitute neglect
- exploitation
- financial or material abuse
- discriminative and organisational abuse
- self-neglect
- domestic abuse
- human trafficking

- modern day slavery

This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident.

From April 2015, the Care Act (2014) provides a statutory footing to safeguard adults, thereby replacing previous guidance such as *No Secrets* (2000). The Care Act (2014) creates a legal framework to promote a shared approach by all agencies with responsibilities for adult safeguarding to work together to keep adults at risk safe.

#### Unexpected Child Death

In the event of an unexpected child death providers are required to complete a notification form and return this to the CCG (appendix F). All forms will be reviewed by the Designated Nurse for Safeguarding Children in line with the unexpected child death serious incident process (appendix E). The Local Safeguarding Children Board is responsible for ensuring that a review of each death of a child normally resident in the LSCB's area is undertaken by a Child Death Overview Panel. The process for review of child deaths is outlined in *Working together to Safeguard Children* (2015).

#### NHS Screening Programme Serious Incidents

The national guidance for screening programme serious incidents is currently under review. The final guidance will be issued in Summer 2015. Until that point the revised national guidance in relation to screening incidents issued in March 2015 should be followed. The guidance details the accountabilities for reporting, investigating and managing screening safety incidents. It covers the management of safety concerns, safety incidents and serious incidents in screening programmes.

#### Pressure Ulcer Serious Incidents

The revised Serious Incident Framework states that that blanket reporting of all grade 3 and 4 pressure ulcers by providers can lead to debilitating processes which do not effectively support learning. However, providers should continue to report pressure ulcers where they meet the serious incident criteria.

For patients admitted or transferred to a healthcare setting without any obvious signs or symptoms of skin damage, the development of a grade 3 or 4 pressure ulcer within 72 hours of admission to that institution is likely to be related to pre-existing damage incurred prior to admission or transfer of care. Any pressure area damage arising after 72 hours is likely to be related to care provided within the healthcare setting and must be regarded as a new event.

*It is anticipated that further guidance will be issued by NHS England to support the multi-incident investigation root cause analysis (RCA) model. This model provides a useful tool for thoroughly investigating reoccurring problems of a similar nature (such as a cluster pressure ulcers in a similar setting or amongst similar groups of patients) in order to identify the common problems, contributing factors and root causes. The tool allows one comprehensive action plan to be developed and monitored and, if used effectively, moves the focus from repeated investigation to learning and improvement. CRCCG is working toward developing a system wide approach to learning from pressure ulcers.*

### Information Governance (IG) Incidents

Serious incidents relating to information governance must be reported on SORD and STEIS, as well as the IG toolkit as required by the Health and Social Care Information Centre (HSCIC) guidance. The severity of the incident must be assessed using the scale and severity factors outlined within the HSCIC guidance and all incidents which reach the threshold for a level 2 IG related serious incidents should be reported publicly via the IG toolkit and reported and investigated as serious incidents. All IG incidents should be referred to the Head of Corporate Affairs who will liaise with the Governance and Compliance Team with regard to reporting the incident on the IG Toolkit.

### Duty of Candour

A statutory requirement has been introduced to ensure health care providers operate in a more open and transparent way. The regulation for Duty of Candour applied to health service bodies from 27 November 2014, and was extended to all other providers from 1 April 2015. This regulation requires an NHS body to:

- ensure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity
- tell the relevant person in person as soon as reasonably practicable after becoming aware that a 'notifiable safety incident' has occurred, and provide support to them in relation to the incident, including when giving the notification
- provide an account of the incident which, to the best of the health service body's knowledge, is true of all the facts the body knows about the incident as at the date of the notification
- advise the relevant person what further enquiries the health service body believes are appropriate
- offer an apology
- follow this up by giving the same information in writing, and providing an update on the enquiries
- keep a written record of all communication with the relevant person

The duty of candour section of the STEIS reporting form must be completed for all incidents reported.

### Caldicott Principles, Data Protection and Information Governance

Reporting organisations must comply with Caldicott Principles, Data Protection and Information Governance requirements when reporting a serious incident. Particular attention must be paid to confidentiality, sensitivity and person identifiable information – apart from the name of the reporter within STEIS all other reports and correspondence should not contain any patient or staff identifiable information. The incident will be given a unique identifier which should be quoted as a reference during all associated correspondence.

Managers should be aware of Department of Health guidance that may exempt details of individual serious incidents being made available to third parties, under either or both Section 31(2) and Section 40 (2 and 3) of the Freedom of Information Act.

### Media Interest

Where potential media interest exists, it is important that the reporting organisation prepares a media response based on the available information. The Commissioner must be informed of the media approach/strategy being taken by the reporting organisation so as to ensure any necessary media management is proportionate and well managed. The communication team should be alerted in accordance with local CCG guidance. Where a number of organisations are involved, a lead organisation will be agreed to manage and coordinate any external communications.

## **9. Management of Serious Incidents**

### Initial Review of Incident Notifications

Following notification of a Serious Incident an initial review will be undertaken by an appropriate member of the CRCCG Nursing and Quality Team. Where required specialist advice will be sought. A 72 hour update may be requested from the provider at the discretion of the CCG in order to provide assurance that any necessary immediate actions have been taken to ensure the safety of staff, patients and the public; and to assess the incident in more detail. The update should be uploaded onto the SORD system by the provider.

Where a serious incident indicates an issue/problem that has significant implications for the wider healthcare system, or where an incident may cause widespread public concern, the initial reviewer will consider the need to share information with NHS England and other partner agencies as required.

### Investigation of serious incidents

The responsibility for investigating Serious Incidents lies with the reporting organisation, however the CCG has a responsibility to quality assure the robustness of the providers investigation. The investigation should be underpinned by a clear terms of reference, a robust management plan and communication/media handling strategy (as required). Investigations should follow root cause analysis (RCA) methodologies and an investigation toolkit can be accessed from National Reporting and Learning Service. The table below outlines the 3 levels of investigation currently recognised for NHS serious incident investigations.

Information in this table provides an outline of the levels of systems-based investigations recognised in the NHS (currently referred to as RCA investigation). Within the NHS, most serious incidents are investigated internally using a comprehensive investigation approach. Resources to support systems-based investigation in the NHS are available online from: <http://www.england.nhs.uk/ourwork/patientsafety/root-cause/>. For further information relating to the circumstances and requirements for commissioning independent investigations see appendix 3.

Level	Application	Product/ outcome	Owner	Timescale for completion
Level 1 <b>Concise internal 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  All internal investigation should be supported by a clear investigation management plan
Level 2 <b>Comprehensive internal investigation</b>  (this includes those with an independent element or full independent investigations commissioned by the provider)	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a 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	
Level 3 <b>Independent investigation</b>	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 (see Appendix 1 and 3 for further details)	Comprehensive investigation report including all elements of a credible investigation	The investigator and all 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.	6 months from the date the investigation is commissioned

National reporting templates should be used unless agreed that adaptations are required. National templates will be reviewed on a continuous basis. Recommendations to inform changes should be sent to [england.RCAinvestigation@nhs.net](mailto:england.RCAinvestigation@nhs.net)

### Withdrawal of Incident Report

If at any time during a Serious Incident investigation, it becomes apparent that the incident does not constitute a Serious Incident it may be withdrawn. The provider must make a formal request to the CCG for consideration, including a clear rationale for withdrawal. At this point the incident will be removed from SORD and STEIS but be recorded on a local database for audit purposes if agreed.

### Timescales for Investigation

Serious incident reports and action plans must be submitted to the relevant commissioner within 60 working days of the incident being reported, unless an independent investigation is required, in which case the deadline is 6 months from the date the investigation commenced. In certain circumstances, Trusts may find it difficult to complete a final report within these timescales due to:

- enforced compliance with the timetable of an external agency, such as police, Coroner, Health and Safety Executive or Local Children Safeguarding Board or Safeguarding Adult Board;
- investigation of highly specialised and multi-organisation incidents, such as those involving a national screening programmes; or
- incidents of significant complexity.

Extensions to timescales may also be approved in circumstances meet the CCGs local criteria, including:

- awaiting outcome of court proceedings
- awaiting forensics post-mortem findings
- awaiting toxicology results

The CCG should be notified of extension requests in writing including the reason for the delay, the anticipated delay period and a new reporting timescale. Where a compelling reason is provided an extension may be agreed by the CCG and a “clock stop” will be recorded on STEIS and SORD. It is essential where a clock stop is in place that providers ensure that the CCG is regularly updated on the progress of the investigation.

### Final Report and Action Plan

Providers must upload the final Root Cause Analysis report to SORD upon completion of the investigation. Providers who cannot access SORD must submit the report via the CSU secure email address. The CCG recommends that providers utilise the locally agreed templates for the final report and action plan.

*This policy does not contain the report and action plan templates as these are currently subject to review in line with the national guidance.*

## **10. Quality Assurance and Closure of the Investigation**

The CCG will undertake a quality assurance review of each investigation report within 20 calendar days (an alternative timescale may be agreed if appropriate). An appropriate member of the CRCCG Nursing and Quality team (according to the nature of the incident) will review the report and complete a locally agreed closure checklist (Appendix B) to ensure that the report meeting the standard for a robust investigation and action plan. A secondary review may be requested by another member of the team where concerns have been identified. Any concerns or areas requiring further action will be logged on the RCA review database and highlighted to the provider as appropriate to facilitate action and resolution of any issues raised.

Where the CCG requires additional assurance in relation to the implementation of an investigation action plan, the incident may remain open on SORD and STEIS to ensure close review and monitoring or preventative actions.

## **11. Dissemination of Learning**

Serious Incident investigations are conducted for the purposes of learning to prevent recurrence. In line with the national Serious Incident Framework CRCCG aims to facilitate learning by:

- seeking assurance that providers have a fair, open, and just culture
- quality assuring incident investigation reports to ensure that areas for improvement are identified and incorporated into robust action plans
- ensuring providers have systems in place to monitor the implementation of actions plans
- identifying systemic issues in order to prevent recurrence and developing quality improvement plans, e.g. through thematic review and triangulation of incident data with other intelligence
- challenging “the status quo” and prompting providers to undertake “deep dive” reviews into areas of concern
- sharing patient safety information with other local CCGs and partner agencies as appropriate
- participating in the Coventry and Warwickshire Learning Forum
- supporting smaller providers (e.g. nursing homes) to report and investigate incidents
- encouraging providers to share investigation reports where appropriate

## **12. Monitoring and Reporting Committees and Groups**

### CRCCG Governing Body

The Governing Body has oversight of the management of serious incidents through the minutes of the Clinical Quality and Governance Committee.

### Clinical Quality and Governance Committee (CQGC)

The Clinical Quality and Governance Committee is a sub-group of the CRCCG Governing Body which provides assurance that robust processes are in place to monitor the clinical quality and safety of commissioned services. The Committee will receive regular reports to provide assurance in relation to serious incidents. Key areas of concern will be escalated as appropriate.

To comply with national guidance for Never Events the CQGC will monitor Never Events within CRCCG commissioned services and publicly report through Governing Body on the national Never Events list as part of annual quality reporting arrangements. This will include the frequency and type of Never Events which have occurred and a summary of the actions that these providers have implemented following root cause analysis of significant event audit.

### Clinical Quality Review Group (CQRG)

CRCCG makes explicit reference to expectations regarding serious incident reporting and management within provider contracts. In order to ensure continuous improvement a range of key performance indicators are built into provider contracts which are monitored via each providers CQRG. The relevant CQRG will monitor performance of



serious incident management and highlight any concerns in relation to trends, robustness of actions and lack of assurance regarding quality and safety.

#### Cross CCG Patient Safety & Quality Group

The Patient Safety and Quality Group meets monthly to facilitate collaborative review of serious incidents and Never Events by CRCCG, Warwickshire North CCG and South Warwickshire CCG.

#### Coventry and Warwickshire Learning Forum

The Coventry and Warwickshire Learning Forum meets quarterly to share changes in practice resulting from serious incidents. The group aims to ensure that learning from serious incidents and Never Events is shared across local CCGs and providers, the NHSE Area Team and other interested parties from the wider health economy.

### **13. Themed Reviews**

In cases where there is evidence that an incident is part of a trend or where the circumstances or consequences of the incident are exceptionally serious the CCG may instigate a wider investigation or themed review.

### **14. Training & Awareness**

Staff will be made aware of this policy through the staff induction process, when directed to review policies and procedures of the organisation. The policy will be held on the Internet.

### **15. Equality and Diversity**

Reporting organisations must comply with Equalities and Human Rights requirements and legislation when reporting, managing, and preventing serious incidents. Understanding and upholding the rights and dignity of patients from protected groups can aid in the early identification of potential risks and risk groups. The policy identifies a number of protected characteristics including older people who are frail, maternity, and mental health that may potentially be at higher risk of a serious incident.

Reporting organisations are required to collect patient equality monitoring information by gender, ethnicity, and age via STEIS, and are encouraged to supply any additional relevant equality information in the additional text section. The CCG's may also from time to time request additional equality information. The CCG's will undertake regular analysis of this information in order to identify any trends, as part of its on-going routine monitoring processes. The identification of any concerning equality trends or issues will prompt an immediate themed investigation by the CCG's.

### **16. Policy Review**

The CCG's Serious Incident Policy will be reviewed bi-annually or sooner in the event that there are significant changes within legislation, good practice guidance or case law in respect to the investigation and management of serious incidents and/or there are significant changes to organisational infrastructure within the CCG.

# Appendices

## **Appendix A – Definitions**

### **Being Open**

Open communication of patient safety incidents that result in harm or the death of a patient while receiving healthcare.

### **[Clinical] Governance**

A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

### **Information Governance**

All Information Governance serious incidents are to be handled in accordance with the guidance developed by the Department of Health “Checklist for reporting Managing and Investigating information Governance Serious Untoward Incidents”. This guidance includes details on assessing the severity of the incident and reporting requirements via the Information Governance (IG) Toolkit.

### **Risk**

The chance of something happening that will have an impact on individuals and/or organisations. It is measured in terms of likelihood and consequences.

### **Root Cause Analysis (RCA)**

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

### **Safeguarding**

Safeguarding is effectively protecting children and vulnerable adults from abuse or neglect. All NHS commissioned services have a key role to play in safeguarding and promoting the welfare of children and vulnerable adults, as safeguarding is everybody’s business. Safeguarding children is a statutory duty under section 11 of the Children Act 2004 and in accordance with government guidance in ‘Working Together to Safeguard Children’ 2015.

### **SORD (Serious Incident On-line Reporting Database)**

SORD is the local risk management database used in parallel to STEIS to record SIs for all contracted and commissioned services. SORD is used to facilitate local reporting, monitoring and trends analysis. It also allows secure document storage, aggregates data collection and an online methodology for commissioners to score the quality of provider investigation reports against best practice.

### **STEIS**

The Strategic Executive Information System (STEIS) is one of the modules of UNIFY. Users are enabled to electronically log, track and report serious incidents. UNIFY is the source of Performance Management information for NHS England.

## **Appendix B - References and Further Reading**

Serious Incident Framework 2015, NHS England

<http://www.england.nhs.uk/ourwork/patientsafety/serious-incident/>

Revised Never Events Policy and Framework 2015, NHS England

<http://www.england.nhs.uk/ourwork/patientsafety/never-events/>

National Reporting and Learning Service investigation toolkit

<https://report.nrls.nhs.uk/rcatoolkit/course/index.htm>

National Patient Safety Agency, 'Seven Steps to Patient Safety', 2004 – 2009

<http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/>

National Patient Safety Agency, 'Being Open: communicating patient safety incidents with patients, their families and carers', November 2009

<http://www.nrls.npsa.nhs.uk/resources/?EntryId45=83726>

National Patient Safety Agency Tools and training resources to support RCA investigation in the NHS

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

National Patient Safety Agency information for multi-incident investigations

<http://www.nrls.npsa.nhs.uk/resources/?entryid45=75355>

CQC Regulation 20: Duty of candour Guidance for NHS bodies November 2014

[http://www.cqc.org.uk/sites/default/files/20141120\\_doc\\_fppf\\_final\\_nhs\\_provider\\_guidance\\_v1-0.pdf](http://www.cqc.org.uk/sites/default/files/20141120_doc_fppf_final_nhs_provider_guidance_v1-0.pdf)

Royal College of Surgeons (2015) Duty of Candour Guidance For Surgeons And Employers

<https://www.rcseng.ac.uk/news/docs/1-duty-of-candour-web-final.pdf>

NHS Litigation Authority Advice on saying sorry

<http://www.nhsla.com/claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf>

Health and Social Care Information Centre guidance (HSCIC) Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation (2015)

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

Managing Safety Incidents in NHS Screening Programmes – updated interim guidance (March 2015)

<http://www.screening.nhs.uk/incidents>

Working Together to Safeguard Children A guide to inter-agency working to safeguard and promote the welfare of children (2015)  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/419595/Working\\_Together\\_to\\_Safeguard\\_Children.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/419595/Working_Together_to_Safeguard_Children.pdf)

Guidance for adult safeguarding concerns  
<http://careandsupportregs.dh.gov.uk/category/adult-safeguarding/>

NHS Emergency Preparedness Framework, May 2015  
<http://www.england.nhs.uk/ourwork/epr/gf/>

Prison and Probation Ombudsmans Guidance for Clinical Reviews  
<http://www.ppo.gov.uk/updated-guidance-for-clinical-reviews/>

Guidance on running Quality Surveillance Groups, *National Quality Board, 2nd Edition, March 2014*  
<http://www.england.nhs.uk/wp-content/uploads/2014/03/quality-surv-grp-effective.pdf>

Quality in the New Health System, *Maintaining and Improving Quality*. National Quality Board, January 2013  
<https://www.gov.uk/government/publications/quality-in-the-new-health-system-maintaining-and-improving-quality-from-april-2013>

Human Rights Review (2012) Article 2: The Right to Life  
[http://www.equalityhumanrights.com/sites/default/files/documents/humanrights/hrr\\_article\\_2.pdf](http://www.equalityhumanrights.com/sites/default/files/documents/humanrights/hrr_article_2.pdf)

Mental Capacity Act: making decisions  
<https://www.gov.uk/government/collections/mental-capacity-act-making-decisions>

Mental Capacity Act 2005: Deprivation of liberty safeguards - Code of Practice to supplement the main Mental Capacity Act 2005 Code of Practice  
[http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_085476](http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085476)

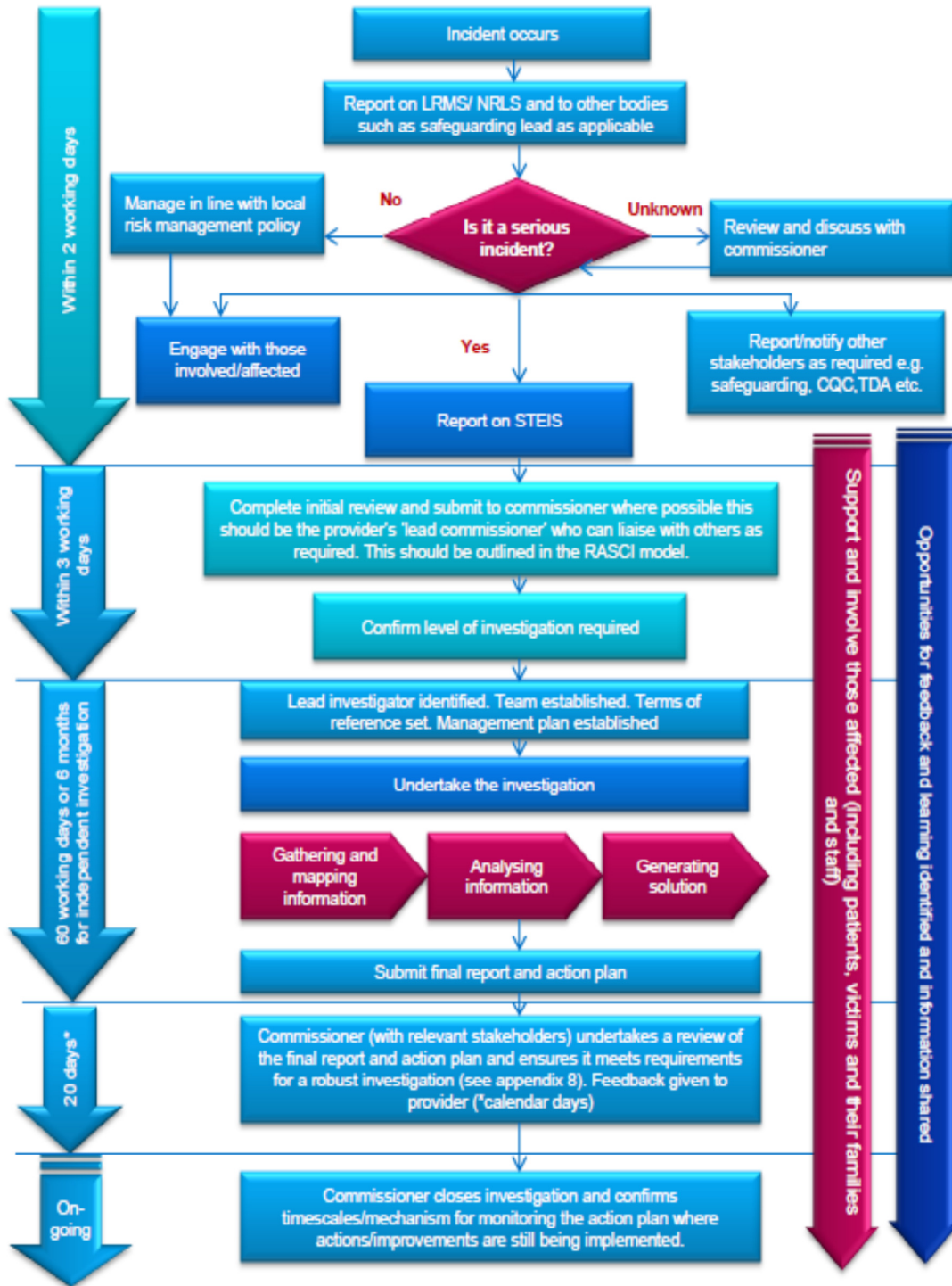
Care Act 2014  
<http://www.legislation.gov.uk/ukpga/2014/23/contents/enacted>

Warwickshire Safeguarding Children Board (WSCB) – resources  
<http://www.warwickshire.gov.uk/wscbresources>

Coventry Safeguarding Children Board Procedures Manual  
<http://coventryscb.proceduresonline.com/chapters/contents.html>

# Appendix C – Overview of the Serious Incident Management Process

## 1. Overview of the Serious Incident Management Process



## Appendix D – CRCCG RCA Report Closure Checklist

<b>Provider:</b>		<b>Date Received:</b>	
<b>Category:</b>		<b>Date Reviewed:</b>	
<b>SORD No.</b>		<b>Reviewer:</b>	
<b>STEIS No.</b>			

Phase of Investigation	Element	Yes/No	If no, was there a robust rationale that prevents this affecting the quality of the investigation?
<b>Set up/ preparation</b>	Is the Lead Investigator appropriately trained?		
	Was there a pre-incident risk assessment		
	Did the core investigation team consist of more than one		
<b>Gathering &amp; Mapping</b>	Were national, standard NHS investigation guidance and process used		
	Was the appropriate evidence used (where is was available) i.e. patients notes/records, written account		
	Were interviews conducted		
	Is there evidence that those with an interest were involved ( <i>making use of briefings, de-briefings, draft reports etc</i> )		
	Is there evidence that those affected ( <i>including patients /staff/victims/perpetrators and their families</i> ) were involved and supported appropriately		
	Is a timeline of events produced		
	Are good practice guidance and protocols referenced to determine what should have happened		
	Are care and service delivery problems identified ( <i>this includes what happened that shouldn't have and what didn't happen that should have. There should be a mix of care (human error) and service (organisational) delivery problems</i> )		
	Is it clear that the individuals have not been unfairly blamed? <i>Disciplinary action is only appropriate for acts of wilful harm or wilful neglect</i>		
	<b>Analysing Information</b>	Is there evidence that the contributory factors for each problem have been explored	
Is there evidence that the most fundamental issues / or root causes have been considered			
<b>Generating Solutions</b>	Have strong and targeted recommendations and solutions (targeted towards root causes/ contributory factors/ service delivery issues) been developed? Are actions assigned appropriately?		
<b>Throughout</b>	Is there evidence that those affected have been appropriately involved and supported		
<b>Next Steps</b>	Is there a clear plan to support implementation of change and improvement and method for monitoring		

**TRENDS & THEMES**

Please tick all those which apply	Themes:
	Individual Staff Issue
	Team and Social Factors
	Communications Factors
	Task Factors
	Education and Training
	Equipment / Resources
	Working Environment / Conditions
	Organisational / Strategic Factors
	Staffing
	Patient Factors

**ISSUES TO BE RAISED WITH PROVIDER**

**REFERRED FOR SECOND REVIEW TO:**

**COMMENTS FROM SECOND REVIEW**



## Appendix E - Unexpected Child Death Serious Incident Process



**Appendix F – Form for notification of unexpected child death to the CCG**

**FORM FOR NOTIFICATION OF UNEXPECTED CHILD DEATHS TO THE CCG  
COVENTRY AND RUGBY CLINICAL COMMISSIONING GROUP**

To be sent by fax to: 024 76246179 **or** Secure email to: [CRCCG.Safeguarding@nhs.net](mailto:CRCCG.Safeguarding@nhs.net)

**This form must be forwarded within 1 working day**

**Information on File:**

**Name of Child:** ..... **NHS No:** .....

**Date of Birth:** ..... **Date of Death:** .....

Place of death: .....

Place of resuscitation: .....

Brief description of case (if not on FormA): .....

Has the child been seen in the last week  
by a GP or Out of Hours Service? **Y / N** if Yes please provide details:  
.....  
.....  
.....

Details of any recent hospital admissions (in last month): .....

CAE completed? **Y / N**  
Notified as **SUI** within provider Trust? **Y / N**  
Is an **RCA** being undertaken? **Y / N**

**SI FORM FOR NOTIFICATION OF UNEXPECTED CHILD DEATHS TO THE CCG**  
COVENTRY AND RUGBY CLINICAL COMMISSIONING GROUP

**Name of Child:** ..... **NHS No:** .....

**Child Death**

Was a Strategy Meeting undertaken?	
Was a Rapid Response required?	
Was rapid response undertaken?	
Which provider did rapid response? UHCW / SWFT / GEH	
Which Paediatrician did rapid response?	
Which Paediatrician for Unexpected Child Death is managing the case?	

## Appendix G Equality Impact Assessment

Directorate  Team  Name of lead person

Piece of work being assessed

Aims of this piece of work

Date of EIA  Other partners/stakeholders involved

Who will be affected by this piece of work?

Serious Incidents are reported in line with national framework (2015) and are managed anonymously by CRCCG. The purpose of reporting serious incidents is to identify and share learning to help prevent future occurrences and improve patient safety. The policy does not appear to have any adverse effects on people who share Protected Characteristics. It is intended that the CRCCG population will benefit from the process of continuous learning and quality improvement.

Single Equality Scheme Strand	Baseline data and research on the population that this piece of work will affect. What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. <b>Include consultation with service users wherever possible</b>	Is there likely to be a differential impact? Yes, no, unknown
<b>Gender</b>	Serious Incidents are reported relating for male and female, however it is uncertain whether transgender people can be identified.	Yes
<b>Race</b>	Serious Incidents are reported relating to people of different races. Patients and their families should be informed by the Provider service of all incidents and the resulting actions following investigations. Some people do not have English as a first language and therefore may require translation to fulfil the requirements of Being Open and Duty of Candour.	Yes
<b>Disability</b>	Some Serious Incidents may affect people who have a learning disability, mental health problem, speech and language disability, hearing or visual impairment or other health condition which may affect their ability to be involved and informed during the Serious Incident process. An individual's disability status may or may not be recorded depending upon the nature of the report.	Yes
<b>Religion/ belief</b>	Serious Incidents may affect people who come from a variety of religious backgrounds. An individual's religious belief is not recorded within reports. There is no evidence to suggest that an individual of a particular religious belief may be more or less likely to be affected.	No
<b>Sexual orientation</b>	Serious Incidents may affect people of a variety of sexual orientations. An individual's sexual orientation is not recorded within reports. There is no evidence to suggest that an individual of a particular sexual orientation may be more or less likely to be affected.	No

<b>Age</b>	Serious Incidents may involve all ages within the population. An individual's age is recorded within reports. People of an older age may be more likely to suffer from ill-health however this is not directly linked to reporting/occurrence of a serious incident.	No
<b>Social deprivation</b>	Serious Incidents can involve people from all social demographics. An individual's socio-economic status is not recorded within reports. People from or of a more deprived background may be more likely to suffer from ill-health however this is not directly linked to reporting/occurrence of a serious incident.	No
<b>Carers</b>	Serious Incidents may involve people who are cared for by another person.	No
<b>Human rights</b>	Will this piece of work affect anyone's human rights?	No

## Equality Impact Assessment Action Plan

Strand	Issue	Suggested action(s)	How will you measure the outcome/impact	Timescale	Lead
Potential barrier for the patient/relative /carer where English is not the first language	Translation and interpreting services are available at the Provider Service. If a CCG serious incident occurs translation and interpreting services should be available if required. CRCCG will review each RCA investigation to ensure that information has been sought from key people involved in the case ie patient/relative/carer	Potential barrier for the patient/relative/carer where English is not the first language	Monitor Duty of Candour KPI within the Provider Quality Schedules	Monthly	Patient Safety leads / Contract Managers
Disability	Potential barrier for a patient/relative/carer with sensory, learning or mental health impairments	The Provider Service/CCG reporting the serious incident must ensure that systems and processes are in place for patients, families and carers involved in adverse incidents to comply with Duty of Candour and Being Open. An independent advocate may be used to facilitate the involvement of the individuals in the process. CRCCG will review each RCA investigation to ensure that information has been sought from key people involved in the case ie patient/relative/carer.	Monitor Duty of Candour KPI within the Provider Quality Schedules	Monthly	Patient Safety leads / Contract Managers
Carers	Serious Incidents may involve people who are cared for by another person.	Patients, families and carers involved in Serious Incidents should expect a common culture of openness, transparency and candour which is explicit within the Serious Incident Policy. CRCCG will review each RCA investigation to ensure that information has been sought from key people involved in the case ie patient/relative/carer.	Monitor Duty of Candour KPI within the Provider Quality Schedules	Monthly	Patient Safety leads / Contract Managers