Leicester City Clinical Commissioning Group

West Leicestershire Clinical Commissioning Group

East Leicestershire and Rutland Clinical Commissioning Group

LOCAL POLICY FOR THE REPORTING, INVESTIGATION AND LEARNING FROM SERIOUS INCIDENTS

RELATING TO COMMISSIONED HEALTHCARE SERVICES BY LEICESTER, LEICESTERSHIRE AND RUTLAND CLINICAL COMMISSIONING GROUPS

DOCUMENT CONTROL	
Document purpose	Local policy aligned to NHS England Serious Incident Framework 2015 and Revised Never Events Policy and Framework 2015
Supercedes	Corporate Policy 043, Policy and Procedure for Reporting, Investigating and Managing Incidents, Accidents, Near Misses and Dangerous Occurrences (Including Serious Incidents) 2012
Author	Tracy Ward, Head of Patient Safety Hosted Patient Safety Team, East Leicestershire and Rutland Clinical Commissioning Group
Target audience	LLR CCGs, Commissioned Healthcare Provider Organisations, NHS England (NHSE), Joint Commissioning Organisations and other External Stakeholders identified within this policy
Consultation period	4 to 9 June 2015
Cross reference	NHSE Serious Incident Framework 2015, NHSE Never Events List 2015/16 and NHSE Revised Never Events Policy and Framework 2015 Equality Act 2010 Section 149, Health and Social Care Act 2012
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Document status

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LLR CCGs Director on call	Pager via	07623 908865
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Incidents to be reported by telephone in addition to the reporting requirements within this local policy:

- Incidents which activate the NHS Trust or Commissioner Major Incident Plan
- Incidents which will be of significant public concern;
- Incidents which will give rise to significant media interest or will be of significance to other agencies such as the police or other external agencies

1 POLICY STATEMENT

This revised policy replaces the Policy and Procedure for Reporting, Investigating and Managing Incidents, Accidents, Near Misses and Dangerous Occurrences (Including Serious Incidents) 2012 (Corporate Policy 043) and supports the requirements of the Serious Incident published by NHS England, 27 March 2015 (NHSE SI Framework, 2015) and the Never Events List 2015/16.

This revised policy relates to the reporting, management and learning from Serious Incidents only and is applicable across Leicester, Leicestershire and Rutland Clinical Commissioning Groups (LLR CCGs) and its contracted providers including primary care, secondary acute and non-acute organisations.

This policy is therefore designed to complement the NHSE SI 2015 Framework and make explicit, local requirements in relation to the reporting, management and learning from SIs within commissioned healthcare providers ('providers').

2 PURPOSE

This policy seeks to engage with providers and LLR CCGs to ensure that robust systems are in place for the reporting, management and learning from SIs so that lessons are learned and appropriate action taken to prevent future harm. It details roles and responsibilities between providers and LLR CCGs to ensure that localised processes fulfil the expected assurance mechanisms.

This policy also seeks assurance that everyone involved in the investigation of Serious Incidents in provider and commissioner organisations address the needs of those affected by such Incidents.

Local operational guidance for serious incident management within provider organisations must be consistent with this policy and the NHSE SI Framework 2015.

3 SEVEN KEY PRINCIPLES

Making services safe for patients is fundamental to the provision of high quality care and it is essential that providers of healthcare have sound and reliable systems in place for staff to report when patients have, or could have, been harmed. Open and honest reporting is a vital and integral component of commitment to the safety and welfare of patients As Serious Incidents are important for learning to avoid their future recurrence, the mainstay of reporting is an unimpeachable analysis of the root cause or causes of any given incident. Only through scrutiny and learning of, with service improvement in response to, Serious Incidents can patient experience, safety and quality be assured.

LLR CCGs has a responsibility to expect SIs to be reported in a timely manner, to be effectively and appropriately investigated, with robust action plans developed and implemented with learning shared as appropriate. Additionally, LLR CCGs will utilise SI intelligence for triangulation of information augment other monitoring systems such as Clinical Quality Review Groups (CQRGs) and Quality Surveillance Groups.

LLR CCGs are supported by a hosted patient safety team.

LLR CCGs require its providers to comply with the 7 key principles in the management of all SIs (NHSE SI Framework 2015, part 2). These will be monitored by LLR CCGs via reporting on the National reporting system the Electronic Strategic Executive Information System (StEIS) reporting, review of SI investigation reports and CQRGs will be:

1. **Open and transparent**
   NHS Being Open guidance and the Duty of Candour must be followed in relation to a 'notifiable incident' (i.e. an incident involving moderate or severe harm or death).
2. **Preventative**
   There must be a focus on learning and developing safe systems and processes, emphasizing accountability and avoidance of apportioning inappropriate blame. The Incident Decision Tree (IDT) must be used (a relaunch of the IDT will be issued by NHSE during 2015/16 and any updates included in the revision of this local policy).
3. **Objective**
   Those involved in the direct care of affected patients must not be investigators, and neither should investigators work directly with those involved in the delivery of that care.
4. **Timely and responsive**
   SIs on StEIS must be reported within 48 hours of the incident being identified and investigations completed within 60 working days (see section 10 regarding reporting process).
5. **Systems based**
   Root Cause Analysis (RCA) methodology of investigation must be utilised by staff with the appropriate skills, training and capacity.
6. **Proportionate**
   SIs require a comprehensive investigation but LLR CCGs recognise that some incidents can be investigated by an individual (with support from others as required). Investigation reports should detail the selection of the panel or individual investigating and provide assurance of their objectivity (re 3 above).
7. **Collaborative**[1]
   The provider with the responsibility for the majority of the care must be the lead investigator in incidents where more than one organisation is involved in the provision of care. The lead provider must report the SI on StEIS and produce a 72-hour report (see **Appendix 1**) detailing all other care providers, indicating how they will engage with those providers and co-ordinate any multi-agency investigation report that will be agreed by all parties involved.

4 DUTY OF CANDOUR

In recognition of the Francis Report (2013) (accessible at http://www.midstaffspublicinquiry.com/report) relating to healthcare responsibilities to be open and transparent with those affected by incidents, LLR CCGs requires providers to comply with the Care Quality Commission (CQC) Regulation 20 in relation to Duty of Candour. Additionally, compliance with Duty of Candour is a national requirement within the NHS standard contract from 2014/15 and subsequently 2015/16

[1] For multiple commissioners, LLR CCGs will adhere to the RASCI (Responsible, Accountable, Supporting, Consulted, Informed) model in line with the NHSE SI Framework, 2015.

Providers are required to include in SI investigation reports that they have:

- Acknowledged and sincerely apologised to patients/families with explanations when things have gone wrong;
- Involved and supported patients/families from the onset of an incident and arranged an early meeting to explain what action is being taken and how they can be informed of what support processes have been put in place – including being informed of any significant findings during the course of the investigation;
- Given the opportunity for patients/families to raise concerns and for these to be included in the investigation Terms of Reference;
- Agreement on how the findings of the investigation and any learning actions will be shared with patients/families;
- A plan for a formal written apology to the patient/family from a suitably senior member of the organisation.

Compliance with the Duty of Candour in relation to serious incidents will be monitored via completed Serious Incident reports and their associated action plans.

5 SUPPORTING STAFF

Providers are required to include in investigation reports how staff have been supported throughout and provide confirmation that staff have access to professional advice from their relevant professional body or union, staff counselling services and occupational health services.

6 DEFINITIONS

6.1 What is a Serious Incident?

Serious incidents are

"events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare." (NHSE SI Framework, 2015)

There is no definitive list of events/incidents that constitute a SI therefore providers should not produce a local list as this could lead to inconsistent or inappropriate management of incidents.

Whilst recognising that every incident must be considered on a case-by-case basis, the definitions provided in the NHSE SI Framework, 2015 in part 1, section 1 describe circumstances where a SI must be declared. This includes Never Events from the Never Events List 2015/16 accessible at:

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

6.2 Assessing whether an incident is a serious incident / downgrading SIs

Where it is not clear whether an incident fulfils the definition of a SI, providers should engage in open and honest discussions with the LLR CCG and relevant parties to agree the appropriate and proportionate response.

The first point of contact from providers should be to the LLR CCG Head of Patient Safety (hosted by ELR CCG) and rationale on whether an incident is a SI may result in the provider undertaking an immediate localised investigation to determine the key facts and to determine if the incident meets the threshold for a SI. Additionally, if a SI is declared but further investigation reveals that the definition of a SI is not fulfilled, providers should agree downgrade with the Head of Patient Safety.

6.3 Assessing the level of harm (As a result of the incident)

Providers should use the National Patient Safety Agency (NPSA) definitions of harm (accessible at http://www.npsa.nhs.uk/corporate/news/npsa-releases-organisation-patient-safety-incident-reporting-data-england/)

No harm:
Impact prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care.

Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.

Low harm:
Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care.

Moderate harm:
Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.

Severe harm:
Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.

Chronic pain (continuous, long term pain of more than 12 weeks as a result of the incident)
Psychological harm, impaired or sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days).

Death:
Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care.

In relation to assessing the severity of information governance incidents, see section 7.12

6.4 Assessing near-miss incidents as SIs

Providers should risk assess near miss incidents and not solely focus on the outcome of near miss incidents. Decisions should be informed by an assessment of risk that takes into consideration:

- The likelihood of the incident occurring again if current systems/processes remain unchanged;
- The potential for harm to staff, patients, and the organisation should the incident occur again.

A risk mature organisation with a healthy incident reporting culture can be expected to report a number of near-miss SIs each year and LLR CCG will monitor incident types reported via its Patient Safety Reports that inform Clinical Quality and Review Groups.

6.5 Routes for identification of SIs

Providers should have robust reporting mechanisms with other healthcare providers that may not necessarily be commissioned by LLR CCGs (e.g. subcontractors) in order that third party identification of incidents including SIs are reported between organisations.

Where a SI is identified because of receipt of a complaint, providers should investigate the event/incident under the principles of this policy and the NHSE SI Framework 2015. The investigation should extend to examining if there were opportunities for the organisation to identify the incident.

(For further guidance see the NHSE SI Framework 2015, part one, section 1-1.3)

6.6 Prioritising and investing time in learning

Providers should assess the following incidents (see list below)[2] on an individual basis using the organisation's incident management procedure and the SI criteria outlined in section 6.2 of this policy. If any such incident is found to meet the SI criteria, it should be reported as such at the point it is identified and entered on StEIS.
The following are not reported on StEIS:-

- Grade 3 pressure ulcers; (Grade 4 pressure ulcers will continue to be reported as an SI and entered on StEIS)
- Fractures as a result of slips, trips and falls; (Unless deemed to have caused severe harm or death)
- Health care acquired infections (HCAI) unless deemed to have caused severe harm or death e.g. Clostridium difficile (C.diff) deaths meet the SI criteria and should be reported on StEIS.

For frequently recurring incidents that do not meet the SI criteria providers should have processes in place which will enable a multi-incident root cause analysis or equivalent investigation to help identify common themes and problems which leads to the

[2] There is no longer a requirement to report incidents listed in section 6.6 as SIs every time they occur (i.e." blanket reporting"), as this may not support effective learning (NHSE SI Framework 2015, section 1.4.1).

development of one organisational action plan. This places the emphasis on learning and improvement rather than conducting repetitive investigations.

Providers should have internal mechanisms in place to ensure all incidents are reported including those that do not meet the SI criteria. All patient safety incidents must be reported to the National Reporting and Learning System (NRLS).

(For further guidance see the NHSE SI Framework 2015, part 1, section 1.3 -1.4)

7 SUPPORT AND INTERFACE WITH OTHER SECTORS

7.1 Provider infrastructure support

Providers should have a governance infrastructure with capacity to manage patient safety and quality, including undertaking SI investigations with learning mechanisms. This applies to providers, irrespective of the size of the organisation. LLR CCGs will provide advice and support to all organisations.

Co-operation and collaborative working between partner agencies is essential for minimising duplication, uncertainty and/or confusion relating to the investigation process. Only one investigation should be undertaken by a team of representatives from relevant agencies to meet the requirements of all parties. In practice this might be difficult to achieve as investigations may have different aims, which may inhibit joint investigations. Where this is the case, efforts must be made to ensure duplication is minimised.

A lead provider should be appointed to coordinate a joint investigation. This should be agreed upon by all organisations involved and will normally be the provider with the most involvement with the patient. The CCG will support with identifying a lead provider.

Should there not be one clear provider or where the CCG consider there to be exceptional circumstances LLR CCGs may facilitate or lead this process.

Where any joint investigation is undertaken all identified learning must be shared across all organisations involved in the investigation.

7.2 SIs linked with criminal proceedings

Providers should continue with SI investigations where there are criminal proceedings linked to the event/incident.

LLR CCGs accept that there will be exceptional cases where SI investigations may be put on hold (i.e. following a formal request by police, HM Coroner or Judge) and in such cases, providers must submit written evidence of this to Head of Patient Safety as part of the Extension Request process and make reference to this when the SI report is produced.

7.3 Deaths in custody – where health provision is a commissioned service

Providers are required to report as an SI, any severe harm or death of people in custody who are receiving healthcare within the custody setting, including those detained under the Mental Health Act (1983).

For prison and police custody, whilst there is a requirement to report the incident as an SI, providers must refer the incident to the Prison and Probation Ombudsman (PPO) or the Independent Police Complaints Commission (IPCC) who are responsible for carrying out the relevant investigations. Providers should conduct their own internal investigation and share this information with the PPO or IPCC to support their investigations. Providers must ensure that they receive a copy of the PPO or IPCC final report and additionally share this with LLR CCGs for identification of potential additional learning opportunities.

For mental health patients who die whilst detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies, providers must report the incident to the CQC as soon as the incident is identified. All such incidents must be subject to an investigation by the provider. For those deaths where the cause of death is unknown and/or where there is reason to believe the death may have been avoidable or unexpected (i.e. not caused by the natural course of the patient's illness or underlying medical condition when managed in accordance with best practice – including suicide and self-inflicted death) then the death must be reported as a SI and investigated through this route. Consideration should be given to commissioning an independent investigation (see section 12).

7.4 Safeguarding

The Care Act 2014 introduces new safeguarding duties for local authorities including: leading a multi-agency local adult safeguarding system; making or causing enquiries to be made where there is a safeguarding concern; hosting safeguarding adults boards; carrying out safeguarding adults reviews; and arranging for the provision of independent advocates. Providers and commissioners must ensure that information about abuse or potential abuse is shared with Local Authority safeguarding teams.

Providers and commissioners must liaise regularly with the local authority safeguarding lead(s) to ensure that there is a coherent multi-agency approach to investigating safeguarding concerns, which is agreed by relevant partners.

The interface between the serious incident process and local safeguarding procedures are articulated in the local multi-agency safeguarding protocol and policies.

http://www.llradultsafeguarding.co.uk/

For further guidance please refer to LLR CCGs Safeguarding adults and children policy
LINK TO BE ADDED AS PUBLISHED

Leicestershire Interagency Procedures are detailed at **Appendix 2**

7.5 Safeguarding Children

A flowchart relating to the interface between SIs and Child Death Reviews is at **Appendix 3.**
Child deaths, significant harm and serious sexual abuse review are all reported to the LSCB (Local Safeguarding Children's Board). An SI may also be reported in accordance to the criteria below:

Unexpected death

Where the death of the child was not anticipated within a 24 hour period following the incident, the following criteria apply to determine the reporting route:

- There are suspicious concerns and/or healthcare management issues identified.
- There are no suspicious concerns, but healthcare management issues have been identified. The case needs to be reported as an SI and reported to the LSCB CDOP Child Death Overview Panel (CDOP). Once the SI investigation report is complete, it must be submitted to the LSCB CDOP and LLR CCGs patient safety team for review and closure;
- There are possible suspicious circumstances or child protection concerns, but no care management issues identified. The case needs to be reported to the LSCB for consideration as to whether or not a serious case review (SCR) should take place and to the CDOP. If no care management issues are confirmed, the case does not require reporting as an SI
- There are possible suspicious circumstances or child protection concerns and healthcare management issues. The case needs to be reported to the LSCB for consideration as to whether or not a SCR is required, however, this should not hamper the Trust's internal investigation. The final SI report must be submitted to the LSCB and LLR CCGs patient safety team in accordance to agreed timescales.
- Where the death of a child is caused by a mental health service user and the LSCB investigation would not cover the full requirements of HSG 94/27.

Expected (anticipated) death

Where the expected death of a child was anticipated within a 24 hour period following the incident, no SI investigation is required but the case needs to be reported to the LSCB (CDOP) for review; (unless the death was anticipated but was following a patient safety incident)

Processes have been developed regarding the interface between SI reporting in health services serious case reviews and child death reviews.

Child harm (significant)

Where a child has been significantly harmed but not died as a result of, the following considerations need to be explored as to whether the incident is an SI or not:

- Has the harm occurred on NHS premises, as a result of NHS funded care, or caused by the direct actions of healthcare staff? If not to all the above, it is useful to consider whether or not the child has been in receipt of healthcare within the last 12 months. If so, the case will need to be reported as an SI as well as to the LSCB;
- Any child under the age of 18 admitted to an adult mental health ward qualifies as an SI
- Allegations of serious abuse (physical/mental/sexual) against healthcare staff who work with children must be reported as an SI and to the designated safeguarding professional.

For further guidance, please refer to LLR Safeguarding children and adults policy

7.6 Serious Case Reviews (SCR) and Safeguarding Adult Reviews

This section is to be read in conjunction with the NHSE SI Framework 2015/16 and:

- LLR Adult Safeguarding Procedures - www.llradultsafeguarding.co.uk
- Care and Support Statutory Guidance Issued under the Care Act 2014 Department of Health - https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/366104/43380_23902777_Care_Act_Book.pdf

The interface (Memorandum of Understanding) between the SI process and local safeguarding procedures is articulated in the LLR Adult Safeguarding Procedures. The flowchart at **Appendix 3** should be referred to.

Providers should contribute towards the statutory requirement on safeguarding reviews (and enquiries) as required to do so by the Local Safeguarding Board and where it is indicated that a SI within healthcare has occurred, this must be reported to LLR CCGs under the SI procedures in addition to the joint working arrangements.

7.7 Reporting safeguarding alerts to Adult Social Care

In Leicester, Leicestershire and Rutland all alerts will usually be made to the lead agency, which is Leicester City Council, Leicestershire County Council or Rutland County Council, depending on the individual's place of residence.

7.8 Adult Serious Reviews (ASRs) and Domestic Homicide Reviews (DHRs)

Domestic homicide incidents should be declared and managed as SIs in line with the NHSE SI Framework 2015, **Appendix 4.** The NHSE SI Framework 2015 provides definitions and indicates that the initiation of a DHR does not automatically constitute a SI in the healthcare service.

Providers should contribute towards the statutory requirement on all ASRS and DHRs (and enquiries) as required to do so by the Local Safeguarding Board.

Where it is indicated that a SI within healthcare has occurred, this must be reported to LLR CCGs under the SI procedures in addition to the joint working arrangements.

7.8.1 Monitoring Compliance

Providers will continue to report compliance for engagement with ASR and DHR processes and embedding the learning from the reviews. This will be reported with the submission of the Safeguarding Adult Assurance Framework (SAAF) as agreed within the commissioning Quality Schedule.

LLR CCGs nominated safeguarding leads will liaise regularly with the local authority safeguarding lead(s) to ensure that the multi-agency approach is agreed by all parties and will seek assurance that providers are also involved in this coherent approach.

CCGs and NHSE may be directed by the Secretary of State to participate in a DHR, under Section 9(3) of the Domestic Violence, Crime and Victims Act (2004). However, on all DHRs, LLR CCGs must provide a panel member and work with the CSP to ensure that any action plans arising from a DHR Panel (that would be established by the CSP) are implemented locally and learning shared across NHS providers.

LLR CCGs will work in partnership with NHSE to ensure that local services deliver high quality, safe and effective services through the implementation of action plans. NHSE's role is to collate learning from domestic homicides and make recommendation to Education Commissioning organisations for professional development opportunities for all professionals.

NHSE regional teams are expected to keep a library of recommendations for panel members to access and LLR CCGs should utilise this for learning opportunities where cases are reported within its population.

Individual Management Reports may be requested from providers or LLR CCGs by the Chair of a DHR or CSP and NHSE's regional offices will designate a regional lead and provide co-ordination providing a central point contact for providers and LLR CCGs to report into.

7.9 Homicide by patients in receipt of mental health care

NHS England will consider and, if appropriate, commission an investigation 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 six months prior to the event. (Discretion can be used to consider an SI for a patient discharged more than 6 months prior to the incident). NHS's England's regional investigation team oversees this process. The Regional investigation teams have each established an Independent Investigation Review Group (IIRG), which reviews and considers cases requiring investigation. Central to this process is the involvement of all relevant parties, which includes the patient, victim(s), perpetrator(s) and their families and carers, and mechanisms to support openness and transparency throughout.

The three main stages of this process are:

1. Providers report an incident onto (StEIS) and conduct an initial review to produce a 72 hour report:

2. Providers conduct an internal investigation and produce an investigation report within 60 days:

3. The NHS England Regional Investigation Teams in conjunction with the Independent Investigations Review Group (IIRG) reviews these reports and considers commissioning an independent investigation.

Further guidance regarding investigation of homicide by those in receipt of mental health can be found in Appendix 1 of the NHSE SI Framework 2015

7.10 SIs in National Screening Programmes

These are managed with specialised input from Public Health England's Screening Quality Assurance Service and providers should follow guidance in accordance with "Managing Safety Incidents in NHS Screening Programmes (2015).

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/422566/Managing_Safety_Incidents_in_NHS_Screening_Programmes_March_15_interim_guidance.pdf

7.11 Reporting to HM Coroner/Inquests

Providers must inform the Head of Patient Safety (hosted by ELR CCG) of any Serious Incident that is being taken to inquest and of any additional investigation that is required and additions to the action plan as a result. The Head of Patient Safety must also be informed where an organisation identifies care failings that were not known at the time of the patient's death and reporting to the Coroner, but comes to light during the course of the investigation this should be proactively reported to HM Coroner by the Provider. Should a preventing future death report be received by a provider this will be communicated via the Chief Nurses of the respective CCG.

7.12 Loss of Confidential Information and Information Technology Incidents

The assessment and reporting of the loss of or breach of confidential information is guided by the Department of Health, *Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation (V5.1 29th May 2015)*

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

http://www.connectingforhealth.nhs.uk/systemsandservices/info gov/security/risk/

The guidance clarifies that "*any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious"*

LLR CCGs require providers to have a named individual responsible for Information Governance and for the assessment of these types of incidents. The IG lead at provider organisations is required to be involved in the assessment of severity of any IG incident using the assessment tools provided by the Department of Health (DoH) and report as required, those that meet the threshold for SI notification (graded between 1-5 via the DoH tool).

7.13 Specialised Commissioners

Where specialised services are commissioned by those other than LLR CCG in relation to patients within the LLR CCGs population, the Head of Patient Safety is responsible for ensuring that SIs reported on StEIS are known of by specialised commissioners and that

they are involved in the review and closure of investigation reports together with assurances around learning actions.

7.14 Public Health Local Authority

Where specialised services are commissioned by the Local Authority for example Health Visiting, School nursing, Sexual health these will currently be reported to StEIS by the provider to LLR CCG (LA do not have access to StEIS**)** and the Head of Patient Safety will also ensure that they are informed and that the agreed process for sign off is followed.

8 NEVER EVENTS

All Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. For the national definition and reporting requirements see the Revised Never Events Policy and Framework 2015 accessible at;

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

In addition to reporting onto StEIS and submitting an initial 72 hour report, providers are required to telephone and give verbal notification to the Head of Patient Safety within 24 hours of the incident being identified as a Never Event. The Head of Patient Safety has the responsibility to ensure that the Chief Nurses and responsible Quality Contract Lead are made immediately aware of the event.

9 LLR CCGs AND PROVIDER ROLES AND RESPONSIBILITIES

9.1 Providers

Providers must comply with the NHSE SI Framework 2015 requirements. Local requirements in addition to this are that providers must:

- Populate the 72 hour template at **Appendix 1** and ensure that equality and diversity information is included;
- Include a patient information sheet (as indicated in **Appendix 5**) in all SI investigation reports (**Appendix 10**) that contains non-patient identifiable information, but assists with the context of the patient involved, the staff group involved, commissioning CCG, if any safeguarding concerns have been identified (and reported through normal safeguarding routes) through the investigation process and equality information covering the nine protected characteristics in line with the Equality Act (2010);
- Provide Duty of Candour compliance information within investigation reports and details in the action plan covering engagement and support with those affected on discovery of the incident, throughout the investigation and proposals for sharing findings with them;
- Have a process in place that reviews reports internally at an appropriately senior level and by submitting the report to the CCG they confirm that the report is both robust but also in a suitable format to be shared with the patient/family

- Have a process in place where investigation reports are kept 'open' until LLR CCGs have agreed 'closure' in line with the NHSE SI Framework (2015) requirements and the Terms of Reference of LLR CCGs SI Review Group;
- Report to and agree with the Head of Patient Safety (hosted by ELR CCG) immediately on identification of an SI, where information has come to light that the incident may be downgraded and investigated outside of the NHSE SI Framework 2015.
- Verbally report to the Head of Patient Safety, Never Events in addition to normal reporting routes;
- Respond to queries raised by the LLR CCGs SI Review Group on investigation reports and action plans within 10 working days;
- Amend 'open' investigation reports where additional information is required for the SI Review Group to be assured that the investigation and learning action plans demonstrate RCA methodology and appropriate learning;
- Meet the reporting and investigation timescales and where timescales cannot be adhered to, submit an extension request authorised by the organisation's most senior manager responsible for patient safety, ensuring that the reasons for the extension are exceptional in line with the NHSE SI Framework 2015 definitions (see **Appendix 6** for form to be used and **Appendix 7** for extension request guidance criteria)
- Regularly review SI learning actions and identify opportunities for organisation-wide learning actions and to avoid repeated isolated learning actions;
- Link SI learning actions to existing work programmes ongoing for improvement of safety and quality;

9.2 LLR CCG

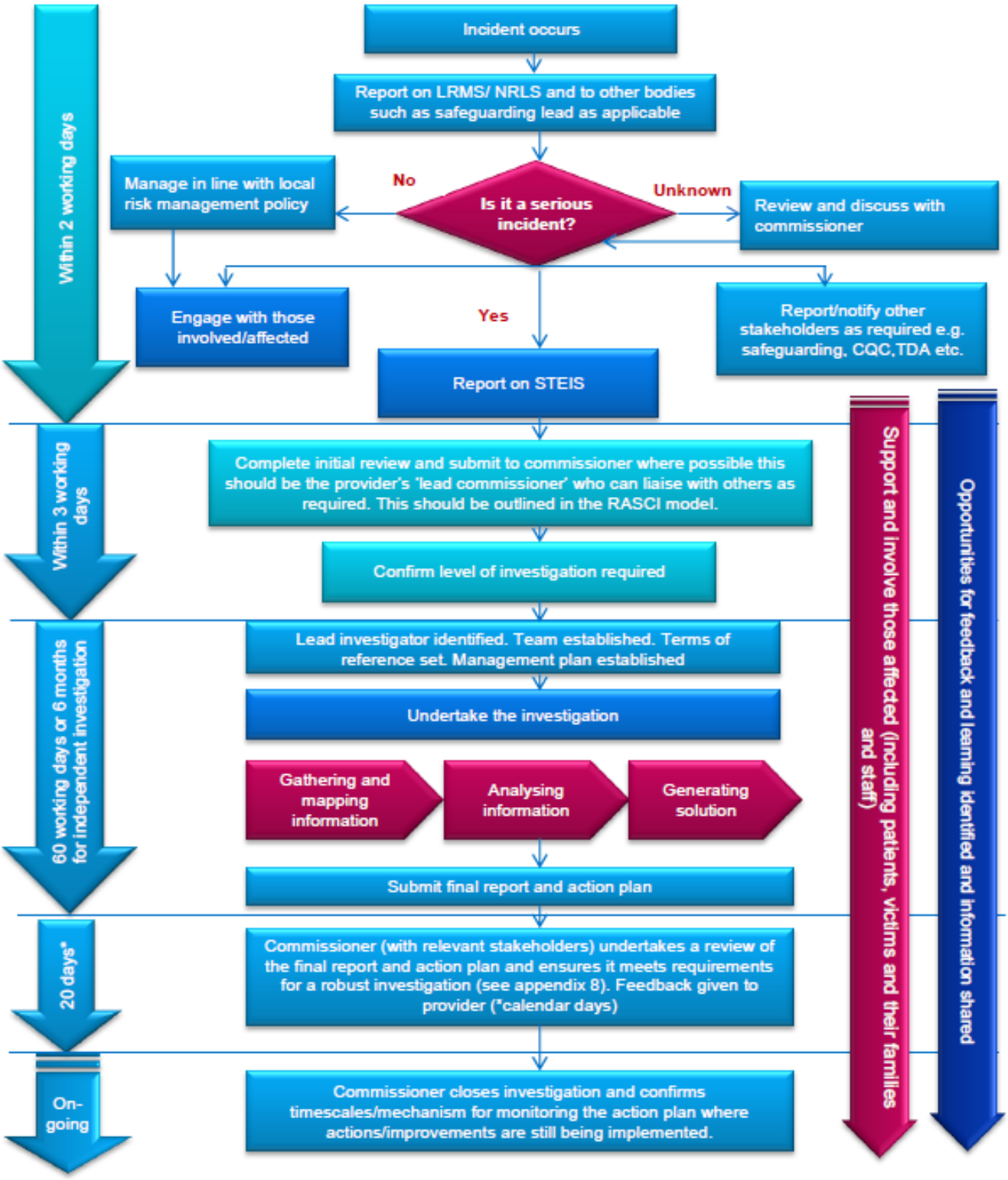
Local requirements in addition to the NHSE SI Framework 2015:

- Provide a hosted Patient Safety Team lead by a Head of Patient Safety on behalf of LLR CCGs;
- Have an effective reporting mechanism supported by StEIS and DatixWeb;
- Produce monthly and quarterly SI reports which identify themes and learning to inform commissioning governance;
- Consider extension requests from providers with authorisation from the Head of Patient Safety. Where requests do not meet the 'exceptional' criteria, the request will be refused with clear rationale provided;
- Ensure close working between the Head of Patient Safety and other hosted functions, specifically the Safeguarding and Infection and Prevention and Control Lead Clinicians;
- In line with NHS Protect Anti-crime Standards for Commissioners, the organisation holds its contracted providers to account for their response to security incidents. This includes oversight of Investigations into serious untoward incidents which relate to security, and may, on occasion, require the organisation to carry out its own investigations
- Consider any professional practice issues linked to General Practitioners in line with local agreed policy and escalate to NHSE Medical Director through CCG agreed arrangements.

- Ensure effective reporting to specialised/other commissioners on SIs and arrange for joint review of SI investigation reports;
- Provide specialised advice on patient safety reporting mechanisms for those providers where a requirement has been identified via the Quality Contracting processes;
- Engage with the Commissioning Support Unit in relation to Nursing, Care and Residential Homes for NHS funded service users involved in SIs to ensure there is effective governance systems for patient safety provided;
- Engage with Private hospitals/hospices who provide NHS funded care.
- Ensure the mechanism for review and closure of SI investigation reports and actions plans via the SI Review Group is effective, meeting internal review timescales (see **Appendix 4** for Terms of Reference);
- Ensure there is an effective audit trail demonstrating good governance on the function of the SI Review Group with regular monitoring of attendance of core members and review of investigations, together with note taking and action logs leading to feedback to providers;
- Identify SI action plans for a dedicated learning assurance process in line with the Terms of Reference of the SI Review Group and page 31 of the NHSE SI Framework (2015).

10 SERIOUS INCIDENT MANAGEMENT PROCESS

The following process must be complied with in accordance with the NHSE SI Framework 2015.



11 INVESTIGATIONS

NHSE recommends use of the national reporting templates, available online:

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

Providers should follow this format in addition to the requirements stipulated in this policy.

For further guidance please refer to the NHSE SI Framework 2015, part 3, section 4.

12 INDEPENDENT INVESTIGATIONS

12.13 Types of independent investigations

LLR CCGs recognise that there are two types of independent investigations:

1. LLR CCGs may commission an independent investigation that is provider focused, either on completion of the provider's internal investigation, or as a result of triangulated patient safety information that gives commissioners cause for concern around aspects of the organisations system/culture.
2. The second type of independent review is a wider independent investigation of the role of the commissioning system or the configuration of services. The most appropriate organisation to commission and quality assure the investigation must be agreed on a case by case basis in line with the NHSE SI Framework 2015.

Providers are required to fully participate with independent reviews.

For further information, see **Appendix 3** of the NHSE SI Framework 2015.

12.14 Audit of learning from independent investigations

For LLR CCGs commissioned independent investigations, The Head of Patient Safety will work closely with the responsible Chief Nurse/Director of Nursing of LLR CCGs to consider including in the contract held with the investigators, an agreement that the team will undertake an independent audit to assess how far the recommended actions have been implemented 6-12 months after the investigation.

The audit should highlight areas where providers need additional support from other areas of the system to deliver change and improvement.

12.15 Closure and publication of independent investigations

For LLR CCGs commissioned investigations:

- LLR CCGs via the Head of Patient Safety will have the responsibility of sending it to the relevant stakeholders including the patient/family involved to check for factual accuracy.

- Providers are expected to review the report and provide an updated action plan based on the recommendations/findings within 10 working days.

- Once the report and action plan is finalised, LLR CCGs via the Head of Patient Safety will make arrangements for a meeting with the relevant key stakeholders to approve the draft report and action plan. Once agreed, LLR CCGs via the Head of Corporate Governance and Head of Patient Safety will liaise if required with legal advisers, investigators, families, providers and other commissioners/stakeholders to agree closure of the investigation and publication of the final report.

- Providers are required to publish signed-off reports and action plans on their websites within 21 days.

- LLR CCGs will publish signed-off reports and action plans on the websites of each CCG within LLR within 21 days with support from the Head of Communications of each CCG.

13 MINIMUM STANDARDS FOR INVESTIGATION REPORTS

Investigation reports have a wide audience and therefore how they are written should take each of those people into account e.g. patients, family members, board members, commissioners, HM Coroner etc. It is recommended that the reports are always written on the basis that they may become public.

The minimum standards of the NHSE SI Framework 2015 should be complied with and LLR CCGs requires providers to ensure reports:

- Demonstrate RCA methodology;
- Include an action plan that is SMART;
- Contain an executive summary; that as a minimum includes incident description and consequence, key findings, root cause, conclusion and recommendations.
- Be simple and easy to read (jargon free with medical terminology explained/Glossary to assist with patient/family understanding);
- Have a patient information page (see **Appendix 5** and section 17 linked to Equality and Diversity monitoring) ensuring non-identifiable information, but inclusive of equality and potential safeguarding information;
- Include a Terms of Reference unique to each incident and demonstrating that any individual patient/family/carer has had the opportunity to contribute to the Terms of Reference.
- Provide assurance on the independence of the investigator(s)/panel members to the area being investigated;
- Contain a dedicated safeguarding section prompting the investigator(s)/panel to consider if any safeguarding concerns have come to light during the course of the investigation and if so, what reporting has occurred;
- Provide robust Duty of Candour information (as detailed in section 4);
- Clarify root causes that may have impacted to the incident and quality of care;

- To include a conclusion providing the view of the investigator(s)/panel and the learning required (and not a summary of events being investigated).

14 LEARNING

A template action plan is attached at **Appendix 9** and must be used to address learning actions from investigations. This supports a SMART approach (specific, measureable, attainable, relevant and time-bound).

Action plans must be submitted at the same time as submission of the final investigation report.

The action plan must contain an overall completion date and timely completion will be monitored by the Patient Safety Team.
Organisations to submit completed action plans to the patient safety team and where an action plan is delayed a reason supplied with a revised completion date.

Action plans must confirm that the actions have been discussed with those responsible for implementing and assuring the required improvements, together with describing how organisations will assure themselves not only that actions have been implemented, but that they are improving the quality and safety of care.

Where there have been repeat incidents or there is sufficient concern the LLR CCG Patient Safety Team will liaise with the quality contracting team who may request evidence of learning and embedding of actions.

15 OPENNESS AND TRANSPARENCY

LLR CCGs Chief Nurses/Directors of Nursing will engage with the Directors responsible for Patient Safety at provider organisations to encourage publication of serious incident investigation reports and action plans. The NHSE SI Framework 2015 promotes this as best practice.

Where an organisation wishes to publish such information, this The Chief Nurses/Directors of Nursing via the LLR CCGs Head of Patient Safety will receive assurance from the provider that their organisation's Caldicott Guardian, Risk Manager and legal advisor/team has considered and agreed publication.

16 EQUALITY AND DIVERSITY

LLR CCGs are committed to the ethos and requirements of the Equality Act 2010 to ensure there are equal, accessible services that meet the needs of the population it serves. In relation to monitoring equality and diversity of those involved in SIs, providers are required to include in SI investigation reports, a patient information sheet that in addition to explaining the diagnosis of the patient and clinical disciplines involved, it gives an indication of the protected characteristics that may be relevant to the patient (see **Appendix 5** for the template to be used).

17 LLR CCGs ANALYSIS AND REPORTING

The Head of Patient Safety is responsible for producing monthly and quarterly reports on SIs to inform the governance processes within LLR CCGs.

There must be regular dialogue between the Patient Safety Team and Quality Contract Leads so that emerging trends, risks and any concerning information can be shared to inform the quality contract monitoring processes.

The patient safety team must maintain a local database (Datix) in order to produce timely analysis of SIs.

The minimum standard for reports must contain for trend analysis:

- Number and types of SIs;
- Level of harm experienced;
- Learning outcomes;
- Performance management against timescales including extension requests;
- Liaison with Quality Contract Leads and interface with providers/CQRG;
- Triangulation of information from other sources, including the NRLS, provider patient safety reports, NHSE, GP Feedback Process and infection prevention and control.
- Assurance on the performance of the SI Review Group and its effectiveness;
- Equality and diversity information on patients involved in SIs

18 MONITORING COMPLIANCE WITH THE REQUIREMENTS OF THIS POLICY

Performance of both the LLR CCGs in complying with commissioner requirements of the management of SIs and that of provider reporting, management and learning will be measured through a variety of methodologies. This will include, but not be limited to:

- Analysis via monthly and quarterly patient safety reports;
- Quality contracting monitoring including monitoring against quality schedules;
- The SI Review Group;
- Provider organisation patient safety and quality reports;
- Analysis of LLR CCGs internal database and StEIS;

19 RELATED GUIDANCE/DOCUMENTS

The guidance and publications detailed in the NHSE SI Framework 2015 should be referred to alongside local policies/procedures, namely:

- Provider organisation SI policies;
- Leicester, Leicestershire and Rutland Safeguarding Procedures and that of the Local Authority (links available throughout this policy);
- The NHS Complaints Procedure and provider organisation Complaints Procedures;
- Information Governance and Code of Conduct Guidelines;
- Major Incident Plan/Event policies;

- Memorandum of Understanding in place between the Care Quality Commission, Health and Safety Executive and Local Authorities in England 2015 in line with the Regulated Activities Regulations 2014, accessible at: http://www.hse.gov.uk/aboutus/howwework/framework/mou/mou-cqc-hse-la.pdf
- Care Quality Commission Regulation 20: Duty of Candour (November, 2014)

20 APPENDICES

Appendix 1 - 72 Hour Incident Report Form

NHS Leicester, Leicestershire and Rutland Clinical Commissioning Groups

Reporting organisation			
Reporter Details			
Reporter name		Reporter Job title	
Reporter Tel. no		Reporter E-mail	
Incident Details			
Date of incident		Date incident identified	
Incident Site (if other than reporting org)		Incident Location	
Who was involved			
Type of Patient. In patient/outpatient			
GP Practice			
Gender	Male ☐	Female ☐	
Date of Birth? (Dd/mm/yyyy or n/a)			
Degree of Harm as a result of the incident	None ☐ Low ☐ Moderate ☐ Severe ☐ Death ☐		
What Happened			
Type of Incident			
Actual/Near Miss?			
Never Event?	Yes ☐	Expected level of investigation	

Appendix 1 (Continued)

Description of Incident			
Safeguarding Information			
Is this a Safeguarding Incident?	Yes ☐	No ☐	
Child Safeguarding Incident – Has this incident been reported to Children's Social Care?	Yes ☐	No ☐	
Adult Safeguarding Incident – Has this incident been reported to Adult Social Care?	Yes ☐	No ☐	
Does this incident meet criteria for an Adult or Child Serious Case Review	Yes ☐	No ☐	Not yet determined……..
Immediate Action Taken to ensure safety of patients/public/staff			
Duty of Candour Information			
Terms of Reference			
Media Interest?	Yes ☐ No ☐	Comms Informed?	Yes ☐ No ☐
Externally reportable?	Yes ☐ No ☐	Externally reported to?	
Any Other Comments: e.g. multiagency incident, police and /or HSE investigation, Coroner's inquest, CQC involvement, Health Visiting, school nurse, sexual health or GP			

Appendix 2 - Leicestershire Interagency Procedures

Interface between serious incidents reporting in health services, serious case reviews and child death reviews.

1. **Aims and objectives**
   This procedure seeks to ensure effective interface between child protection procedures and procedures carried out through the serious incident investigation process for health services.

   An effective interface ensures comprehensive investigation, transparency and learning across the multi-agency safeguarding children partnership.

2. **Context**
   Health organisations providing NHS care are required to report serious incidents to their commissioning body. Serious incidents include incidents such as serious harm, unexpected or avoidable death and abuse (inflicting or failing to act to prevent harm)

   In relation to children and young people, It is important to consider whether the nature of the serious incident has implications for safeguarding children and whether any lessons learned will be beneficial to share across the multi-agency safeguarding partnership.

   Where a child dies, the death is notified through the child death review process in order for themes and individual lessons to be identified. In some circumstances, the child's death may also be notifiable to health commissioners as a serious incident.

3. **Process for serious case review**
   Where a serious incident is reported to the health commissioner, the patient safety team will identify whether there are potential implications for safeguarding children in the broadest sense. The team will seek specialist advice via the Designated Professionals for Safeguarding Children. The Designated Professionals will identify whether the case meets the threshold for referral through to the SCR committee in line with inter-agency procedures.

a. **Referral of the serious incident to SCR committee**
   Where a referral is made to the SCR committee, the committee will determine whether the criteria for a serious case review are met or whether there may be learning from an individual management review (IMR)

   Where the committee decision is to manage the case as a SCR or IMR, the serious incident investigation process will be integrated with this process so that the serious

incident investigation forms the basis of the IMR carried out under the remit of the SCR committee.

Terms of reference for the SCR/IMR should be shared with the investigating health organisation and the health commissioners designated professionals & patient safety team so that they are aware of any additional requirements not currently covered under the serious incident terms of reference. The patient safety team must also be made aware of timeframes for the SCR/IMR as this may have an implications for timeframes required for the serious incident investigation.

b. Decision that serious incident should not be referred to SCR committee

Where a serious incident is assessed by the Designated Professionals as not reaching the threshold for referral to SCR committee, the serious incident will continue to be investigated as defined by patient safety procedures.

The investigation may identify new information and trigger referral to the SCR committee as described in 3.1 above.

4. Process for child deaths

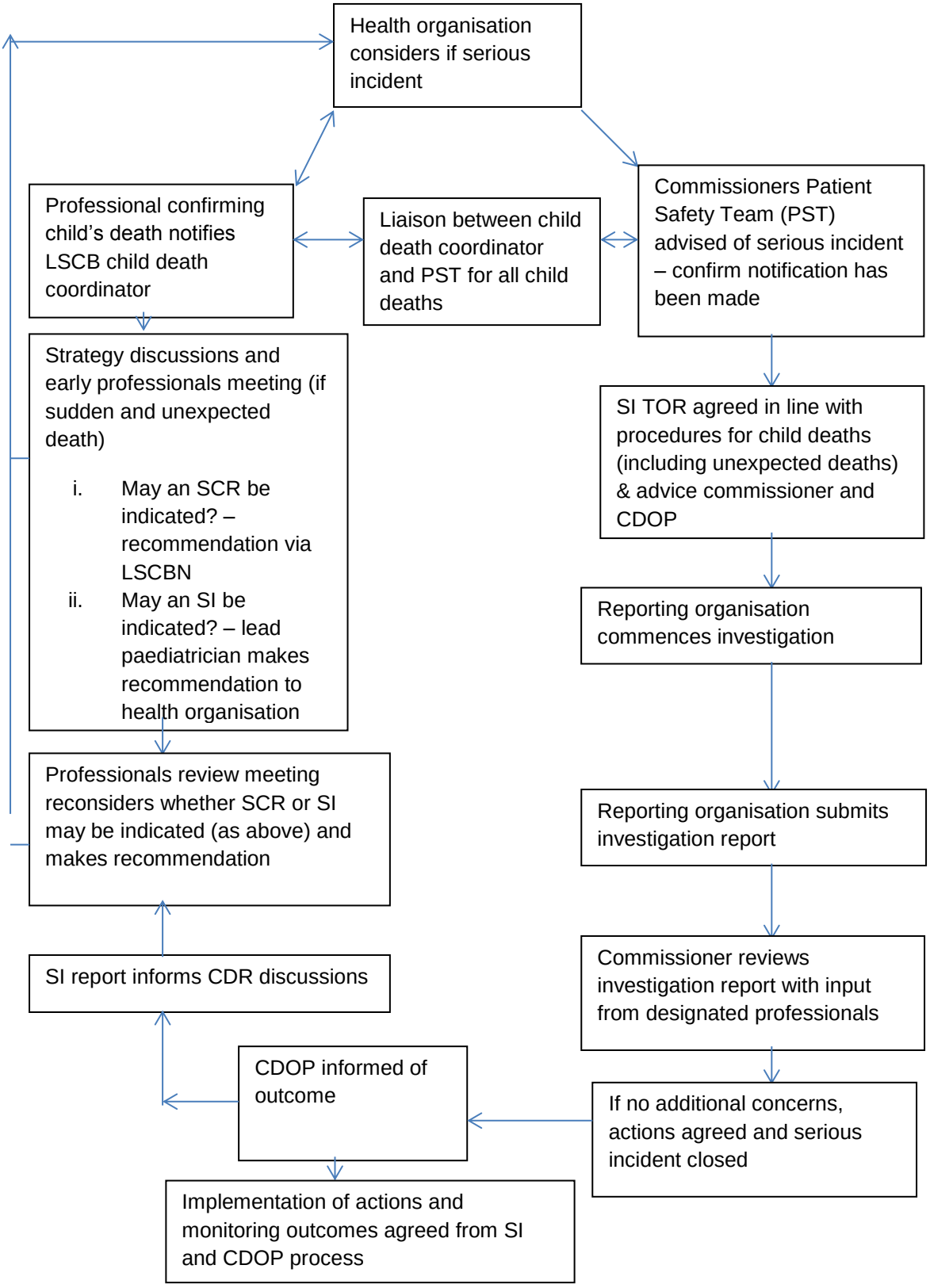
When a child dies, deaths are notified by the professional confirming the child death to the LSCB child death coordinator (designated person). The lead paediatrician carries out a review with the relevant agencies and professionals involved and present findings to the Child Death Overview Panel.

Health organisations that have provided NHS care must also consider whether the circumstances of the death constitute a serious incident. Where investigation as a serious incident is required, this will be reported to their commissioning body.

Where a child's death is being investigated as a serious incident, the investigation may also identify learning that the patient safety team and Designated Professionals identify as beneficial to share across the multi-agency safeguarding partnership. This will be shared through the CDOP.

The child death coordinator will share information with the patient safety team about all child deaths in order to triangulate information and provide robust assurance that deaths are being appropriately reported as serious incidents.

Appendix 3 - Flowchart in Interface between Serious Incidents and Child Death Review



Appendix 4 – LLR Serious Incident Review Group Terms of Reference

LEICESTER, LEICESTERSHIRE AND RUTLAND (LLR)
SERIOUS INCIDENT REVIEW GROUP (SIRG)

ACCOUNTABILITY

LLR SIRG is accountable to the three CCGs within LLR and is a function managed by the hosted Patient Safety Team. It is accountable to each of the CCGs governance structures to provide assurance on the management, investigation and learning from serious incidents (SIs).

PURPOSE

To provide robust governance system on commissioner review of SIs reported by provider organisations, together with assurance on identification and implementation of learning actions.

RESPONSIBILITIES

- SIRG will receive notification of all reported SIs and receive assurance from the Head of Patient Safety that each incident meets the criteria for grading as an SI, providing SIRG with the opportunity to request additions to the provider organisation's terms of reference for investigation;
- To ensure that the LLR Policy for the Management, Investigation and Learning from Serious Incidents is adhered to by provider organisations in the reporting, investigation and learning of SIs;
- SIRG will review all SI investigation reports for assurance that robust Root Cause Analysis (RCA) Methodology has been applied to SIs and that identification of learning is appropriate and addressed by SMART (Specific, Measureable, Achievable, Realistic and Time-bound) action plans;
- To provide feedback to provider organisations on the quality of SI investigation reports and learning action plans, closing those that meet LLR policy requirements and providing constructive feedback for those reports that do not;
- To receive assurance and reports from the Head of Patient Safety that an assurance mechanism is in place to spot check completed learning actions for assurance that learning is embedded and improving practice in provider organisations;
- To receive patient safety reports from the Head of Patient Safety with identification of themes, hotspots and emerging patient safety risks and to contribute to escalation of concerns to the Chief Nurses and quality contracting process;
- To receive assurance via provider organisation investigation reports that the Duty of Candour/Being Open duties in accordance with LLR policy are being applied at the beginning, throughout and at the conclusion of SI investigations;
- Work in conjunction with NHS England Midlands and East in the review of those SI investigations that are reportable and jointly managed by the regional team.

- To consider emerging themes and identify the requirement for thematic reviews , providing the rationale and request to the Head of Patient Safety in order that this can be relayed to the relevant Chief Nurse CCG within LLR;
- To contribute to the review of update to the LLR Policy on the Reporting, Management and Learning from Serious Incidents, ensuring that it is compliant with national guidance and the NHSE SI Framework 2015/16;

MEMBERSHIP

- GP membership from each CCG
- Head of Patient Safety (Chair)
- Chief Nurse from each CCG or nominated deputy
- Patient Safety Officer
- Quality Contract Lead from each CCG
- Safeguarding Designated Nurse

To attend by invite as required**:**

- NHSE AT representative
- Public Health Local Authority (City/County)
- Specialist CCG leads (Infection Prevention and Control, etc)
- Ad-hoc attendees where specialist knowledge is required

QUORUM

In addition to the Chair, a minimum of one representative from each CCG together with a minimum of one GP within LLR is required for the group to be quorate.

REPORTING ARRANGEMENTS

A summary of the Group's work will be provided by the Head of Patient Safety and themes escalated to the Chief Nurses and to the quality forums of each CCG, together with a progress and assurance report as part of the quarterly Patient Safety Report.

Version: Final
Date: **December 2015**
Review date: **December 2016**

Appendix 5 - Patient & Equality Act 2010 Information

Age	
Gender	Male Female Other
Marital/Civil Partnership Status	Married C/P Single Divorced Widowed
Disability	Yes ☐ No ☐
If Yes	Sensory Physical Mental Health Learning Disability
Race	
Religion/Belief	
Sexual Orientation	Heterosexual Homosexual Bi Sexual other
Language	English Fluent English Limited No English
Level of Harm	No Harm Low Harm Moderate Harm Severe Harm Death
GP Location	
Clinical Speciality Involved	
Clinical Management Group or Division	
Safeguarding Incident	Yes ☐ No ☐

This information must be included as an information sheet in all SI investigation reports.

Appendix 6 - Serious Incident Final Report: Extension Request Form

Name of person completing this form:

Trust/Provider name

StEIS NUMBER:

Reason for request (on grounds of exceptional circumstances):   Length of extension requested: Signed off by Director/Governing Body:

CCG Patient Safety Team Use Only Date request received …… Date response sent to Trust/Provider ……. Extension granted: YES/NO Name of decision maker …… Revised submission date ……..

Appendix 7 - Serious Incident Extension Request Guidance

Providers are given timeframes in accordance with the NHSE SI Framework 2015/16 to complete a full RCA and produce a final report and action plan following a Serious Incident. If a provider organisation is unable to meet deadlines an extension can be requested. Such requests will be granted under the following circumstances: -

- Sickness/availability/absence of a Key individual

If short-term sickness/absence – LLR CCGs to consider length of absence and extend accordingly.

  - Negotiation of extension to a maximum of 20 working days.

If long-term sickness/absence (exceeds 20 working days) – a contingency plan must be in place to ensure that the report is investigated within the agreed time frame.

- Multi-agency involvement – if a serious incident investigation involves multi-agencies and a delay is encountered.

  - Negotiation of extension to a maximum of 20 working days.

- Ad hoc requests outside the categories above will be considered on a case by case basis.

  - Extension may be granted to a maximum of 20 working days.

Failure by the provider to co-ordinate internal discussions is not a sufficient reason and no extension will be granted.

Please ensure that extension requests are made as soon as it is apparent a deadline will not be met.

Please email the request to: lcrsi@nhs.net

Appendix 8 – Investigation Types

Resources to support systems-based investigation in the NHS are available online from: http://www.england.nhs.uk/ourwork/patientsafety/root-cause/				
Level	Application	Product/ outcome	Owner	Timescale for completion
Level 1 **Concise internal Investigation**	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 **Comprehensive internal investigation** (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 **Independent Investigation**	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved (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 adaptions are required. National templates will be reviewed on a continuous basis. Recommendations to inform changes to be sent to england.RCAinvestigation@nhs.net				

Appendix 9 - Example SMART (Specific, Measurable, Achievable, Realistic, Time bound) ACTION PLAN

ACTION PLAN

STEIS NUMBER:_____ **CATEGORY:**_____

ACTION PLAN DEVELOPED BY:_____ **TITLE:**_____

EXPECTED OVERALL COMPLETION DATE:_____ **ACTUAL COMPLETION DATE:**_____

ACTION PLAN SIGNED OFF BY:_____ **TITLE:**_____

Recommendation	Agreed Action	By Whom *Include job title or group or committee*	Expected Completion Date	Evidence Required for Completion	Actual Completed Date	Ongoing Monitoring Method

Appendix 10 – Serious Incident Investigation Report Template

ORGANISATION LOGO

Serious Incident Investigation Report

Date of incident:

Incident Title:

Incident Number:

STEIS Incident Number:

Report Author (s):
Designation:

Version:

Local Sign Off By:

Date:

Divisional Sign Off by:

Date:

Date of Commissioner Sign Off:

CONTENTS

EXECUTIVE SUMMARY

Need to include:

- *Incident description and consequences*
- *Care and Service Delivery Problems*
- *Contributory Factors*
- *Conclusion*
- *Root Cause*
- *Recommendations*
- *Actions already taken*

SUMMARY INCIDENT DESCRIPTION AND CONSEQUENCES

Need to include:

Brief description of incident

Then specify:

Incident type:

Specialty:

Effect on patient:

Severity level:

TERMS OF REFERENCE (must be in and specific to incident)

Example:

- To establish the facts
- To identify system failures
- To form recommendations and action plans
- Scope and level of investigation

INVESTIGATION TEAM

Need to specify names, roles, qualifications, depts. Consideration of inclusion of Patient/Relative.

INFORMATION AND EVIDENCE GATHERED (a few suggestions have been inserted below)

- Interviews with key staff involved, conducted by …..(job title only)
- Statements obtained and reviewed from the nursing and medical staff involved in the incident, dated and signed.
- Review of the Incident Report Form
- Review of medical and nursing records
- Site visit carried out
- Review of current situation in relation to procedures and protocols National guidelines in place
- Interview or written comments of Patient/Relative

BEING OPEN DUTY of CANDOUR - INVOLVEMENT AND SUPPORT OF PATIENT AND RELATIVES

- *Has the patient/relative been advised of the incident.*
- *Has the patient/relative been informed that an investigation is taking place*
- *Has a meeting taken place with the patient / family and do they wish any specific areas relating to the incident to be included in the investigation.*
- *How does the patient/relative wish to receive feedback*
- *Detail in the action plan how and when the patient/family received a written apology*

INVOLVEMENT AND SUPPORT PROVIDED FOR STAFF INVOLVED
Include support offered to staff during and after the incident

BACKGROUND AND CONTEXT TO THE INCIDENT

A brief description of the service type, size, clinical team, care type, treatment provided. Outline of relevant local and national policy/guidance in place at the time.

On *(date)* the incident was formally reported to East Leicestershire and Rutland Clinical Commissioning Group in accordance with the Policy for the Reporting and Management of Serious Incidents in the East Midlands December 2015

CHRONOLOGY OF EVENTS *(may be attached as an appendix if lengthy)*

GOOD PRACTICE POINTS IDENTIFIED *(e.g. management of the incident was excellent; good documentation, etc)*

CARE DELIVERY/SERVICE DELIVERY PROBLEMS *to be identified, and for each one, the* **Contributory Factors** *to be highlighted and discussed.* ***(Refer to the National Patient Safety Agency Contributory Factor Classification Framework)***

Identify what it was about the factor that contributed to the incident and then identify why that happened

- *Individual Factors (member of staff, Individual Circumstance)*
- *Team including culture, behaviour and dynamics*
- *Communication Factors (written, verbal, electronic, documentation)*
- *Task Factors (policy. procedures, SOP, guidance)*
- *Education and Training Factors (Have staff received appropriate training)*
- *Equipment and Resource Factors (including staffing)*
- *Working conditions / Environment*
- *Organisational Factors*

- *Patient Factors (e.g. compliance, condition – this would not be a root cause as this should have been identified and actions put in place)*

ROOT CAUSE

These are the most fundamental underlying factors contributing to the incident that can be addressed and if they hadn't occurred would have meant the incident would not have happened.

KEY CONTRIBUTORY FACTORS

CONCLUSION
Should answer the critical questions in the ToR and links back to analysis and findings

LESSONS TO BE LEARNED
These are the key things that went well and things that went badly (either in terms of the investigation or the incident) from which others can learn.

RECOMMENDATIONS

Recommendations should be directly linked to root cause and key contributory factors and need to be clear but not detailed (bullet points).

ARRANGEMENTS FOR SHARED LEARNING

Describe how lessons to be learned have been or will be shared with staff and other organisations.

IMPLEMENTATION, MONITORING AND EVALUATION ARRANGEMENTS
The action plan identifies the recommended actions to minimise future risk, who should action them and the time frames for the actions. The action plan will be reviewed by the Governance Leads for the Division with the to ensure compliance in relation to their application and lessons learnt.

ACTION PLAN

STEIS NUMBER:_____ **CATEGORY:**_____

ACTION PLAN DEVELOPED BY:_____ **TITLE:**_____

EXPECTED OVERALL COMPLETION DATE:_____ **ACTUAL COMPLETION DATE:**_____

ACTION PLAN SIGNED OFF BY:_____ **TITLE:**_____

Recommendation	Agreed Action	By Whom *Include job title or group or committee*	Expected Completion Date	Evidence Required for Completion	Actual Completed Date	Ongoing Monitoring Method

APPENDICES

(As appropriate, perhaps the chronology if documented as a tabular timeline or if lengthy, etc)