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1. Introduction

In March 2015, NHS England published a revised version of the Serious Incident (SI) Framework (March 2015). The fundamental principles remain unchanged, continuing to provide the detail of the responsibilities and actions for dealing with serious incidents and is relevant to all NHS funded care in the primary, secondary and tertiary sectors. In addition to a number of amendments, two key operational changes have been made in relation to timescale and removal of grading.

NHS West Lancashire Clinical Commissioning Group’s (CCG) Serious Incident policy is based on this revised national framework and local arrangements agreed with the NHS England Area Team. This policy is intended to support the CCG’s commitment to the provision of high quality care that puts the safety of patients and staff first.

Serious incidents requiring investigation in healthcare are rare, but when they do occur, everyone must make sure that there are systematic measures in place to respond to them. These measures must protect patients and ensure that robust investigations are carried out, which result in organisations learning from serious incidents to minimise the risks of the incident happening again. When an incident occurs, it must be reported to all relevant bodies, to ensure that patients are protected.

The role of West Lancashire CCG is to gain assurance from the provider organisations that incidents are properly identified, reported and then investigated to identify lessons learnt in order to ensure that the risk of a similar incident happening again is minimised as much as possible.

It is a requirement of all registered organisations to report serious incidents to the Care Quality Commission. This process in no way replaces this requirement.

2. Purpose

The purpose of this document is to outline the overarching governance arrangements for the management of serious incidents reportable on the Strategic Executive Information System (StEIS) and ensure that patient safety and other reportable incidents are appropriately managed within commissioned and contracted NHS services in order to address the concerns of the patients and promote public confidence. This document describes the requirements for SI reporting and management.

3. Scope

This document applies to all staff employed by West Lancashire CCG. It should also be complied with by all organisations whose services are commissioned by the CCG. Furthermore, this document applies to all third parties and others authorised to undertake work on behalf of the CCG, including any organisation commissioned to manage the process associated with the reporting of SIs.

This document should also be read in conjunction with the following guidance:

- Serious Incident Framework – NHS England (March 2015)
- Information Governance Policy – West Lancashire CCG
- Safeguarding Policy – West Lancashire CCG
4. **Serious Incident Requiring Investigation (SIRI)**

Defined in the Serious Incident Framework (2015) ‘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 directly impact patient safety or an organisation’s ability to deliver ongoing healthcare’.

There is no definite list of events / incidents that constitute a serious indent and lists should not be created locally. The Serious Incident Framework (2015) sets out circumstances in which a serious incident must be declared stating that every incident must be considered on a case by case basis using the provided information. See Appendix 1 for further details.

In many cases it will be immediately clear that a serious incident has occurred and further investigation will be required.

Where it is not clear whether or not an incident fulfils the definition of a serious incident, providers and commissioners must engage in open and honest discussions to agree the appropriate and proportionate response.

5. **Never Events**

All Never Events are defined as a Serious Incidents (see appendix 1). Never Events are defined as a particular type of serious incident that meet all the following criteria:

- They are **wholly preventable**, where guidance or safety recommendations that provide strong systematic protective barriers are available at a national level, and should have been implemented by all healthcare providers.

A Never Events list is defined by NHS England, updated annually and published on the Department of Health website.

6. **Interface with Other Sectors**

There may be occasions were the principles set out in this document coincide with other procedures. In such circumstances it is important that cooperative and collaborative working is established to avoid duplication and confusion where possible. This may be challenging if investigations have different aims. Wherever possible, serious incident investigations should continue alongside criminal proceedings but this should be considered in discussion with the police.

In exceptional cases the investigation may be put on hold following discussion with involved parties. More information can be found at Appendix 2.

7. **Roles and Responsibilities**

**Chief Accountable Officer**

The Chief Accountable Officer has responsibility for ensuring that the CCG has the necessary processes and procedures in place to support the effective management of serious incidents.

**Chief Financial Officer**

The Chief Financial Officer has executive responsibility for ensuring that lessons learned from SIRIs influence quality and safety standards for finance. Chief Financial Officer is the CCG Senior
Information Risk Owner (SIRO). The SIRO has a corporate responsibility for overseeing incidents relating to information governance breaches.

Chief Nurse
The Chief Nurse has executive responsibility for ensuring the necessary management systems are in place for the effective implementation of serious incident reporting for commissioned services.

Head of Quality, Performance and Contracting
The Head of Quality, Performance and Contracting is responsible for ensuring that there are specific references to Serious Incident reporting and management in all contracts. The Head of Quality, Performance and Contracting is also responsible for ensuring that lessons learned from incidents and SIs influence the quality and safety standards for care pathway and service development.

Quality Assurance Manager
The Quality Assurance Manager is responsible for the day to day management of the serious incident reporting processes described in Appendix 4 and ensuring there is a consistent and robust approach in line with policy. The facilitation of this will be through the Midlands and Lancashire Commissioning Support Unit (MLCSU). Specific responsibility will include:

- having the authority to make a decision regarding any extension requests received from provider organisations
- disseminate the Root Cause Analysis to relevant CCG staff for comment in order to assess whether the Root Cause Analysis (RCA) and action plan submitted provide adequate assurance to close the Serious Incident (with agreement of the Chief Nurse). Where the decision is made not to close the serious incident the comments will be collated and fed back to the lead commissioner via the LCSU. The lead commissioner will then inform the provider.
- ensure the analysis and triangulation of themes is undertaken and escalated appropriately and any learning is disseminated where necessary.
- act as a point of contact for provider organisations to report any never events or serious incidents via telephone or email, prior to reporting these via the StEIS.
- escalate concerns and exceptions in the management of serious incidents and or never events to the governing body of the CCG via the Chief Nurse and Quality and Safety Committee.

Midlands and Lancashire Commissioning Support Unit (MLCSU)
MLCSU has responsibility for facilitating and supporting the serious incident investigation processes described in Appendix 4 on behalf of the CCG. When MLCSU are notified of a serious incident it is logged on the SI database and an email sent to CCG staff: Lead Nurse, Quality Assurance Manager, the safe guarding team and others as appropriate. MLCSU staff will facilitate communication between lead providers and the CCG and update the database with progress of all serious incidents.

The quality team within MLCSU will undertake analysis of serious incident themes and organisation performance, based on timeliness of submission, report completeness and reporting levels. This analysis will take the form of a standard monthly report agreed with the CCG and ad hoc reports. MLCSU will escalate concerns and exceptions to the management of serious incidents by providers to the Quality Assurance Manager within the CCG.
Quality & Safety Committee
The committee will receive performance reports regarding serious incidents reportable on StEIS, trends and lessons learned to ensure organisational learning to prevent recurrence. If the Committee have any concerns the Chair of the committee will draw them to the attention of the Governing Body.

NHS England Area Team
NHS England (via its Area Team), as part of its assurance, will have oversight of serious incident investigations undertaken in NHS funded acute, community, mental health and ambulance care including reviewing trends, quality analysis and early warnings via the Quality Surveillance Group (QSG). It will also hold to account providers of NHS funded primary care, specialised care and other directly commissioned services for their responses to serious incidents and, where appropriate, commissioning and co-ordinating serious incident investigations.

West Lancashire CCG staff
Any internal incident that occurs within the CCG and meets the SI criteria must be escalated to the MLCSU team within 2 working days of identifying the incident by completing the form given in appendix 7 and emailing it to seriousuntowardincidents@nhs.net (the Quality Assurance Manager can be contacted for advice). The investigation and subsequent production of a Root Cause Analysis (RCA) Report is the responsibility of the CCG. Sign off and closure of the SI must be carried out by NHS England Sub Region office, however, the MLCSU will update STEIS prior to any request for closure.

Provider Organisations
NHS organisations must report any incident meeting the StEIS reportable criteria within a maximum of 48 hours post incident, or as soon as the incident comes to light, by inputting the incident onto the national StEIS database where available. This automatically notifies the lead commissioner for the provider who will notify the CCG of the patient involved.

Providers of primary care services or independent sector healthcare providers without direct access to StEIS (e.g. Care Homes) should report any serious incident to the CCG via the MLCSU in line with the terms of the contract. Root Cause Analysis (RCA) investigations are usually carried out by the Nursing Home itself or by the CCG. The logging on STEIS, management and monitoring is via the MLCSU SI team with any closure agreed by West Lancashire CCG.

Within 3 working days the reporting organisation must complete and submit an initial review. Confirmation of the level of investigation will be agreed. The recognised system-based method for conducting investigations, commonly known as Root Cause Analysis (RCA), should be applied for the investigation of serious incidents. An overview of the serious incident management process can be found within Appendix 4.

The CCG requires the providers they commission to fulfil the following requirements:
- collaborate with external scrutiny of investigations and any remedial work required following investigations, including full and open exchange of information with other investigatory agencies such as the police, Health and Safety Executive, Coroner and local safeguarding boards;
• publish information about serious incidents including data on the numbers and types of incidents, excluding material that would compromise patient confidentiality, within annual reports, board reports and other public facing documents;
• comply with national requirements and guidance in relation to being open with patients or their representatives when things have gone wrong;
• support and enable staff in disclosing incidents to patients and their representatives;
• involve patients and families/carers in investigations, sharing findings and providing timely referral for specialist support and guidance where appropriate;
• provide relevant guidance and training for staff to help them identify and report and investigate incidents using recognised methodologies (e.g. RCA));
• include the reporting and management of serious incidents as part of staff induction and ongoing training;
• ensure timely closure of serious incident cases is enabled by effective communication with the relevant commissioner(s);
• ensure that action plans are implemented and that there are mechanisms for Board oversight of overdue actions; and
• regularly review changes made as a consequence of learning from serious incidents to ensure the changes are embedded, sustained and effective

8. Out of Hours
Where the authorised named individual in the NHS organisation believes that an incident has significant implications for the NHS in terms of clinical care and management of media issues, and warrants the immediate involvement of the CCG out of ours, the CCG on call Director should be contacted. They will agree the action that needs to be taken with the relevant NHS organisation.

9. Safeguarding
Whilst reviewing serious incidents, safeguarding adults children and young people must be considered. 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. Safeguarding adults is a statutory duty under part 1 of the Care Act 2014. The responsibilities in respect to safeguarding can be found in the CCG safeguarding policy.

10. Information Governance
All Information Governance serious incidents are to be handled in accordance with the guidance developed by the Department of Health ‘Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation’ (May 2015).

This guidance includes details on assessing the severity of the incident and reporting requirements via the Information Governance (IG) Toolkit. An Information Governance Serious Incident Requiring Investigation (IG SIRI) deemed reportable to national bodies e.g. the Information Commissioner, should be recorded and communicated via the IG Toolkit Incident Reporting Tool.
11. Multiple Commissioners
In a commissioning landscape where multiple commissioners may commission services from providers spanning local and regional geographical boundaries a RASCI (Responsible, Accountable, Supporting, Consulted, Informed ) model should be used to agree the identification of a ‘lead commissioner’. They will have responsibility for managing the oversight of serious incidents with a particular provider. It is expected that where a lead commissioner is not West Lancashire CCG, clear lines of communication are established to ensure West Lancashire CCG can fulfil its requirements as a commissioning body in relation to serious incidents. This is described in appendix 4. A list of the main providers used by West Lancashire patients and their lead commissioner is given in appendix 5.

12. Duty of Candour
Central to the CCG’s strategy to improve patients safety is the commitment to provide good communication between healthcare organisations and patients and/or carers.

The CCG expects all providers to meet the requirements of the Duty of Candour as defined within the Regulation 20 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This includes providing reasonable support, truthful information and an apology to patients and/or their carers when they have been involved in a serious incident.

13. Serious Incident Extensions
It is acknowledged that whilst every effort should be made to ensure that all serious incident investigations are completed in a timely manner (60 working days for level 1&2 incidents, up to 6 months for level 3, see Appendix 4: The National Serious Incident Management Process). However, there are instances when this is impossible due to circumstances which are beyond the immediate control of the reporting organisation.

Such delays may be caused by:
- Awaiting outcomes of court proceedings;
- Awaiting Coroner Inquests;
- Awaiting forensic post-mortem findings;
- Awaiting Toxicology results;
- Awaiting completion of an external review;
- In direct response to a Police request under Memorandum of Understanding.

It is the decision of the lead CCG whether or not a serious incident meets the criteria for an extension. In order to ensure robust governance, the CCG will monitor/review extensions on a regular basis.

14. Closure of Serious Incidents
When the provider has submitted a completed investigation and Root Cause Analysis (RCA) with a request to close the incident, this is sent to the CCG for review. The CCG will make the decision to close based on evidence submitted by the provider. This will include ensuring that the action plan contains action points to address all root causes identified and that they include a named lead for each action and a timescale for completion.

If the CCG deems that further action or clarification is required this will be communicated to the provider. The CCG aims to respond to submitted RCAs within 10 working days and to give providers effective feedback if an SI is deemed not ready for closure.
A more detailed description of the processes involved in reviewing and closing StEIS, as well as the associated timescales can be found in Appendix 4.

If, at any stage during a SI investigation it becomes apparent that the incident does not constitute a SI it can be downgraded by formal notification, including reasons for downgrading and agreement with the CCG. At this point the SI will be removed from STEIS and the MLCSU database noted accordingly. Even after the serious incident is closed it remains the responsibility of the lead commissioner to ensure the action plan laid out in the RCA is completed.

15. Learning from Experience and Post Incident Review (PIR)
The CCG may request a Post Incident Review (PIR) for incidents where it is deemed appropriate. This review does not replace any internal mechanisms for a review the provider may have. The PIR will take place after the performance management process has concluded and following receipt of the internal investigation report from the provider organisation. The reviews will provide the opportunity to facilitate the sharing of good practice and lessons learned.

16. Dissemination of Learning
All organisations are responsible for ensuring that learning from serious incidents is disseminated appropriately. Depending on the outcome, it may be useful to share an anonymous version of learning more widely with other organisations if it could prevent harm coming to other patients in the future.

The Quality Assurance Manager will feed back any learning to the Quality & Safety Committee, Quality and Surveillance Groups (QSGs) and to NHS England and other bodies where relevant and liaise with the Communications team as appropriate.

17. Monitoring Compliance and Effectiveness
An annual review of this policy and associated processes shall be carried out to review the effectiveness of the performance management of SIs reportable on StEIS, the process of reporting, recording and lessons learned. This review and monitoring process shall be carried out by the Quality and Safety Committee.

18. References and Associated Documents
NHS England Serious Incident Framework (March 2015)
NHS England Revised Never Events Policy and Framework (March 2015)
The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
West Lancashire CCG Information Governance Policy
West Lancashire CCG Safeguarding Policy
Appendix 1

Serious Incidents in the NHS; definitions

In broad terms, 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. This includes
    - suicide/self-inflicted death; and
    - homicide by a person in receipt of mental health care within the recent past;
  - 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.

- 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 many extend to a large population;
  - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act. Deprivation of Liberty Safeguards (MCA DOLS);
  - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/unit closure or suspension of services); or
  - Activation of major Incident Plan (by provider, commissioner or relevant agency)

- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of health or an organisation
Appendix 2 Interfaces with Other Sectors

Deaths in Custody - where health provision is delivered by the NHS

People in custody, including either those detained under the Mental Health Act (1983) or those detained within the police and justice system, are owed a particular duty of care by relevant authorities. The obligation on the authorities to account for the treatment of an individual in custody is particularly stringent when that individual dies.

In prison and police custody, any death will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the Independent Police Complaints Commission (IPCC) who are responsible for carrying out the relevant investigations. Healthcare providers must fully support these investigations where required to do so. The PPO has clear expectations in relation to health involvement in PPO investigations into death in custody. Guidance published by the PPO23 must be followed by those involved in the delivery and commissioning of NHS funded care within settings covered by the PPO.

In NHS mental health services, providers must ensure that any death of a patient detained under the Mental Health Act (1983) is reported to the CQC without delay. However providers are responsible for ensuring that there is an appropriate investigation into the death of a patient detained under the Mental Health Act (1983) (or under the Mental Capacity Act (2005)). Where an individual dies at a time when they are deprived of their liberty under the Mental Capacity Act 2005 (MCA 2005) a coroner must investigate the death of an individual subject to a DoL. Under the MCA 2005 a person who lacks capacity and is in a hospital or care home for the purpose of being given care or treatment may be detained in circumstances which amount to deprivation of liberty. The court of protection may make similar authorisation authorising deprivation in a personal domestic setting (own home). A death in custody is automatically reportable to the coroner and a death certificate must not be issued.

In circumstances 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 to the provider’s commissioner(s) as a serious incident and investigated appropriately. Consideration should be given to commissioning an independent investigation.

Serious Case Reviews and Safeguarding Adult Reviews

The Local Authority via the Local Safeguarding Children Board or Local Safeguarding Adult Board (LSCB, LSAB as applicable), has a statutory duty to investigate certain types of safeguarding incidents/ concerns. In circumstances set out in Working Together to Safeguard Children (2013) the LSCB will commission Serious Case Reviews and in circumstances set out in guidance for adult safeguarding concerns the LSAB will commission Safeguarding Adult Reviews. The Local Authority will also initiate Safeguarding Adult Enquiries, or ask others to do so, if they suspect an adult is at risk of abuse or neglect.

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 within healthcare has occurred, the necessary declaration must be made.
Whilst the Local Authority will lead SCRs, SARs and initiate Safeguarding Enquiries, healthcare 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 (in a timely and proportionate way) to minimise the risk of further harm and/or recurrence. The interface between the serious incident process and local safeguarding procedures must therefore be articulated in the local multi-agency safeguarding policies and protocols. Providers and commissioners must liaise regularly with the local authority safeguarding lead to ensure that there is a coherent multi-agency approach to investigating and responding to safeguarding concerns, which is agreed by relevant partners. Partners should develop a memorandum of understanding to support partnership working wherever possible.

**Domestic Homicide Reviews**

A Domestic Homicide is identified by the police usually in partnership with the Community Safety Partnership (CSP) with whom the overall responsibility lies for establishing a review of the case. Where the CSP considers that the criteria for a Domestic Homicide Review (DHR) are met, they will utilise local contacts and request the establishment of a DHR Panel. The Domestic Violence, Crime and Victims Act 2004, sets out the statutory obligations and requirements of providers and commissioners of health services in relation to domestic homicide reviews.

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

Where patients in receipt of mental health services commit a homicide, NHS England will consider and, if appropriate, commission an investigation. This process is overseen by NHS England’s Regional investigation teams. The Regional investigation teams have each established an Independent Investigation Review Group (IIRG) which reviews and considers cases requiring investigation. Clearly there will be interfaces with other organisations including the police and potentially the Local Authority (as there may be interfaces with other types of investigation such as DHRs and/or SCRs/SARs, depending on the nature of the case). To manage the complexities associated with such investigations (and to facilitate joint investigations where possible), a clearly defined investigation process has been agreed. Central to this process is the involvement of all relevant parties, which includes the patient, victim(s), perpetrator and their families and carers, and mechanisms to support openness and transparency throughout.

**Serious Incidents in National Screening Programmes**

Serious Incidents in NHS National Screening Programmes must be managed in line with the guidance: Managing Safety Incidents in National Screening Programmes, which is aligned with the principles and processes set out in this Framework. The guidance provides further clarity with regards to the accountabilities, roles and processes for managing screening safety incidents and serious incidents in national screening programmes. These are often very complex, multi-faceted incidents that require robust coordination and oversight by Screening and Immunisation Teams working within Sub-regions and specialist input from Public Health England’s Screening Quality Assurance Service.

The Screening Quality Assurance Service is also responsible for surveillance and trend analysis of all screening incidents. It will ensure that the lessons identified from incidents are collated nationally and disseminated. Where appropriate these will be used to inform changes to national screening programme policy and education/training strategies for screening staff.
### Appendix 3

**Levels of Investigations (currently referred to as a Root Cause Analysis (RCA) Investigation)**

<table>
<thead>
<tr>
<th>Level</th>
<th>Application</th>
<th>Product/Outcome</th>
<th>Owner</th>
<th>Timescale for Completion</th>
</tr>
</thead>
</table>
| Level 1  
**Concise internal investigation** | Suited to less complex incidents which can be managed by individuals or a small group at local level | Concise/ compact investigation report which includes 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. |
| 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 includes 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 due to the size of the organisation or the capacity/capability of the available individuals and/or number of organisations involved | Comprehensive investigation report includes all elements of a credible investigation | The investigator and all members of the investigation team must be independent to 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. |
Appendix 4: **STEIS processes**

LCFT (Mental Health) SteIS report review process

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**LCFT**

- Post incident review
- RCA Report
- CSU and CCG comments considered and further assurances provided
- Review/closure form with further assurances
- Incident closed on STEIS and Logged on SUI database

**CSU**

- Logged on SUI database
- Observations recorded on Review/closure form
- Report reviewed

**CCG**

- Report and review/closure form prepared
- Review/closure form with CCG observations
- Report reviewed
- Observations recorded on Review/closure form
- SI Review panel

Decision:
- Satisfactory assurance provided?
- Yes
- No
STEIS report review process with Southport and Formby CCG as the lead Commissioner (Southport and Ormskirk/ Aintree NHS Trusts)
Care Home (private provider, no access to datix) Incident Review Process

Incident Occurs
Incident reported internally. Provider to determine actual incident severity

No harm / minor reported internally. Nursing home providers are to submit a quarterly report to the CSU via prmhub.submissions@nhs.net detailing themes, trends and lessons learned and any actions taken to improve practice and reduce risk of further occurrence.

Moderate impact incidents reported to the CSU via seriousuntowardincidents@nhs.net within 48 hours (examples; fractures following a fall, pressure ulcers grade 3 and above)

Severe and catastrophic harm to be reported to CSU via seriousuntowardincidents@nhs.net within 48 hours (examples; an incident that directly led to the death of the service user)

Notification to external Organisations (as appropriate) Examples CQC, Safeguarding team, Coroner, RIDDOR, HSE

No harm / minor

Lessons learned to be disseminated to staff within the organisation

Themes and trends to be communicated to CCG’s through the Quality and Performance Quarterly report

Severe and catastrophic

CSU serious incident team will log the incident and cascade to the Quality and Performance Clinical Specialists, IPA/CHC team.

Quality and Performance Clinical Specialists review incident,

StEIS criteria not met

Provider to submit a Post Incident Review (PIR) report within 30 days

PIR report (to include RCA) to be reviewed by CSU, recommendations sent to CCG via SI team

Action plan to be monitored by CSU Quality and Performance Clinical Specialists and CCG

Incident Closed
Themes and trends to be communicated to CCG’s through the Quality and Performance Quarterly report

StEIS criteria met (SI framework NHSE, March 2015)

Quality and Performance Specialists to liaise with SI Team who will contact CCG
The National Serious Incident Management Process, including timescales

1. **Incident occurs**
   - Report on LRMS/NRLS and to other bodies such as safeguarding lead as applicable
   - Manage in line with local risk management policy
   - Engage with those involved/affected

2. **Is it a serious incident?**
   - **Yes**
     - Report on StEIS
   - **No**
     - **Unknown**
     - Review and discuss with the commissioner
     - Report/notify other stakeholders as required eg safeguarding, CQC, TDA

3. **Complete initial review and submit to commissioner where possible**
   - This should be the provider’s ‘lead commissioner’ who can liaise with others as required. This should be outlined in the RASCI model.
   - Confirm level of investigation required

4. **Lead investigator identified. Team established. Terms of reference set. Management plan established.**

5. **Undertake the investigation**
   - Gathering and mapping information
   - Analysing information
   - Generating solution

6. **Submit final report and action plan**
   - Commissioner (with relevant stakeholders) undertakes a review of the final report and action plan and ensures it meets requirements for a robust investigation. Feedback given to provider (*calendar days)

7. **Commissioner closes investigation and confirms timescales/mechanism for monitoring the action plan where actions/improvements are still being implemented**

Timeframes:
- **Within 2 working days**
- **Within 3 working days**
- **60 working days or 6 months for independent investigation**
- **20 days**
- **Ongoing**

Support and involve those affected including patients, victims, and their families and staff

Opportunities for feedback and learning identified and information shared
Appendix 5: List of Providers and their Lead Commissioner for Serious Incident oversight

<table>
<thead>
<tr>
<th>Provider</th>
<th>Lead Commissioner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Southport and Ormskirk Hospital NHS Trust</td>
<td>Southport and Formby CCG</td>
</tr>
<tr>
<td>Lancashire Care NHS Foundation Trust</td>
<td>Blackburn and Darwin CCG/ Area Team/ Chorley and South Ribble CCG</td>
</tr>
<tr>
<td>Mersey Care NHS Trust</td>
<td>Liverpool CCG</td>
</tr>
<tr>
<td>Calderstones Partnership NHS Foundation Trust</td>
<td>Area Team</td>
</tr>
<tr>
<td>University Hospital Aintree</td>
<td>Southport and Formby CCG</td>
</tr>
<tr>
<td>Care Homes in West Lancashire</td>
<td>West Lancashire CCG</td>
</tr>
</tbody>
</table>

Appendix 6: Equality Impact & Risk Assessment Policy Development & Review

[SI policy Stage 2 EIA _V1.0_170216.pdf]
### West Lancashire CCG template for reporting Serious Incidents

Completed forms should be returned to: seriousuntowardincidents@nhs.net

<table>
<thead>
<tr>
<th>Serious Incident Reference Number: (leave blank)</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEIS Identification Number: (leave blank)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date/Time/Location of Incident including hospital / ward / team level information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident type</td>
</tr>
<tr>
<td>Type of investigation expected to be required: Level 1, 2 or 3</td>
</tr>
<tr>
<td>Description of incident including reason for admission and diagnosis (for mental health please include Mental Health Act status and date of referral and last contact)</td>
</tr>
<tr>
<td>Details of any police or media involvement/interest</td>
</tr>
<tr>
<td>Details of contact with or planned contact patient/family or carers</td>
</tr>
<tr>
<td>Immediate actions taken including actions to mitigate any further risk</td>
</tr>
<tr>
<td>Details of other organisations/individuals notified</td>
</tr>
<tr>
<td>Lead Commissioner</td>
</tr>
<tr>
<td>Report completed by</td>
</tr>
<tr>
<td>Designation</td>
</tr>
<tr>
<td>Date / time report completed</td>
</tr>
</tbody>
</table>

A brief chronology of key events (to be inserted) if required
Equality Impact
and Risk Assessment
Policy Development
and Review

Equality Impact
and Risk Assessment
Serious Untoward Incident Policy & Procedure

Equality & Inclusion Team, Corporate Affairs
For enquiries, support or further information contact
Email: equality.inclusion@nhs.net
Date of commencing the assessment: 9\textsuperscript{th} February 2016

<table>
<thead>
<tr>
<th>Date for completing the assessment:</th>
</tr>
</thead>
</table>

Policy implementation Date:
Working draft since December 2005

Responsible Director/CCG Board Member:
Claire Heneghan, Chief Nurse

Directorate/Team:
Quality

Policy Assessment Lead and Contact Details:
Allison Sathiyanathan, Quality Assurance Manager 01695 588320

Who else will be involved in undertaking the assessment?
N/A

<table>
<thead>
<tr>
<th>EQUALITY IMPACT ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please tick which group(s) this policy will or may impact upon?</td>
</tr>
<tr>
<td>Patients, service users</td>
</tr>
<tr>
<td>Carers or family</td>
</tr>
<tr>
<td>General public</td>
</tr>
<tr>
<td>Staff</td>
</tr>
<tr>
<td>Partner organisations</td>
</tr>
</tbody>
</table>

How was the need for the policy identified?

National policy was updated in March 2015 and procedural changes were introduced by

What are the aims and objectives of the policy?
To outline the overarching governance arrangements for the management of serious incidents reportable on the Strategic Executive Information System (StEIS) and ensure that patient safety and other reportable incidents are appropriately managed within commissioned and contracted NHS services in order to address the concerns of the patients and promote public confidence. It describes the requirements for SI reporting and management.
SECTION 2
In this section you will need to consider:

What activities you currently do that help you to comply with the Public Sector Equality Duty (three aims).

Will your policy affect your ability to meet the Public Sector Equality Duty?

How you will mitigate any adverse impact?

- Eliminate, unlawful discrimination, harassment, victimisation and any other conduct prohibited by the Act;
- Advance equality of opportunity between people who share a protected characteristic and those who do not;
- Foster good relations between people who share a protected characteristic and those who do not.

Please answer ‘Yes’ or ‘No’ and explain your answer

<table>
<thead>
<tr>
<th>Does the policy aim to eliminate discrimination, harassment and victimisation?</th>
<th>Yes</th>
<th>No</th>
<th>Explain</th>
</tr>
</thead>
<tbody>
<tr>
<td>From the policy: Section 9. Safeguarding incidents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safeguarding is effectively protecting children and adults at risk 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’ 2013. Safeguarding adults is a statutory duty under part 1 of the Care Act 2014. In addition to reporting serious safeguarding incidents, there are specific arrangements in place for safeguarding. The responsibilities of investigating safeguarding incidents can be found in the CCG Safeguarding policy.</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Does the policy aim to consider advance equality of opportunity between people who share a protected group and those who don’t share it?**

What do we mean? Equality of opportunity is about making sure that people are treated fairly and given equal access to opportunities and resources. Promoting is about:

- Encouraging people/services to make specific arrangements
- Take action to widen participation
- Marketing services effectively
- Remove or minimise disadvantages
- Take steps to meet different needs

Securing special resources for those who may need them

**Does the policy aim to foster good relations between people who share a protected characteristic and those who don’t share it?**

What do we mean? Foster Good Relations between People: This is about bringing people from different backgrounds together by trying to create a cohesive and inclusive environment for all. This often includes tackling prejudice and promoting understanding of difference.

- Tackle prejudice
- Promote understanding
- Community cohesion (involvement, engagement)

**Has engagement/involvement or consultation?**

- **Y**

**CCG and CSU staff have been**

<table>
<thead>
<tr>
<th>Does the policy aim to consider advance equality of opportunity between people who share a protected group and those who don’t share it?</th>
<th>N</th>
<th>From the policy: section 12. Duty of Candour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central to the CCG’s strategy to improve patients safety is the commitment to provide good communication between healthcare organisations and patients and/or carers. The CCG expects all providers to meet the requirements of the Duty of Candour as defined within the Regulation 20 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This includes providing reasonable support, truthful information and an apology to patients and/or their carers when they have been involved in a serious incident.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Does the policy aim to foster good relations between people who share a protected characteristic and those who don’t share it?</th>
<th>Y</th>
<th>Under section; provider organisations:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The CCG requires the providers they commission to fulfil the following requirements:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- comply with national requirements and guidance in relation to being open with patients or their representatives when things have gone wrong;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- support and enable staff in disclosing incidents to patients and their representatives;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- involve patients and families/carers in investigations, sharing findings and providing timely referral for specialist support and guidance where appropriate;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Serious Untoward Incident Policy

Has the engagement/involvement or consultation highlighted any inequalities?

N

The safeguarding team made changes to the policy at an early stage that reinforces their involvement.

SECTION 3

Does the ‘policy’ have the potential to:
- Have a positive impact (benefit) on any of the equality groups?
- Have a negative impact / exclude / discriminate against any person or equality groups?
- Explain how this was identified? Evidence/Consultation?
- Who is most likely to be affected by the proposal and how (think about barriers, access, effects, outcomes etc.)

<table>
<thead>
<tr>
<th>Equality Group / Protected Group</th>
<th>Positive effect</th>
<th>Negative effect</th>
<th>Neutral effect</th>
<th>Please explain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Y</td>
<td></td>
<td></td>
<td>Lessons learnt from serious incidents are used to improve services for the protected groups identified</td>
</tr>
</tbody>
</table>

Lessons learnt from serious incidents are used to improve services for the protected groups identified.

The purpose of this policy is to outline the overarching governance arrangements for the management of serious incidents reportable on the Strategic Executive Information System (StEIS) and ensure that patient safety and other reportable incidents are appropriately managed within commissioned and contracted NHS services in order to address the concerns of the patients and promote public confidence irrespective any of the protected equality groups.

This policy describes the requirements for SI reporting and management.

The role of West Lancashire CCG
in relation to the policy is to gain assurance from the provider organisations that incidents are properly identified, reported and then investigated to identify lessons learnt in order to ensure that the risk of a similar incident happening again is minimised as much as possible.

<table>
<thead>
<tr>
<th>Category</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disability</td>
<td>y</td>
<td>As above</td>
</tr>
<tr>
<td>Sexual Orientation</td>
<td>n</td>
<td></td>
</tr>
<tr>
<td>Gender Reassignment</td>
<td>n</td>
<td></td>
</tr>
<tr>
<td>Sex (Gender)</td>
<td>y</td>
<td>As above</td>
</tr>
<tr>
<td>Race</td>
<td>n</td>
<td></td>
</tr>
<tr>
<td>Religion or Belief</td>
<td>n</td>
<td></td>
</tr>
<tr>
<td>Pregnancy and Maternity</td>
<td>y</td>
<td>As above</td>
</tr>
<tr>
<td>Marriage and Civil Partnership</td>
<td>n</td>
<td></td>
</tr>
<tr>
<td>Carers</td>
<td>n</td>
<td></td>
</tr>
<tr>
<td>Deprived Communities</td>
<td>n</td>
<td></td>
</tr>
<tr>
<td>Vulnerable Groups e.g. Homeless, Sex Workers, Military Veterans</td>
<td>y</td>
<td>As above</td>
</tr>
</tbody>
</table>

SECTION 4: EQUALITY IMPACT AND RISK ASSESSMENT CHECKLIST

This is the end of the Equality Impact section, please use the embedded checklist to ensure and reflect that you have included all the relevant information

SECTION 5: HUMAN RIGHTS ASSESSMENT

How does this policy affect the rights of patients set out in the NHS Constitution or their Human Rights?

If the Stage 1 Equality Impact and Risk Assessment highlighted that you are required to complete a full Human Rights Assessment, please request a Stage 2 Human Right Assessment form the Equality and Inclusion Team, and bring the issues over from Stage 1 into this section. Once completed, please embed the Human Rights Stage 2 into this section:
**SECTION 6: PRIVACY IMPACT ASSESSMENT**

If the Stage 1 Equality Impact and Risk Assessment highlighted that you are required to complete a Privacy Impact Assessment, please request a Stage 2 Privacy Impact Assessment either from the Equality and Inclusion Team or the Information Governance Team, and email your completed Stage 2 to your Information Governance Support Officer either at the CCG or the CSU, once finalised embed your completed PIA into this section:

**SECTION 7: RISK ASSESSMENT**

Please identify any possible risk for patients and / or the Clinical Commissioning Group if the policy is implemented without amendment. All risks will be monitored for trends and provided to the policy author when the policy is due to be reviewed.

**IMPLEMENTATION RISK: CONSEQUENCE SCORE**

<table>
<thead>
<tr>
<th>DOMAIN</th>
<th>INSIGNIFICANT</th>
<th>MINOR</th>
<th>MODERATE</th>
<th>MAJOR</th>
<th>CATASTROPHIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact on the safety of patients, staff or public (physical/psychological harm)</td>
<td>Minimal injury requiring no/minimal intervention or treatment.</td>
<td>Minor injury or illness, requiring minor intervention</td>
<td>Moderate injury requiring professional intervention RIDDOR/agency reportable incident An event which impacts on a small number of patients</td>
<td>Major injury leading to long-term incapacity/disability Mismanagement of patient care with long-term effects</td>
<td>Incident leading to death An event which impacts on a large number of patients</td>
</tr>
<tr>
<td>Complaints / Audit</td>
<td>Informal complaint / inquiry</td>
<td>Formal complaint (stage 1) Local resolution Single failure to meet internal standards Reduced performance rating if unresolved</td>
<td>Formal complaint (stage 2) complaint Local resolution (with potential to go to independent review) Repeated failure to meet internal standards</td>
<td>Multiple complaints / independent review Low performance rating Critical report</td>
<td>Inquest / ombudsman inquiry Gross failure to meet national standards Severely critical report</td>
</tr>
<tr>
<td>Statutory Duty / Inspections</td>
<td>No or minimal impact or breach of guidance/ statutory duty. For example: unsatisfactory patient experience which is not directly related to patient care.</td>
<td>Breach of statutory legislation Reduced performance rating if unresolved. For example: a minor impact on people with a protected characteristic</td>
<td>Single breach in statutory duty Challenging external recommendations/ improvement notice. For example: a moderate impact on people with a protected characteristic has been identified.</td>
<td>Multiple breaches in statutory duty Enforcement action Low performance rating Critical report. For example: a major impact on people with a protected characteristic has been identified. Consideration</td>
<td>Multiple breaches in statutory duty Prosecution Zero performance rating Severely critical report. For example: a catastrophic impact on people with a protected characteristic has been identified that</td>
</tr>
<tr>
<td>Adverse Publicity / Reputation</td>
<td>Rumours Potential for public concern</td>
<td>Local media coverage short-term reduction in public confidence Elements of public expectation not being met</td>
<td>Local media coverage Long-term reduction in public confidence</td>
<td>National media coverage &lt;3 days service well below reasonable public expectation</td>
<td>National media coverage &gt;3 days MP concerned (questions in the House) Total loss of public confidence</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------------------</td>
<td>-------------------------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Business Objectives / Projects</td>
<td>Insignificant cost increase No impact on objectives</td>
<td>&lt;5 per cent over project budget Minor impact on delivery of objectives</td>
<td>5–10 per cent over project budget</td>
<td>Non-compliance with national 10–25 per cent over project budget Major impact on delivery of strategic objectives</td>
<td>Incident leading &gt;25 per cent over project budget Failure of strategic objectives impacting on delivery of business plan</td>
</tr>
<tr>
<td>Finance Including Claims</td>
<td>Small loss Risk of claim remote</td>
<td>Loss of 0.1–0.25 per cent of budget Claim less than £10,000</td>
<td>Loss of 0.25–0.5 per cent of budget Claim(s) between £10,000 and £100,000</td>
<td>Loss of 0.5–1.0 per cent of budget Claim(s) between £100,000 and £1 million</td>
<td>Loss of &gt;1 per cent of budget Claim(s) &gt;£1 million</td>
</tr>
</tbody>
</table>

### IMPLEMENTATION RISK: LIKELIHOOD SCORE

<table>
<thead>
<tr>
<th>Frequency: How often might it / does it happen?</th>
<th>RARE</th>
<th>UNLIKELY</th>
<th>POSSIBLE</th>
<th>LIKELY</th>
<th>ALMOST CERTAIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not expected to occur for years</td>
<td>&lt;1%</td>
<td>1-5%</td>
<td>6-20%</td>
<td>21-50%</td>
<td>&gt;50%</td>
</tr>
<tr>
<td>Expected to occur annually</td>
<td>Expected to occur monthly</td>
<td>Expected to occur weekly</td>
<td>Expected to occur daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will only occur in exceptional circumstances</td>
<td>Unlikely to occur</td>
<td>Reasonable chance of occurring</td>
<td>Likely to occur</td>
<td>More likely to occur than not occur</td>
<td></td>
</tr>
</tbody>
</table>

### RISK MATRIX

<table>
<thead>
<tr>
<th>Negligible</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RARE</strong></td>
<td><strong>1</strong></td>
</tr>
<tr>
<td><strong>UNLIKELY</strong></td>
<td><strong>2</strong></td>
</tr>
<tr>
<td><strong>POSSIBLE</strong></td>
<td><strong>3</strong></td>
</tr>
<tr>
<td><strong>LIKELY</strong></td>
<td><strong>4</strong></td>
</tr>
<tr>
<td><strong>ALMOST CERTAIN</strong></td>
<td><strong>5</strong></td>
</tr>
</tbody>
</table>
What are the key reasons for the change in the risk score?

EQUALITY IMPACT AND RISK ASSESSMENT AND ACTION PLAN

<table>
<thead>
<tr>
<th>Risk identified</th>
<th>Actions required to reduce / eliminate the negative impact</th>
<th>Resources required* (see guidance below)</th>
<th>Who will lead on the action?</th>
<th>Target completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

‘Resources required’ is asking for a summary of the costs that are needed to implement the changes to mitigate the negative impacts identified

SECTION 8
FINAL SECTION

Date completed: 9th February 2016

Date received for quality check: 9th February 2016

Signature of person completing the assessment: Allison Sathiyanathan

Date reviewed by Equality and Inclusion Team: 9th February 2016

Signature and Date signed off by Equality and Inclusion Team: 17th February 2016 Catherine Bentley

Date signed off by CCG / CSU Committee:

This is the end of the Equality Impact and Risk Assessment process: By now you should be been able to clearly demonstrate and evidence your thinking and decision(s).

Save this document for your own records, once this is signed off by your organisation you should published on your website.

Send this document and copies of your completed Stage 2 Human Rights Screening document and Stage 2 Privacy Impact Assessment to the Equality & Inclusion Team equality.inclusion@nhs.net