Fylde and Wyre Clinical Commissioning Group

GOVERNING BODY MEETING

Date of meeting	20 September 2016	**Agenda item number**	17.2
Title of report	Serious Incident Reporting and Management Policy		
Paper Presented by:	Ms Claire Lewis, Head of Quality		
Paper prepared by:	Mr Nick Medway Practice Engagement, Quality & Governance Manager		

CCG strategic objective supported by this paper: (please tick ✓)	Develop and maintain an effective organisation	✔
	Commission high quality, safe and cost effective services which reduce health inequalities and improve access to healthcare	
	Effectively engage patients and the public in decision making	
	Develop excellent partnerships which lead to improved health outcomes	✔
	Make the best use of resources	

Purpose of report
To present to the Governing Body the Serious Incident Reporting and Management Policy for approval. The Policy replaces the Policy adopted from the former North Lancashire Primary Care Trust that has become outdated. The final page of the policy includes a list of reviewers and consequent actions taken. The Quality Improvement Governance and Engagement Committee has reviewed the Policy and recommends it for approval by the Governing Body.
Recommendation
The Governing Body is asked to approve the Serious Incident Reporting and Management Policy.

Please indicate which Group this has been discussed with (please tick ✓)			
Executive Management Team		Quality Improvement and Governance Cttee	✔
Clinical Commissioning Committee		Finance and Performance Committee	
Audit Committee		Remuneration Committee	
Council of Members		Primary Care Commissioning Committee	
Other/Not Applicable			
Patient and Public Engagement:		N/A	
Equality Impact Assessment:		Policy screened by originator MLCSU June 2015	
Resource Implication(s):		Nil	
For further information please contact:		N B Medway	

NHS
Fylde and Wyre
Clinical Commissioning Group

Serious Incident Reporting and Management Policy

Author(s) (name and post):	Janinne Lake, MLCSU Governance and Compliance Lead
Version No.:	V1.1
Approval Date:	
Review Date:	

Purpose of the policy

This policy describes the overarching process for ensuring that serious incidents occurring within the CCG and in provider organisations are promptly reported and managed, and that assurances are received that lessons have been learned.

Document Control Sheet

Document Control				
Version No	Draft Issued	Page(s)	Author	Draft approved
1	25th June 2015		J Lake	
1.1	Reviewed for FWCCG 18 July 2016		Reviewer - Medway	

Equality Impact Assessment

This policy has been screened to ensure that there is no discrimination on the basis of race, colour, nationality, ethnic or national origins, religious beliefs gender, marital status, age, sexual orientation or disability.

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Executive Summary

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 by ensuring that thorough and robust investigations are carried out. When an incident occurs it must be reported to all relevant bodies.

The 7 key principles in managing SIs are as follows:

- Open & Transparent
- Preventative
- Objective
- Timely & Responsive
- Systems based
- Proportionate
- Collaborative

The fundamental purpose and principles of Serious Incident management is to learn from incidents to prevent the likelihood of recurrence of harm by:

- Having a process, procedures and ethos that facilitate organisations in achieving this fundamental purpose;
- Clarity on key accountabilities of those involved in Serious Incident management, which is to support those affected including patients, victims, their families and staff and to engage with them in an open, honest and transparent way;
- Recognition of key organisational accountabilities where the provider is responsible for their response to Serious Incidents and where commissioners are responsible for assuring this response is appropriate.

This policy establishes a clear approach to the handling of an incident defined as a serious incident (SI). It contains the minimum reporting requirements expected by NHS Fylde and Wyre Clinical Commissioning Group in line with the principles laid out in the National Patient Safety Agency (2010) framework for Reporting and Learning from Serious Incidents Requiring Investigation and updated in NHS England Serious Incident Reporting and Never Event Frameworks. (March 2015)

Underpinning this process is a system of good governance that promotes a culture of openness and an attitude that facilitates learning from all incidents. This should include prompt reporting, appropriate and robust investigation, action planning, learning and follow-up, and where necessary communications management.

This policy and procedure contains serious incident reporting criteria to guide the NHS Fylde and Wyre CCG and Midlands & Lancashire Commissioning Support Unit (MLCSU) in support of any incident meeting the Serious Incident (SI) criteria that occurs within any provider. Where there are any doubts about thresholds of reporting these should be discussed with the Quality Lead at NHS Fylde and Wyre CCG or the Governance & Compliance Lead/Serious Incident Performance Manager at MLCSU, who provide the SI Management function on behalf of the CCG

1.0 Introduction

1.1 This policy is based on the NHS England Serious Incident Reporting Framework published in March 2015. Organisations providing NHS funded care in England are required to demonstrate accountability for effective governance and learning following a Serious Incident or Never Event. Serious incidents in healthcare are relatively uncommon, but when they occur the National Health Service (NHS) has a responsibility to ensure there are thorough and systematic measures in place for safeguarding people, property, NHS resource and reputation. This includes the responsibility to learn from these incidents to minimise the risk of reoccurrence (NHS IMPROVEMENT, 2010).

1.2 The revised SI Framework contains guidance in relation to the requirements of the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2010 and CQC 13 Fundamental Standards on Quality and Safety, particularly in relation to reporting serious incidents; contractual terms in relation to reporting serious incidents, including reporting to commissioners of services; guidance on reporting, disclosing, investigating and responding to serious incidents; duties under the Health and Social Care Act 2012 to continuously improve the quality of services; reporting requirements in relation to other bodies such as the NHS Trust Development Authority, Police, Health and Safety Executive, local Safeguarding Boards, Monitor, Coroners and others.

2.0 The purpose of this policy

2.1 The NHS IMPROVEMENT (and subsequently NHS England) have provided a clear framework to ensure consistency across the reporting and the management of SIs. The purpose of this policy is to outline the overarching governance arrangements for the management of Serious Incidents and/or Never Events occurring within independent providers.

2.2 Promoting safety by reducing error is a key priority for the NHS, particularly since the publication of '*An Organisations with a memory'* (Department of Health, 2000) which emphasises the importance of learning from adverse events.

2.3 NHS Fylde and Wyre CCG Clinical Commissioning Group is committed to the commissioning of high quality care and services and the achievement of a high standard of health, safety and welfare at work for all its employees and others visiting, engaged in or affected by its activities and services.

2.4 This policy supports openness, trust, continuous learning and service improvement from SI's reporting, monitoring and learning from incidents.

2.5 NHS Fylde and Wyre CCG makes explicit in its contracts with all providers its expectations regarding serious incident reporting and management, the indicators and the process for performance management.

2.6 The role of NHS Fylde and Wyre CCG in dealing with Serious Incidents is to ensure that:

1. Serious incidents are thoroughly investigated and the duty of candour is applied
2. Action is taken where necessary, to improve clinical quality and patient safety
3. Lessons are learned in order to minimise the risk of similar incidents occurring in the future and that learning is shared across the wider health community
4. Commission independent investigations where appropriate
5. Engage in Safeguarding Boards, Serious case reviews or Serious Adult Reviews when requested

3.0 The scope of this policy

3.1 This policy is designed to help providers take appropriate steps in the best interests of their service users, staff and the NHS as a whole. It contains the minimum reporting requirements expected by NHS Fylde and Wyre CCG. This policy does not replace the duty to inform other relevant authorities relating to serious incidents as required. Where regulated activities take place, registration with the Care Quality Commission and compliance with 13 Fundamental Standards of Quality and Safety are required.

4.0 Definitions

4.1 There is no definitive list of incidents that constitute an SI, although the STEIS (Strategic Executive Information System) does include a list of types of incident for ease of categorisation. The following is the criteria stated in the new Framework:-

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 (This may include failure to take a complete history, gather information from which to base care plan/treatment, assess mental capacity and/or seek consent to treatment, or fail to share information when to do so would be in the best interest of the client in an effort to prevent further abuse by a third party and/or to follow policy on safer recruitment)

- This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident
- 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 may extend to a large population;
- Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
- Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or
- Activation of Major Incident Plan (by provider, commissioner or relevant agency)
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation (As an outcome loss in confidence/ prolonged media coverage is hard to predict. Often serious incidents of this nature will be identified and reported retrospectively and this does not automatically signify a failure to report)

4.2 As a minimum, patient safety incidents leading to unexpected death or severe harm should be investigated to identify root causes and enable improvement action to be taken to prevent recurrence. The definition of SIs requiring

investigation extends beyond those which affect patients directly, and includes incidents which may indirectly impact patient safety or an organisation's ability to deliver on-going healthcare. All serious patient safety incidents should be reported to NHS Improvement, and to notifiable partner organisations.

4.3 Definitions of key types and levels of harm

NHS-funded healthcare – all services providing NHS funded care including independent providers where NHS funded services are delivered

Serious Harm - Severe harm (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 or after the time that healing would have been thought to have occurred in pain after trauma or surgery); or

- Psychological harm, impairment to 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).

Unexpected/Avoidable death - Caused or contributed to by weaknesses in care/service delivery (including lapses/acts and/or omission) as opposed to a death which occurs as a direct result of the natural course of the patient's illness or underlying condition where this was managed in accordance with best practice

Homicide by a person in receipt of mental health care includes those in receipt of care within the last 6 months but this is a guide and each case should be considered individually - it may be appropriate to declare a serious incident for a homicide by a person discharged from mental health care more than 6 months previously

Security breach/concern - includes absence without authorized leave for patients who present a significant risk to themselves or the public.

Patient Safety Incident - Any unintended or unexpected incident that could have led or did lead to harm for one or more patients receiving NHS-funded healthcare

4.4 'Never Event'

Never Events are *"serious, largely preventable, patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers (DOH, 2012). Never events are patient safety incidents that are preventable because:*

- *There is guidance that explains what the care or treatment should be;*
- *There is guidance to explain how risks and harm can be prevented;*

- *There has been adequate notice and support to put systems in place to prevent them from happening."*

4.5 Details of the categories of Never Events, as defined by the Department of Health and the former NHS IMPROVEMENT, are reviewed and published annually on the Department of Health website. A link to the list of current Never Events can be found under section 10.0

4.6 Fair Blame statement

NHS Fylde and Wyre CCG recognises that most incidents occur because of problems with systems as opposed to individuals and is committed to a 'fair blame' culture. To foster a fair blame culture, no disciplinary action will result from the reporting of an adverse event, mistake, serious incident or near miss, except where there has been criminal or malicious activity, professional malpractice, acts of gross misconduct, repeated mistakes or where errors or violations have not been reported. Lessons need to be learned from these events in order that every effort is made to prevent a recurrence.

4.7 Being Open Statement/Duty of Candour Compliance

NHS Fylde and Wyre CCG is committed to a culture of openness and accountability and encourages openness and honesty in accordance with the NHS England framework for effective communication with patients and/or their carers 'Being Open Framework (2009) and works to the principles set out within. The requirement to comply with the statutory Duty of Candour is explicitly required and should be reflected within contracts with providers.

5 Accountabilities

5.1 Provider Serious Incidents

For main providers (who are themselves responsible for logging, investigating and learning from their SIs), the CCG is accountable for ensuring information is used from SIs for continuous improvement across the wider health economy. There should also be clear lines of communication and nominated individuals for the quality management of the SI process.

Arrangements should also be explicit for co-commissioning and, where necessary, a Memorandum of Understanding developed or built in to joint policies to ensure clarity of management

5.2 CCG Serious Incidents

Any internal incident meeting the SI criteria must be escalated to the MLCSU team for logging on STEIS. 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. (Note:

an internal incident for Fylde and Wyre CCG may still involve other organisations)

5.3 Independent Providers

CCGs are also responsible (via MLCSU) for ensuring that all providers have a route to report in to STEIS. For SIs that occur in independent providers such as Nursing Homes, based on the CCG area in which the Nursing Home is sited, the CCG may report these on behalf of independent providers who do not have access to STEIS. RCA investigations regarding nursing homes are usually conducted by the Nursing Home itself or the Quality Lead or other CCG nominated person. The logging on STEIS, monitoring and management is via the MLCSU SI team with any closure agreed by the CCG/Panel. The MLCSU may close an SI on STEIS once agreed.

5.4 The NHS England Sub Region Team will support CCGs to ensure they have the right systems and capability to hold providers to account for their response to serious incidents.

Where serious incidents originate in or involve the actions of commissioning organisations or the NHS Trust Development Agency, they are accountable for their response to the serious incident according to the principles in this document.

5.5 Most healthcare providers have to register with CQC and most providers of NHS-funded care have to be licensed by Monitor. The regulators will use the details of incident reports to monitor organisations' compliance with 13 Fundamental Standards of quality and safety and their licence terms.

CQC-registered organisations are required to notify CQC about events that indicate or may indicate risks to compliance with registration requirements, or that lead or may lead to changes in the details about the organisation in CQC's register. They are required to report serious incidents as defined in CQC's guidance, *13 Fundamental Standards of Quality and Safety*. Most of these requirements are met by reporting via the National Reporting and Learning System (NRLS), who will forward relevant information to CQC. The exception is for independent sector providers and primary medical service providers who must report serious incidents directly to CQC. They can also report to the NRLS.

6.0 Serious Incident Reporting Management

6.1 For any SI that occurs outside of normal office hours 08:30 – 17:30 (Monday – Friday, excluding Bank Holidays) providers should initially alert their own Directors/Senior Management via the providers own on-call system. It will be the decision of the Provider on-call whether to escalate the matter to the CCG on-call Director, dependant on severity of incident and whether media attention is expected, or wait until the next working day.

NHS Fylde and Wyre CCG Director on-call will make the decision on whether to alert NHS England sub region office via the on-call system.

6.2 Where a SI involves a vulnerable adult or child / young person consideration must be given to initiating local safeguarding processes and followed by the reporting organisations Safeguarding Team (refer to NHS Fylde and Wyre CCG Safeguarding policy).

6.3 If more than one organisation is involved in a SI, the organisation that is responsible for the care of the patient at the time of the incident will report the SI. Providers of NHS-funded care (e.g. Nursing Homes) should contact the NHS Fylde and Wyre CCG / MLCSU to discuss reporting requirements and the CCG/MLCSU will determine who will lead the investigation.

6.4 Where potential media interest exists, NHS Fylde and Wyre CCG will prepare a media response based on the available information, this will be shared with NHS England Sub Region to ensure any necessary media management is proportionate and well managed. In instances where Serious Case reviews or Serious Adult Reviews are in progress, media management may be led by a multiagency partner such as Police or Social care.

6.5 Information Governance Incidents

Information Governance incidents that fulfil the criteria of being a SI must be handled in accordance with the process detailed in the Health & Social Care Information Centre/Department of Health (1st June 2013) Checklist Guidance for reporting, managing and investigating information governance serious incidents requiring investigation.

The immediate response to the incident and the escalation process for reporting and investigating this will vary according to the severity of the incident. All incidents rated as 2-5 are to follow the SI process and the following additional information should be provided in each case:

Date, time and location of the incident.

- Breach Type (definitions and examples of these can be found in Annex C).
- Details of local incident management arrangements.
- Confirmation that appropriate and documented incident management procedures are being followed and that disciplinary action will be invoked, where appropriate, following the investigation.
- Description of what happened.
- Theft, accidental loss, inappropriate disclosure, procedural failure etc.
- The number of patients/service users/staff (individual data subjects) involved.
- The number of records involved.

- The format of the records (paper or digital).
- If digital format, whether encrypted or not.
- The type of record, breach or data involved and sensitivity.
- Whether the IG SIRI is in the public domain.
- Whether the media (press etc.) are involved or there is a potential for media interest.
- Whether the IG SIRI could damage the reputation of an individual, a work-team, an organisation or the Health or Adult Social Care sector.
- Whether there are legal implications to be considered.
- Initial assessment of the severity level of the IG SIRI (see Annex A for further detail on how this is calculated).
- Whether the following have been notified (formally or informally):
    - Data subjects
    - Caldicott Guardian
    - Senior Information Risk Owner
    - Chief Executive
    - Accountable Officer
    - Police, Counter Fraud Services, etc.
- Immediate action taken, including whether any staff have been suspended pending the results of the investigation.

The IG SIRI category is determined by the context, scale and sensitivity. Every incident can be categorised as level:

1. Confirmed IG SIRI but no need to report to ICO, DH and other central bodies.
2. Confirmed IG SIRI that must be reported to ICO, DH and other central bodies.

A further category of IG SIRI is also possible and should be used in incident closure where it is determined that it was a near miss or the incident is found to have been mistakenly reported:

Near miss/non-event

Where an IG SIRI has found not to have occurred or severity is reduced due to fortunate events which were not part of pre-planned controls this should be recorded as a “near miss” to enable lessons learned activities to take place and appropriate recording of the event.

Step 1 Establish the scale of the incident. If this is not known it will be necessary to estimate the maximum potential scale point.

Baseline Scale		
0	Information about less than 10 individuals	
1	Information about 11-50 individuals	
1	Information about 51-100 individuals	

2	Information about 101-300 individuals	
2	Information about 301 – 500 individuals	
2	Information about 501 – 1,000 individuals	
3	Information about 1,001 – 5,000 individuals	
3	Information about 5,001 – 10,000 individuals	
3	Information about 10,001 – 100,000 individuals	
3	Information about 100,001 + individuals	

Step 2: Identify which sensitivity characteristics may apply and the baseline scale point will adjust accordingly.

Low: For each of the following factors reduce the baseline score by 1
No clinical data at risk
Limited demographic data at risk e.g.address not included, name not included
Security controls/difficulty to access data partially mitigates risk
Medium: The following factors have no effect on baseline score
Basic demographic data at risk e.g. equivalent to telephone directory
Limited clinical information at risk e.g. clinic attendance, ward handover sheet
High: For each of the following factors increase the baseline score by 1
Detailed clinical information at risk e.g. case notes
Particularly sensitive information at risk e.g. HIV, STD, Mental Health, Children
One or more previous incidents of a similar type in past 12 months
Failure to securely encrypt mobile technology or other obvious security failing
Celebrity involved or other newsworthy aspects or media interest
A complaint has been made to the Information Commissioner
Individuals affected are likely to suffer significant distress or embarrassment
Individuals affected have been placed at risk of physical harm
Individuals affected may suffer significant detriment e.g. financial loss
Incident has incurred or risked incurring a clinical untoward incident

Step 3 - Final Score

Final Score	**Level of SIRI**
1 or less	Level 1 IG SIRI (Not Reportable)
2 or more	Level 2 IG SIRI (Reportable)

6.6 All staff dealing with SI information must comply with Caldicott Principles, Data Protection and Information Governance requirements. Particular attention must be paid to confidentiality, sensitivity and person identifiable information – apart from the name of the reporter and the file holder within STEIS all other reports and correspondence should not contain any patient or staff identifiable information. The SI will be given a unique identifier which should be quoted as a reference during all associated correspondence, final RCA and Action Plan,

6.7 Initial Review

Following notification of a SI MLCSU will liaise with the organisation to request any additional information/clarify details, confirm the appropriate level of

investigation, terms of reference and reports required. An entry will be made onto STEIS to this effect. In addition to ensuring entry onto STEIS conforms to the minimum dataset, MLCSU will also ensure that their internal database (Datix) is updated to enable the production of reports and monitoring on behalf of NHS Fylde and Wyre CCG.

6.8 72 Hour Brief

There is greater emphasis on providers completing a 72 hour review/update. The aim is for an initial incident review to be undertaken by a clinician/manager with relevant expertise (but not directly involved in the delivery of care/service) which will:

- Identify and provide assurance that any immediate action has been taken to ensure safety of patients/staff/public
- Assess the incident in more detail to clarify whether it does meet the reporting requirements of an SI
- Propose a proportionate level of investigation (*this must be agreed with the commissioner)*

This information should be updated on STEIS. . A draft proforma for use is attached at Appendix A

6.9 All actions and correspondence taken by NHS Fylde and Wyre CCG /MLCSU will be recorded on STEIS within the Trust/Commissioner section on STEIS under the "Correspondence" or "Comments field". The name and title of the person adding the detail should be recorded against the comments.

7.0 Serious Incident Investigation Process

7.1 The reporting organisation is responsible for ensuring that all SI are investigated and documented. Investigations should follow the NHS IMPROVEMENT's best practice on conducting investigations using root cause analysis (RCA) methodologies. The principles of RCA will be applied to all investigations, but the scale, scope and timescales of investigation will be appropriate to the incident. Advice, where required or identified, will be given to providers in the completion of RCAs by the MLCSU lead/ Serious Incident Performance Manager.

7.2 Level of Investigation

There are three levels of investigation;

Level 1-concise; internal - for less complex incidents manageable by individuals or a small group at local level

Level 2 – comprehensive; internal - for complex issues manageable by a multi-disciplinary team – it can involve experts/specialists and the provider can involve external members to add a level of scrutiny/objectivity

Level 3- independent – two types.

The first is a provider–focussed investigation where the provider has been unable to carry out an effective/objective and timely investigation due to the

complexity or involvement of other agencies and where significant systemic failures appear to have occurred. There may also be conflicts of interest identified. This investigation will normally be commissioned by the commissioner of the care and undertaken by individuals independent of the provider.

The second type is SIs that involve the examination of the roles of wider commissioning systems or configuration of services including multi agency and multiple SIs. Any investigation must be independent of the directly involved commissioners and will usually be led by a regional or centrally led team from NHS England

The levels should be agreed between provider and commissioner within the first 72 hours following the reporting on STEIS. Commissioners may decide to undertake an independent investigation at any stage including following the outcome of a providers own internal investigation.

The level of investigation may need to be reviewed and can be changed as new information emerges-with the agreement of the commissioner/provider.

7.3 Initial Reporting

When an organisation identifies an incident which is assessed as meeting the definition of a serious incident, that organisation should report the incident via the Strategic Executive Information System (STEIS) **within two working days** of the SI being identified. Any delay in notifying the MLCSU should be explained.

7.4 Timescales

The timescale of the investigation, including notification to NHS Fylde and Wyre CCG, in normal circumstances will not exceed the 60 working day deadline (for Level 1 and 2 incidents. Level 3 external investigation may take up to 6 months), and should be completed within the terms of the agreed contract.

7.5 Extension Requests

In view of the increased timescale nationally from 45 to 60 days for the completion and submission of the RCA, it is not expected that extensions will routinely be required. However, if the reporting organisation faces unavoidable delays in its investigation of a SI then NHS Fylde and Wyre CCG should be notified of the reason for the delay, the anticipated delay period and a new reporting timescale will be negotiated on a case by case basis but there must be compelling reasons for doing so e.g. where new information comes to light during the RCA process which requires further investigation. Agreement of the commissioner must be obtained before the expiry of the original deadline and any extension will be effective from the date on which the SI Report was originally due.

7.6 Downgrades

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 NHS Fylde and Wyre CCG /MLCSU. At this point the SI will be removed from STEIS and the MLCSU database noted accordingly.

7.7 Action Plans

Assurance will be sought by NHS Fylde and Wyre CCG that action plans resulting from a SI investigation are completed within appropriate timescales. Therefore evidence demonstrating that actions have been completed may be requested by NHS Fylde and Wyre CCG /MLCSU as part of their quality schedule monitoring processes by the quality team during visits. Providers must reference in action plans how shared learning will be implemented both in the specialty involved and across the wider organisation.

7.8 Duty of candour

In October 2014, the Department of Health introduced regulations for the Duty of Candour (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) in response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust. It requires providers to notify anyone who has been subject (or someone lawfully acting on their behalf, such as families and carers) to a 'notifiable incident' i.e. incident involving moderate or severe harm or death. This notification must include an appropriate apology and information relating to the incident and should be given in person as soon as reasonably practicable (guidance states within 10 days of the incident being logged). This should be followed up with a written account and any further actions since the meeting. Failure to do so may lead to regulatory action by the CQC. This effectively applies to all SIs where a patient has suffered serious harm or death.

Moderate harm means - a moderate increase in treatment such as an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care).

Compliance with the Duty of Candour in cases below the SI threshold can be recorded on the provider's local incident reporting system. However, in all cases a written record should be kept of when and what was conveyed to the patient or their family/carer and by whom.

Importantly, these Regulations have from 1st April 2015, been extended to all other healthcare providers registered with the Care Quality Commission. e.g. GPs, Nursing homes, independent providers.

The STEIS system has been updated to record compliance with the Duty of Candour and this should be completed by providers when logging a Serious Incident. Compliance should also be referenced in the RCA Report

7.9 Stop the Clock

It is acknowledged that whilst every effort should be made to ensure that all SI investigations are completed in a timely manner, in accordance with the National Framework, there are instances when this is impossible due to circumstances which are beyond the immediate control of the reporting organisation due to issues of primacy. Where unavoidable delays are due to an external party, e.g. where the Police, HM Coroner or Judge has requested that any internal investigation is placed on hold as it may potentially prejudice any criminal investigation and subsequent proceedings. In such cases discussion between the organisation undertaking the investigation and NHS Fylde and Wyre CCG /MLCSU are required with the rationale for the request to stop the clock. It is the decision of NHS Fylde and Wyre CCG/MLCSU whether or not a SI meets the criteria for a 'stop the clock'. This rationale will be reported on STEIS

7.10 In order to ensure robust governance MLCSU will regularly monitor/review Stop the Clock agreements. In cases where such delays are evident it is essential that a clear entry is made onto STEIS by the provider to explain the rationale for the delay.

7.11 Process for restarting the clock

In order to ensure that RCA investigations progress in a timely manner, once the outcome of the recorded delay is known e.g. outcome of court proceedings, post mortem findings, the provider and NHS Fylde and Wyre CCG /MLCSU will discuss the removal of the clock-stop and agree a timeframe for completion of the RCA investigation. This date will then become the timeframe for closure of that incident and an entry made on STEIS by MLCSU. This timeframe whilst negotiated with the provider will be required to be a realistic yet prompt timeframe in order to ensure timely closure of the incident.

7.12 Process for Closure and Sign-Off

Where a SI investigation has been completed and a full investigation report received from the provider including an agreed action plan, NHS Fylde and Wyre CCG initially determine whether an investigation has met the appropriate quality level to be closed (see Checklist at Appendix B). On receipt of the RCA, NHS Fylde and Wyre CCG /MLCSU will review and where appropriate ask for expert/specialist advice to ensure the investigation and actions are appropriate. RCAs will normally be reviewed at regular SI Panel meetings, but may also be reviewed outside of this arrangement if closure deadlines fall between meetings. The decision will be recorded at the next meeting to allow an audit trail of outcomes.

7.13 Commissioners have 20 calendar days in which to review and confirm decisions on closure. In the circumstances where the report is deemed unsatisfactory and extra assurance or information is required this will be sought from the reporting

organisation, within five working days of any review meeting, and the SI will remain open until the extra information/feedback is received. STEIS will be updated to reflect the request for extra information.

7.14 Where the SI investigation report is deemed by NHS Fylde and Wyre CCG to be complete and details of the findings/lessons learned/actions have been entered onto STEIS by MLCSU the incident will be authorised for closure. Closure will only be actioned where STEIS has been updated with the RCA outcome including recommendations; actions; lessons learnt; how shared across the organisation and notable practice. Where there has been a death of the patient, the actual cause of death should be recorded on STEIS.

7.15 Where the SI is subject to a Level 3 (external investigation) , closure cannot be effected until evidence is supplied by the provider that all actions have been implemented.

7.16 If the reported SI is either a Never Event or a Homicide a copy of the investigation report and associated action plan will be shared with NHS England sub Region upon completion. **N.B.** Homicide closures cannot take place until such time as a decision has been taken as to whether or not an Independent Inquiry/Domestic Homicide Review should be commissioned, in accordance with Department of Health guidance. In cases where an Independent Inquiry is commissioned by NHS England sub Region the case should not be closed on STEIS until this is fully completed.

7.17 Where an incident occurs within an independent provider in the NHS Fylde and Wyre CCG area, but involves a patient from an external CCG area, this information should be relayed to the MLCSU to enable the home CCG to be informed.

7.18 Where the investigation has been commissioned by NHS England as part of a regionally led response (Regional Investigation Team), they will meet with relevant stakeholders to approve the report. Once this is complete, there will be a number of pre-publication checks e.g. legal review, media handling etc. before publication of the final report being published on the websites of the relevant commissioner, NHS England and the provider within 21 days of sign off. Advice should be taken from the Caldicott Guardian before any publication regarding compliance with information governance requirements

8.0 Monitoring of Serious Incidents

8.1 CCG is committed to improvement in quality and safety in commissioned services. A systematic approach to the analysis of patient safety intelligence has been developed which supports the commissioning of safe services.

8.2 The role of NHS Fylde and Wyre CCG in the monitoring of serious incidents is to ensure that they are properly investigated, action is being taken to improve patient safety and that lessons are learned in order to minimise the risk of similar incidents occurring in the future.

8.3 Contract Quality Review Meeting (CQRM)

NHS Fylde and Wyre CCG makes explicit reference within its contracts to its expectation regarding incident reporting and management. To ensure continuous improvement in serious incident management NHS Fylde and Wyre CCG has a range of key performance indicators built into provider contracts which it uses for monitoring purposes. The QCRM held with providers monitor the provider's SI performance and highlight any concerns in relation to trends, robustness of actions and lack of assurance with regard to quality and safety. Lessons learnt from incidents are also shared via this forum.

8.4 Dissemination of Shared Learning

One of the key aims of the serious incident reporting and learning process is to reduce the risk of recurrence, both where the original incident occurred and elsewhere in NHS funded care. The timely and appropriate dissemination of learning following a serious incident is core to achieving this and to ensure that lessons are embedded in practice (NHS IMPROVEMENT, 2010). Providers (or CCG) and must identify lessons and learning from the incident within the RCA and demonstrate how they are shared using an Action Plan Format and reviewed as part of the monitoring process and recorded on the SI closure form / StEIS database that is

9.0 Roles and Responsibilities for the reporting and management of serious incidents within NHS Fylde and Wyre CCG

- Overall accountability sits with the Quality Improvement Governance and Engagement Committee (QIGEC) - scrutiny is exercised and reported via the Assurance Group – exceptions will be reported to QIGEC
- The Fylde and Wyre CCG Clinical Governance and Quality Manager is the nominated lead for the management and review of serious incidents. Agreement to closure of incidents will be signed off by both the nominated lead and Chief Nurse or Head of Quality (as deputy).
- Overall day to day management of SI / StEIS system (on behalf of Fylde and Wyre CCG) sits with the MLCSU Governance & Compliance Lead/SI Performance Manager. This role has delegated responsibility for the management of the serious incident reporting system, including notifications to reviewing and performance monitoring, acting as a liaison between the Commissioner and provider organisations. The Governance & Compliance Lead/SI Performance Manager has responsibility for the monitoring, closure,

downgrading and extraction of information from STEIS and will provide the nominated leads with information on individual SIs as they are reported. A weekly report is also distributed to nominated CCG Leads, along with a monthly report showing detail and graphs to enable trends to be highlighted.

- Where specialised services are commissioned, the responsibility for monitoring, management and closure of any SIs that occur within those services is with NHS England sub region

10.0 References and relevant documents

SI Framework 2015/16
http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf

Never Events List 2015/16
http://www.england.nhs.uk/wp-content/uploads/2015/03/never-evnts-list-15-16.pdf

Never Event FAQs
http://www.england.nhs.uk/wp-content/uploads/2015/03/nepf-faqs.pdf

APPENDICES

APPENDIX A

Serious Incident 72 hour Update Brief			
STEIS Ref		Date of Incident	
Reporting Organisation			
Location of incident			
Incident category			
Summary of Immediate actions taken to ensure safety of patients/staff: Agreed level of investigation Additional information since original report			
SI meets reporting criteria (Yes/No):			
Completed by :			
Please send response to : Janinne Lake, Head of Governance & Compliance, Midlands & Lancashire CSU			
By:			

APPENDIX B

CSU/ CCG STEIS CRITICAL REVIEW / CLOSURE FORM			
STEIS number :		Date of Incident:	
Incident category:		Level of investigation	
Date due for completion		Extension requests/STC	
Provider			
Date RCA received by CSU			
Date of SI review Meeting:			
Root Causes Identified:			
Lessons learned:			
Areas of Good Practice:			
Duty of Candour Fulfilled:	☐Yes ☐ No		
Any comments on Duty of Candour:			
Does the Action Plan offer assurance that the recommendations have been accepted/risks have been reduced?			
Closure agreed	☐ Yes ☐ No (*complete section below*)		
Incident areas of on- going concern:			

Trends and Areas identified:	
Additional comments:	
FOR MLCSU ONLY	
RCA attached to Datix	
Datix updated with comments/RCA checklist	
STEIS updated with comments	
Datix closed	
STEIS closed	

Policy Review:

Serious Incident Reporting and Management Policy

July 2016 : Policy circulated for review to:

1: FWCCG Assurance group members

2. FWCCG QIGEC

3. Head of Quality

4. Head of Safeguarding

5. Clinical Governance & Quality Manager

Feedback / Comment has been received from:

K Toole	Lay Member	Comments incorporated
DR I Stewart	Lay Member	Comments noted / answered
A Marquiss Carr	Head of Safeguarding	Comments incorporated
C Lewis	Head of Quality	Comments incorporated
J Alexander	IG Manager MLCSU	Technical advice provided
N Medway	Clincal Governance / Quality Manager	Comments incorporated