Serious Incident Reporting and Management Policy

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1	12/11/2021	Written by J Lake CSU
2	15/11/2013	J Lake
3	17/12/2013	J Lake addition of updated reference to IG guidance
4	13/06/2016	J Lake-incorporating 2015 SI Framework revisions and IG Guidance
5	25/10/2018	Reviewed by L Dalton CSU
6	07/11/2018	J Blay added SICB Terms of Reference
7	05/07/2019	Charlotte Dunn (incorporating reference to both ICBs and process amendments)
8	07/2020	Charlotte Dunn – Updating Downgrade process
9	09/2020	Charlotte Dunn- Updating Root Cause requirement, Names of roles, Terms of Reference for Internal SI meeting, flowchart
10	01/04/2021	Moving over into new template for STW ICB
11	23/05/2022	Update of Appendices

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Contents

Executive Summary

Serious Incidents (SIs) 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 SIs to minimise the risk of the incident happening again. 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 SI 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 SI 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 SIs 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 SI. It contains the minimum reporting requirements expected by Shropshire, Telford and Wrekin Integrated Care Board (the ICB) in line with the process laid out in the NHS Oversight Framework 22/23and updated in NHS England Serious Incident Reporting and Never Event Frameworks (2018). 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 SI reporting criteria to guide organisations and supports their own internal SI policies but where there are any doubts about thresholds of reporting, these should be discussed with the ICB Quality Leads

Promoting safety by reducing error is a key priority for the NHS, particularly since the publication of '*An Organisation with a memory*' (Department of Health, 2000) which emphasised the importance of learning from adverse events to the more recent report by Professor D Berwick *"A promise to learn - a commitment to act: improving the safety of patients in England"* (August 2013), following the publication of the Francis Report into the breakdown of care at Mid Staffordshire Hospitals NHS Trust.

1 Purpose of the Policy

Shropshire Telford and Wrekin ICB is committed to ensuring that its population receives high-quality healthcare services that are safe, effective and provide a continuously improving patient experience.

We adopt the position of the NHS Patient Safety Strategy that safe services require safer systems that provide the right care, as intended, every time. To achieve this, healthcare systems need to focus on increasing the likelihood that things will go right in healthcare while minimising the possibility for things to go wrong for people experiencing healthcare.

An essential foundation to improving the safety of services is through identifying and responding to patient safety incidents. This requires healthcare organisations to recognise the needs of those affected, examine what happened to understand the causes and respond to the findings with action to mitigate the risks identified.

Serious Incidents are a type of patient safety incident identified in NHS-funded care where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified.

To support the NHS in ensuring there are robust systems in place for reporting, investigating and responding to Serious Incidents, there are two national frameworks that this policy aligns with:

- NHS England Serious Incident Framework: Supporting Learning to prevent recurrence (2015)
- NHS England Never Events Policy and Framework. Revised January 2018

Shropshire Telford and Wrekin ICB recognises that these frameworks are due to be replaced by the Patient Safety Incident Response Framework in 2023/24.

The purpose of this policy is to outline the overarching governance arrangements for the management of SIs and/or Never Events 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. The policy describes the requirements for SIs and Never Events reporting and management.

The ICB makes explicit in their contracts with all providers its expectations regarding SI reporting and management, the indicators and the process for performance management.

The role of the ICB in dealing with SIs is to ensure that:

- SIs are thoroughly investigated and the duty of candour is applied,
- Action is taken where necessary, to improve clinical quality and patient safety
- Lessons are learned in order to minimise the risk of similar incidents occurring in the future and that learning is shared and embedded across the wider health community and
- Independent investigations are commissioned where appropriate.

2 The Scope of this Policy

The NHS Standard Contract for 2023/24 states that healthcare providers must comply with the NHS Serious Incident Framework and the Never Events Policy Framework. This policy is therefore intended to complement (rather than replace) the Serious Incident reporting systems already operating within healthcare provider organisations.

Shropshire Telford and Wrekin ICB asks that all organisations following this policy note that that certain Serious Incidents require interfaces between the NHS England Serious Incident Framework and other national and regional guidance as listed below:

- Deaths in Custody- where health provision is commissioned by NHSGuidelines for Health & Justice Clinical Reviewers Child Safeguarding Practice Reviews and Safeguarding Adult Reviews
- Working Together to Safeguard Children: A guide to inter-agency working to safeguard and promote the welfare of children
- Domestic Violence, Crime and Victims Act 2004, Section 9 (3)
- Home Office Multi-agency Statutory Guidance for the Conduct of Domestic Homicide Reviews
- NHS England. Serious Incident Framework: Appendix 4 Homicide by patients in receipt of mental health care
- NHS England. Serious Incident Framework: Appendix 1 Serious Incidents in National Screening Programmes
- Managing Safety Incidents in NHS Screening Programmes

• The Police in incidents with criminal implications such as incidents where there is evidence or suspicion that the actions leading to harm (including of omission) were reckless, grossly negligent, wilfully neglectful or that harm/adverse consequences were intended

- The Care Quality Commission in accordance with the Health and Social Care Act
- The Provider's Accountable Officer in cases related to controlled drugs
- The relevant Coroner in cases of unexpected deaths or detained patient deaths
- The Department of Health and Social Care through the defect and failure reporting process in cases relating to a defect or failure involving engineering plants, infrastructure and/or non-medical devices
- The Health and Safety Executive where cases relate to workplace death or over 7 days incapacitation in accordance with the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995
- The relevant Director of Education and Quality at Health Education England for Serious Incidents involving trainees
- The Information Governance Toolkit where incidents relate to serious Information Governance Issues in accordance with the Health and Social Care Information Centre Checklist.
- The Local Authority where incidents relate to public health services they commission
- The Local Authority Safeguarding Team where an incident raises concerns of abuse or potential abuse or relates to adults, children or young people in vulnerable circumstances.
- The Medicines and Healthcare products Regulatory Agency (MHRA) through the Yellow Card Scheme where a Serious Incident raises suspected problems with a medicine or medical device
- NHS England where a Serious Incident may raise potential concerns over the Provider's compliance with their licence
- NHS Counter Fraud Authority through the Security Incident Reporting System where an incident involves physical or non-physical assault of staff or loss or damage to property and assets of NHS organisations, staff and patients.
- NHS England of all Serious Incidents
- Professional Regulators such as the Nursing & Midwifery Council, Health and Care Professions Council and General Medical Council if the incident suggests Grounds for Professional Misconduct after the Incident Decision Tree has been applied and the appropriate Provider Lead has been informed
- Screening and Immunisation Leads where an incident occurs within a screening or immunisation programme
- The relevant NHS England Team where the incident has the potential to have adversely affected the health of a wider population (such as decontamination failures, inadvertent patient/staff contact with transmissible infectious diseases, health care associated infection outbreaks, Health care workers with blood borne viruses, failures of microbiological laboratory practice and the release/widespread exposure of harmful chemicals or radiation)

- The Medicines and Healthcare products Regulatory Agency (MHRA) in cases of serious adverse incidents and serious adverse reactions related to blood and blood components, in accordance with the UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive

Shropshire Telford and Wrekin ICB would also recommend that the following local and national guidance is referenced as part of the management of Serious Incidents:

- Local Agreement for the Management of Reports to Prevent Future Deaths (Coroners' Regulation 28 Rule)
- National Guidance on Learning from Deaths
- NHS Oversight Framework
- NRLS Learning from patient safety incidents which will be replaced in September 2023 by LFPSE

3 Definitions

3.1 Serious Incident

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 2015 Framework:-

Acts and/or omissions occurring as part of NHS-funded healthcare 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

- 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) 2009;
- 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)

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.

3.2 '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."*
- *A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death*

Details of the categories of Never Events, as defined by the Department of Health and NHS England are reviewed and published annually on the Department of Health website.

3.3 Just and Learning Culture

The ICB recognises that most incidents occur because of problems with systems as opposed to individuals and are committed to a 'just and learning culture'. Therefore 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.

3.4 Being Open Statement

The ICB is committed to a culture of openness and accountability and encourage openness and honesty in accordance with the NPSA's framework for effective communication with patients and/or their carers 'Being Open Framework (2009) and work to the principles set out within this document (see link in section 12). The duty of candour is explicitly stated in contracts with providers.

4 Accountabilities

The key organisational accountability for SI management is from the provider in which the incident took place to the commissioner of the care. Where the incident occurs across a pathway commissioned by both NHS England – Specialised Commissioning and by the ICB, both should be informed.

4.1 Accountabilities to patients and carers

The principal accountability of all providers of NHS-funded care and commissioners is to patients and their families/carers. The first consideration following a SI is that the patient must be cared for, their (and other patients') health and welfare secured and further risk mitigated. Patients must be fully involved in the response to the SI. Where a patient has died or suffered serious harm, their family/carers must be similarly cared for and involved. Consideration must be given to their needs first. That means prioritising further treatment they may require, including offering treatment at an alternative provider if appropriate, and at all times showing compassion and understanding, even if simply making regular contact to keep them informed of the progress of investigations or action plan implementation.

4.2 Provider Serious Incidents

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

4.3 ICB Serious Incidents

Any internal incident which the SI criteria must be escalated to the MLCSU team for logging on STEIS under the ICB login. The investigation and subsequent production of an Investigation Report is the responsibility of the ICB. 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.

4.4 Independent Providers including Primary Care

The ICB is also responsible for ensuring that all providers have a route to report into STEIS. For SIs that occur in independent providers such as nursing homes, based in the ICB area in which the nursing home is sited, the ICB 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 ICB nominated person. The logging on STEIS and monitoring and management is via the MLCSU SI team.

Where SIs originate in or involve the actions of commissioning organisations, they are accountable for their response to the SI according to the principles in this document.

4.5 Accountability to Care Quality Commission

All healthcare providers who provide regulated activities such as personal or nursing care are required to register with CQC. The regulators will use the details of incident reports to monitor organisations' compliance with essential standards of quality and safety and their licence terms. CQC do have access to the STEIS system (a national database used to record all SIs reported)

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 SIs as defined in CQC's guidance, *Essential 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 SIs directly to CQC. They can also report to the NRLS.

5 Serious Incident Reporting Process

The ICB must ensure that there are robust incident reporting systems which are already in place within NHS organisations. This policy also does not replace the duty to inform other authorities of SIs, for example the police, social services, local safeguarding boards for children and adults. In such circumstances this SI policy and procedure should be followed as well as specific national guidance. A flow chart is attached (Appendix D) which outlines the SI reporting process.

When an incident is of such a serious nature that an external enquiry is required, it will need to be established in line with relevant national guidance. The responsibility for commissioning an external inquiry depends on the nature of the incident. Such incidents will require discussion with the appropriate patient safety ICB Executive Lead prior to establishing the enquiry.

When an organisation identifies an incident which is assessed as meeting the definition of a SI, that organisation should contact the relevant personnel within the provider organisation, to discuss the details, category and grading of the incident. Organisations are then required to report the incident via STEIS within two working days of the incident occurring or being classified as a SI, or at the earliest point thereafter with an explanation for any delay.

Electronic notification will be made from STEIS to inform delegated key personnel at NHS England. The Governance & Compliance Team at MLCSU will also be

automatically notified when a new SI is logged on STEIS, in addition to the direct email or initial proforma report from the reporting organisation.

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 Director on-call whether to escalate the matter to the ICB on-call Director, dependant on severity of incident and whether media attention is expected, or wait until the next working day.

The ICB Director on-call will make the decision on whether to alert NHS England via the on-call system.

Independent practitioners/other providers of NHS-funded care must contact the relevant commissioner to report and register a SI. Where the ICB is deemed the responsible commissioner for independent contractors (GPs, dentists, optometrists, pharmacists) the details should be logged on STEIS under the ICB is primary care log on credentials. 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.

Where potential media interest exists, the ICB will prepare a media response based on the available information, this will be shared with NHS England to ensure any necessary media management is proportionate and well managed.

NHS 111/WMAS
The Lead Commissioner for this service is Black Country ICB They will be responsible for the monitoring and closure of NHS 111/WMAS SIs but will be required to inform “home” ICB of any SIs involving their patients.

Initial Review
Following Provider notification of a SI the ICB the CSU will liaise with the reporting 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 is updated to enable the production of reports and monitoring on behalf of the ICB.

72 Hour Update
All providers must complete 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

All actions and correspondence taken by the ICB/MLCSU will be recorded on STEIS by the MLCSU Governance & Risk team within the Trust/Commissioner 'Correspondence' or Comments field. The name and title of the person adding the detail should be recorded against the comments.

6 Serious Incident Investigation Process

The reporting organisation is responsible for ensuring that all SIs are investigated and documented. Investigations should follow the NPSA'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.

Where possible the reporting organisation should seek to find the root cause of the incident and any themes, so that they can work towards preventing future recurrence. The root cause should link in with the recommendations and associated action plans to ensure improvements are identified and embedded.

Where a SI involves a child, young person or vulnerable adult consideration must be given to raising an alert as a safeguarding concern and local safeguarding processes initiated and followed by the reporting organisations Safeguarding Team (refer to the ICB safeguarding policies).

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 involves 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 ICB /MLCSU.

Incidents that meet certain criteria may be logged as an incident of interest to the ICB for further surveillance and monitoring, this criteria is as follows but not limited to; never events, incidents which are likely to attract significant adverse media attention, domestic homicides, safeguarding deaths, inpatient deaths resulting from actual or suspected self-inflicted harm, incidents where more than one person has suffered significant harm/death, incidents where multiple providers have been involved,

allegations against staff, and incidents where there are significantly high numbers of patients affected and level of harm has not yet been established.

Initial Reporting

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

Timescales

The timescale of the investigation, including notification to the ICB/MLCSU, in normal circumstances will not exceed the 60 working day deadline this should be completed within the terms of the agreed contract.

Extension Requests

Where the Provider requires an extension past the agreed 60 days for the completion and submission of the RCA, the Quality Lead must approve and must have an understanding of any mitigation in place, 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 the ICB/MLCSU 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.

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 the ICB/MLCSU.

Where a downgrade request is based on a clear rationale the ICB quality lead will agree the downgrade, providing their reasons to CSU. However, if the downgrade is more complex, the ICB quality lead will share their reasoning with the other ICB quality leads and a decision will be made as to whether a downgrade should be agreed or not.

If a downgrade is agreed, the SI will be removed from STEIS and the MLCSU database noted accordingly. If the downgrade is not agreed, perhaps owing to the valuable learning as part of the initial review, then the process continues, and the provider organisation will have to submit the RCA within the agreed timescale.

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 the ICB/MLCSU are required with the rationale for the request to stop the clock. It is the decision of the ICB/MLCSU whether a SI meets the criteria for a ‘stop the clock’. This rationale will be reported on STEIS.

In order to ensure robust governance, the ICB will monitor/review clock-stop 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.

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 must inform the Quality lead and CSU to ensure 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.

Action Plans

Assurance will be sought by the ICB that action plans resulting from a SI investigation are completed within appropriate timescales. There will be occasions when it is deemed that a satisfactory investigation has taken place and appropriate actions have been identified. SI's will not always be kept open whilst actions are being implemented, but the ICB will still require the evidence that these actions are being implemented outside of the SI process and as part of routine quality monitoring and surveillance processes. Therefore, evidence demonstrating that actions have been completed may be requested by the ICB as part of their quality schedule monitoring processes by the quality team during visits and CQRM meetings. Providers must reference in action plans how shared learning will be implemented both in the specialty involved and across the wider organisation, oversight for this progress and implemtation will be obtained via quality meetings inline with the National Quality Board (NQB) Guidance.

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. Therefore, an SI cannot be closed until evidence of Duty of Candour has been met. This includes plans to share the report and its findings with the person/ family after the investigation is completed.

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.

These Regulations apply to all other healthcare providers registered with the Care Quality Commission. e.g. GPs, nursing homes, independent providers.

The STEIS system records compliance with the duty of candour and this should be completed by providers when logging a SI. Compliance mustshould also be referenced in the Investigation Report.

Process for Closure and Sign-Off

Where a SI investigation has been completed and an RCA report received from the provider, including an action plan, the ICB will determine whether an investigation incident has met the appropriate quality level to be closed. On receipt of the RCA, the ICB/MLCSU will review and where necessary ask for expert/specialist advice to ensure the investigation and actions are appropriate. RCA's will be reviewed by the quality lead and returned to MLCSU with the necessary actions on the checklist form, as set out in Appendix B.

Commissioners have 20 working 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 required from the reporting organisation within 10 working days of the RCA Checklist being returned to them via MLCSU (see Appendix D). The SI will remain open until the extra information/feedback is received and MLCSU will update STEIS to reflect the request for extra information. If the quality is still not satisfied and further assurance is still required, the details of the SI will be shared with the Associate Director of Quality and will be discussed with the provider at the joint ICB/ provider SI review meetings.

Where the RCA report is reviewed as per the process in Appendix D and deemed by the ICB to be complete the incident will be authorised for closure and referred to the MLCSU for action. Closure will only be actioned by the MLCSU where STEIS has been updated with the necessary information including recommendations; actions; lessons learnt; how shared across the organisation, notable practice and the category of the incident is completed; i.e. there is no reference to Pending Review. Where there has been a death of the patient, the actual cause of death should be recorded on STEIS. As stated above, on occasions the quality leads may agree to closure but on the provision that certain actions are followed through at a

later date, as identified by the provider. These actions will be monitored by the quality leads via System Quality review meetings.

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

If the reported SI is either a Never Event or a Homicide, a copy of the full RCA report and associated action plan will be shared with NHS England upon closure.

Where an incident occurs within an organisation in the Shropshire or Telford area, but involves a patient from an external ICB area, this information should be relayed to the MLCSU Governance & Compliance team to enable the home ICB to be informed.

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-publications 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

7 Monitoring of Serious Incidents

The ICB 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.

The role of the ICB in the monitoring of SIs 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. Following receipt of monthly reports from MLCSU, Quality Leads will be mindful in considering the themes and trends that are identified, ensuring provider improvement plans are implemented and monitored as per the Quality Assurance Framework.

The ICB makes explicit reference within it's contracts to their expectations regarding incident reporting and management. To ensure continuous improvement in SI management the ICB have a range of key performance indicators built into provider contracts which they use for monitoring purposes. The quality meetings held with providers monitors the provider's SI performance and highlights 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. As

aforementioned, quality leads may also request updates for actions that have been identified in providers' investigation reports.

Dissemination of Shared Learning

One of the key aims of the SI reporting and learning process is to reduce the risk of recurrence, both where the original incident occurred and elsewhere in the NHS. The timely and appropriate dissemination of learning following a SI is core to achieving this and to ensure that lessons are embedded in practice (NPSA, 2010). Lessons learnt from incidents are shared through a variety of ways. Lessons learnt are shared through reporting to the Quality Committee/PPQ meetings and to the ICB Governing Body. Lessons are also shared via bulletins, presentations and via prescribing newsletters.

Where information lessons identified can/should be shared with other organisations to share learning these will be identified by the MLCSU/ICB and included in the local SI Network Bulletin which will be distributed to commissioners and commissioned services by NHS England North Midlands.

NHS England Monitoring of Serious Incidents

Oversight of SI management by NHSE will be proportionate to the circumstances at the time and will be undertaken primarily through Quality Surveillance Groups (QSGs) in relation to the providers. The NHSE, ICB, and the CQC should fully exploit the opportunities for sharing information about SIs in relevant providers with partner organisations that make up the relevant local and regional QSGs.
Where systems are functioning well, oversight activities via QSGs (or elsewhere) will be limited. In these circumstances, QSGs will support providers and commissioners, review routine data, help to disseminate relevant learning and information, and resolve individual issues escalated to them, for example with more complex serious incident cases.

8 Roles and Responsibilities for the reporting and management of serious incidents within the ICB

Overall accountability sits with the Chief Nurse.

Overall day to day management sits with the ICB Quality and Performance Monitoring Officer, ICB quality leads and MLCSU. The Governance & Compliance Lead at MLCSU has delegated responsibility for the management of the SI reporting system, including notifications to reviewing and performance monitoring, acting as a liaison between the Commissioner and provider organisations. The Governance & Compliance Lead 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 ICB leads, along with a monthly report, as aforementioned, 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 and UK Heath Security Agency (UKHSA).

9 Acknowledgement of evolving organisational process

This policy is an overarching policy relating to the current local process for reporting and the management of incidents defined as serious incidents. In view of pending organisational changes and national changes to the Patient Safety Strategy this policy will be reviewed in July 2023 to update any process changes if not before.

10 Incidents of significant interest to the ICB

Serious Incidents which meet certain criteria require further surveillance and monitoring by the ICB to ensure follow-ups are being actioned in a timely manner. The following would meet the threshold of being an incident of significant interest but not limited to:

- Never Events.
- Incidents which are likely to attract significant adverse media attention.
- Domestic Homicides.
- Safeguarding deaths.
- Inpatient deaths resulting from actual or suspected self-inflicted harm.
- Incidents where more than one person has suffered significant harm/death.
- Incidents where multiple providers have been involved.
- Allegations against staff.
- Incidents where there are significantly high numbers of patients affected and level of harm has not yet been established.

References and links to 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

Serious Incident FAQs
https://www.england.nhs.uk/wp-content/uploads/2020/08/serious-incdnt-framwrk-faqs-mar16.pdf

Local Guidance on Serious Incident Categories and Reporting

Draft Guidance on SI
reporting criteria for t

National Patient Safety Strategy - https://www.england.nhs.uk/patient-safety/the-nhs-patient-safety-strategy/

Patient Safety Incident Response Framework- https://www.england.nhs.uk/patient-safety/incident-response-framework/

HSCIC/ Department of Health (2015) Checklist for Reporting, Managing & Investigating Information Governance Serious Untoward Incidents [online] https://www.igt.hscic.gov.uk/resources/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_111498

Department of Health (2008) Health and Social Act [Online] Health and Social Care Act 2008

Memorandum of Understanding (2006) Investigating Patient Safety Incidents (unexpected death or serious untoward harm); Department of Health; Association of Chief Police Officers; Health and Safety Executive. [Online]; Memorandum of understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm : Department of Health - Publications

National Patient Safety Agency (2009) Being Open: Communicating patient safety incidents with patients, their families and carers [Online] Being open: communicating patient safety incidents with patients, their families and carers

National Patient Safety Agency (2010) National framework for Reporting and Learning from Serious Incidents Requiring Investigation [Online] National framework for reporting and learning from serious incidents requiring investigation

Appendix A – 72 hours report template to be used by all providers

Serious Incident 72 hour Update Brief			
STEIS Ref		Date of Incident	
Reporting Organisation			
Location of incident			
Incident category			
Brief Detail of Incident **Physical/Mental Health History** **Brief description of current episode of care**			
1. Summary of immediate actions taken to ensure safety of patient/staff:			
2. Immediate learning/actions taken to mitigate any further risk (eg individual, patient group, environmental, procedural etc) and details of actions taken or agreed.			

Agreed Action or ActionTaken	Person Responsible	Target date

Agreed level of investigation
Additional information since original report on STEIS
Additional questions from ICB for response.
SI meets reporting criteria (Yes/No):Yes
Completed by :
Please send response to : MPFTInvestigationsTeam@mpft.nhs.uk

Appendix B - Checklist

CSU/ CCG STEIS SERIOUS INCIDENT REVIEW FORM			
Section 1 – to be completed by CSU			
Provider			
STEIS Number			
Incident Category			
Date of Incident			
Date logged on STEIS			
Level of Investigation			
Extension/STC			
Date due for Completion			
Date RCA Received by CSU			
Date RCA & Checklist sent to CCG			
Part A - to be completed by the CCG			
A	**Dates of review**		
B	**Duty of Candour *fulfilled*:**	Yes ☐ No ☐	
C	**Comments on Duty of Candour:**		
D	**Closure not agreed.** **The RCA is annotated with comments requiring a response prior to closure.**		
E	**Closure agreed.** **The RCA is annotated with comments requiring a response, not preventing closure.** **Further comments: Please see table on page 2**		
F	**Monitoring tab:** Additional information and response is required outside of closure process (see section E): Yes ☐ No ☐ Actions requiring monitoring: Yes ☐ No ☐ Please identify what action points need to be added to the monitoring tab : Please see page 2 table		
G	Trend/Theme Identified: Please hi-light	Patient Factors Individual Factors Team Factors Task Factors Communication factors Social Factors Education and Training Factors Equipment Resources Work environment Factors Organisational and Strategic Factors	
H	**Further discussion required?**	SI review meeting: Yes ☐ No ☐ Other : Yes ☐ No ☐ If yes, please specify:	
I	**Closure agreed :**	Yes ☐ Agreed by: Date:	
		No ☐ Agreed by: Date:	

Action points for monitoring

Area where additional assurance required	Monitoring Evidence requested/suggested by Quality Lead	Evidence log of requested assurance from Provider	By When

Appendix C – Serious Incident Closure Form 2nd Review pages

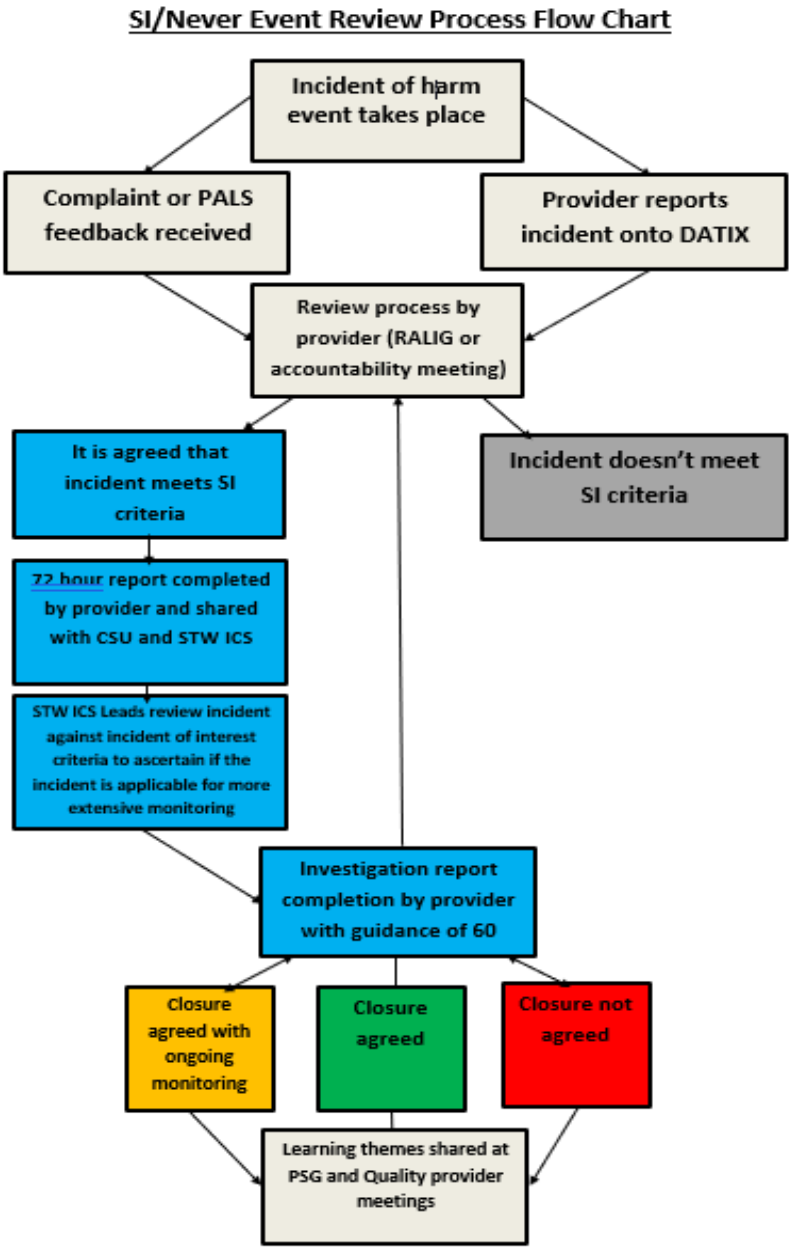
CSU/ ICB STEIS SERIOUS INCIDENT REVIEW FORM	
Section 1 – to be completed by CSU	
Provider	
STEIS Number	
Incident Category	
Date of Incident	
Date logged on STEIS	
Level of Investigation	
Extension/STC	
Date due for Completion	
Date RCA Received by CSU	
Date RCA & Checklist sent to ICB	

Part A - I to be completed by the ICB		
A	**Dates of review**	
B	**Duty of Candour *fulfilled*:**	Yes ☐ No ☐
C	**Comments on Duty of Candour:**	
D	**Closure not agreed.** **The RCA is annotated with comments requiring a response prior to closure.**	
E	**Closure agreed.** **The RCA is annotated with comments requiring a response, not preventing closure.** **Further comments: Please see table on page 2**	
F	**Monitoring tab:** Additional information and response is required outside of closure process (see section E): Yes ☐ No ☐ Actions requiring monitoring: Yes ☐ No ☐ Please identify what action points need to be added to the monitoring tab : Please see page 2 table	
G	Trend/Theme Identified: Please hi-light	Patient Factors Individual Factors Team Factors Task Factors Communication factors Social Factors Education and Training Factors Equipment Resources Work environment Factors Organisational and Strategic Factors
H	**Further discussion required?**	SI review meeting: Yes ☐ No ☐ CQRM : Yes ☐ No ☐ Other : Yes ☐ No ☐ If yes, please specify:
I	**Closure agreed :**	Yes ☐ Agreed by: Date:
		No ☐ Agreed by: Date:
J	**2nd review by ICB**	Date: Agreed by:

Action points for monitoring

Area where additional assurance required	Monitoring Evidence requested/suggested by Quality Lead	Evidence log of requested assurance from Provider	By When

APPENDIX D - SI/Never Event review process



APPENDIX E – Serious Incident Framework Closure checklist for information

This checklist provides a tool which can be used by providers and commissioners in their assessment of systems investigation into serious incidents. The STEIS report must be fully completed including date investigation is completed, lesson learned and actions taken			
Phase of investigation	Element	Answer (yes/no)	If no, was there a robust rationale and that prevents this affecting the quality of the investigation?
Set up/ preparation	Is the Lead Investigator appropriately trained?		
	Was there a pre-incident risk assessment?		
	Did the core investigation team consist of more than one person?		
	Were national, standard NHS investigation guidance and process used?		
Gathering and mapping	Was the appropriate evidence used (where it was available) i.e. patients notes/records, written account?		
	Were interviews conducted?		
	Is there evidence that those with an interest were involved (*making use of briefings, de-briefings, draft reports etc.*)?		
	Is there evidence that those affected (*including patients/staff/ victims/ perpetrators and their families*) were involved and supported appropriately?		
	Is a timeline of events produced?		
	Are good practice guidance and protocols referenced to determine what should have happened?		
	Are care and service delivery problems identified? *(This includes what happened that shouldn't have, and what didn't happen that should have. There should be a mix of care (human error) and service (organisational) delivery problems)*		
	Is it clear that the individuals have not been unfairly blamed? (*Disciplinary action is only appropriate for acts of wilful harm or wilful neglect*)		
Analysing information	Is there evidence that the contributory factors for each problem have been explored?		
	Is there evidence that the most fundamental issues/ or root causes have been considered?		
Generating solutions	Have strong (effective) and targeted recommendations and solutions (targeted towards root causes) been developed? Are actions assigned appropriately? Are the appropriate members i.e. those with budgetary responsibility involved in action plan development? Has an options appraisal been undertaken before final recommendation made?		
Throughout	Is there evidence that those affected have been appropriately involved and supported?		
Next steps	Is there a clear plan to support implementation of change and improvement and method for monitoring?		
Overall assessment and feedback			