

SERIOUS INCIDENT REPORTING & MANAGEMENT POLICY

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RELATED DOCUMENTS

These documents will provide additional information:

REFERENCE NUMBER	DOCUMENT TITLE	VERSION

GLOSSARY OF TERMS

TERM	ACRONYM	DEFINITION

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1 INTRODUCTION

- 1.1 Ensuring services are safe for patients is fundamental to the provision of high-quality care, and it is essential that healthcare providers have robust and effective systems in place for staff to report when patients have, or could have, been harmed.
- 1.2 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 for safeguarding people, property, NHS resources, reputation and in responding to them.
- 1.3 Open and honest reporting of SIs demonstrates a commitment to improving patient safety and through subsequent investigation and learning can help to minimise the risk of them happening again. This process of reporting and learning should be focused on identifying the root cause of the incident to ensure appropriate lessons are learnt and actions taken.
- 1.4 NHS England (NHSE) has provided a clear framework for managing SIs, with the intention that the framework is embedded through local policy.
- 1.5 Dudley CCG (DCCG) is responsible for ensuring that there are robust systems in place for reporting and monitoring performance of commissioned services. This includes ensuring SIs arising from its commissioned services are properly managed in line with the principles outlined above and according to national frameworks.

2 PURPOSE

- 2.1 The purpose of this policy is to clearly define the local requirements for the management of Serious Incidents and/or Never Events by providers of NHS-funded services commissioned by DCCG. It is the explicit expectation of DCCG that all providers of commissioned NHS care services will incorporate the requirements of this policy into their own organisational policies in order to support the local implementation of the [NHSE Serious Incident Framework](#).
- 2.2 Compliance with the requirements for reporting and managing incidents and SIs will be included within the monitoring of quality contracts.
- 2.3 Current contracts for GP services do not contain a clause requiring incidents to be reported to any external body (including commissioners), however, the contract does state that there should be robust processes in place to recognise and respond to serious incidents, and compliance with the Duty of Candour.
- 2.4 This policy also describes the internal SI management processes employed within DCCG, including the review and closure of RCA investigation reports produced by provider organisations and the monitoring of the effectiveness of action plans arising from investigations.
- 2.5 The management of SIs is only applicable to incidents related to NHS-funded care; however, this policy does not replace the duty of organisations to report incidents to all relevant bodies in line with local policy and national guidance, for instance safeguarding incidents.

2.6 Wherever possible, references have been provided to additional supporting information, either within the relevant section itself or as part of [Appendix 1](#).

2.7 An overview of the SI management process is provided in [Appendix 2](#).

3 ROLES & RESPONSIBILITIES

3.1 Provider Organisations

3.1.1 Providers of NHS funded care must have clear systems and procedures in place to:

- appropriately assess each incident and determine whether it meets serious incident criteria, and to be able to demonstrate how this decision was made in each case
- ensure that DCCG are notified of any newly identified serious incidents in a timely – within two working days - and secure manner, in line with any relevant confidentiality or Data Protection Act requirements using the identified secure serious incident email address.
- ensure SIs get logged onto STEIS in a timely manner, either directly where STEIS access is available to the provider, or via DCCG
- respond to any queries from DCCG relating to a serious incident in a timely manner, including those made as part of a 72-hour brief request
- identify an executive director (or an appropriate representative) responsible for leading on the serious incident process
- via appropriate and agreed routes, inform other relevant bodies as required in accordance with relevant national guidance (see [Section 5.10](#)).
- support robust and appropriate serious incident investigations, including processes to ensure:
 - Meaningful and sensitive engagement with affected patients and/or their families/carers, in line with Being Open and Duty of Candour from the point at which a serious incident is identified through to closure of the investigation process.
 - Appropriate immediate actions are taken following a serious incident, including the collection and retention of any relevant evidence such as clinical records and written accounts from individuals involved.
 - Appropriate resources are available to undertake investigations, including the use of suitably trained staff and access to relevant specialists / experts where required.
 - Investigations follow a systems-based approach to ensure any issues / problems with care delivery are fully understood from a human and systems factors perspective.
 - Wherever possible, the 'root causes' are clearly identified in order to produce relevant and appropriate recommendations that result in the definition of SMART (specific, measurable, attainable, relevant, time-bound) actions and learning to prevent recurrence.

- Action plans are monitored until fully implemented and learning embedded, and there is clear evidence as to whether or not the action plan has resulted in the expected improvement.
- Appropriate quality assurance processes to ensure completion of high quality investigation reports and robust action plans to enable timely learning and closure of investigations in order to prevent recurrence.
- Effective sharing of lessons learned across the organisation, and more widely where required.
- The timely submission of serious incident investigation reports to DCCG in line with agreed timescales.
- Appropriate consideration of any feedback from DCCG following their review of completed investigation reports, including the subsequent revision of those reports.
- Where, following logging on STEIS, an incident is deemed to not meet the requirements of a serious incident, to provide all relevant information and rationale to DCCG as part of the request for removal from STEIS using the DCCG template for deletions (see [section 6.7](#)).
- Where an extension to an existing timescale is requested this should be accompanied by clear and open communication to DCCG about the reason for the request.
- Support to investigations being led by external agencies such as the police, HSE or local authority. Where required, providers must submit evidence to contribute towards external investigations.
- Collaboration and partnership working where joint investigations are required to avoid duplication of activity or confusion of responsibility; this may include interagency investigation policy and / or memorandum of understanding with the relevant organisations

3.2 Dudley CCG

3.2.1 DCCG has a responsibility to assure itself of the quality of commissioned services, and to hold providers to account for the appropriate fulfilment of their responsibilities as described above. This will include having clear systems and procedures in place to:

- Report and investigate serious incidents occurring within the CCG itself such as an information governance breach relating to patient identifiable data.
- Monitor the reporting and investigation of serious incidents, including the monitoring of the NHS Strategic Executive Information System (STEIS) for new incident reports on a daily basis.
- Provide a secure e-mail address for all SI-related communication.
- Acknowledge all provider notifications of new serious incidents and any subsequent information provided in relation to serious incidents.
- Report incidents in a timely manner onto STEIS on behalf of provider organisations that do not have access themselves.
- In the interests of confidentiality and the Data Protection Act, ensure entries to STEIS and subsequent investigation reports are anonymous

- Review any requests for deletion and action the removal of an incident from STEIS in a timely manner once it has been agreed with the provider that it does not meet the criteria for a serious incident.
- Ensure the safe receipt and timely acknowledgement of serious incident investigation reports and any related documentation.
- Adequately review the findings of investigations in a timely manner, seeking appropriate expertise as required.
- Inform other relevant bodies in accordance with relevant national guidance (see [Section 5.10](#)) via appropriate and agreed routes.
- Involve any other interested parties in the review process, such as other commissioning bodies.
- Provide objective and constructive feedback on investigation reports in a timely manner, requesting additional information or assurance where required.
- Monitor compliance with Being Open and Duty of Candour.
- Close incidents on STEIS only once they have been subject to the DCCG review process and closure has been agreed, including the satisfactory response to any requests for additional information.
- Share intelligence with relevant regulatory and partner organisations.
- Utilise the expertise of clinical specialists where necessary.

3.2.2 Where DCCG commissions a service but is not the lead commissioner, it is expected the appropriate team within the lead commissioner will notify DCCG of Serious Incidents involving Dudley registered patients. DCCG should also be provided with regular updates as appropriate about these incidents and involved in the RCA review process.

3.3 NHS England

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

4 DEFINITIONS

4.1 Statement of Definitions

4.1.1 Where stated, definitions are taken from the appropriate national frameworks and/or policy documents which can be found on the [NHS England website](#) - please refer to these documents for more details.

4.2 Serious Incident (SI)

4.2.1 *“Serious Incidents in health care are adverse events, 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.”*

4.2.2 *“Serious Incidents include acts or omissions in care that result in; unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm - including those where the injury required treatment to prevent death or serious harm, abuse, Never Events, incidents that prevent (or threaten to prevent) an organisation’s ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in healthcare services.”* (Ref: [NHSE Serious Incident Framework](#))

4.3 Never Event

4.3.1 Incidents that are *“...wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.”* (Ref: [NHSE Never Events Policy and Framework](#))

4.3.2 All Never Events are defined as SIs although not all Never Events necessarily result in serious harm or death. For a list of all Never Events please refer to the Never Events List on the NHS England website.

4.4 Strategic Executive Information System (STEIS)

4.4.1 The Strategic Executive Information System (STEIS) is a web-based system for reporting serious incidents.

4.4.2 Each NHS provider with access to STEIS has a unique username and password which enables them to securely log and monitor SIs through to their ultimate closure on STEIS.

4.5 Root Cause Analysis (RCA)

4.5.1 Root Cause Analysis (RCA) is a method of problem solving that tries to identify the root causes of faults or problems that led to the incident.

4.5.2 RCA practice tries to solve problems by attempting to identify and correct the root causes of events as opposed to simply addressing their symptoms. By focusing correction on root causes, problem recurrence can be prevented.

5 REPORTING & INITIAL REVIEW

5.1 Identification

5.1.1 Where organisations become aware of an incident which has the potential to be categorised as an SI, an initial assessment should be undertaken to determine whether it should indeed be investigated as an SI.

5.1.2 To determine whether an incident requires a serious incident investigation, providers should consider whether the following (as defined by the national guidance) has occurred:

- Acts and/or omissions occurring as part of NHS funded healthcare (including in the community) that result in:

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- 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
 - abuse occurred during the provision of NHS funded care. 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 e.g. data loss or Information Governance-related issues
 - Property damage
 - Security breach/concern
 - Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population
 - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act (MCA), Deprivation of Liberty Safeguards (DoLS)
 - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services)
 - 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.
- 5.1.3 Where there is ambiguity if an incident fulfils the definition of a serious incident, providers and DCCG will engage in open and honest discussions to agree the appropriate and proportionate response. If a serious incident is reported but the investigation reveals that the definition of a serious incident is not fulfilled the incident can be removed from STEIS (see [section 6.7](#)).

5.2 Reporting & notification of SIs - NHS Providers WITH access to STEIS

- 5.2.1 SIs must be reported onto STEIS within two working days of the incident being identified, and the DCCG Quality and Safety team notified directly by e-mail (dudleyccg.seriousincidents@nhs.net).
- 5.2.2 Any delays in reporting within this timescale must be accompanied by an explanation for the delay directly to the DCCG Quality and Safety team and recorded on STEIS.
- 5.2.3 As much information as possible should be recorded on STEIS, including a summary of the incident, details of immediate actions taken, and all required demographic details including the patient's GP. Where agreed with the provider, it is expected that the following will be recorded on STEIS within 10 working days of the incident being reported:
- A record of the Duty of Candour including the date of engagement with the patient/family, questions that have been raised (if any) and if feedback has been offered and accepted/declined.
 - Terms of Reference and the scope of the investigation
 - Completion of all generic STEIS fields e.g. clinical area, care sector, patient status.
 - Incident specific information in the description e.g. for pressure ulcers at a minimum the description should include how the pressure ulcer was identified, the grade and location; for slips, trips and falls at a minimum the description should include how the patient fell and the outcome/harm caused by the fall.
- 5.2.4 All subsequent actions and correspondence taken by either the provider or DCCG must reference the STEIS number and be recorded on STEIS, each entry clearly stating the date and name of the individual making the entry.
- 5.2.5 The DCCG Quality and Safety team will acknowledge receipt within two working days of all SI notifications received and continue to liaise with the provider to clarify any further information required.
- 5.2.6 Reporting organisations must comply with Caldicott Principles, Data Protection and Information Governance requirements when reporting SIs (see [Section 5.4](#))

5.3 Reporting & notification of SIs - Providers WITHOUT access to STEIS

- 5.3.1 Where a provider does not have direct access to STEIS, notification must be provided directly to the DCCG Quality and Safety team using the 'Serious Incident Report Form' (see [Appendix 3](#)) and e-mailing the completed form to dudleyccg.seriousincidents@nhs.net within one working day of the incident being identified.
- 5.3.2 DCCG will be responsible for ensuring that the incident is correctly logged onto STEIS and informing the provider of the unique STEIS reference number. All subsequent actions and correspondence taken by either the provider or DCCG must reference the STEIS number and will be recorded on STEIS by DCCG, each entry clearly stating the date and name of the individual making the entry.

5.3.3 The DCCG Quality and Safety team will continue to liaise with the provider to clarify any further information required.

5.4 Data Protection Act (DPA) & Information Governance (IG) requirements

5.4.1 Reporting organisations must comply with Caldicott Principles, the Data Protection Act (DPA) and Information Governance (IG) requirements when reporting SIs. 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.

5.5 Duty of Candour

5.5.1 [The Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2014](#) has introduced a statutory duty of candour for provider organisations. This sets out the way in which providers act in an open and transparent way to notify the patient or their representative where an incident has resulted in severe, harm or prolonged psychological harm to the service user.

5.5.2 Consideration must always be given to the Duty of Candour requirements both on initial identification of an SI and during the course of the subsequent investigation.

5.6 Safeguarding

5.6.1 Where an SI involves a child or young person or a vulnerable adult, consideration must be given to raising an alert as a safeguarding concern and local safeguarding processes must be initiated and followed by the reporting organisations' Safeguarding Team. This should include robust communication with Local Safeguarding Boards and other interested bodies, and where appropriate agreeing the arrangements for the management of Serious Case Reviews (SCRs) including action planning and learning

5.6.2 Specific actions for the CCG include:

- Ensuring that the Designated Nurses for Safeguarding Children, Adults and Looked After Children are informed, who will then ensure that the local safeguarding procedures are followed.
- Ensuring the safeguarding incidents are reported to the relevant Local Safeguarding Board(s).
- When a serious incident involves two or more commissioners, liaising with other relevant CCG(s) to ensure that all relevant parties are notified, a coordinating commissioner is identified, and a timescale agreed.
- Upon reviewing an action plan, ensuring that all actions are consistent with the local multi-agency safeguarding protocol and policies.

5.6.3 Reporting arrangements

- The full extent of a safeguarding SI is sometimes not clear until after the initial fact finding exercise. Therefore, unless there is media attention a safeguarding SI should

be reported no later than two working days of the strategy meeting taking place. Where an SI has received media attention this should be reported immediately.

- If an unexpected child death SI is reported where there are clearly unexplained circumstances / safeguarding concerns, these should be reported no later than 2 working days from when the death is known.
- A death which was originally believed not to be suspicious and not therefore reported follows the Child Death Overview Panel (CDOP) process. The Child Death Overview Panel (CDOP), with a fuller picture of the evidence, may decide that there are safeguarding issues and that it should be referred to the Local Safeguarding Children Board Serious Case Review Panel. The panel may then determine that the SI meets the criteria for a Serious Case Review (SCR). In this case, the date of the SI would be the date of the incident rather than the date of referral to the SCR panel which may be several weeks/months later with the caveat that the SI process will recognise the effect on timescales.

5.6.4 SIs Involving a Child / Infant and Adult at Risk

- In all cases where there is a child / siblings and/or adult at risk their safety is paramount. Children and/or adults at risk should be made safe before reporting the SI. However, it is important that reports are timely and consistent. When reporting a SI, the premise of 'right first time' should prevail in that the organisation who will undertake the majority of the investigation should be the one to report onto STEIS.
- SIs involving children and/or adults at risk will be managed in accordance with this policy and the DCCG Safeguarding policy & procedures.
- Those SIs impacting on children and/or adults at risk will be overseen within DCCG by the Designated Nurses for Safeguarding Children, Adults and Looked After Children and in line with 'Working Together to Safeguard Children' and the relevant safeguarding adult guidance. The Designated Nurses will liaise with the wider Q&S team to ensure that local safeguarding procedures are followed.

5.7 Pressure ulcer incidents

5.7.1 For patients admitted or transferred to a healthcare setting without any obvious signs or symptoms of skin damage, the subsequent development of a pressure ulcer of grade 3 or above is likely to be related to care within that healthcare setting. This must therefore be regarded as a new event.

5.7.2 All professionals must ensure that pressure ulcer details are recorded in any clinical correspondences. In line with the National Institute for Health & Clinical Excellence guidance of 2005 an incident form should be completed for all identified pressure ulcers of grade 3 or above. Pressure ulcers must, in addition, be reported as a Serious Incident (SI) in line with the SI Framework by the organisation identifying it.

5.7.3 Through the investigation process an agreement that a pressure ulcer was unavoidable will be determined and ratified by an appropriately qualified clinician. *Unavoidable* means that the individual developed a pressure ulcer even though that individual's clinical

condition and pressure ulcer risk had been assessed and evaluated and all preventative measures implemented.

5.7.4 The SI Framework does provide the opportunity for flexibility when managing pressure ulcer SIs, particularly given the relatively high numbers that may be reported compared to other types of SIs. Where it would be beneficial to future learning and prevention of recurrence, DCCG may, by mutual agreement with a provider, agree to alternative methods of reporting and managing pressure ulcer SIs.

5.8 Healthcare-Acquired Infection (HCAI) incidents

5.8.1 Where an SI relates to an HCAI, the relevant local and national guidance must be followed to ensure it is investigated and reported appropriately. In Dudley, it is important that all partners are involved in the investigation; this includes close liaison with the Office of Public Health who support the CCG in the investigation of potential cases of HCAI, and have a duty to assure the Director of Public Health, that all parties are working together to learn from incidents.

5.8.2 The following HCAI incidents must be reported as a serious incident:

- HCAI Outbreaks
- Where *Clostridium difficile* has been reported on part 1 of the death certificate
- A Period of Increased Incidence of *Clostridium difficile* (two or more new cases (occurring >48hours post admission, not relapses) in a 28-day period on a ward)
- A case of Meticillin-resistant *Staphylococcus aureus* (MRSA) blood stream infection

5.8.3 For MRSA bloodstream infections, particular reference should be made to NHSE [‘Guidance on the reporting and monitoring arrangements and post infection review process for MRSA bloodstream infections’](#)

5.9 Role of the CCG Medicines and Medical Devices Safety Officer (MSO)

- The CCG MSO is alerted as soon as the CCG becomes aware of a medicines or devices related SI.
- The CCG MSO has oversight of any medicines or devices related SI at all times.
- The CCG MSO will provide expert advice on the management and review of any SI RCA involving medicines or medical devices.
- Similarly, provider organisations will be expected to engage with and involve their own MSOs where applicable to ensure the appropriate oversight of any investigation and subsequent action plans.
- Where appropriate, the CCG MSO may provide advice to a provider organisation on appropriate actions to take; this may be particularly applicable to any immediate actions required to ensure patient safety.

5.10 Notification to other organisations

5.10.1 There will be occasions where there is a requirement to inform other organisations that an SI has been reported. Procedures must be in place to provide any relevant information in the required timeframes via appropriate and agreed routes, and in accordance with relevant national guidance where relevant. Exactly which organisation requires informing will clearly be determined by the nature of the incident but may include (but is not restricted to) one or more of the following:

- The Police
- Social Care
- Local Safeguarding Boards (Adult and Children)
- Medicines & Healthcare Products Regulatory Agency (MHRA)
- Care Quality Commission (CQC)
- Public Health England (PHE)
- Monitor / NHS Trust Development Authority (NTDA)
- Health & Social Care Information Centre (HSCIC)
- Health Education England (HEE)
- National Reporting and Learning System (NRLS)
- Health & Safety Executive (HSE)

5.10.2 If the police or Health and Safety Executive (HSE) are involved in any SI then the principles outlined in the Memorandum of Understanding between the Police, HSE and DH should be followed (DH Guidance 22/11/2006). The purpose of the protocol is to promote effective working relationships setting out general principles when liaising with each other. A decision to report an incident to the Police or HSE needs to be made at a sufficiently senior level.

5.10.3 Other CCGs

- Where an SI has implications for another CCG – for example, where the provider is commissioned by DCCG but the patient involved is registered with a GP practice in another CCG area – then DCCG will ensure that the other CCG is also informed of the SI and updated on progress. They will also be invited to contribute to questions for any 72-hour brief request, and subsequently invited to review the RCA report prior to formal closure.
- Conversely, where another CCG is the lead commissioner for a service commissioned by DCCG, it is expected that CCG will notify, provide regular updates and involve DCCG in the review of these incidents (see [section 3.2.2](#)).

5.10.4 Joint investigations

- Where an SI involves two or more services / organisations it is the responsibility of the reporting organisation to make contact with the other organisation(s) involved via their respective quality / governance teams, and a lead organisation appointed to co-ordinate

the investigation. An example may be where the acute trust requires information from a GP practice to understand the full medical history and chronology of events. The DCCG Quality and Safety team may be contacted to facilitate these discussions if required, however it is the responsibility of the lead organisation to liaise with all relevant organisations and ensure they have all information as part of their investigation prior to submitting the RCA. DCCG may lead the investigation process where no one provider is best placed to assume overall responsibility.

5.11 Adverse media

5.11.1 Where there is the potential for adverse media attention relating to an SI being reported, the Communication team within DCCG must be informed regarding the approach being taken by the reporting organisation to manage any such media attention. The Quality and Safety team will ensure that all appropriate senior managers within the CCG are informed.

5.12 72-hour brief

5.12.1 If an SI is deemed to pose a significant risk and / or commissioners feel that further, immediate assurance is required, a 72-hour brief will be requested from the relevant provider by DCCG. This will comprise of the 'Serious Incident 72-Hour Brief Template' (see [Appendix 4](#)) being circulated to relevant individuals who will be asked for questions they wish to raise – this may include other members of DCCG, other CCGs or experts in the relevant field. These questions should be collated within 24 hours. The questions raised on the Serious Incident 72-Hour Brief will be sent to the provider and who must respond to within 3 working days of receipt. Once returned, the responses will be circulated to members of the team who generated the questions for assurance.

5.12.2 The SI Framework advises a 72-hour review should be undertaken and added onto STEIS by the provider. However, DCCG will typically not require a 72-hour brief for all incidents but will request this from the provider when appropriate. The 72-hour brief process will always be initiated for Never Events.

5.12.3 Where any information is not known at the time of request, this should be incorporated into the terms of reference for the investigation.

5.13 Out of hours reporting

5.13.1 If a serious incident occurs out-of-hours; local on-call management procedures must be followed. Such incidents might include, fire, flood, untoward death, adverse media or other incidents of significant public or political concern.

5.14 Dudley CCG SI Management System (Datix)

5.14.1 Once an SI has been logged onto STEIS, the relevant information must be transferred onto the DCCG SI Management System (Datix). The record on Datix must then be kept updated throughout the course of the investigation in line with local procedure.

6 INVESTIGATION

6.1 Investigation types

6.1.1 The level of investigation required for an incident will be determined by the severity of the incident and the complexity of the investigation required, categorised as below. It is the responsibility of the provider to ensure STEIS accurately reflects the type of investigation required.

6.1.2 Concise internal

- These investigations are suited to less complex incidents which can be managed by individuals or a small group at a local level. The investigation will result in a concise investigation report which includes the essentials of a credible investigation. A concise investigation must be completed and a report submitted to the CCGs within 60 working days of the incident being reported.

6.1.3 Comprehensive internal

- These investigations are suited to complex incidents conducted by an investigation team or multidisciplinary team, possibly involving experts and specialist investigators. The investigation will result in a comprehensive investigation report including all elements of a credible investigation.
- This type of investigation may be appropriate for joint investigations (see [section 5.10.4](#)). It is the responsibility of the reporting organisation to ensure all relevant stakeholders are involved in the investigation and findings are incorporated into the RCA submitted to the DCCG Quality and Safety team.
- A comprehensive investigation must be completed and a report submitted to the CCGs within 60 working days of the incident being reported.

6.1.4 Independent

- These investigations are required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size or organisation or the capacity/capability of the individuals and/or number of organisations involved. An independent investigation must be completed and a report submitted to the CCGs within six months of the investigation being commissioned.
- An independent investigation may also be commissioned in the event the commissioner(s), provider(s) or the patient/family feel that the nature of the potential causes of an incident warrant independent scrutiny in order to ensure lessons are identified and acted upon in a robust, open and transparent manner.
- When an independent investigation needs to be considered regarding a provider service, this must be declared to DCCGs Quality and Safety team as soon as this decision is made and information must be provided including the rationale for the independent investigation.

- In some cases it will be immediately possible to identify from the initial review, or even before, that an incident requires an independent investigation. Where this is the case, then DCCG as the commissioner will take the necessary action to commission an independent investigation without delay. In most cases however, the provider will complete their own internal investigation and this will be reviewed by the DCCG Quality and Safety team before the need to commission an independent investigation is agreed.
- With the exception of NHS England commissioned investigations described below, DCCGs Quality and Safety team is responsible for making the final decision as to the level/type of investigation required.
- NHS England, in rare and exceptional circumstances (for example, where an incident has the potential to cause significant harm throughout the system and/or where investigation of the commissioning system or configuration of services is required), may identify the need for a regionally or centrally led response, initiated by the commissioning of an independent investigation. Where this is the case an appropriate incident management plan (overseen by appropriate Officer/ Responsible Owner at either regional or national level) must be developed and implemented in line with the principles in this Framework.
- Further guidance regarding independent investigations can be found in Appendix 3 of the NHS England Serious Incident Framework.

6.1.5 Independent investigation: Homicide by a patient in receipt of mental health care

- Such incidents have a huge impact have on all those involved, are often require complex, multi-agency investigations. To ensure a standardised approach is adopted and any wider involvement and / or learning is considered, the investigation of these incidents must involve the Regional Investigation Team.
- The reporting / investigation process for these incidents is defined by three stages:
 - a) Providers report an incident onto STEIS, conduct an initial review, and produce a 72 hour report
 - b) Providers conduct an internal investigation and produce an investigation report within 60 days
 - c) The NHS England Regional Investigation Teams, in conjunction with the Independent Investigations Review Group (IIRG), review these reports and consider commissioning an independent investigation.
- Further guidance regarding independent investigations can be found in the NHS England Serious incident Framework.

6.2 Terms of reference (ToR)

- 6.2.1 Terms of reference should be developed at the very start of every investigation, but it is acknowledged that in some cases more information is needed before these are agreed. The ToR should clearly define the remit, timescales and focus of the investigation. Input

should be sought from all relevant parties, including the patient themselves (or their family).

- 6.2.2 Depending on the nature of the incident, DCCG may wish to raise some specific questions that would need to be considered as part of the investigation and therefore form part of the ToR.
- 6.2.3 DCCG will request the ToR for all never events, joint and independent investigations, but may also request ToR for other SI investigations depending on the individual circumstances of the incident.
- 6.2.4 Where agreed with the provider, ToR should be included on STEIS under 'Comments / further action required' within 10 working days. If the ToR are deemed to be not appropriate upon review by DCCG Quality and Safety team a discussion will be held with the provider to review these.

6.3 Additional Investigation Requirements for NEVER EVENTS

- 6.3.1 Where an SI has been identified as a Never Event, all providers must ensure that they also meet the requirements of the Never Event Policy and Framework and have appropriate internal policies and procedures in place to support this.
- 6.3.2 The ToR for Never Events must be agreed with the DCCG Quality and Safety team prior to starting the investigation. This can be through a meeting with the appropriate representative from the provider or by email.
- 6.3.3 A 72-hour brief will be initiated for all Never Events. In helping to provide DCCG with a clear understanding of the incident as soon as possible it may be appropriate for the provider to invite the DCCG Quality and Safety team to internal fact finding meetings.
- 6.3.4 DCCG should be invited to relevant internal RCA review meetings prior to the submission of the RCA to the DCCG Quality and Safety team.

6.4 Information Governance (IG) incidents

- 6.4.1 Information Governance incidents that fulfil the criteria of a serious incident must be handled in accordance with the Health & Social Care Information Centre '[Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation](#)'.

6.5 Extensions

- 6.5.1 It is acknowledged that there may be occasions where the organisation responsible for carrying out an SI investigation encounters an unavoidable delay in completing the investigation within the defined timescale. Should this occur, an extension should be requested from DCCG (via the Serious Incident mailbox) as soon as the requirement has been identified. This request must include details of the reason for the delay and an anticipated delay period.

- 6.5.2 DCCG will review and agree each request on a case by case basis but extensions will only be granted in exceptional circumstances. Poor internal co-ordination or inability to obtain executive sign-off will not normally be suitable reasons. It is expected that the request for an extension will be made in advance of any expected RCA submission date.
- 6.5.3 Once agreed DCCG will update STEIS accordingly to ensure that there is a clear record of the reason for the extension.
- 6.5.4 Where delays are due to circumstances beyond the immediate control of the investigating organisation it may be appropriate to put a 'Stop Clock' in place (see [Section 6.6](#) below for details).

6.6 Stop Clock

- 6.6.1 It is acknowledged that there may be instances when it is impossible for an organisation to complete the investigation within the defined timescale due to circumstances which are beyond their immediate control.
- 6.6.2 Such delays may be due to one or more of the following:
- Awaiting outcomes of court proceedings
 - Awaiting Coroner Inquests
 - Awaiting forensic post-mortem findings
 - Awaiting Toxicology results
 - Awaiting the completion of a Serious Case Review (SCR) or Safeguarding Adult Review (SAR)
 - Awaiting completion of an external review
 - In direct response to a Police request under Memorandum of Understanding
- 6.6.3 In such instances, it may be more appropriate to request (via the Serious Incident mailbox) a 'Stop Clock' rather than an extension, providing details of the reason and an indication of when the stop clock is likely to be able to be lifted. As with extension requests, DCCG will review and agree each request on a case by case basis and if agreed will update STEIS accordingly to ensure that there is a clear record of the reason for the stop clock. DCCG will review all stop clocks on a regular basis.
- 6.6.4 Where investigations are being conducted by external agencies, it is acknowledged that SIs can potentially remain open for very significant periods of time beyond the relevant deadline. Therefore, to avoid SIs remaining open for unnecessary or infinite periods of time DCCG will, where possible, close serious incident cases on STEIS where:
- all immediate actions for the health care services derived from internally conducted or commissioned investigations are satisfactorily in hand
 - where organisations are assured that there are external processes for ensuring any outcomes from external investigation will be communicated and acted upon
- 6.6.5 If necessary, cases can be re-opened upon receipt of new information derived from the activities of external agencies

6.6.6 Where there is any doubt about the incident being appropriately coordinated, managed and responded to by external processes the incident should remain open on STEIS.

6.7 Downgrading of incidents (Deletion from STEIS)

6.7.1 If, at any time during an SI investigation, it becomes apparent that the incident does not constitute an SI a formal request can be made to the DCCG Quality and Safety team for the incident to be removed from STEIS using the Serious Incident Deletion Request template ([Appendix 5](#)). Once agreed, a request will be made via the Department of Health SUI Helpdesk for the SI to be removed.

6.7.2 It is expected that any downgraded incident would continue to be managed in line with the provider's own incident management policy.

7 ROOT CAUSE ANALYSIS, REVIEW & CLOSURE

7.1 Root Cause Analysis (RCA)

7.1.1 The reporting organisation is responsible for ensuring that all SIs are investigated and documented, so it is essential that work undertaken throughout the investigation is fully documented.

7.1.2 Investigations should follow [NPSA](#) best practice on conducting investigations using root cause analysis (RCA) methodologies, and should include not only the thinking and decisions made with regards to the incident occurring, but also their timing. This is a valuable safeguard for all individuals involved, as well as being a useful aide, should it be needed, for the preparation of reports for external agencies such as the Coroner or a Committee of Inquiry. A full record of telephone calls, discussions and meetings should be taken, clearly indicating the conversation, actions agreed and the persons responsible.

7.1.3 The principles of RCA will be applied to all investigations, but the scale, scope and timescales of investigation will be appropriate to each incident.

7.1.4 Appropriate resources must be made available to support the completion of a robust investigation, including the availability of staff trained in carrying out RCAs.

7.2 Investigation report

7.2.1 Investigations should ultimately be documented in a final report which provides details of the findings of that investigation, including relevant details and fact, and describe how any conclusions have been reached. Any action plan arising from the investigation should also be produced (see [Section 7.3](#) below), and where appropriate other documentation may be provided to support the information within the report itself e.g. any relevant literature or information referred to during the investigation.

7.2.2 The exact format of the final report is down to the preference and requirements of each provider providing it contains all the key elements required in line with the Serious Incident Framework; further guidance is provided by the key areas that will be used by DCCG to focus the review of the report (see [Section 7.4](#) below).

- 7.2.3 Given the wide range of incidents that may occur it may even be appropriate to provide different reporting templates for different types of incident. For example, using a report specifically designed for documenting pressure ulcer incidents, or for healthcare-acquired infection (HCAI) incidents.
- 7.2.4 Any documentation generated, including the report itself, must be kept in line with local document retention policy and any relevant national IG requirements.
- 7.2.5 [Appendix 6](#) provides an example report template that contains all the relevant elements required.

7.3 Action plans

- 7.3.1 In addition to the investigation report itself, an appropriate action plan should also be provided which describes how the recommendations from the investigation will be achieved. It is expected that action plans will usually be developed with input from a much wider group of individuals, not just those directing the investigation itself. This will not only ensure that the actions have the best chance of successful implementation, but that any wider learning in areas other than that directly affected by the incident will not be missed.
- 7.3.2 Actions must be SMART – specific, measurable, attainable, relevant, and time-bound – and consider the following as a minimum:
- There should be a clear and logical link from each recommendation identified from the findings of the investigation, through to a clear action within the action plan
 - Actions should be designed to eliminate or significantly reduce the risk of recurrence of the incident by targeting the root causes and key contributory factors which represent the main ‘weaknesses’ within the current system
 - An appropriate individual must be identified for the ownership of implementation of each action
 - There should be a clear deadline for each action that realistically represents the time required to successfully implement the change required to address the issue as soon as is practicably possible
 - There should be a clear description as to what evidence will be available to confirm completion and successful implementation in terms of reducing the risk of recurrence
- 7.3.3 Following full closure of the incident, assurances will be sought by the CCG that action plans resulting from the investigation of SIs are completed within appropriate timescales. Evidence of those actions completed should be retained by the provider and be available to the CCG if requested; this may be audited as part of announced visits (see [Section 8](#) below).

7.4 Preparation for submission

- 7.4.1 Prior to a provider closing the incident and submitting the completed report to DCCG for review (see [Section 7.5](#) below), care must be taken that the report is checked and confirmed as ready for final review. This should include:

- **Factual accuracy** – this includes consistency of the same details throughout the document, the timeline information being correct, sufficient detail for key information and alignment with information recorded on STEIS
- **IG compliant** - relevant adherence to Caldicott regarding the provision of any patient information, patient names not used, and staff only referred to by role titles not names
- **Duty of Candour** - carried out appropriately, patient / family aware of investigation, involvement of patient/family in defining the scope of the investigation, support provided to individuals during the investigation and clear plans for them being updated with the findings
- **Complete chronology** – all key events captured with no long time periods unaccounted for, including the actual incident date and identification of the incident
- **Root cause and Contributory Factors** – Contributory factors have been properly explored clearly established and root cause(s) are clearly identified, understood, and appropriately worded
- **Action plan** – Appropriate lessons learnt and associated recommendations are clearly identified, the action plan must be fit for purpose and clearly address the root cause(s) and any relevant contributory factors; must be 'SMART'

7.5 Investigation completion

7.5.1 Once an investigation has been completed, fully documented, and checked in line with the guidance provided above:

- The provider should send the completed investigation report to the DCCG Serious Incidents e-mail address for review
- STEIS must be updated as follows to reflect closure by the provider, either directly by providers who have access to STEIS or by DCCG for organisations who do not:
 - The following fields must be completed: 'Date Internal Investigation Report and action plan submitted', 'Key findings (i.e. fundamental/root causes) and recommendations', and 'How will lessons be disseminated to interested parties'
 - Other fields must be updated as appropriate to reflect any further information that has become available during the course of the investigation – for example, the date of the incident if it wasn't known at the outset.

7.6 Review of investigation reports

7.6.1 Once a copy of the completed investigation report and action plan has been received, the DCCG Quality and Safety team will:

- Acknowledge receipt of the report via e-mail
- Update STEIS and Datix accordingly

- Undertake a review of all completed investigation reports and associated action plans to ensure that they are fit for purpose prior to final closure of the incident.

7.6.2 Allocation of review

- The review process starts with the report being allocated to a member of the DCCG Quality and Safety team who will take responsibility for the review through to completion. Allocation of RCA reviews will usually be via a weekly SI review meeting (see [Section 8.2](#) below).
- Other individuals will be asked to contribute to the review process as required, either from within DCCG or elsewhere. This might include:
 - Other members of the Quality and Safety team
 - Individuals with specific expertise relevant to the incident type, such as medicines management, HCAI, safeguarding or IG
 - The DCCG GP Quality Lead
 - The DCCG Chief Nurse
 - Representatives from other CCGs who have an interest in the incident, such as where it involves a patient from another CCG area but a service commissioned by DCCG
- Feedback from other individuals may simply be provided on an e-mail or may require the completion of a 'Serious Incident RCA Review template' (see [Section 7.6.3](#) below). The nominated lead for the review process will be responsible for ensuring that all relevant individuals provide feedback, and that that feedback is collated into a single review document.

7.6.3 Review template

- To ensure consistency when reviewing RCAs, DCCG will use a standard 'Serious Incident RCA Review template' to capture review feedback (see [Appendix 7](#)). This form allows comments to be made relating to key elements that are expected to be provided by the report (as described in 'Preparation for submission' above) and the outcome of the review to be documented, as well as provide feedback back to the provider where further information is required.

7.6.4 Requests for further information

- Once a report has been reviewed and all feedback collated, the outcome of the review process will be to either close the incident or request further information.
- Where the investigation and/or action plan is not sufficient to provide appropriate assurance that appropriate actions have been / will be taken to avoid recurrence, further information will be requested and reviewed prior to the incident being closed.
- Where further information is required, the reason for the information will be clearly detailed on the RCA review form together with the specific questions or points that require a response. The review form will then be sent back to the provider, usually within 10 working days, with a request for responses to be returned within 5 working

days. During this time the incident will remain open on STEIS which will be updated to reflect the request for additional information.

- In some instances, any responses may simply be added into the relevant sections of the RCA review form. However, where the additional information or clarification is integral to the understanding of the actual report itself then an addendum to the original report or an entirely new revision will be required.
- Once the additional information has been received it will be subject to a further review as described above, with any additional comments being added onto the original review form. This process will be repeated until no further queries are required and the RCA is appropriate for closure.
- Where appropriate and by local agreement, DCCG will also provide a weekly summary of all SI reviews in progress.

7.7 Incident closure

7.7.1 Once DCCG have reviewed all documentation and are assured that the risk of a recurrence of the incident has been sufficiently mitigated then the incident will be closed on STEIS. The DCCG Quality and Safety team Datix system will subsequently be updated and the provider informed.

7.7.2 Please note the following:

- Homicide closures cannot take place until such time as a decision has been taken as to whether or not an Independent Inquiry should be commissioned, in accordance with the Department of Health guidance. In cases where an Independent Inquiry is commissioned the case will not be closed on STEIS until this is fully completed.
- Safeguarding SIs involving SCRs / SARs will not be closed on STEIS until the SCR / SAR has been completed and published by the Local Safeguarding Boards.

8 ASSURANCE & ONGOING MONITORING

8.1 DCCG Assurance and Ongoing Monitoring

8.1.1 The CCG is committed to improvement in quality and safety in commissioned services. It has a robust process for monitoring serious incidents consisting of various regular meetings, together with an internal tracking system.

8.1.2 The monitoring of the effectiveness of SI investigations and the implementation of any associated actions continues after the formal closure of an SI.

8.2 Quality and Safety Review Meeting (QSRM)

8.2.1 Each week the DCCG Quality and Safety team hold a QSRM which includes discussions on a number of elements related to SIs.

8.2.2 Review of RCAs

The DCCG Quality and Safety team will review completed RCA reports and the provider's responses to questions asked from previous RCA reviews. A decision will be made regarding whether an incident should be closed or not.

8.2.3 Deletions and Learning

The QSRM also enables wider discussion and learning relating to SIs and potential SIs including:

- Provider requests for deletions from STEIS
- Discuss useful learning points from the reviews undertaken
- Identify potential themes

8.2.4 Complaints monitoring

The DCCG Quality and Safety team monitor on a regular (usually weekly) basis the complaints being received by the CCG Complaints team to identify any potential SIs. These are then discussed at the weekly QSRM and the relevant actions agreed. This includes liaising with NHS England to ensure that the incident gets formally logged on STEIS and that any subsequent SI investigation is best aligned with the formal complaints process.

8.3 Action plan assurance

8.3.1 Information related to the action plan monitoring will be recorded on Datix. This will include implementation dates to enable effectiveness checks to be carried out on the implementation of actions. This may include review and discussion at an appropriate Clinical Quality Review Meeting (CQRM) or equivalent forum, or may on occasion require a site visit to be arranged with the relevant provider in order to gain appropriate assurance.

8.4 Dudley CCG Governance and Review of SIs

8.4.1 There will be a focus on SI reviews within the provider CQRM or equivalent quality review forum such as within a formal contract review meeting. This will include the monitoring of SI management and associated action plans, and highlighting any concerns in relation to potential trends.

8.4.2 In addition, the CCG Quality & Safety Committee (Q&SC) receives trend reports for SIs for triangulation alongside other quality metrics for the relevant providers and may request further actions to be taken.

END

SEE APPENDICES

9 APPENDICES

9.1 Appendix 1 - Key references

Please note that any links to references listed here are the most current version available when this document was issued. To ensure you are always referring to the most current reference it is advisable to check any link from the home page on which the information sits.

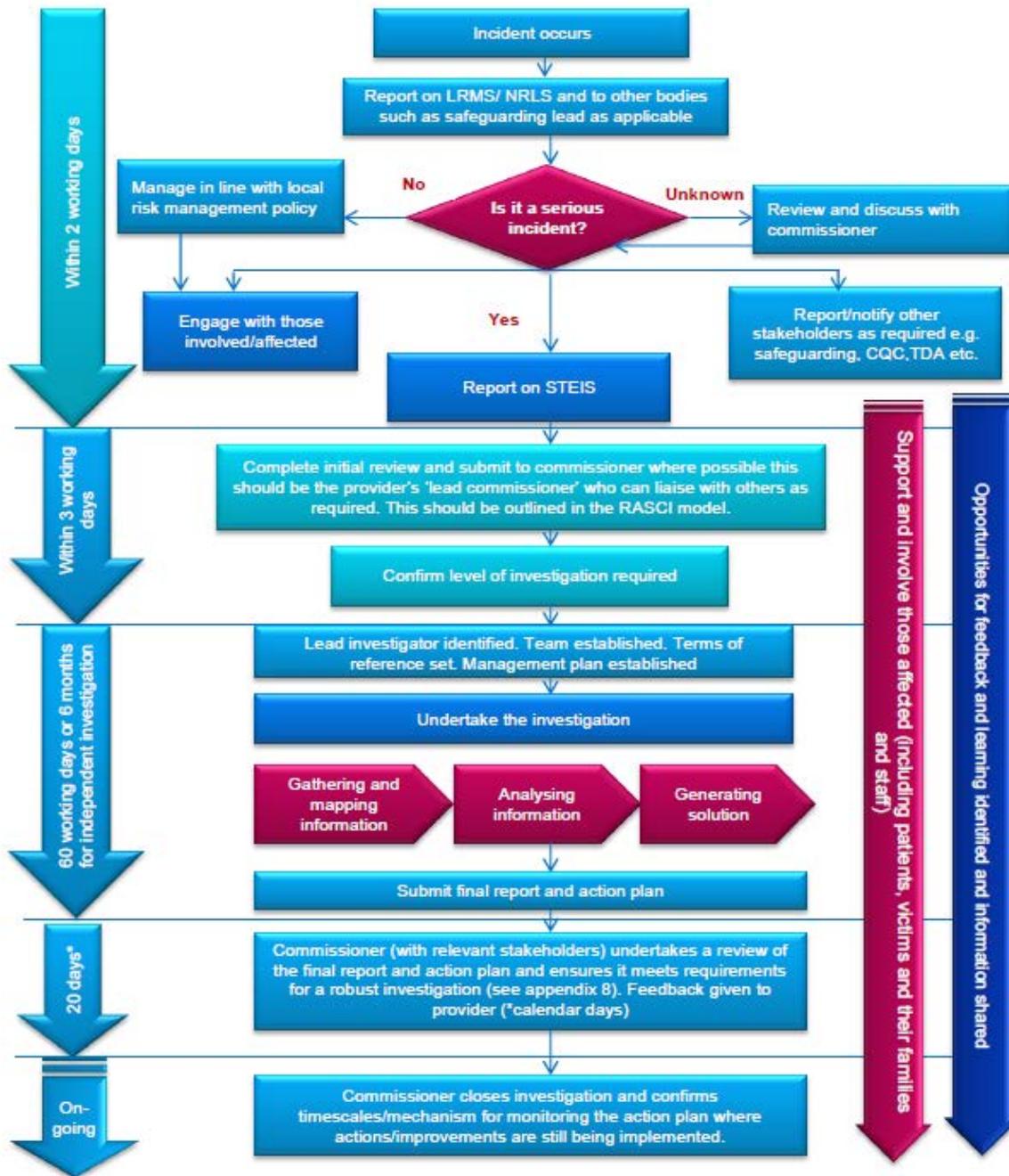
9.1.1 Websites:

- NHS England - <https://www.england.nhs.uk/patientsafety/>
- Care Quality Commission - <http://www.cqc.org.uk/>
- National Patient Safety Agency - <http://www.npsa.nhs.uk/>

9.1.2 Key documents

- Serious Incident Framework
<https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framework-upd.pdf>
- Never Events Policy and Framework and Never Events List 2018
<https://improvement.nhs.uk/resources/never-events-policy-and-framework/>
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
http://www.legislation.gov.uk/ukdsi/2014/9780111117613/pdfs/ukdsi_9780111117613_en.pdf
- Duty of Candour - CQC guidance
http://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf
- Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation
<https://www.igt.hscic.gov.uk/resources/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf>
- CQC notification
<http://www.cqc.org.uk/content/notifications>
- Guidance on the reporting and monitoring arrangements and post infection review process for MRSA bloodstream infections
<https://www.england.nhs.uk/wp-content/uploads/2014/04/mrsa-pir-guid-april14.pdf>

9.2 Appendix 2 - Overview of the SI management process



9.3 Appendix 3 - Serious Incident Report Form



SI Report form

9.4 Appendix 4 - Serious Incident 72-Hour Brief Template



72-hour brief
template

9.5 Appendix 5 - Serious Incident Deletion Request template



Serious Incident
Deletion Request Form

9.6 Appendix 6 - Root Cause Analysis Investigation Report Template



RCA investigation
report template

9.7 Appendix 7 - Serious Incident RCA Review template



RCA Review
template v4 FINAL 17