NHS Warrington Clinical Commissioning Group

NHS Halton Clinical Commissioning Group

NHS Halton CCG and NHS Warrington CCG

Serious Incident Management Policy

Document Control

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Contents

1. Executive Summary

1. Serious incidents requiring investigation in healthcare are rare, but when they do occur, everyone must make sure that there are systematic measures in place to respond to them. These measures must protect patients and ensure that robust investigations are carried out. When an incident occurs it must be reported to all relevant bodies.

2. The 7 key principles in managing Serious Incidents are as follows:

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

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

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

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

5. This is pending release of the final version of the Patient Safety Incident Response Framework (PSIRF) following publication of the introductory version in March 2020. Some changes to language and process included in the introductory version have been included in this policy for information and in order for the CCGs to 'familiarise themselves with the new concepts, start to consider the new approaches' (PSIRF 2020)

6. 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.

7. This policy and procedure contains serious incident reporting criteria to guide the CCGs in support of any incident meeting the Serious Incident (SI) criteria that occurs involving an NHS funded patient in Halton and Warrington. Where there are any doubts about thresholds of reporting these should be discussed with the Serious Incident Lead.

2. Introduction

The CCGs aspire to the highest standards of corporate behaviour and clinical competence, to ensure that safe, fair and equitable procedures are applied to all organisational transactions, including relationships with patients, their carers, public, staff, stakeholders and the use of public resources. In order to provide clear and consistent guidance, the CCGs will develop documents to fulfil all statutory, organisational and best practice requirements and support the principles of equal opportunity for all.

The NHS treats over one million patients every single day. The vast majority of patients receive high standards of care however incidents do occur and it is important they are reported and managed effectively.

The CCGs as Commissioners seek to assure that all services which may be commissioned meet nationally identified standards and this is managed through the local contracting process. Compliance with Serious Incident (SI) and Never Event (NE) reporting is a standard clause in all contracts and service level agreements as part of a quality schedule.

The role of the CCGs as Commissioners is to gain assurance that incidents are properly investigated, that action is taken to improve clinical quality, and that lessons are learnt in order to minimise the risk of similar incidents occurring in the future. It is intended that intelligence gained from SIs will be used to influence quality and patient safety standards for care pathway development, service specifications and contract monitoring.

Serious incidents in healthcare are relatively uncommon, but when they occur the National Health Service (NHS) has a responsibility to ensure there are systematic measures in place for safeguarding people, property, NHS resource and reputation. This includes the responsibility to learn from these incidents to minimise the risk of reoccurrence (NPSA, 2010).

This policy is intended to reflect the responsibilities and actions for dealing with SIs and NEs and the tools available.

It outlines the process and procedures to ensure that SIs and NEs are identified, investigated and learned from as set out in the Serious Incident Framework 2015 and recently published Never Event Framework 2018 (updated 2021). This revised Framework replaces the Serious Incident Framework and Never Event Framework published in 2013 and is due to be replaced by the Patient Safety Incident Response Framework, due for publication in Spring 2021.

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

3. Purpose

The purpose of this policy is to identify what is meant by a SI or NE and to describe the role of the CCGs when a SI or NE occurs across a number of organisations.

This policy aims to ensure that the CCGs, as Commissioners, comply with current legislation as well as current national guidance, NHS England and requirements with regard to accident/incident reporting generally, but in particular reporting, notifying, managing and investigating SIs and NEs.

The CCGs are explicit in their contracts with all providers its expectations regarding serious incident reporting and management, the indicators and the process for performance management.

The role of the CCGs in dealing with Serious Incidents is to ensure that:

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

4. Scope

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

This policy applies to all employees of the CCG and is recommended to independent contractors e.g. GPs, Dental Practitioners, Optometrists and Pharmacists.

All NHS providers including Independent Healthcare Sector providers, where NHS services are commissioned, need to comply with the CCGs' reporting requirements within this policy, which reflects the Serious Incident Framework 2015 & Never Events Framework 2018.

5. Roles and Responsibilities

Chief Officer	The Chief Officer has overall responsibility for the strategic direction and operational management, including ensuring that CCG process documents comply with all legal, statutory and good practice guidance requirements. The Chief Officer has responsibility for ensuring that the CCG has the necessary management systems in place to enable the effective management and implementation of all risk management and governance policies and delegates the responsibility for the management of SIs to the Executive Lead for Patient Safety and Safeguarding**.**

Chief Nurse/Deputy Chief Nurse	The Chief Nurse/Deputy Chief Nurse has overall responsibility for ensuring: • The incident management process is robust and adhered to. • Incidents are maintained and managed in timely manner. • Staff have the necessary training required to implement the policy. • Mechanisms are in place within the organisation for regular reporting and monitoring of incident themes and lesson learned. • They confirm that incidents can be marked as fully completed. • Responsibility for ensuring the necessary management systems are in place for the effective implementation of serious incident reporting for the CCG
Heads of Functions	All Heads of Functions are responsible for the adherence and monitoring compliance within this policy. They have responsibility for promoting the policy directly with their staff and, where appropriate, take responsibility for the co-ordination of investigations in support of the Chief Nurse/Deputy Chief Nurse.
CCG Quality Team and Serious Incident Review Group	The Quality Team will • Consider if a serious incident falls into the category of a STEIS reportable SI and report accordingly. • Review clinical quality incidents reported by the CCG. • Provide clinical quality incident reports as requested. • Provide incident management support and advice. • Produce CCG reported incident reports as requested. • Identify trends, lessons learned and themes in incident reporting in order to identify any issues of concern for the CCG. • Provide training and assistance to the CCG in incident reporting and management. • Manage the administration of Ulysses for SIs. • Undertake an incident investigation in conjunction with CCG managers if required e.g. health and safety and IG incidents.
All staff	All staff, including temporary and agency staff, are responsible for: • Compliance with relevant process documents. • Co-operating with the development and implementation of policies and procedures as part of their normal duties and responsibilities. • Identify the need for a change in policy or procedure as a result of becoming aware of changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising there line manager. • Attending training/awareness sessions when provided.

6. Definitions

6.1 Serious Incident

An incident is a single distinct event or circumstance that occurs within the organisation which leads to an outcome that was unintended, unplanned or unexpected.

NHS England has produced an information resource to support the reporting and management of serious incidents.

Whilst the definition of a SI is quite broad, and there is no definitive list of incidents that constitute an SI, the following criteria outline the type of incidents which should be included:

1. Unexpected or avoidable death of one or more people. This includes:

   a. Suicide/self-inflicted death
   b. Homicide by a person in receipt of mental health care within the recent past

2. Unexpected or avoidable injury to one or more people that has resulted in serious harm.

3. Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:

   a. The death of the service user
   b. Serious harm

4. Actual or alleged abuse; sexual abuse, physical or psychological ill- treatment or acts of omissions 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)

5. 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

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

7. An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:

- Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues
- Property damage;
- Security breach/concern;
- Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
- Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
- Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or
- Activation of Major Incident Plan (by provider, commissioner or relevant agency)
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation (As an outcome loss in confidence/ prolonged media coverage is hard to predict. Often serious incidents of this nature will be identified and reported retrospectively and this does not automatically signify a failure to report)

As a minimum, patient safety incidents leading to unexpected death or severe harm should be investigated to identify root causes and enable improvement action to be taken to prevent recurrence. The definition of SIs requiring investigation extends beyond those which affect patients directly and includes incidents which may indirectly impact patient safety or an organisation's ability to deliver on-going healthcare. All serious patient safety incidents should be reported to the NPSA, and to notifiable partner organisations.

6.2 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

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

6.3 NHS-Funded Care

All services providing NHS funded care including independent providers where NHS funded services are delivered.

6.4 Serious Harm

Severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care);

- Chronic pain (continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery); or

- Psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days).

6.5 Unexpected/Avoidable Death

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

6.6 Homicide by a person in receipt of mental health care

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

6.7 Security breach/concern

Includes absence without authorised leave for patients who present a significant risk to themselves or the public.

6.8 Patient Safety Incident

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

6.9 Each Baby Counts

The Royal College of Obstetricians & Gynaecologists' national quality improvement programme to reduce the number of babies who die or are left severely disabled as a result of incidents occurring during term labour. Each Baby Counts cases include: all cases of early neonatal deaths, term intrapartum stillbirths and cases of severe brain injury in babies.

7. Just Culture

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

The Just Culture Guide (2018) encourages managers to treat staff involved in a patient safety incident in a consistent, constructive and fair way.

A just culture guide is useful when assessing concerns about individuals to ensure they are treated consistently, constructively and fairly. This should have a particularly positive effect on staff groups who have traditionally faced disproportionate disciplinary actions, eg Black, Asian and Minority Ethnic (BAME) groups. (PSIRF 2020)

The PSIRF (2020) goes on to state that the purpose of a patient safety incident investigation (PSII) is to support system learning and continuous improvement in patient safety, rather than address individual concerns or performance management issues which are the remit of other types of investigation. By focusing on patient safety, it insulates against other remits/scope creep that can frustrate safety improvement (such as performance management).

8. Being Open/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.

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

Duty of Candour information should be recorded on StEIS and referenced in the investigation report.

9. Organisation Accountabilities

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

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

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

CQC-registered organisations are required to notify CQC about events that indicate or may indicate risks to compliance with registration requirements, or that lead or may lead to changes in the details about the organisation in CQC's register. They are required to report serious incidents as defined in CQC's guidance, *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 serious incidents directly to CQC. They can also report to the NRLS.

9.1 Provider Accountabilities

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

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

9.2 The CCGs Serious Incidents

Any internal incident meeting the SI criteria must be logged on StEIS. The investigation and subsequent production of a Serious Incident Investigation Report is the responsibility of the CCGs, sign off and closure of the SI must be carried out by NHS England Sub Region office.

9.3 Independent Providers

The CCGs are also responsible for ensuring that all providers have a route to report in to StEIS. For SIs that occur in independent providers such as Nursing Homes, based on the CCG area in which the Nursing Home is sited, the CCG may report these on behalf of independent providers who do not have access to StEIS. Serious Incident investigations regarding nursing homes are usually conducted by the Nursing Home itself with support from the Quality Improvement Nurse where necessary.

9.4 The RASCI Model: assigning accountability

Providers of NHS funded care often deliver services commissioned by different commissioning organisations. These may include, NHS England, multiple CCGS and Local Authorities. This can lead to uncertainty and ambiguity in relation to serious incident management.

Therefore, within each provider (where there are multiple commissioners), it is recommended that a 'lead commissioner' (usually the commissioner with the greatest contract value) is identified to lead oversight of serious incident management across the organisation. This should be formally agreed for each contract (e.g. through a collaborative agreement).

Accountable commissioners (i.e. contract signatory) must work collaboratively with and through other commissioners, to ensure the reporting arrangements are included within contracts. Whilst they may delegate responsibilities for serious incident management to other commissioners, they remain accountable for quality assuring the robustness of the serious incident investigation, learning and action plan implementation undertaken by their providers.

It is recommended that each contract should have a RASCI (Responsible; Accountable; Supporting; Consulting; Informed) matrix to support the robust and effective oversight management of serious incidents. The matrix must clearly identify the Accountable (Contracting) Commissioner (whether NHS England or a CCG) regardless of any delegation of management responsibilities.

Where serious incidents occur within services without a RASCI model, it is recommended that a model is developed and agreed by the relevant commissioning organisations to ensure roles and responsibilities in relation to managing the incident are clearly set out.

9.4.1 Involving NHS England as direct commissioners:

NHS England has direct commissioning responsibilities (GP services, community pharmacy, dental services etc.) which are discharged via its sub-regions. The commissioning functions within the sub-regions vary (some have specific functions in commissioning specialised services or healthcare within the health and justice system for example). Wherever possible however, NHS England is working towards a consistent approach where quality and safety concerns are managed at a local level providing this is feasible given the level of local resource and expertise to manage such concerns.

The functions of NHS England Sub-regions are described as follows:

- **Originating Sub-region** – Sub-region where the patient comes from.

- **Geographical Host Sub-region** (or Local Sub-region) – the Sub-region in whose local boundary a service is located.

- **Functional Host Sub-region** – Sub-regions with additional commissioning responsibilities i.e. specialised commissioning. These Sub-regions have an extended functional boundary. For specialised commissioning it has been agreed that the Functional Host will support the Geographical host to manage responsibility for quality concerns. The Functional Host will therefore populate a RASCI template (Responsible; Accountable; Supporting; Consulting; Informed) for each provider within their "functional" area in readiness to support the Geographical Host Sub-region to undertake their quality assurance functions

- **Accountable (contracting) Sub-region** – the Sub-region which negotiates and holds the contract for NHS England and is accountable for quality assuring the robustness of the serious incident investigation, learning and action plan implementation undertaken by their providers accountable for the quality of the services. This Sub-region may also be the geographical and/or functional host.

In some circumstances the originating, geographical host, functional host and accountable (contracting) Sub-region are all located in different Sub-regions and in such circumstance a RASCI model proves fundamental for ensuring serious incident are appropriately managed.

10. Working with other sectors/Parallel Processes

10.1 Deaths in Custody

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

Any death in prison or police custody will be referred to the Prison and Probation Ombudsman (PPO) or the Independent Police Complaints Commission (IPCC) who are responsible for carrying out the relevant investigations. Healthcare providers must fully support these investigations where required to do so.

In NHS Mental Health services, providers must ensure that any death of a patient detained under the Mental Health Act (1983) is reported to CQC without delay. However, providers are responsible for ensuring that there is an appropriate investigation into the death of a patient detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies. In circumstances where the cause of the death is unknown and/or where there is reason to believe the death may have been avoidable or unexpected then the death must be reported to the provider's commissioner(s) as an SI and investigated appropriately.

10.2 Serious Case Reviews and Safeguarding Adult Reviews

The Local Authority via the Local Safeguarding Children Board or Local Safeguarding Adult Board (LSCB, LSAB as applicable) has a statutory duty to investigate certain types of safeguarding incidents/concerns.

Healthcare providers must contribute towards safeguarding reviews as required to do so by the Local Safeguarding Board where it is indicated that a serious incident within healthcare has occurred.

The interface between the serious incident process and local safeguarding policies must therefore be articulated in the local multi-agency safeguarding policy and protocol.

10.3 Homicide by patients in receipt of mental health care

Where patients in receipt of mental health services commit a homicide, NHS England will consider and, if appropriate, commission an investigation. This process is overseen by NHS England's Regional investigation teams.

10.4 Serious Incidents in National Screening Programmes

There are a number of immunisation or screening programmes which require a broader approach to handling incidents.

The Screening Quality Assurance Service is responsible for surveillance and trend analysis of all screening incidents. It will ensure that the lessons learned from incidents are collated and disseminated nationally.

Screening SIs are often very complex, multi-faceted incidents that require robust coordination and oversight by Screening and Immunisation Teams working within Sub-regions and specialist input from Public Health England's Screening Quality Assurance Service.

Further details on the management of incidents within the screening programme are available in "Managing Safety Incidents in NHS Screening Programme" in appendix 3.

For SIs linked to national screening programmes (e.g. ante natal and child health screening, retinal screening etc.) the Regional Screening Lead will provide advice to local organisations and will inform the national coordinating bodies as appropriate.

The flow chart for managing screening incidents can be found in Appendix 1.

10.5 Information Governance and Cyber Security Serious Incidents requiring Investigation

There is no simple definition of an information governance serious incident.

The scope of an Information Governance Serious Incident may include:

- A breach of one of the principles of the General Data Protection Regulation and Data Protection Act 2018 and/or the Common Law Duty of Confidentiality.
- Unlawful disclosure or misuse of confidential data, recording or sharing of inaccurate data, information security breaches and inappropriate invasion of people's privacy.
- Personal data breaches which could lead to identity fraud or have other significant impact on individuals.

There are many possible definitions of what a Cyber incident is, for the purposes of reporting the definition is anything that could (or has) compromised information assets within Cyberspace. "Cyberspace is an interactive domain made up of digital networks that is used to store, modify and communicate information. It includes the internet, but also the other information systems that support a businesses, infrastructure and services." These types of incidents could include:

- Denial of Service attacks

- Phishing emails
- Social Media Disclosures
- Web site defacement
- Malicious Internal damage
- Spoof website
- Cyber Bullying

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

- Confirmed IG SI but no need to report to Information Commissioners Office (ICO), Department of Health (DH) and other central bodies.
- Confirmed IG SI that must be reported to ICO, DH and other central bodies.

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

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

Baseline Scale	
0	Information about less than 10 individuals
1	Information about 11-50 individuals
1	Information about 51-100 individuals
2	Information about 101-300 individuals
2	Information about 301 – 500 individuals
2	Information about 501 – 1,000 individuals
3	Information about 1,001 – 5,000 individuals
3	Information about 5,001 – 10,000 individuals
3	Information about 10,001 – 100,000 individuals
3	Information about 100,001 + individuals

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

Low: For each of the following factors reduce the baseline score by 1
No clinical data at risk
Limited demographic data at risk e.g.address not included, name not included
Security controls/difficulty to access data partially mitigates risk
Medium: The following factors have no effect on baseline score
Basic demographic data at risk e.g. equivalent to telephone directory
Limited clinical information at risk e.g. clinic attendance, ward handover sheet
High: For each of the following factors increase the baseline score by 1
Detailed clinical information at risk e.g. case notes
Particularly sensitive information at risk e.g. HIV, STD, Mental Health, Children
One or more previous incidents of a similar type in past 12 months
Failure to securely encrypt mobile technology or other obvious security failing

Celebrity involved or other newsworthy aspects or media interest
A complaint has been made to the Information Commissioner
Individuals affected are likely to suffer significant distress or embarrassment
Individuals affected have been placed at risk of physical harm
Individuals affected may suffer significant detriment e.g. financial loss
Incident has incurred or risked incurring a clinical untoward incident

Step 3 - Final Score

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

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

The Health and Social Care Information Centre (HSCIC) has provided additional guidance for how SIs relating to information governance and cyber security should be reported, managed and investigated; see Appendix 2.

10.6 Serious Incidents involving Controlled Drugs

SIs that involves controlled drugs must also be notified to the appropriate CCG Head of Medicines Management who will implement the appropriate action.

10.7 Health Safety Investigation Branch (HSIB) and maternity investigations

The purpose of HSIB is to improve patient safety through effective and independent investigations that don't apportion blame or liability.

They conduct independent investigations of patient safety concerns in NHS-funded care across England. The safety recommendations they make aim to improve healthcare systems and processes in order to reduce risk and improve safety.

They undertake patient safety investigations through two programmes; national investigations and maternity investigations.

They investigate maternity incidents that meet the Each Baby Counts criteria or their defined criteria for maternal deaths.

Trusts are required to refer all cases meeting the criteria in accordance with the HSIB Maternity Investigations Directions 2018. HSIBs maternity investigations have replaced the trust's internal maternity serious incident investigations. They involve the trust and share the investigation reports as they are completed. Trusts continue to investigate maternity events that fall outside the specified criteria.

If the incident meets the criteria of a serious incident in accordance with the Serious Incident Framework (2015) the trust is still responsible for the Duty of Candour, 72 hour report and reporting to the STEIS.

In addition, the incident should be reported to Each Baby Counts, NHS Resolution – Early Notification Scheme and MBRRACE-UK where required. Where cases meet the criteria for reporting to the Perinatal Mortality Review Tool, they complete this in collaboration with the trust once the investigation is complete.

11. Reporting and Management of Serious Incidents

11.1 General Principles

Each NHS Trust/organisation must nominate a single point of contact or lead officer for managing all SIs.

Organisations should ensure that mechanisms are in place to report all incidents meeting the criteria

The Independent Healthcare Sector (IHS) should be subject to contractual obligations for the reporting of SIs. The CCG should ensure that appropriate reporting arrangements are in place with the IHS in relation to SIs.

The CCG should ensure that IHS SIs are reported via NHS England's web based serious incident management system STEIS (the Strategic Executive Information System) and investigated appropriately.

If an incident spans organisational boundaries, **it is the responsibility of the organisation where the incident took place** to formally report it through STEIS. All other additional organisations involved must contribute and fully cooperate with the process in line with the agreed timescales. Where there is doubt about who should report the incident then clarity must be sought through the CCG Clinical Quality Team.

If an incident involves more than one NHS organisation a decision will be made (mutually agreed) as to which is the lead investigating organisation. Where an incident involves the independent sector or contracted services, it is the role of the commissioning CCG to lead. The RASCI (Responsible, Accountable, Supporting, Consulted, Informed) model should be completed in order to assign accountability.

This guidance must not interfere with existing lines of accountability and does not replace the duty to inform the police and/or other organisations or agencies where appropriate. Further guidance can be obtained from the Department of Health publication *Memorandum of Understanding: Investigating Patient Safety Incidents* June 2004 and accompanying NHS guidance of December 2006. The need to involve outside agencies should not impede the retrieval of immediate learning.

SIs which have impacted or have had potential to impact on children and/ or vulnerable adults must be investigated in conjunction with the identified safeguarding lead and in accordance with related guidance.

Once SIs are identified in NHS or HIS providers, the appropriate providers procedure should be followed.

The Standard Operating Procedure for the Internal Management of Serious Incidents should be referred to for the specifics of SI management by the CCGs.

11.2 Independent Contractors

Once an SI is identified, in a CCG commissioned service, the Independent Contractors Procedure for the Reporting and Management of Serious Incidents should be followed, or where applicable NHS England should be notified.

Where an SI raises professional concerns about a GP, CCG local arrangements for assuring high standards of professional performance should be invoked, where this is applicable, or NHS England notified.

Independent Contractors should have systems in place to ensure that staff are supported appropriately following the identification of a SI.

11.3 Staff involved in Serious Incidents

Serious incidents can be distressing for those involved.

The Director, Assistant Director or appropriate Manager should ensure that staff are supported at all stages of a SI with reference to CCG HR policies.

The Director, Assistant Director or appropriate Manager are responsible for ensuring that a de-briefing session occurs at an appropriate stage following a SI.

Information should be given regarding accessing a Mental Health First Aider.

If staff have a concern about the organisation failing to respond to a patient safety incident, or about the nature of its response, they can seek support from their organisation's Freedom to Speak Up Guardian.

If, during the course of a SI investigation, it becomes apparent that a member of staff may be subject to a disciplinary hearing, appropriate advice and support should be taken via Human Resources and the relevant policy followed.

11.4 Education and Training Organisations

In the event an incident involves a student or trainee, the relevant academic institution will be notified by the NHS Trust/CCGs as appropriate.

Where a SI concerns the commissioning or provision of medical or dental education or training, or a medical or dental trainee or trainees, there will be appropriate communication between the CCGs and NHSE

11.5 Serious Incident Escalation Out of Hours

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

The CCGs Director on-call will make the decision on whether to alert NHS England sub region office via the on-call system.

Where potential media interest exists, NHS Warrington CCG will co-ordinate a media response, with the appropriate stakeholders, based on the available information, this will be shared with NHS England Sub Region to ensure any necessary media management is proportionate and well managed.

11.6 Levels 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. *The term concise investigation will be discontinued on publication of the Patient Safety Incident Response Framework (PSIRF) as the Introductory version (March 2020) states this will be replaced by audits and reviews.*
Level 2- comprehensive	Conducted internally- 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. *When the PSIRF is published, this level investigation will be referred to as Patient Safety Incident Investigation (PSII) The PSII will only relate to 'comprehensive' and 'independent' investigations*
Level 3- independent	– two types. The first is a provider–focussed investigation where the provider has been unable to carry out an effective/objective and timely investigation due to the complexity or involvement of other agencies and where significant systemic failures appear to have occurred. There may also be conflicts of interest identified. This investigation will normally be commissioned by the commissioner of the care and undertaken by individuals independent of the provider. The second type is SIs that involve the examination of the roles of wider commissioning systems or configuration of services including multi agency and multiple SIs. Any investigation will be independent of the directly involved commissioners and will usually be led by a regional or centrally led team identified by NHS England *When the PSIRF is published, this level investigation will be referred to as Patient Safety Incident Investigation (PSII) The PSII will only relate to 'comprehensive' and 'independent' investigations*

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

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

11.7 Initial Reporting

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

11.8 Timescales

Concise and comprehensive investigations should be completed within 60 days and independent investigations should be completed within 6 months of being commissioned.

Once the final version of the PSIRF is published, the guidance on this timeframe is likely to change. The introductory version states patient safety incident investigations (which include comprehensive and independent) must start as soon as possible after the incident is identified, and usually be completed within **one to three months**. The PSII timeframe should be agreed with the patient/family/carer in each case as part of the terms of reference for the PSII, provided the patient/family/carer are willing and able to be involved in that decision. In exceptional circumstances a longer timeframe may be needed for completion of the PSII. In this case, any extension to timescales should also be agreed with the patient/family/carer.

The introductory version of the PSIRF states that no local PSII should take longer than six months because the time needed to conduct a thorough investigation has to be balanced against the impact of lengthy timescales on those involved in the incident, and the risk that a delay in reporting findings may adversely affect safety or require further checks to ensure the recommended actions remain relevant.

11.9 Extension Requests

Providers can request extensions to the report submission deadline, but there must be compelling reasons for doing so; for example, new information coming to light which requires further investigation. This must be agreed and confirmed by the appropriate commissioner in advance of the original deadline. Extensions are effective from the day on which the serious incident report was due for submission.

11.10 De-escalating/Downgrading a Serious Incident

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 CCGs. At this point the SI will be removed from StEIS.

11.11 Action Plans

Once an investigation has been finalised, recommendations can be formulated, and actions developed to reduce the risk of an incident happening again by addressing the key underlying causal factors. The PSIRF (2020) states this is where the improvement journey starts.

Organisations must have processes to ensure actions recommended by investigation reports are monitored and reviewed, to check they are delivering the required changes and improvement.

The CCGs may request completed action plans, along with evidence demonstrating that they have been completed, for further assurance.

Providers must reference in action plans how shared learning will be implemented both in the specialty involved and across the wider organisation.

11.12 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 appropriate CCG is required with the rationale for the request to stop the clock. It is the decision of the CCGs whether or not a SI meets the criteria for a 'stop the clock'. This rationale will be reported on StEIS

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

In order to ensure that investigations progress in a timely manner, once the outcome of the recorded delay is known e.g. outcome of court proceedings, post-mortem findings, the provider and the appropriate CCG will discuss the removal of the clock-stop and agree a timeframe for completion of the investigation. This date will then become the timeframe for closure of that incident and an entry made on StEIS. 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.

11.13 Re-starting the clock

In order to ensure that Serious Incident investigations progress in a timely manner, once the outcome of the recorded delay is known e.g. outcome of court proceedings, post mortem findings, the provider and the CCGs will discuss the removal of the clock-stop and agree a timeframe for completion of the Serious Incident Investigation. This date will then become the timeframe for closure of that incident and an entry made on StEIS. 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.

11.14 Closure and Sign-off

The CCGs, as part of their monthly separate Serious Incident Review Group panels will undertake a review of the final report and action plan to ensure it meets the requirements for a robust investigation. Expert/specialist advice will be sought where necessary to ensure the investigation and actions are appropriate.

Commissioners have 20 calendar days in which to review and confirm decisions on closure.

In the circumstances where the report is deemed unsatisfactory and extra assurance or information is required this will be sought from the reporting organisation and the SI will remain open until responses to queries are returned and reviewed. StEIS will be updated to reflect the request for extra information.

Where the SI investigation report is deemed by the CCGs to be complete and details of the findings/lessons learned/actions have been entered onto StEIS the incident will be authorised for closure. Closure will only be actioned where StEIS has been updated with the Serious Incident Investigation outcome including recommendations; actions; lessons learnt; how it was shared across the organisation and notable practice. Where there has been a death of the patient, the actual cause of death should be recorded on StEIS.

Incidents can be closed before all actions are complete but there must be mechanisms in place for monitoring on-going implementation. This ensures that the fundamental purpose of investigation (i.e. to ensure that lessons can be learnt to prevent similar incidents recurring) is realised.

Where the SI is subject to an external investigation, closure cannot be effected 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 investigation report and associated action plan will be shared with NHS England sub-Region upon completion. **N.B.** Homicide closures cannot take place until such time as a decision has been taken as to whether or not an Independent Inquiry/Domestic Homicide Review should be commissioned, in accordance with Department of Health guidance. In cases where an Independent Inquiry is commissioned by NHS England sub-Region the case should not be closed on STEIS until this is fully completed.

Where an incident occurs within an independent provider in the CCGs area, but involves a patient from an external CCG area, the home CCG should 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-publication checks e.g. legal review, media handling etc. before publication of the final report being published on the websites of the relevant commissioner, NHS England and the provider within 21 days of sign off. Advice should be taken from the Caldicott Guardian before any publication regarding compliance with information governance requirements.

11.15 Monitoring of Serious Incidents

It is important to recognise that the closure of an incident marks only the completion of the investigation process. The delivery and implementation of action and improvement may be in its infancy at this stage. Implementing change and improvement can take time, particularly where this relates to behavioural and cultural change. It is not unreasonable for improvements to take many months or even years in some cases.

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

11.16 Contract and Quality Performance Meetings

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

11.17 Dissemination of Shared Learning

One of the key aims of the serious incident reporting and learning process is to reduce the risk of recurrence, both where the original incident occurred and elsewhere in NHS funded care.

Investigations are not conducted to hold organisations or individuals to account, or to establish how a person died; they are conducted for the purposes of learning. (NHSE 2015)

Learning is facilitated by promoting a fair, open and just culture that abandons blame as a tool and promotes the belief that 'incidents cannot simply be linked to the actions of the individual healthcare staff involved but rather the system in which the individuals were working. Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring'. (NHSE 2015)

Findings should be disseminated to staff so that they can learn from patient safety incidents. A system of accountability through the chief executive to the board is needed to ensure changes are implemented and their effectiveness reviewed. (NHSE/I 2020)

12. Glossary

BAME	Black, Asian and Minority Ethnic groups
CQC	Care Quality Commission
DoC	Duty of Candour
DoLS	Deprivation of Liberty Safeguards
GDPR	General Data Protection Regulation
HM Coroner	Her Majesty's Coroner
HSCIC	Health and Social Care Information Centre
HSIB	Health Safety Investigation Branch
IHS	Independent Healthcare Sector
IPCC	Independent Police Complaints Commission
LSAB	Local Safeguarding Adult Board
LSCB	Local Safeguarding Children Board
MCA	Mental Capacity Act
MHA	Mental Health Act
NE	Never Event
NHSE	National Health Service England
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
PPO	Prison and Probation Ombudsman
PSII	Patient Safety Incident Investigation
PSIRF	Patient Safety Incident Response Framework

RASCI	Responsible; Accountable; Supporting; Consulting; Informed
SAR	Serious Adult Review
SCR	Serious Case Review
SI	Serious Incident
SIRG	Serious Incident Review Group
SIRI	Serious Incident Requiring Investigation
StEIS	Strategic Executive Information System

13. References

NHS England Serious Incident Framework (2015) NHS England.

https://improvement.nhs.uk/documents/920/serious-incidnt-framwrk.pdf

Revised Never Events policy and Framework (January 2018 updated February 2021) NHSI

https://www.england.nhs.uk/wp-content/uploads/2020/11/2018-Never-Events-List-updated-February-2021.pdf

Patient Safety Incident Response Framework 2020: An introductory framework for implementation by nationally appointed early adopters (March 2020) NHSEI

https://improvement.nhs.uk/documents/6516/200312_Introductory_version_of_Patient_Safety_Incident_Response_Framework_FINAL.pdf

A Just Culture Guide (2018) NHSI

https://improvement.nhs.uk/resources/just-culture-guide/

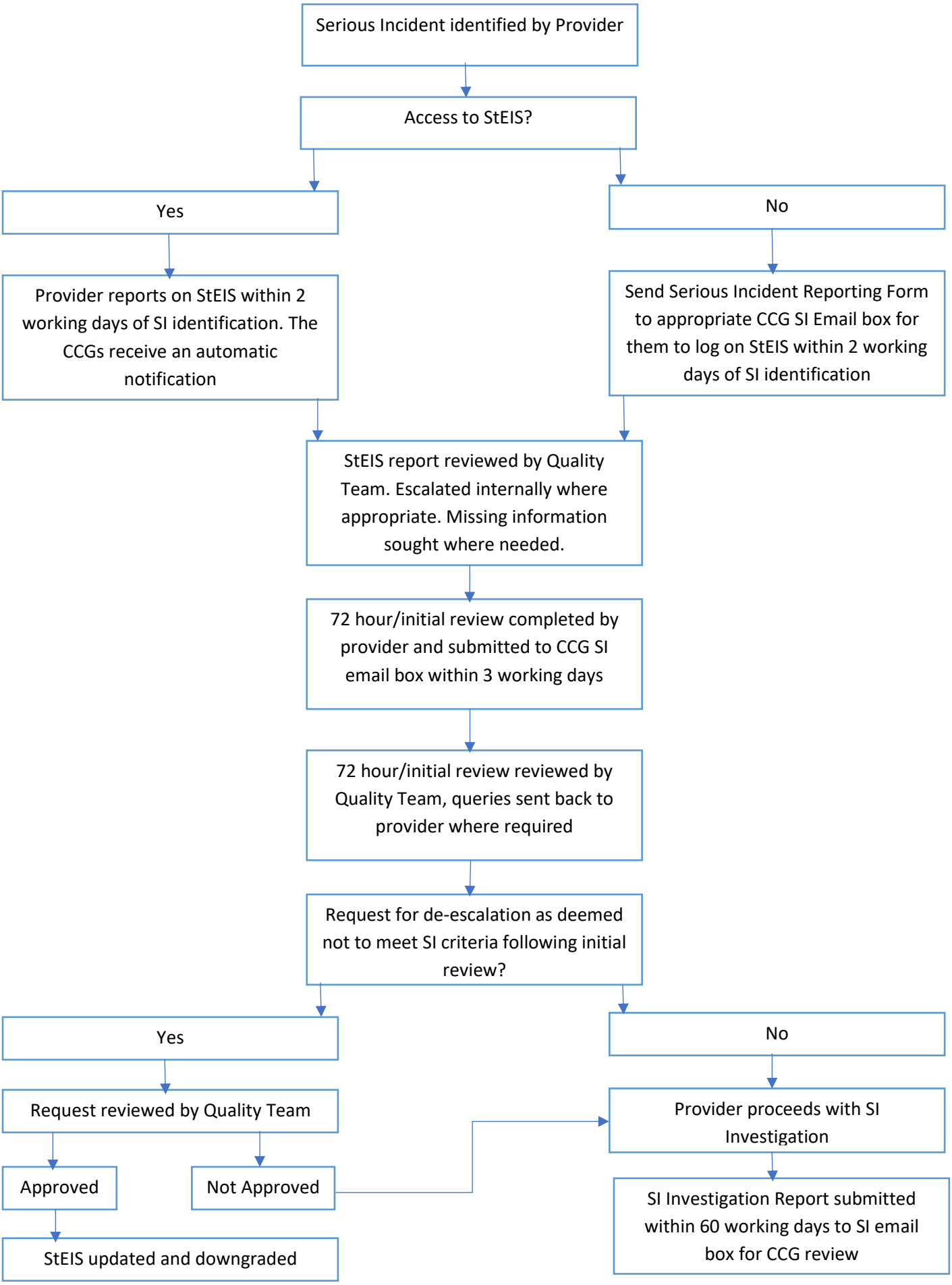
Managing Safety Incidents in NHS Screening Programmes (August 2017) Public Health England

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/672737/Managing_safety_incidents_in_National_screening_programmes.pdf#:~:text=Managing%20Safety%20Incidents%20in%20NHS%20Screening%20Programmes%20Preface,concerns%2C%20safety%20incidents%20and%20serious%20incidents%20in%20screening

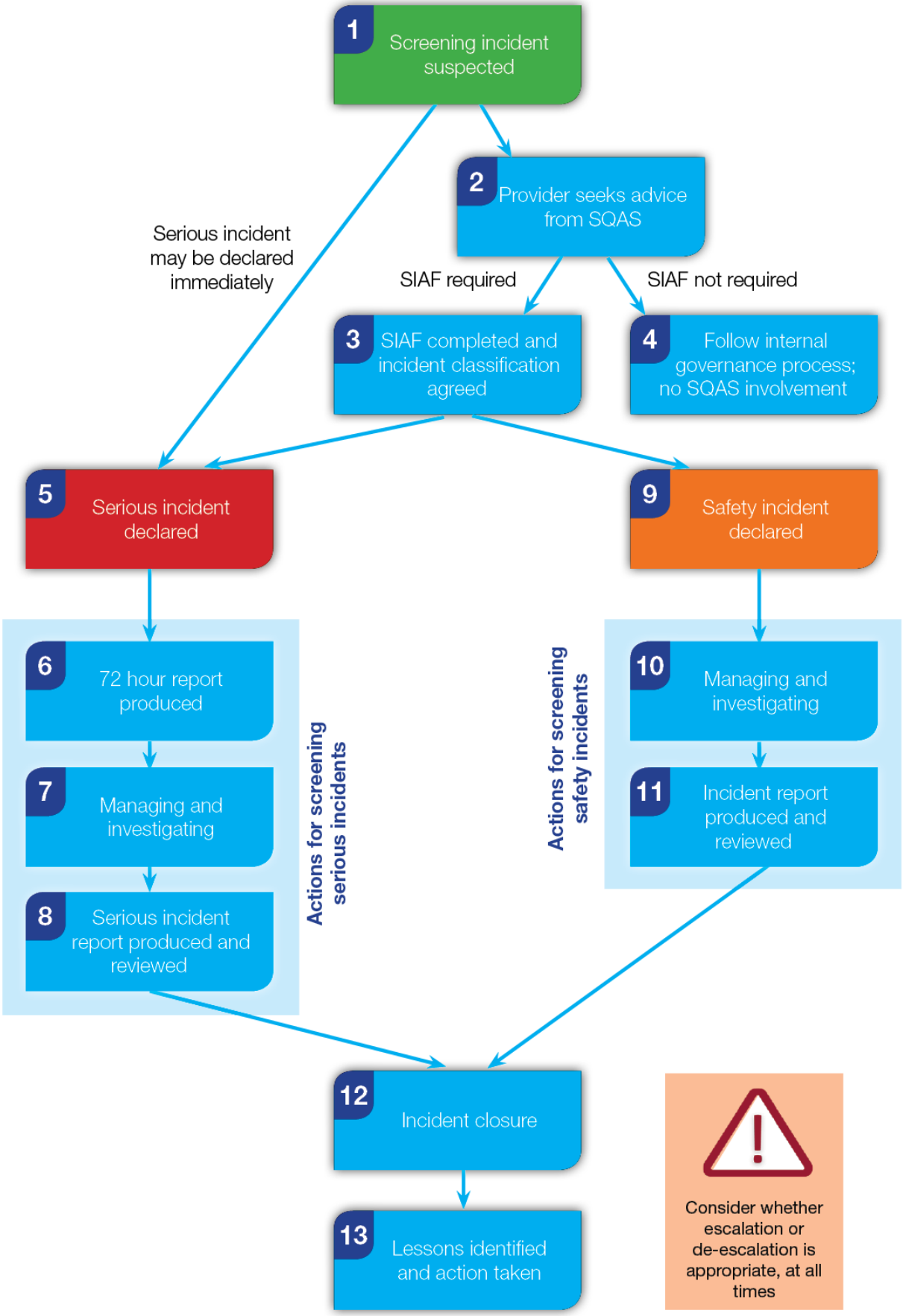
Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation (May 2015) Health and Social Care Information Centre (HSCIC)

https://www.igt.hscic.gov.uk/resources/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf

Appendix 1- Serious Incident Process



Appendix 2- Reporting and Managing Screening Incidents



Notes to accompany reporting and screening incidents flowchart

1. Screening incident suspected

2. Provider seeks advice from SQAS

A serious incident may be suspected but if there is insufficient evidence or a risk to declare a serious incident then ensure advice is sought.

3. SIAF completed and incident classification agreed

Aim to complete within 5 working days.

i. Provider details the facts in section 1 guided by SQAS (region).

ii. Provider registers suspected incident on national reporting and learning system (NRLS) or replacement (reference provided on SIAF).

iii. SQAS assesses and recommends a classification and handling to provider and SIT.

iv. SIT confirms classification and handling to provider and SQAS.

4. Follow internal governance process; no further SQAS involvement This will also apply if a SIAF is completed and the classification is 'not a screening incident'. If there is an incident but it is outside the screening pathway, the responsible commissioner is informed.

5. Serious incident declared

Provider reports serious incident on STEIS within 2 working days. Provider sets up incident panel (should include SIT and SQAS).

6. 72 hour report produced

7. Managing and investigating

Serious incident managed in accordance with agreed handling plan guided by SQAS (region). Changes to the handling plan and classification may be agreed by provider/SQAS (region) and SIT as more information is known.

8. Serious incident report produced and reviewed

Provider produces an incident report within 60 working days or alternative time period agreed with SQAS and SIT. SQAS and SIT comment on report. Aim is for all parties to agree the report within 20 working days.

9. Safety incident declared

If a final incident report is required then ensure the following actions are taken.

10. Managing and investigating

Safety incident managed in accordance with agreed handling plan guided by SQAS (region). Changes to the handling plan and classification may be agreed by provider/SQAS (region) and SIT as more information is known.

11. Incident report produced and reviewed

Provider produces an incident report within 60 working days or alternative time period agreed with SQAS and SIT. SQAS and SIT comment on report. Aim is for all parties to agree the report within 20 working days.

12. Incident closure

SQAS recommend incident for closure and responsible commissioner reviews and closes, governance for incomplete actions agreed, for example Programme Board monitoring.

13. Lessons identified and action taken

SQAS records

Appendix 3- Information Governance and Cyber SIs

Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation

It is essential that all Information Governance Serious Incidents Requiring Investigation (IG SIRIs) which occur in Health, Public Health and Adult Social Care services are reported appropriately and handled effectively.

The purpose of this guidance is to support Health, Public Health and Adult Social Care service commissioners, providers, suppliers and staff in ensuring that

- the management of SIRIs conforms to the processes and procedures set out for managing all Serious Incidents Requiring Investigation;
- there is a consistent approach to evaluating IG SIRIs and Cyber SIRIs;
- early reports of SIRIs are sufficient to decide appropriate escalation, notification and communication to interested parties;
- appropriate action is taken to prevent damage to patients, staff and the reputation of Healthcare, Public Health or Adult Social Care;
- all aspects of an SIRI are fully explored and 'lessons learned' are identified and communicated; and
- appropriate corrective action is taken to prevent recurrence in line with the open data transparency strategy.
- Caldicott 2 recommendations (accepted by the Government) are addressed.
- Transparent reporting of incidents
- Contractual obligations are adhered to with regards to managing, investigating and reporting SIRIs in a standardised and consistent manner, including reporting to Commissioners.

The checklist guidance should be embedded within local processes and procedures and the full guidance can be accessed at
https://www.igt.hscic.gov.uk/resources/HSCIC-SIRIReportingandchecklistGuidance.pdf