Cheshire
Clinical Commissioning Group

Serious Incident Policy 2020/21

Policy Revisions and Amendments			
Date	Section	Reason for Change	Approved By

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1. Introduction

1.1 NHS Cheshire CCG is committed to ensuring that its population receives high-quality healthcare services that are safe, effective and provide a continuously improving patient experience.

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

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

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

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

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

1.6 NHS Cheshire CCG recognises that these frameworks are due to be replaced by the Patient Safety Incident Response Framework in 2021. While NHS Cheshire CCG fully supports the aims and ethos of the Patient Safety Incident Response Framework, NHS England and NHS Improvement are clear that healthcare organisations must continue to use the above two frameworks.

2. Purpose

2.1. This policy sets out how Serious Incidents, including Never Events, should be reported, managed and investigated when they occur within NHS-funded care that has been commissioned by NHS Cheshire CCG. The policy is intended to be used by staff within NHS Cheshire CCG as well as within the organisations NHS Cheshire CCG commissions to deliver NHS-funded care to our patients.

3. Scope

3.1. Section SC 33 of the NHS Standard Contract for 2020/21 states that healthcare providers must comply with the NHS Serious Incident Framework and the Never Events Policy Framework. This policy is therefore intended to complement (rather than replace) the Serious Incident reporting systems already operating within healthcare provider organisations.

3.2. NHS Cheshire CCG asks that all organisations following this policy note that that certain Serious Incidents require interfaces between the NHS England Serious Incident Framework and other national and regional guidance as listed below:

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

- Guidelines for Health & Justice Clinical Reviewers

Child Safeguarding Practice Reviews and Safeguarding Adult Reviews

- Working Together to Safeguard Children: A guide to inter-agency working to safeguard and promote the welfare of children
- Pan Cheshire Safeguarding Children Procedures Manual
- Cheshire West and Chester Local Safeguarding Adults Board (LSAB) Safeguarding Adult Reviews (SARs) Procedure
- Cheshire East Safeguarding Adults Board Safeguarding Adults Review Procedure

Domestic Homicide Reviews

- Domestic Violence, Crime and Victims Act 2004, Section 9 (3)
- Home Office Multi-agency Statutory Guidance for the Conduct of Domestic Homicide Reviews
- NHS England. Serious Incident Framework: Appendix 4

Homicide by patients in receipt of mental health care

- NHS England. Serious Incident Framework: Appendix 1

Serious Incidents in National Screening Programmes

- Managing Safety Incidents in NHS Screening Programmes

3.3. NHS Cheshire CCG would emphasise that this policy does not replace the duty of healthcare providers to inform the following interested bodies when the circumstances of a Serious Incident meet the descriptions set out below (in accordance with Appendix 2 of the NHS England: Serious Incident National Framework):

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

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

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

3.4. NHS Cheshire CCG would also recommend that the following local and national guidance is referenced as part of the management of Serious Incidents:

- Local Agreement for the Management of Reports to Prevent Future Deaths (Coroners' Regulation 28 Rule) NHS England (North) Cheshire and Merseyside
- National Guidance on Learning from Deaths
- NHS Oversight Framework
- NRLS Learning from patient safety incidents

3.5. NHS Cheshire CCG will update this policy to reflect changing national or regional policy and guidance related to Serious Incidents and Never Events

4. Terminology

4.1. Definition of a Serious Incident

4.1.1 The NHS England Serious Incident National Framework defines a Serious Incident as:

'A Serious Incident is an event in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious Incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

The occurrence of a Serious Incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm[1] to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious Incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious Incidents can be isolated, single events or

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[1]NHS England define serious harm as:

- 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).

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

multiple linked or unlinked events signalling systemic failures within a commissioning or health system.'

4.2. Circumstances where a Serious Incident must be declared

4.2.1 The NHS England Serious Incident National Framework states that there is no definitive list of events or incidents that constitute a Serious Incident. Instead NHS England has set out the circumstances in which a Serious Incident must be declared. Providers must therefore consider each incident on a case-by-case basis using the descriptions below to determine if the incident warrants investigation as a Serious Incident:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
    - Unexpected or avoidable death of one or more people. This includes
        - Suicide/self-inflicted death; and
        - homicide by a person in receipt of mental health care within the recent past
    - Unexpected or avoidable injury to one or more people that has resulted in serious harm;
    - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:—
        - the death of the service user; or
        - serious harm;
    - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
        - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
        - where abuse occurred during the provision of NHS-funded care.
        - This includes abuse that resulted in (or was identified through) a Child Safeguarding Practice Review, Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident
- A Never Event. All Never Events are defined as Serious Incidents although not all Never Events necessarily result in serious harm or death
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
    - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issue;

- 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) and the Human Rights Act (1998);
- 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

4.2.2 If an organisation is unclear whether an incident fulfils the definition of a Serious Incident, it must engage in open and honest discussion with NHS Cheshire CCG to agree an appropriate and proportionate response. In cases where it may be unclear whether any weakness in a system or process (including acts or omissions in care) caused or contributed to a serious outcome, the NHS England Serious Incident National Framework states that the most defensible position is to investigate proportionately and to let the investigation decide.

4.2.3 If a Serious Incident is declared but further investigation reveals that the definition of a Serious Incident is not fulfilled i.e. there were no acts or omissions in care which caused or contributed towards the outcome, NHS Cheshire CCG will support the downgrading or ‘undeclaring’ of the incident.

4.3. Never Event Definition

4.3.1 A Never Event is a particular type of Serious Incident which meets all of the following criteria:

- A Never Event is wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers.
- Each Never Event type has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a Never Event.

- There is evidence that the category of Never Event has occurred in the past, for example through reports to the National Reporting and Learning System (NRLS), and a risk of recurrence remains
- Occurrence of the Never Event is easily recognised and clearly defined. This requirement helps minimise disputes around classification, and ensures focus on learning and improving patient safety.[2]

4.4. Never Event List

4.4.1 To support the identification of Never Events, NHS England & NHS Improvement maintains the Never Events list 2018 which details 16 types of incidents and the criteria which makes them a never event.

4.4.2 The current Never Events list is:

1. Wrong Site Surgery
2. Wrong implant/prosthesis
3. Retained foreign object post-procedure
4. Mis-selection of a strong potassium containing solution
5. Administration of medication by the wrong route
6. Overdose of Insulin due to abbreviations or incorrect device
7. Overdose of methotrexate for non-cancer treatment
8. Mis-selection of high strength midazolam during conscious sedation
9. Failure to install functional collapsible shower or curtain rails
10. Falls from poorly restricted windows
11. Chest or neck entrapment in bedrails
12. Transfusion or transplantation of ABO-incompatible blood components or organs
13. Misplaced naso- or oro-gastric tubes
14. Scalding of patients
15. Unintentional connection of a patient requiring oxygen to an air flowmeter
16. Undetected oesophageal intubation*

* The ‘undetected oesophageal intubation’ category was temporarily suspended as a new Never Event by NHS England in January 2018, which remains in force at the time of reviewing this policy. Should such an incident occur, the provider should contact the CCG to discuss if this suspension has been lifted to mean it requires management as a Never Event

4.5. Levels of Investigation

4.5.1 The level of response required in response to a Serious Incident varies on a case-by-case basis.

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[2] See NHS England Revised Never Events Policy and Framework for further information: https://www.england.nhs.uk/wp-content/uploads/2015/04/never-evnts-pol-framwrk-apr.pdf

4.5.2 Healthcare organisations therefore need to assess each incident to determine which of the following levels of investigation it requires:

- Level 1: Concise Investigations These are suited to less complex incidents which can be managed by individuals or a small group of individuals at a local level. These investigations should be completed in 60 working days.

- Level 2: Comprehensive investigations These are suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators. These investigations should be completed in 60 working days.

- Level 3: Independent investigations These are required for incidents where the integrity of the internal 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 of organisation, or the capacity/ capability of the available individuals and/or number of organisations involved. These investigations should be completed within six months of the investigation being commissioned.

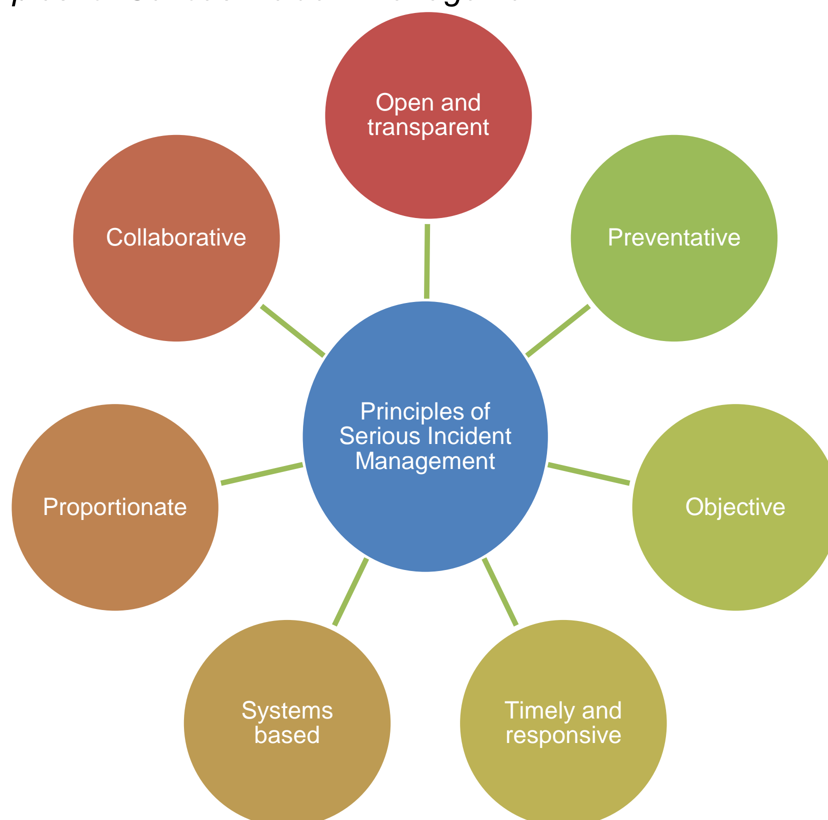
4.6. Principles of Serious Investigation Management

4.6.1 NHS Cheshire CCG is also committed to ensuring that the Serious Incident process facilitates learning by promoting a fair, open and just culture that abandons blame as a tool and recognise the roles that systems play in contributing to incidents. This includes embedding a Human Factors approach which is the consideration of how organisational, individual, environmental, and job characteristics influence people's behaviour in ways that can impact safety[3].

4.6.2 NHS Cheshire CCG endorses the seven key principles for the management of all Serious Incidents as set out in the NHS England Serious Incident Framework (as set out over the page)

[3] See the Clinical Human Factors Group: https://chfg.org/what-are-clinical-human-factors/

Key Principles for Serious Incident management



4.7. RASCI Model

4.7.1 The NHS England National Framework for Serious Incidents states that incidents which involve multiple commissioners must be managed in line with a 'RASCI' model that sets out who is Responsible, Accountable, Supporting, Consulted or Informed.

4.7.2 Under this RASCI model NHS Cheshire CCG is responsible for overseeing all Serious Incidents that occur in NHS –funded care provided by

- Alternative Futures Group (Cheshire)
- Central Cheshire Integrated Care Partnership
- Cheshire West Integrated Care Partnership
- Cheshire East Integrated Care Partnership
- Countess of Chester NHS Foundation Trust
- East Cheshire NHS Trust
- Mid Cheshire Hospitals NHS Foundation Trust
- NHS Cheshire CCG funded care placements/packages
- Nuffield Grosvenor Hospital (Chester)
- GP Practice, Primary Care Network and Care Community services (Cheshire CCG footprint)
- Spire Regency Hospital (Macclesfield)
- Talking Therapies (Eastern Cheshire)

4.7.3 NHS Cheshire CCG will also oversee all Serious Incidents reported by Cheshire & Wirral Partnership NHS Foundation Trust involving patients registered with an NHS Cheshire CCG GP Practice.

4.7.4 NHS Cheshire CCG will be informed and review any incidents that relate to NHS Cheshire CCG patients that occur in other Providers, even if NHS Cheshire CCG is not the co-ordinating commissioner for that Provider, such as out of area providers and incidents that take place in services commissioned by NHS England and NHS Improvement.

4.7.5 The current operational processes adopted by NHS Cheshire CCG are set out in the process map at Appendix A.

5. Roles and Responsibilities

5.1. Providers

5.1.1 The primary responsibility for Serious Incidents is from the provider of the NHS-funded care to the people who are affected and/or their families and carers. Serious Incident management is a critical component of corporate and clinical governance which means that providers are responsible for arranging and resourcing investigations in addition to ensuring that robust systems are in place for recognising, reporting, investigating and responding to Serious Incidents.

5.1.2 The provider also holds an organisational accountability to the commissioner of the care in which the incident took place. This explains why Serious Incidents must be reported to NHS Cheshire CCG.

5.1.3 Providers hold the ultimate responsibility for undertaking and managing investigations, which includes incurring the cost of independent investigations if these are subsequently required.

5.1.4 Providers must ensure that they have mechanisms and process to ensure the following:

- That early, meaningful and sensitive engagement with affected patients, those close to them and staff takes place
- Clear procedures are in place for taking immediate action following Serious Incidents
- That staff are trained and resourced to undertake investigations and who are able to provide an objective view
- That investigations follow a system-based approach
- That investigation teams have access to experts or additional resources to support the investigation

- That mechanisms are in place to follow up and monitor action plans until they are in place
- That mechanisms are in place to support investigations being led by external agencies
- That processes support collaboration and partnership working
- Quality assurance processes are in place to ensure the completion of high quality investigation reports and action plans
- Effective communication channels are in place to facilitate the sharing of lessons learned across and beyond the organisation.

5.1.5 Providers are expected to comply with the Duty of Candour which is a legal duty on hospital, community and mental health trusts to inform and to apologise to patients if there have been mistakes in their care that have led to significant harm.

5.1.6 Providers are required to support NHS Cheshire CCG's Serious Incident Review Groups by ensuring that its senior representatives attend to provide the corporate assurance that Serious Incidents are leading to continuous improvement in patient safety and experience.

5.2. NHS Cheshire CCG

5.2.1. General Responsibilities

5.2.2. NHS Cheshire CCG is responsible for quality assuring providers' responses to Serious Incidents by scrutinising the robustness of the investigation and implementation of the identified actions. This includes triangulating any themes or trends observed from Serious Incidents as well as applying professional curiosity and challenge while undertaking this quality assurance.

5.2.3. NHS Cheshire CCG is committed to working in partnership with its providers to ensure that responses to safety incidents lead to learning and outcomes that lead to tangible and demonstrable improvements in patient safety and experience.

5.2.4. NHS Cheshire CCG will take action if it has concerns about the efficacy of providers' qualitative response to Serious Incidents, notably if providers fail to report Serious Incidents in a timely manner or fail to provide robust and effective investigations and action plans. NHS Cheshire CCG will however not sanction or set performance targets to reduce the number of Serious Incidents as numbers alone do not tell Commissioners how safe a service is.

5.2.5. NHS Cheshire CCG will work with providers to explore how any gaps in resources, capacity, accessibility or expertise to undertake a Serious Incident investigation can

be overcome. This includes supporting and facilitating Serious Incidents that require a multi-agency investigation.

5.2.6. NHS Cheshire CCG will apply this policy to any Serious Incidents that occur in CCG directorates and services.

5.2.7. **Internal Responsibilities**

5.2.8. Director of Quality, Patient Experience and Safeguarding

- Overall responsibility and accountability for NHS Cheshire CCG's management of Serious Incidents

5.2.9. Deputy Director of Quality & Associate Chief Nurse and Associate Director of Safeguarding

- Delegated responsibility from Director of Quality, Patient Experience and Safeguarding to support the Serious Incident process through attending Serious Incident Review Group meetings and reviewing incident data, themes and trends

5.2.10 Patient Safety Team

- Overseeing and undertaking the day to day management of the Serious Incident workload, including all actions outlined in the Serious Incident management process set out at Appendix A.
- Supporting the Serious Incident Review Groups through collating papers, producing minutes/action logs and undertaking actions
- Maintaining and updating DATIX, STEIS and local trackers to ensure full grip of every Serious Incident managed by NHS Cheshire CCG
- Ensuring effective reporting of Serious Incident matters to Quality and Performance meetings and the Quality & Safeguarding Committee
- Liaising with and supporting providers in addressing queries or concerns about Serious Incident work
- Attending relevant meetings with providers, neighbouring clinical commissioning groups and NHS England to review trends and best practice in Serious Incident work.
- Reviewing and updating relevant guidance to reflect changing policy and practice as and when required.

5.2.11 Quality and Safeguarding Committee

- Receiving and discussing reports from the Serious Incident Review Groups about Serious Incidents reported by providers that will detail:

  a) An overview of reported and closed Serious Incidents for providers
  b) Highlights of the investigation reports and action plan outcomes considered and discussed by the Serious Incident Review Groups for that provider

c) Details of any emerging themes and trends identified from patient safety incidents reported by that provider along with the recommended actions

- Considering if any issues, themes or trends identified from Serious Incident require adding to the Corporate Risk Register and/or reporting to the Governing Body

6. NHS Cheshire CCG: Serious Incident procedure

6.1. Identification and notification of a new Serious Incident

6.1.1 When a provider identifies that a Serious Incident has occurred, the provider must declare the incident on the Strategic Executive Information System (STEIS) within two working days of the identification date.

6.1.2 If the incident is a Never Event, likely to be of significant public concern, subject to media interest and/or of significance to other agencies such as the police or other external agencies, the NHS Cheshire CCG Executive Director of Quality, Patient Experience and Safeguarding expects to receive immediate telephone notification of the incident from the healthcare organisation's Director of Nursing or other senior Director.

6.1.3 If the provider is unclear as to whether the incident meets the definition of a Serious Incident, they should contact either the NHS Cheshire CCG Patient Safety Lead or Sector Quality Lead who will discuss and review the incident. In cases where agreement is reached that the incident does not appear to be a Serious Incident, the nominated person should record the discussion on Datix and share with the appropriate Serious Incident Group for their information/ratification.

6.1.4 NHS Cheshire CCG will receive notification of newly reported Serious Incidents via the STEIS alert system or, in Serious Incidents involving out of area providers and specialised commissioning, via email notification to the NHS Cheshire CCG Serious Incident inbox: cheshireccg.si@nhs.net.

6.1.5 The information within the STEIS alert about the newly reported Serious Incident should be recorded on DATIX and the incident added to the NHS Cheshire CCG Serious Incident tracker.

6.1.6 Within three working days, the provider should complete an initial review (characteristically termed the '72 hour review') and update the STEIS incident entry with its findings.

6.1.7 The aim of the 72 hour review is to:

- Identify and provide assurance that any necessary immediate action to ensure the safety of staff, patients and the public is in place;
- Assess the incident in more detail (and to confirm if the incident does still meet the criteria for a serious incident and does therefore require a full investigation); and
- Propose the appropriate level of investigation

6.1.8 If the provider is not able to share the 72 hour review with NHS Cheshire CCG by updating STEIS, it can be emailed to NHS Cheshire CCG at: cheshireccg.si@nhs.net

6.1.9 The NHS Cheshire CCG Patient Safety Lead and a nominated clinical Quality Lead will be sent a completed 'Notification of Incident Reported on STEIS' form. The purpose of this review is to enable NHS Cheshire CCG to determine if it is assured that all necessary immediate action to ensure the safety of staff, patients and the public has been put in place while the investigation is undertaken.

6.1.10 If the outcome of the review is that NHS Cheshire CCG is assured, this will be updated on Datix, STEIS and the Serious Incident tracker. NHS Cheshire CCG will then wait to receive the investigation report.

6.1.11 If the outcome of the review is that NHS Cheshire CCG is not assured, the 'Notification of Incident Reported on STEIS' form will be updated with the information required to provide assurance. This will then be shared with the provider to supply. Once this additional information has been received, the 'Notification of Incident Reported on STEIS' form will be updated and re-sent to the NHS Cheshire CCG Patient Safety Lead and a nominated Quality Lead until assurance is confirmed.

6.1.12 A 'Weekly Notification of new Serious Incidents' will be sent to the Director of Quality, Patient Experience & Safeguarding, Deputy Director of Quality & Associate Chief Nurse, Associate Director of Safeguarding and Quality Leads every Monday. This report will include a year to date list of all Serious Incidents reported to allow for themes and trends to be identified.

6.2. Investigation report completion and submission

6.2.1 The provider should identify a lead investigator and investigation team who will draft terms of reference and a management plan to support the undertaking of the investigation in addition to considering a communication/media handling

6.2.2 The focus of the investigation should be to:
- Gather and map the information
- Analyse the information
- Generate a solution

6.2.3. A primary concern of the investigation should be to ensure the investigation report addresses the priorities and concerns of those affected which means that affected patients, staff, victims, perpetrators, patients/victims' families and carers should be involved and supported throughout the investigation. Providers are also expected to ensure they meet the requirements of the Duty of Candour, Being Open Framework and Just Culture Guide.

6.2.4. In advance of the implementation of the Patient Safety Incident Response Framework, NHS Cheshire CCG will also be looking for providers to be working towards its investigations of Serious Incidents to meet the guiding principles of being:

- Strategic
- Preventative
- Collaborative
- Fair and Just
- Expert/Credible
- People Focused.

6.2.5. The provider should aim to submit the final investigation report and action plan to NHS Cheshire CCG at cheshireccg.si@nhs.net within 60 working days (Level 1 & 2) or 6 months (Level 3 – Independent Investigations).

6.2.6. If the investigation report is received within the appropriate timescale, a copy should be saved in DATIX and local folders with updates made to DATIX and STEIS to confirm receipt and the intended date of Serious Incident Review Group review.

6.2.7. If the investigation has not been received within the timescale, a reminder should be sent to the provider.

6.2.8. If a provider requires an extension, this should be requested from NHS Cheshire in writing to cheshireccg.si@nhs.net with full details provided of why the extension is required, when the report will be received and confirmation that the new timescale will be communicated to the affected people and staff. If an extension is agreed, both STEIS and Datix should be updated to reflect the new date and to record the audit trail of the chaser emails/telephone calls.

6.2.9. If NHS Cheshire CCG has concerns about the number of extension requests, reasons for this or any other issues with investigation report timeliness and quality, these will be highlighted as exceptions at the provider Quality and Performance ('Contract Meetings'). The CCG Quality and Safeguarding Committee will also be informed.

6.2.10. If a Serious Incident has been declared but further investigation reveals that the definition of a Serious Incident is not fulfilled, the provider can request that it is downgraded or 'undeclared'. Any request to for an incident to be undeclared will be considered by the Patient Safety Lead and relevant sector Quality Lead to consider, before being shared with the appropriate Serious Incident Group for their information/ratification.

6.3. Serious Incident Review Group

6.3.1. Investigation reports will be presented to the relevant NHS Cheshire CCG Serious Incident Review Group for the provider/sector. The Serious Incident Review Groups are a sub-group of the Quality and Safeguarding Committee which reports into the Governing Body. The Serious Incident Review Groups have been established to enable NHS Cheshire CCG to undertake an aligned, consistent and single approach to quality assuring the robustness of Serious Incident investigations and action plan implementation.

6.3.2. The duties of the Serious Incident Review Groups are:

i. To review and monitor all Serious Incidents that occur within provider services that are either commissioned by NHS Cheshire CCG or affecting patients registered with NHS Cheshire CCG

ii. To determine if a Serious Incident has been subject to a robust investigation which is defined as:
   a. following a systems-based approach that considers the patient's whole pathway, embodies the principles of a Just Culture Guide (2018) and takes into account relevant quality strategies and improvement programmes (eg Suicide prevention, falls prevention and risk assessments) as well as valuing the contributions of patients and those close to them as partners in the investigation
   b. identifies the correct root causes and contributory factors (where possible to do so)
   c. produces focused recommendations in response to the root causes and contributory factors that inform an action plan that is outcome based (describing what will be achieved) rather than transactional (a list of tasks) as well as being shared and owned across teams, services and organisations (where applicable)

iii. To agree that the outcomes of the action plan have been achieved in an acceptable and timely manner to enable closure of the Strategic Executive Information System (STEIS) record

iv. To note the findings of other statutory review bodies where this intersects with a Serious Incident including (but not limited to) Child Death Overview Panels, Child Safeguarding Practice Review, Safeguarding Adult Reviews, Mental Health Homicide Reviews, Domestic Homicide Review Panels and Serious Incidents in National Screening Programmes as well as escalating any themes or trends observed with these partner review bodies

v. To maintain a focus on emerging themes and trends identified from patient safety incidents to enable the group to make recommendations to commissioners, safety leads and providers to ensure continual improvement and learning implementation. The group will track and reflect on progress in these areas

vi. To escalate any themes, trends or concerns to the Quality and Safeguarding Committee

6.3.3. Providers are expected to support NHS Cheshire CCG's Serious Incident Review Groups by ensuring that senior representatives attend to provide the corporate assurance that Serious Incidents are leading to continuous improvement in patient safety and experience. If the Serious Incident Review Group is not assured that the investigation report meets the requirements of a robust investigation, this will be fed back to the provider at the meeting.

6.3.4. Meetings will take place at a frequency agreed between NHS Cheshire CCG and the provider. Papers will be circulated no later than five working days before each meeting.

6.3.5. The Serious Incident Review Group can close an incident before all preventative actions have been implemented, particularly where these are continuous or long term and the evidence has been received that the actions have been initiated. The Patient Safety Team will maintain a log of future actions for monitoring and review, with updates provided to the Serious Incident Review Group as/when appropriate.

6.3.6. The Serious Incident Review Groups are authorised to investigate any activity within its terms of reference as well as seek any information or guidance as required by the Quality and Safeguarding Committee.

6.3.7. Minutes will be taken of every Serious Incident Review Group that will outline the discussions of the group, decisions reached and actions agreed, with appropriate timescales. Draft versions of the minutes will be prepared within five working days of the meeting and shared with the provider. Formal ratification of these minutes will be undertaken by the Serious Incident Review Group at its next meeting.

6.3.8. The Datix and STEIS records for each incident should be updated with the details from the minutes.

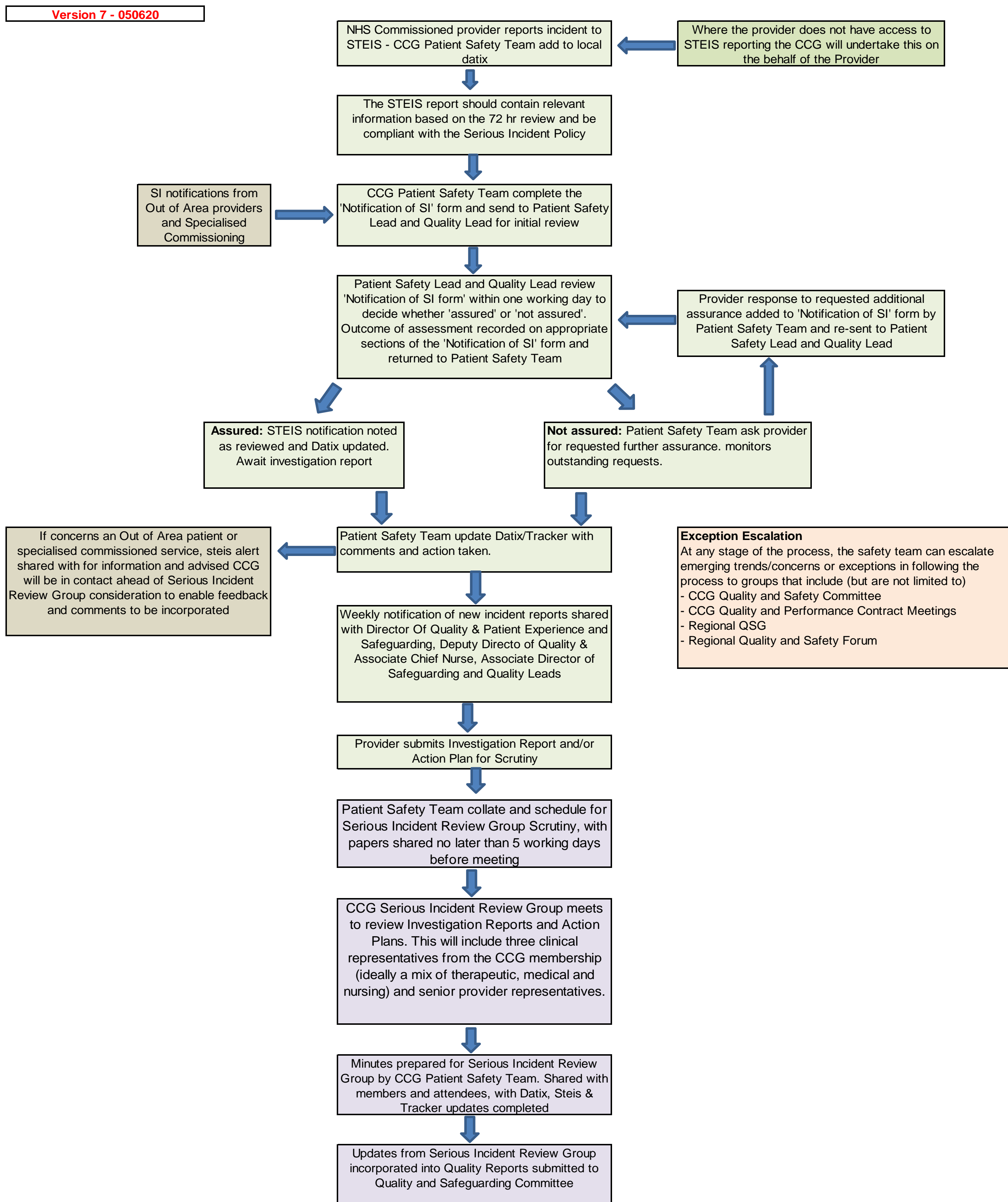
6.3.9. The S6erious Incident Review Groups will maintain an action log to ensure it completes actions assigned to it. Operational oversight of deadlines, timeliness and other forms of incident management will not be added to this action log and instead be overseen through the Patient Safety Team's tracker management and meeting.

6.3.10. Providers should submit any investigation reports or evidence it wishes to supply for Serious Incident Review Group consideration within six working days of the next meeting to ensure timely circulation and inclusion.

6.3.11. If the Serious Incident Review Group recommends closure of an incident on STEIS, the findings (Root cause, Care & Service Delivery Problems and Contributory Factors) and recommendations should be recorded on DATIX and STEIS.

6.3.12. A notification of the closure alongside a confirmation of the timescales/mechanisms for monitoring the action plan where actions/improvements are still being implemented should be shared with the provider.

Appendix A – NHS Cheshire CCG Serious Incident Management: High-level Process Flow



Appendix B - Local Agreement (endorsed by C&M QSG) for the Management of Reports to Prevent Future Deaths (Coroners' Regulation 28 Rule)

Local Agreement (endorsed by C&M QSG) for the Management of Reports to Prevent Future Deaths (Coroners' Regulation 28 Rule)

NHS England (North) Cheshire and Merseyside

NHS England (North) Cheshire and Merseyside
Local Agreement (endorsed by C&M QSG) for the Management of Reports to Prevent Future Deaths (Coroners Regulation 28 Rule)

Version number: 01

First Published:

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	Quality and Safety Forum		30/11/2018
	Joint Directors of Nursing and CCG Chief Nurses Meeting		TBC
Authoriser	Hazel Richards	Director of Nursing & Quality	

Effective from:	November 2018
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1. Introduction

The Coroner has a legal power and duty to write a report following an inquest if it appears there is a risk of future deaths occurring in similar circumstances. This is known as a 'report under Regulation 28' or a Preventing Future Deaths report because the power comes from Regulation 28 of the Coroners (Inquests) Regulations 2013.

The report is sent to the people or organisations that are in a position to take action to reduce risk. Recipients must reply to the Coroner within 56 days to say what action they plan to take.

All reports (formerly known as Rule 43 reports) and responses must be sent to the Coroner and the Coroner will publish the reports and responses on the Judiciary website found here: https://www.judiciary.gov.uk/related-offices-and-bodies/office-chief-coroner/pfd-reports/

2. Purpose

This agreement has been developed in conjunction with both Commissioners and Providers, to provide a comprehensive guide for the management of the Reports to Prevent Future Deaths issued by the Coroner (Regulation 28) within the Cheshire and Merseyside Area. The purpose of the protocol is to:

- Have a framework by which Commissioners and Providers share Regulation 28 reports and their responses to them;
- Detail the actions required by both.

3. Process

Appendix A details the process in place for the escalation and sharing of Regulation 28 Reports as follows:

- Inquests may follow a serious incident that has resulted in the death of a patient. In these cases Providers should have reported the case already on the Strategic Executive Information System (STEIS) and undertaken an investigation (RCA) into the death with learning having been identified.
- Providers must alert Commissioners by updating STEIS of any impending inquest(s) that has the potential to be high profile and/or attract press media attention and/or criticism. If the incident has previously been closed on STEIS the CCG must be informed and they will update.
- Both Providers and Commissioners should ensure they are prepared for any media attention by alerting their Communications Teams and asking that they look to develop press statements as required
- Following an inquest if the Coroner issues a Regulation 28 Report providers must do the following:
    - If the death is already on STEIS as an incident they must contact the Commissioner by phone to alert them and update STEIS.
    - If the death has not previously been identified as a serious incident and is not already on STEIS, it should be considered whether this needs reporting on

STEIS and report as such if appropriate. This report should outline the concerns identified by the Coroner and the date by which the Coroner requires a response, with the Provider informing the Commissioner via a telephone call. If it is considered not to be reportable on STEIS the Commissioners should be informed via a telephone call.

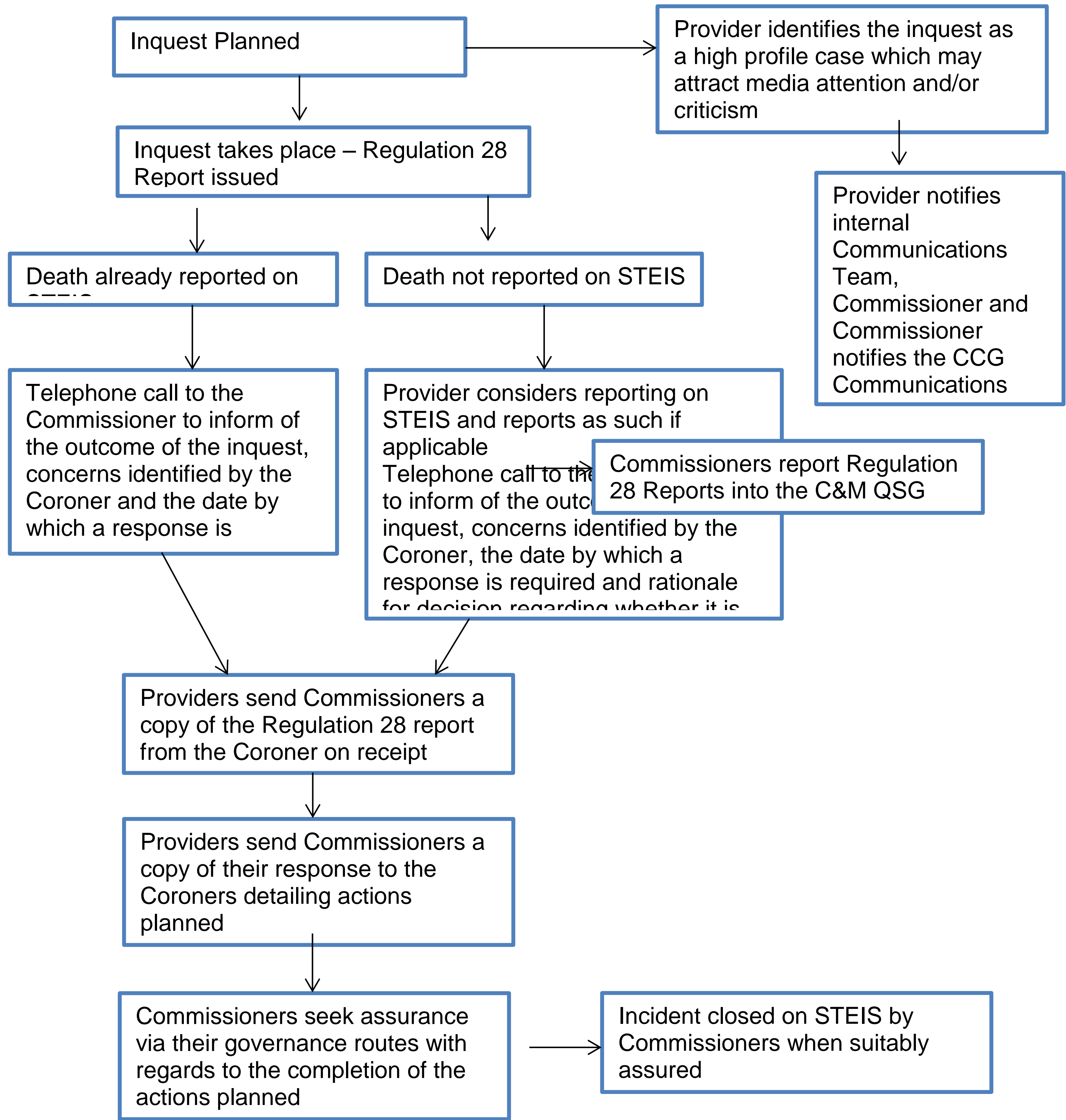
- Providers must send Commissioners a copy of the Regulation 28 report from the Coroner upon receipt of it.
- Providers must send Commissioners a copy of their response to the Coroners detailing actions planned.
- Commissioners must seek assurance via their governance routes with regards to the completion of the actions planned.
- Individual CCGs should develop their own protocols for the management of Regulation 28 reports issued to Primary Care. An example of a system agreed with one CCG - the CCG have contacted the local Coroner and have agreed a protocol where the Coroners officer will inform the CCG of any reports to Primary Care via email to a shared account. If any reports are received they will be escalated internally and followed up for reporting on STEIS, monitoring and assurance purposes by the Primary Care Quality Team.
- CCGs will report all Regulation 28 Reports that they are notified of to the Cheshire and Merseyside Quality Surveillance Group (QSG) via the NHS England reporting template.

4. Appendices

- Appendix One – Regulation 28 Report Management Protocol Flowchart.

Appendix One

Regulation 28 Report Management Protocol Flowchart



Governance Backpage

Version: Version 1.0
Author: Rosemary Kendrew – Senior Corporate Services Manager
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Responsible Committee: Quality and Safeguarding Committee
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